

October 14, 2014

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Dear Administrator Tavenner and Dr. DeSalvo:

The American Medical Association (AMA) is committed to helping physicians have access to affordable, well-developed technology that can drive improvements in patient care. Since the creation of the Electronic Health Record (EHR) Meaningful Use (MU) program in 2009, it is clear that physician use of EHRs has progressed considerably. Despite these achievements, the MU program has faced significant challenges. After three-and-a-half years of provider participation, we are at a critical crossroad where we believe it is important and necessary to pause and fully assess what is working and what needs improvement before moving ahead to Stage 3 of the program.

The purpose of this letter is to outline our vision for the MU program in the future, including Stage 3, the quality reporting program, and the EHR vendor certification requirements. The recommendations we make below are informed by our experience with not only MU, but the numerous other physician reporting requirements, including the Physician Quality Reporting System Program (PQRS). We strongly support a more focused approach for Stage 3, greater quality reporting alignment, and a more streamlined approach to the EHR certification process. **For the reasons outlined in detail below, we strongly recommend the following changes to the MU program:**

1. Adopt a more flexible approach for meeting MU

- a. Remove the existing program's all-or-nothing approach by adopting a 50 percent threshold for incurring a penalty and a 75 percent threshold for earning an incentive for Stages 1-2; at the very least, the Administration should make optional the measures that have been the most challenging for the vast majority of physicians:
 - View, Download, and Transmit
 - Transitions of Care
 - Secure Messaging
- b. Remove percentage/thresholds for measures and the concept of menu vs. core requirements for Stage 3;

- c. Provide new health information technology (health IT) measures to expand the options for specialist participation for Stage 3;
 - d. Retain most of the measures the Health Information Technology Policy Committee (HITPC) recommended for removal to ensure provider participation; and
 - e. Require physicians to meet no more than 10 measures under Stage 3.
- 2. Expand hardship exemptions for all MU stages**
- a. Provide an exemption for physicians who successfully participate in PQRS from the MU quality reporting requirements;
 - b. Expand the “unforeseen circumstances” hardship;
 - c. Continue the exemption for anesthesiologists, radiologists, and pathologists;
 - d. Provide an exemption for hospitalists; and
 - e. Provide an exemption for physicians close to retirement.
- 3. Improve quality reporting**
- a. Improve alignment with the PQRS program;
 - b. Build a sufficient quality infrastructure;
 - c. Ensure public input for new electronic clinical quality measures (eCQMs);
 - d. Continue to allow physicians to report on menu measures;
 - e. Develop a process to eliminate measures that no longer follow the latest clinical evidence; and
 - f. Ensure registry participation and interoperability.
- 4. Address physician EHR usability challenges**
- a. Adopt the Health IT Certification/Adoption Workgroup recommendation to revamp the certification program to focus exclusively on: 1) interoperability; 2) quality measure reporting; and 3) privacy/security;
 - b. Remove the requirement that only licensed medical professionals and credentialed medical assistants are allowed to enter orders;
 - c. Adopt recommended approaches to address User-Centered Design (UCD); and
 - d. Incorporate well-developed data management principles.

I. The Big Picture

The hope and promise of EHRs emphasized greater efficiency in health care, improved care coordination, and clear and legible medical information that could be easily shared among providers, regulators, and public health agencies. Many of the MU requirements were designed to increase patient choice and quality of care. Unfortunately, many of these requirements, especially those in the latter phases of the MU program, are having the opposite effect. Oftentimes the requirements decrease the efficiency of patient visits.

We strongly believe that measures are only meaningful when they meet the ongoing demand and complexity of our health care delivery system and serve the needs of providers and patients. Flexibility is essential to obtaining the envisioned goals of the EHR MU program. The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) could achieve this increased flexibility through a number of ways, including: alternative reporting

options; alignment between the various quality initiatives; and less ridged reporting criteria. In addition, many of the requirements depend upon interoperable EHR systems, which have not yet been realized, as well as the adoption of other new technologies that are still evolving. The MU program should ensure that such health IT is available and effective before holding physicians accountable to these standards.

A. Physician Adoption of EHRs and Participation in Reporting Programs

Incentives made available through the MU program have been instrumental in speeding physician adoption of EHRs. The most recent data from the National Center for Health Statistics (NCHS) on use of EHRs by office-based physicians reflects this progress but also depicts challenges. While 78 percent (2013 data) of office-based physicians are using some form of an EHR, only 23.5 percent (2012 data) are using one that is considered “fully functional.” In addition, the gap between solo practitioners and practices of 11 or more physicians persists. Significantly, NCHS estimated that only 18 percent of physicians will be eligible for MU incentives.¹

B. Evidence on MU

At best, the evidence to support that MU improves patient care is mixed, and there has been no comprehensive evaluation of the MU program. A recent article published in *JAMA Internal Medicine* found mixed results when comparing outcomes of physicians at Brigham and Women’s hospital in Boston who participated in MU compared to those not participating—concluding that that participation in the MU program was “associated with marginally better quality for two measures, worse for two measures, and not associated with better or worse quality for three measures.”²

A meta-analysis published in the *Annals of Internal Medicine* and funded by ONC through RAND reviewed 278 recent publications and existing studies (101 were studies of ambulatory care settings) that covered MU measures or aspects of measures. The authors of the meta-analysis found mixed results concerning the impact of health IT on outcomes. Fifty-six percent reported positive results, 21 percent depicted mixed-positive results, 12.6 percent were neutral, and 10.1 percent were negative. In terms of efficiency, only 45.2 percent of studies were found to have improved efficiency. The authors of the meta-analysis also found that “reporting of context and implementation details was poor, and 61 [percent] of studies did not report any contextual details beyond basic information.” None of the studies reviewed addressed other MU measures, including recording patient demographics, recording and charting changes in vital signs, maintaining an active medication list, recording adult smoking status, implementing

¹ According to NCHS the definition of a basic EHR for 2007-2009 includes six features: recording patient history and demographic information, clinical notes and patient problem lists, viewing lab and imaging results, and ordering prescriptions. In 2010 they also added recording medications, and for 2011 and 2012 recording medications and allergies was added. Their definition of fully functioning EHR included all the features of a basic systems and eight additional ones: medical history and follow-up notes, providing warnings for drug interactions or contraindications, eprescribing, ordering lab tests, sending test orders electronically, providing reminders for guideline-based interventions, providing out-of-range test levels (omitted 2011-2012), and having electronic images returned (omitted 2011-2012).

² Lipika Samal, MD et al., “Meaningful Use and Quality of Care,” *JAMA Internal Medicine*, June 2014, Volume 174, Number 6.

systems to protect privacy and security of patient data in an EHR, and reporting clinical quality measures.^{3,4}

C. Cost to Meet MU

There is growing concern that the cost of the MU program for many physicians far exceeds not only the maximum incentives offered under MU, but also the cost estimated by CMS to purchase and maintain an EHR. Furthermore, physicians have to incur significant expenses to update their EHRs, purchase additional software to share data, or perform other basic functions that many believed were included in the initial price of the system. More concerning is that many physicians are now incurring costs to replace EHRs that do not perform.

A recent article published in *Health Affairs* found a negative return on investment (ROI) for the MU program that, on average, amounted to a loss of \$43,743 over five years.⁵ The negative ROI was almost double for specialists compared to primary care physicians. Also of note, the study found that the most common ongoing cost was physician time, which was reported by 22 percent of practices.

Besides the cost of adopting and maintaining an EHR, there are additional costs associated with data exchange. Today, due to interoperability challenges, only 10 percent of physicians are moving data through a health information exchange (HIE).⁶ Little is known about the cost for physicians to move data on HIEs, which varies by business model. There is also a lack of data available on the cost of using a Health Information Service Provider (HISP), an entity involved in the movement of health data, which can be part of a vendor, HIE, or stand-alone service.

The Government Accountability Office (GAO) found in its March 2014 report on EHRs:

Providers we interviewed reported challenges covering costs associated with health information exchange, including upfront costs associated with purchasing and implementing EHR systems, fees for participation in state or local HIE organizations, and per-transaction fees for exchanging health information charged by some vendors or HIE organizations. Several providers said that they must invest in additional capabilities such as establishing interfaces for exchange with laboratories or other entities such as HIE organizations. For example, many providers told us that the cost of developing, implementing, and maintaining interfaces with others to exchange health information is a significant barrier. One provider and several officials estimated various amounts between \$50,000 and \$80,000 that providers spend to establish data exchange interfaces. Other stakeholders we interviewed or who responded to HHS's March 2013 RFI also identified costs associated with participation in HIE organizations and maintaining EHR systems as a challenge for

³ Spencer S. Jones, et. "Health Information Technology: An updated Systematic Review With a Focus on Meaningful Use," *Annals of Internal Medicine*, January 2014, Volume 160, Number 1.

⁴ The RAND Corporation. "Health Information Technology: An Updated Systematic Review with a Focus on Meaningful Use Functionalities," prepared for ONC, contract HHSP23337020T.

⁵ Julia Adler-Milstein, et., "A Survey Analysis Suggests That Electronic Health Records Will Yield Revenue gains for Some Practices and Losses for Many," *Health Affairs*, March 2013.

⁶ Julia Adler-Milstein, et., "Operational Health Information Exchanges Show Substantial Growth, But Long-Term Funding Remains a Concern," *Health Affairs*, August 2013.

providers.⁷

One Medicare ACO/Medicare Shared Savings participant we spoke with stated the following with respect to EHR cost:

As part of our next Meaningful Use upgrade with X vendor, we will get access to the X vendor HISP for an annual fee. We will also be required to connect to the X HIE in order to deliver some public health data to the state of X. The X HIE will charge a monthly fee for use of their HIE. They also have a HISP if we want to use it instead. While we have rights to all upgrades from X vendor, they are charging us between \$40,000 - \$60,000 for implementation services for the upgrade. Once the X vendor HISP is available to us, it still remains to be seen if the other entities in the community will be available for us to send and receive records with. We still do not know how much work will be required to set up and administer the HISP addresses in our EMR. We were told that the HISP connections with X vendor would cost \$100 per provider per year. Another \$200 per provider per year goes to X vendor for their Meaningful Use reporting portal.

We are concerned that neither CMS nor ONC has studied the cost of purchasing and maintaining an EHR, multiple interfaces, and the expense incurred to exchange data. Moreover, in light of these significant costs, the additional burden of financial penalties is unlikely to further motivate physicians but may impede progress in adopting and using new technology. **We urge CMS and ONC to study the total costs of compliance with MU to understand the impact this program is having on practices.**

D. Path Forward for MU

As we listen to the experience of physicians and other providers, it is clear that even those who have had EHRs and other health IT in place for several years are struggling to keep up with the rapid pace of MU requirements. We are concerned that, if these problems are not remedied moving forward, it will negatively impact the quality of and access to care for patients by:

- **Jeopardizing patient safety** by mandating the use of technology before it is thoroughly tested and evaluated;
- **Increasing administrative burden** such as overly prescriptive data collection mandates and measures;
- **Interrupting access to patient information and hindering care coordination** if physicians and patients are unable to access data stored in an a previous EHR system;
- **Decreasing efficiency** since certain MU requirements add new tasks and EHRs require additional time to input data, which can translate to fewer patients seen;
- **Inhibiting access to innovative technology** where EHRs are designed to meet a voluminous number of MU criteria instead of adopting revolutionary and innovative technology;
- **Hindering other innovative solutions** if physicians are too focused on trying to meet MU and cannot dedicate time to develop health care improvements for their specific specialty or practice;

⁷ GAO report (GAO-14-242), "Electronic Health Records HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones" March 2014.

- **Placing undue costs on physicians** due to poorly developed technology, costly interfaces, expensive data extraction tools, losses in productivity, or other investments aimed at aggregating or exchanging data through cumbersome methods to try and achieve interoperability; and
- **Slowing the movement to alternate payment/delivery models of care**, the result of a combination of the aforementioned challenges.

We think there is a real opportunity to address these challenges now. If changes are not made, we fear the prescriptive nature of both the MU program and the EHR certification requirements will continue to stifle innovation and fuel a growing frustration among physicians. In the end, the loser will be not only the doctor, but the patients they serve. There is, however, cause for optimism if we use the experiences gained to date to shape the program moving forward.

II. Recommendations: Key Considerations and Requested Changes

A. Adopt A More Flexible Approach for Meeting MU

The single greatest barrier physicians face to date in meeting MU is the all-or-nothing approach of the program that results in a zero sum game. Depending on a physician's patient population, specialty, and EHR system, different MU measures pose more of a problem than others. Yet, the program requires 100 percent compliance at all times to earn an incentive and avoid a penalty, despite the fact that certain measures are less relevant in different care settings or that technology may create barriers in meeting certain requirements.

The current program attempted to mitigate these differences by offering percentage thresholds; however, this design creates additional administrative burden—physicians must implement different workflows for different patients and engage in extensive tracking to ensure measures and thresholds are met. We believe that setting arbitrary thresholds is of little help to physicians and may lead to inconsistencies in the care provided to patients.

It is for these reasons that we believe a simple policy change is needed that would allow physicians to work toward meeting the MU requirements but not face penalties for missing a single measure. By affording this flexibility, it will provide the necessary guardrails to ensure successful participation in the program. It will also help mitigate challenges physicians are facing from factors outside of their control, such as EHR interoperability, usability issues, or meeting measures that are contingent upon patient action. In addition, by removing the thresholds for Stage 3, vendors would no longer need to tabulate whether a physician has met a measure, allowing them more time and resources to innovate and improve the physician EHR user experience.

Flexibility also ensures that physicians are not penalized when there are problems with MU measures or standards. As an example, a recent article in the *Journal of the American Medical Informatics Association (JAMIA)* found significant problems with C-CDA, the required standard named by ONC to facilitate data exchange. ONC identified the C-CDA as the backbone exchange technology to meet all interoperability requirements in Stage 2. However, this newly developed technology had very little real world testing, nor was it balloted or approved for standardization by HL7 prior to ONC's decision to require its use in Stage 2. In fact, at the time of this writing, the C-CDA is still considered a draft standard for trial use. This means that although EHR vendors are required to incorporate C-CDAs as the primary method for patient information exchange, the draft standard allows for the C-CDA software,

design, or template specifications to change at any time. This wild variation in technology versioning has created significant issues that have led to limited interoperability.

The JAMIA article found possible disruptions in critical care activities such as drug-allergy interaction alerting, medication prescribing, and medical terminology representation. Overall, EHR-generated C-CDAs scored on average only 63 percent in accuracy. The data depicted in **Attachment 1** shows that more than half of the vendor systems scored less than 60 percent accuracy, by all accounts a failing grade. The article concluded that based on the use of this standard, “C-CDA documents produced from technologies in Stage 2 of MU will omit key clinical information and often require manual data reconciliation during exchange.” It also found that unless timely policy changes are made, “robust document exchange will not happen anytime soon.”⁸

Given these challenges and that the MU program is moving into the penalty phase in 2015, we firmly believe that a pass-fail approach should not apply. Instead, there is precedence for using a lower threshold when determining penalties. Under the Medicare e-Prescribing program, physicians needed to send fewer scripts electronically in order to avoid a penalty than they did to obtain an incentive. There is no evidence to suggest that this approach slowed down the use of e-Prescribing. Physicians also routinely report that, despite the challenges they face using their EHRs, they have no plans to return to paper, a finding also captured in the AMA-funded RAND report discussed below.

We also believe that, for Stage 3, to ensure that physicians are not simply checking the box and meeting measures where there is no added value for their patients, a more robust measure list is needed. We do not see the value in the bifurcated approach of a “menu” list and a “core” list. Rather, a single list with adequate measures from which a physician can choose those that best meet their practice and patient mix is needed. Even with the current exception criteria the program continues to be criticized as being too primary care centric and is not agile enough to meet specialists’ needs. We believe the best way to address this problem is to expand the available measure list and not remove the measures as proposed by the HITPC. New measures should focus on specialists and their patient populations. Subsequent stages should focus on refining this measure list, rather than simply adding on additional requirements that further complicate the technology and the ability to comply with the program. Specifically, we believe that Stage 3 should not expand the number of reporting requirements but should focus on ensuring the primary MU program goals.

It is for these reasons we recommend adopting a more flexible approach for meeting MU by:

- **Removing the existing program’s all-or-nothing approach by adopting a 50 percent threshold for incurring a penalty and a 75 percent threshold for earning an incentive for Stages 1-2; at the very least, the Administration should make optional the measures that have been the most challenging for the vast majority of physicians:**
 - **View, Download, and Transmit**
 - **Transitions of Care**
 - **Secure Messaging**

⁸ John D. D’Amore, et al., “Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative,” *Journal of the American Medical Informatics Association*, 2014;0:1–9.

- **Removing percentage/thresholds for measures and the concept of menu vs. core requirements for Stage 3;**
- **Providing new health IT measures for inclusion in MU to expand the options for specialist participation for Stage 3;**
- **Retaining the measures the HITPC recommended for removal to ensure provider participation; and**
- **Requiring physicians to meet no more than 10 measures under Stage 3.**

We provide extensive feedback and recommendations on the specific health IT measures proposed in Section IV.

B. Expand Hardship Criteria

The Health Information Technology for Economic and Clinical Health Act (HITECH) allows the Secretary to grant hardships to physicians, subject to annual renewal, to avoid a financial penalty if certain circumstances are met. We appreciate that CMS has expanded the number of hardship categories available to physicians and are encouraged by the recent decision to re-open the hardship deadline to physicians who have been unable to fully implement Version 2014 of their certified electronic health record technology (CEHRT) and attest by October 1, 2014. These changes provide necessary relief as many physicians are struggling to meet a number of reporting mandates and avoid multiple penalties. We believe, however, that new hardship categories are warranted and that changes to existing ones are still needed. **Below are our recommended changes and additions to the hardship categories:**

1. Establish a quality hardship

As you are aware, having to report quality measures for both MU and PQRS, which have different reporting periods, places a duplicative burden on physicians. While CMS' and ONC's proposed rule published on May 23, 2014, proposed to allow physicians to choose their edition of CEHRT, either 2011 or 2014, it prevents them from combining their PQRS and EHR quality reporting requirements. We understand that, due to limitations in CMS' registration and attestation system, if a physician elects to use 2011 Edition CEHRT in 2014, the physician would be required to report clinical quality measures according to the criteria originally finalized in the Stage 1 final rule and for only 90 days. This prevents alignment with the PQRS requirements that require a physician report using version 2014 CEHRT and for a full calendar year. Despite our repeated requests that ONC and CMS align the reporting requirements, the proposed rule failed to address this problem. This concern with quality alignment is even more pronounced given that physicians will face payment adjustments if they do not successfully report PQRS and MU quality measures in 2014. **We strongly urge CMS to provide an exemption for physicians from having to meet the MU quality requirements if they have successfully participated in the PQRS program.**

2. Expand the "unforeseen circumstances" hardship

While on the surface this category sounds fairly broad, upon review of the hardship application it is clear that this category is very narrowly construed. Many physicians are small business owners who face a number of challenges that extend beyond practice closures, bankruptcy, and EHR vendor issues that pose a threat to their ability to meet MU. We believe it would be impossible to account for every single type of

scenario within the application. For example, we were contacted by a physician who was moving multiple office locations mid-year. Their primary focus was on ensuring continuity of patient care making it difficult to comply with the MU requirements. Changes to Medicare enrollment alone (like an address change and change of biller) can require significant practice resources. Since CMS has made it clear that each hardship request warrants an individual, manual review, we see no reason why allowing physicians to make their case for qualifying for an unseen circumstance should be precluded. **We urge CMS to expand this category to cover circumstances that may not have been envisioned but clearly impede a physician's ability to meet MU requirements.**

3. Continue the exemption for anesthesiologists, radiologists, and pathologists

Meeting the MU requirements is not always possible for these specialists, it is unduly burdensome given the current state of commercially available EHRs, particularly with respect to standalone specialty system products, certification of technology appropriate for these specialties, workflow challenges, nature of the patient relationship, and patient data needs. Moreover, these specialists are often subject to the capabilities and resources of the hospital facilities in which they work. Whenever those facilities are not proactive partners in enabling all onsite (including contracted) physicians to meet MU via adequate data collection, CEHRT access, and technical support, the barriers to compliance are significantly higher and often impossible to overcome. Due to these barriers only a small minority of physicians with the relevant anesthesiology, pathology, and radiology PECOS designations have attested to MU. **We therefore request assured continuation of the hardship exception for anesthesiologists, pathologists, and radiologists.**

4. Provide an exemption for hospitalists

EPs must meet a 90 percent inpatient services threshold to fall under the hospital-based EP exception from MU. CMS' original definition of hospital-based determined this percentage by place of service codes (POS) 21, 22, and 23; however, the Continuing Extension Act of 2010 (Pub. L. 111-157) limited the POS codes to 21 (hospital inpatient) and 23 (emergency department). Since some hospitalists are treating large numbers of "observation" patients (coded as an outpatient service) they are not qualifying as hospital-based EPs and will be subject to penalties under MU. **We recommend that CMS create a hardship category for hospitalists or observation care falling under POS 22 or request that CMS remove observation patients from the mix of outpatient services counting toward the EP threshold.**

5. Provide an exemption for physicians close to retirement

Purchasing an EHR is a significant capital investment for a physician. In many cases, it simply does not make sense for physicians who are close to retirement to purchase these systems. **Rather than taking what we believe is a wasteful approach, we strongly urge CMS to create a hardship exemption for physicians who are currently eligible or will be eligible for Social Security benefits by the end of 2015.**

C. Improve Quality Reporting

We strongly urge CMS not to expand the quality reporting requirements until the below health IT infrastructure challenges below are resolved, more flexibility is instituted, and quality measures are

updated more frequently to comply with clinical practice guideline changes. Existing quality challenges include:

- Lack of standardized clinical data terminologies to allow information in the EHRs/registries to be exchanged and captured seamlessly;
- Lack of developed standards to appropriately capture electronic quality measures within the EHR;
- Deficient CMS infrastructure to accept electronic transmission of measures (the only way for CMS to accept eQMs is through electronic generation of files);
- Reliance on demographic data that is often not needed for clinical diagnosis and is often housed in the practice management system (PMS), which makes data collection difficult and costly;
- Obstacles for physicians meeting Clinical Decision Support (CDS) since it is tied to MU quality requirements;
- Lack of transparency in the development of eQMS; and
- Module certification for registries to report for MU.

1. Improve alignment with PQRS

Specifically, the quality reporting pieces of the MU and the PQRS programs need to be better aligned to avoid conflicting deadlines and reporting requirements. For MU quality reporting to count towards PQRS, a physician must take into consideration the following detailed rules and requirements:

- PQRS quality measures must be reported for a full year, as opposed to 90 days. This requires first-year MU participants to report twice given the different reporting periods for each program.
- The MU program requires reporting on at least nine eQMs, which must be available through Version 2014 Certified Software and cover three of the National Quality Strategy Domains in the MU program. However, under the 2015 physician fee schedule rule, CMS has proposed that eQMs do not need to be reported through the latest version of certified EHR software. While this may help with reporting quality measures, we are unclear how this change would impact the reporting of health IT functionality measures.
- Some of the MU eQMs include “look-back” or “look-forward” periods requiring data outside of the PQRS and Value Based Modifier (VBM) reporting periods. If CMS cannot calculate a performance rate for that measure, a physician would be subject to both PQRS and VBM penalties.
- Measures reported through the PQRS Qualified Clinical Data Registry (QCDR) option must be part of the MU program, and the QCDR must be certified by ONC.
- For MU, it is acceptable to report zeroes on measures (including not having any denominator-eligible patients for any of the measures for which their EHR is certified). Yet, this is not permissible for any reporting option under PQRS. If a physician does not have any data on Medicare patients (i.e., none of their Medicare patients fall into the denominator of any of the quality measures for which their EHR is certified), then the physician needs to report separately for PQRS.

Therefore, the AMA recommends the following to streamline reporting with PQRS:

- **Deem physicians who successfully participate in PQRS, regardless of the reporting mechanism, to have successfully met the MU quality measure requirements;**
- **Scale back the number of quality measures required for reporting until there are enough eCQM's that work for all physician specialties.** This is more urgent as physicians will face a penalty in 2015 if they do not successfully participate in PQRS, VBM and MU. This also resolves part of the alignment issue involving zeroes in the denominator, which PQRS does not consider successful reporting;
- **Further streamline the reporting requirements for group practices that elect to participate in PQRS through the GPRO web-interface, which is a very popular option for large multi-specialty group practices.** Due to the differing requirements, practices that elect to participate through the GPRO web-interface must report separately and as individuals to meet the MU quality measures; and
- **Establish an additional reporting period for PQRS in 2015 so this reporting period aligns with first-year MU participant requirements.** It is unrealistic for CMS to expect a physician to have the necessary bandwidth to track multiple quality reporting programs when they are in the process of implementing an EHR, complying with multiple new mandates, and will have to switch to ICD-10 in the near future. If CMS allowed for a 90-day PQRS reporting period, physicians would have an additional opportunity in 2015 to avoid the 2017 two percent PQRS penalty and potential four percent VBM penalty. **We remind CMS that the PQRS and VBM statute only states that payment adjustments are for a full year and does not state a specific reporting timeline.**

2. Lack of a quality infrastructure

To move to more outcomes-based measures and longitudinal tracking of patient care, interoperability across EHRs must be resolved. This was a common theme made by workgroup members during their presentations at the July 8, 2014 HIT Policy Committee meeting. Yet, we are disappointed that the HIT Policy Committee, CMS, and ONC are not focusing on resolving underlying challenges with reporting quality measures before recommending more advanced measures and the "Innovation Pathway," an alternative way for meeting MU quality reporting requirements. Many of the proposed measures made by the HIT Policy Quality workgroup assume interoperability and that the advanced stages of MU are seamlessly in-place. Therefore, it is incumbent that before any of these measures go forward there is real-world testing in multiple types of physician practice settings and sizes to ensure the EHR can capture and calculate the measures without putting an undue burden on physicians.

In an effort to address care coordination, the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) recently embarked on a partnership with the Wright Center for Medical Education and the Pennsylvania Department of Health that addressed physician-to-physician referrals in the ambulatory setting by establishing accountability standards and improving information transfer. Through this project, PCPI learned that the current vendor systems do not have the functionality needed to support bi-directional information transfer or measurement. This is leading to extensive customization and cost with each participating practice site for a function that should be a standard operating procedure in the ambulatory setting. We recommend that requirements be included in MU Stage 3 that supports the referral process within a system and to external specialists through the EHR. At a minimum, this should include the requested timeframe on the referral, reason for referral including the clinical question the primary care physician is seeking input on, past medical history/current medications, relevant lab and test

results, and special needs of the patient. In addition, data elements required for the quality measures in development by ONC should be easily extractable from the EHR. Through the MU criteria, ONC has the opportunity to encourage EHR vendors to build these capabilities into their systems.

We also believe that if CMS fixed and updated its internal infrastructure it would allow for an easier eCQM submission process for vendors and physicians. Currently, eCQMs are generated in the EHR based on content documented in the patient chart. However, the actual submission process of quality measures requires a manual upload by the vendor to a CMS website. For patient-level reporting, this can be hundreds or thousands of files per physician. Allowing the submission of quality measures to occur electronically could facilitate real time reporting and feedback for physicians. By maintaining the current infrastructure, CMS is actually hindering the move towards outcomes measures since physicians do not have access to real time information or frequent feedback to determine how they are doing with meeting quality requirements.

3. New eCQMs

One of the biggest challenges with the quality reporting programs is having the opportunity to meaningfully comment and inform the measure development process. Despite making numerous requests of CMS and ONC on how to put forward a request for a measure and for a status update on possible ONC/CMS contracted measures, this process remains opaque and illusive. Without this feedback, we are concerned that Stage 3 will miss the mark in meeting the needs of physicians.

We are unaware of ONC, CMS and/or its contractors informing the public on the ability to publicly comment on eCQMs. Specifically, we did not learn of the new eCQMs until we saw measures posted on the JIRA portal, CMS' tracking system. Many of the quality measures are novel and require goal setting between the physician and patient, and we are concerned that such measures hold physicians accountable for patient behavior outside of their control. Complying with the recommended goal setting measures require longitudinal tracking and collecting patient data; however, this may not be feasible given the lack of ability to exchange information. Many patients may also not feel comfortable with physicians tracking their data, which could deter a patient from seeking care. Outcomes for patients most likely will vary depending on the availability of resources. In addition, there are risk-adjustment issues on socioeconomics that CMS has yet to tackle in its quality programs.

Because many of these measures are new and have not been utilized in any other CMS quality program, we are concerned with the scientific and statistical validity, the ability to actively collect patient data over time, and what the level of accountability will be. **Therefore, we recommend that:**

- **Before new measures go forward that there is real-world testing in multiple types of physician practices settings and sizes to ensure the EHR can capture and calculate the measures without putting an undue burden on physicians;**
- **CMS establish a public comment period before proposing and implementing new measures; and**
- **If CMS moves forward with the new quality measures, CMS should consider these measures in the beta-phase and not hold physicians accountable until we learn more about the feasibility of the measures. Physicians should have the opportunity to report on the measures for two years, at a minimum, before they are held accountable.**

4. Core measures

We strongly urge CMS not recommend core measures as part of the quality objective requirement. Stage 1 required physicians to report on three core measures or three alternate core measures and three menu measures. Due to varying physician specialty practice patterns it is extremely difficult to hold physicians accountable to measures that do not fit into their scope of practice. **We urge CMS to continue to allow physicians to report on a menu set of measures for compliance with the quality objective. We also reiterate for CMS to scale down the number of required quality measures due to the lack of eCQMs in the program.** This would make quality reporting more meaningful and allow physicians to focus their quality improvement efforts.

5. eCOM rulemaking cycle

We are aware of a handful of quality measures in the MU program that are no longer following the most recent clinical practice guidelines. These measures remain in the program despite their lack of relevance because CMS has not yet issued the next MU rule. By establishing a program that is not nimble and able to adjust to changing practice patterns, CMS is not improving quality of care for patients. **We therefore recommend:**

- **CMS and ONC should develop a process to eliminate measures that no longer follow the latest clinical evidence; and**
- **More clearly define what constitutes a minor specification change that can be incorporated into CMS' implementation guides versus a major change that requires rulemaking.** What might be considered a major change in the vendor community may be minor for measure developers and/or physicians and vice versa. Therefore, CMS must issue clear guidance on measure specification updates, particularly if it is outside of certification.

6. Registry participation and interoperability

We continue to be disappointed with CMS' requirements for QCDRs, a new reporting option for MU clinical quality measures. The QCDR requirements to report quality MU measures are currently not feasible. Essentially, QCDRs must electronically specify their measures which, as CMS has discovered, is not a simple task and not all measures lend themselves to this process. In addition, because CMS operates on a three-year rulemaking cycle to incorporate new eCQMs into the program, it is our understanding from communications with CMS that they would have already had to have received new eCQMs for Stage 3. Therefore, it is effectively not feasible for a QCDR to even incorporate and propose their measures to CMS for Stage 3, nor Stage 1 or 2.

To be used for MU, QCDRs would need to go through the CEHRT module process; however, we are unaware of a clinical data registry that is going through this process. True clinical data registries are not EHRs and their purpose is different. We do not believe certification vendors are set up to certify or understand clinical data registries. Finally, requiring QCDRs to go through the CEHRT process will force registries to meet qualification requirements for both PQRS and MU, which is overly burdensome and costly for the vendor.

In terms of interoperability and data silos, problems persist not just among physician practices and hospital systems, but also between EHR systems and clinical data registries. EHR code extraction is not available for the vast majority of clinical data registries and the registry objective continues to miss the mark. The proposed Stage 3 objective only requires a CEHRT EHR to transmit to one registry and does not recommend a standard. **We believe CMS needs to play a greater role in facilitating the use of clinical data registries by encouraging the development of standards for sharing/transmitting data between EHRs and registries.** Presently, practices are forced to manually enter data into a registry because no streamlined process exists and because of the proprietary nature of HIT products. This existing data sharing process is particularly challenging for solo and small practices; thus preventing many from participating in registries. Finally, the manual data entry process requires a full-time or half-time employee, which is an added cost that most practices cannot easily absorb.

Instead of each registry developing their own interoperability standards, EHRs should accept data from registries using national data standards, e.g., those used in the QCDR program (CMS-approved XML format, QRDA category III format). We believe CMS and ONC should expand this requirement to include bi-directional connectivity based on those same national standards, i.e., transmit data from CEHRT to a registry and from a registry to CEHRT. Bi-directional connectivity allows CEHRTs to not only send data to registries but for the CEHRT to accept information from registries. As an example, in CDS, registry data can be combined with CEHRT data to show the risk of various approaches to treatment, individualized to the characteristics of individual patients. Transmitting registry data to the CEHRT also improves physician workflow by eliminating the need to switch back and forth between the CEHRT and the registry.

The current certification requirements also fail to address the need for bi-directional exchange for national clinical data registries or clinical data standardization for any other purpose. Cancer and immunization registries, while helpful, are primarily used for surveillance, epidemiology, and point of care information transfer. In comparison, national clinical data registries can be used for quality improvement support (such as reporting and benchmarking) or other related activities. In addition, EHR vendors charge providers a cost to map and transmit data from an EHR to a registry. The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems move to a more advanced state of quality measurement.

Capturing data through a registry allows for the collection and tracking of data across care settings and disease states; inpatient and/or outpatient; acute episode or chronic disease; surgical versus nonsurgical interventions; and resource intensive versus relatively inexpensive therapies. Quality measurement must move beyond single episodes or a “snapshot” of care, which focuses solely on clinicians and individual patients to a learning system with a broad focus. Utilizing third-party registries provides an opportunity to evaluate the care provided within an entire specialty, as well as at the individual physician level.

Therefore, the AMA recommends:

- **ONC require EHR vendors to provide clinical data in a standard format that is backed by standardized data definitions instead of providers incurring the cost of middleware vendors to map and transmit the data;**
- **Engage with the physician community and the AMA to ensure the clinical content of this work is accurate and widely adopted; and**

- **CMS move away from the development and expansion of a one-size-fits-all data reporting system.**

D. Address Physician Usability Challenges

1. Growing level of dissatisfaction

As EHR adoption has increased over the past decade, physician satisfaction with these tools has declined. An AMA-funded RAND report, published in October 2013, found widespread dissatisfaction with EHRs and the MU program.⁹ Issues identified by those surveyed included “poor usability, time-consuming data entry, interference with face-to-face patient care, regulatory requirements, insufficient health information exchange, and degradation of clinical documentation.” A report by Black Book Rankings also suggests that MU incentives have created an artificial market for dozens of immature products.¹⁰ Insights from this survey highlighted concerns that many EHR vendors have been so preoccupied with backlogged implementations that they are neglecting development priorities that could improve usability.

The growing frustration by physicians could spell lower participation levels in MU. A recent IDC Health Insights survey found that 58 percent of ambulatory physician users were not satisfied with their EHR technology and that “despite achieving meaningful use, most office-based providers find themselves at lower productivity levels than before the implementation of their EHR. Workflow, usability, productivity, and vendor quality issues continue to drive dissatisfaction.”¹¹

2. Impact on workflow

Physicians are also vocalizing concerns related to the EHR’s impact on workflow,¹² including challenges meeting the specific MU requirements. The workflow challenges are leading to productivity losses and longer work days. An article published in the *American Journal of Emergency Medicine* found, “the time spent on documentation to be 30 percent to 40 percent of a workday, with electronic charting taking 30 percent longer than paper charts.” These challenges were also reflected in the RAND report referenced above.

Others have experienced significant changes in their administrative duties, especially related to entering orders into an EHR. Many of the complaints stem from the MU requirement that only licensed medical professionals and credentialed medical assistants are permitted to enter certain orders, a requirement that is creating confusion and serious workflow challenges for many physicians. For example, medical scribes, who are not licensed but often aid physicians in entering information into an EHR while the physician speaks with the patient, can be precluded from entering physician orders under this policy.

⁹ Mark William Friedburg, et. al, “Factors Affecting Physician Professional Satisfaction and Their Implications for Patient Care, Health Systems, and Health Policy,” RAND, October 2013.

¹⁰ Black Book Rankings 2013 User Survey Top Practice Management and Revenue Cycle Management Ambulatory EHR Software Vendors.

¹¹ Hanover, J. Business Strategy: The Current State of Ambulatory EHR Buyer Satisfaction. IDC Health Insights. <http://www.idc.com/getdoc.jsp?containerId=HI244027>. Accessed June 2014.

¹² Spencer S. Jones, et al., “Unraveling the IT Productivity Paradox — Lessons for Health Care,” *New England Journal of Medicine*, June 14, 2012.

We understand the intention behind this restriction to ensure that the physician or other provider sees and responds to alerts and other CDS tools. We believe, however, that the better approach is to allow the individual physician or their institution to decide how to facilitate computerized physician order entry (CPOE) and ensure timely patient access to medically necessary drugs or therapies through the utilization of its specific care team. **To best address the significant usability issues, we believe that physicians, medically licensed professionals, credentialed medical assistants, and other trained individuals as deemed appropriate by the individual provider or institution should be able to enter orders for patients.**

We also recognize that not all workflow issues are directly related to EHR software design. Some stem from limited training and sub-optimal implementation required by practice or organizational policy. Some are related to regulatory requirements—state and federal—including overly proscriptive MU requirements and requirements imposed by commercial payers. Ultimately, workflow disruptions are likely to get worse as the MU program becomes increasingly challenging.

3. EHR usability and vendor certification requirements

Concerns are also mounting with the federal requirements EHR vendors must meet to obtain certification. These mandates are hindering their ability to address usability concerns and develop more user-friendly products. Federal agencies like the Agency for Healthcare Research and Quality (AHRQ) and the National Institute of Standards and Technology (NIST) are also devoting more attention to this matter. According to the NIST:

Usability represents an important yet often overlooked factor impacting the adoption and meaningful use of electronic health record (EHR) systems. Without usable systems, doctors, medical technicians, nurses, administrative staff, consumers, and other users cannot gain the potential benefits of features and functions of EHR systems.

Similarly a recent AHRQ report stated:

Current best practices and standards of design, testing, and monitoring EHR product(s), particularly for usability, are varied and not well disseminated...Driving the EHR market toward creation of usable products requires development of a process that accurately identifies usable products, establishes and disseminates standards, and encourages innovation.

There is growing awareness across stakeholders that the MU vendor certification process should be streamlined to enable higher performing products that focus on interoperability, quality measurement reporting, and privacy/security. We strongly support this change.

Another concern that we believe should be addressed is having EHRs undergo better testing. While some EHR vendors are implementing User Centered Design (UCD)—defined as “the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in

a specified context of use”¹³—few vendors have fully embraced this model. It is vital that proper UCD techniques are adhered to so that EHR vendors can incorporate both user interface and cognitive workflow design in the development of their products.

New data, that we expect to be published soon, is also suggesting increased cognitive burden on physicians due to EHRs, even after three months of frequent use. EHRs increase how frequently physicians must multi-task, which is known to pose potential patient safety risks. In short, physicians and residents are spending more time on computers and less time with patients. **These negative effects are shown to persist even after frequent use of the EHR and beyond the “acquaintance period.”** We are deeply concerned about the implications that this has on physicians’ ability to diagnose, treat, and manage patient care. To reduce cognitive strain, we support the following approach outlined by the MedStar Institute—one of ONC’s SHARPC grantees—and believe that EHR certification should allow for both summative and formative testing options.

- For those vendors who do not already have a rigorous summative testing process, they should be allowed to attest to their UCD process and provide the summative testing results. ONC should set minimum requirements such as guidelines on sample size and type of participant. Doing so could help avoid challenges with vendors providing varying levels of detail and would bring more consistency to the process.
- For vendors with a rigorous UCD process in place, they can opt to demonstrate the process as opposed to providing summative test results. This would include evidence of formative testing, among other things.

4. Patient safety

Various journals, whitepapers, and other publications have also highlighted patient safety concerns related to EHR usability.^{14,15,16,17} In most cases a disconnection with EHR design, implementation, and the clinician’s workflow was cited as a major contributor to patient safety issues and events. In the case of the Veteran’s Health Administration, “most (94 percent) safety concerns related to either unmet data-display needs in the EHR (i.e., displayed information available to the end user failed to reduce uncertainty or led to increased potential for patient harm), software upgrades or modifications, data transmission

¹³ International Organization for Standardization (ISO) 9241-11 (1998) Guidance on Usability. Ergonomic requirements for office work with visual display terminals (VDTs) — Part 11: Guidance on usability. Accessed August, 2014 from: <https://www.iso.org/obp/ui/#iso:std:iso:9241:-11:ed-1:v1:en>.

¹⁴ Findings and Lessons From the Improving Management of Individuals With Complex Health Care Needs Through Health IT Grant Initiative. (Prepared by Westat Under Contract No. HHS 290200900023I.) AHRQ Publication No. 13-0058- EF. Rockville, MD: Agency for Healthcare Research and Quality. September 2013.

¹⁵ Meeks DW, Smith MW, Taylor L, et al. An analysis of electronic health record-related patient safety concerns. *J Am Med Inform Assoc* Published Online First: June 2014. doi:10.1136/amiainl-2013-002578.

¹⁶ Middleton B, Bloomrosen M, Dente MA, et al. Enhancing patient safety and quality of care by improving the usability of electronic health record systems: recommendations from AMIA. *J. Am Med Inform Assoc* Published Online First: January 2013. doi:10.1136/amiainl- 2012-001458.

¹⁷ Gardner, E. *I.T. Behaving Badly*. HealthData Management Online. http://www.healthdatamanagement.com/issues/22_6/IT-Behaving-Badly-48154-1.html?zkPrintable=1&nopagination=1. Accessed June 2014.

between components of the EHR, or ‘hidden dependencies’ within the EHR.”¹⁸ Authors agree that incorporation of UCD in the EHR design process would increase usability; however, the adaptation of such a design process would be difficult to apply to legacy systems.

The AMA views MU vendor certification as a starting place to ensure the safety, usability, and reliability of health IT products. We are encouraged by the steps taken by the federal government to develop a health IT Patient Safety Center. Yet, there is still not a clear role for this Center nor is there an identifiable timetable for its construction. As many physicians are utilizing legacy systems we fear that, without further attention to the EHR certification process, the safety and usability of EHRs will continue to be lax and wanting. In May, ONC sponsored an EHR certification hearing where testimony highlighted a need for all stakeholders to examine certification issues. **While we are hopeful that certification changes will occur, we are concerned with how long it will take to implement and the time vendors will need to modify, test, and deploy new products. We question if these changes can align with CMS’ and ONC’s intended timetable for Stage 3.**

5. Maximizing the use of EHRs: better care coordination, interoperability, and data liquidity

One of the initial promises of health information technology was the ability to leverage the technology’s computing power to cull through various evidence-based resources and provide the clinician instant information at his or her fingertips. **EHRs should enhance the ability for automatic tracking of referrals/consultations to ensure that the referring physician does not lose track of their patient.** The same approach is needed for tracking whether lab order results are reported and, where possible, that prescriptions are filled. Current EHRs are not yet capable of providing this information seamlessly to physicians. The focus on Stage 3 should be on achieving these coordination goals, rather than simply identifying new data elements. **In particular, Stage 3 should recognize the need to focus less on data collection and more on methods and technologies that facilitate the coordination of care and new payment models.**

True interoperability, both syntactic and semantic (the ability to send/receive and fully incorporate information) enhances usability and protects physicians against EHR “lock-in.” Today’s HIE environment, characterized by a mix of public and privately funded exchanges cannot support true interoperability without a commitment on the part of EHR vendors and ONC to support current and future data exchange standards. This commitment must also extend to the type and frequency of systems testing—ensuring that data being exchanged between EHRs is accurate, timely, and resistant to errors. EHRs should facilitate interoperability among various facilities that comprise our health care system, including hospital inpatient, ambulatory settings, lab, and pharmacies. Moreover, interoperability extends beyond EHRs and will be need to support emerging technologies, including mobile health and telehealth. Identity proofing of physicians, patients, and organizations is critical and must be addressed to ensure true interoperability.

We recognize that true interoperability is complex and may not be achievable within the current information exchange environment, data standards, and certification constructs. It will take a concerted effort and cooperation by standards bodies, information exchanges (both public and private), EHR

¹⁸ Meeks DW, Smith MW, Taylor L, et al. An analysis of electronic health record-related patient safety concerns. J Am Med Inform Assoc Published Online First: June 2014. doi:10.1136/amiajnl-2013-002578.

vendors, testing authorities, and ONC to achieve this goal and improve certification of EHRs. We are encouraged by ONC's recently released roadmap for interoperability. We believe efforts such as Healthway, Common Well, and the newly announced Carequality will contribute to the interoperability goal.

To make data useful, it must be accurate, timely, and contextually sensitive. This strongly depends on the quality of the data submitted to registries and exchanged between health care organizations. It is vital that entities contributing to data exchange follow certain procedures designed to minimize inaccurate and incomplete data. Moreover, the structure and definitions of metadata (data that describe data) may need to be standardized. Technologies such as FHIR, which rely on metadata schemes, are gaining more attention and platforms such as SMART on FHIR are becoming more mature. More development and refinement, however, is required before this technology is fully ready for wide scale use, and therefore, should not be identified as a cornerstone of meaningful use Stage 3.

As previously mentioned, ONC's premature requirement of a developing standard like C-CDA stunted the growth of meaningful data exchange in Stage 2. **It is imperative that further meaningful use stages are either held back until there is sufficient guidance and testing of new standards or the required use of new technology is incorporated into aspects of the program which do not interfere with direct patient care.** For example, as a precursor to future wide-scale deployment, FHIR application programming interfaces (APIs) could be required in version 2017 certification to enhance patient engagement, data reporting, or as a possible method to facilitate EHR to EHR migration. If adopted, this method may allow for the incorporation of new, innovative technologies without anchoring an EHR's functionality to a draft standard framework that is still in flux.

The ability for a consumer to make a choice between products has driven much of the innovation in other industries we see today. Breaking down the notion of "walled gardens" by advancing data migration methods will help drive more finely honed products as vendors compete for the needs of their consumers. Furthermore, once data is identified it must be moved completely, in a timely manner, and at little cost to the physician or medical practice. Pulling data from disparate sources rather than the traditional "package and transport" method can reduce downtime, lower migration costs, and allow tracking to ensure all patient data has completely moved from EHR to EHR. **Having the ability to identify, match, and classify data are key requirements in a successful migration strategy and could be supported by expanding the use of metadata in EHRs.**

6. Moving beyond EHRs

It is important to recognize that current EHR technology should not be viewed as the final answer for efficient and effective care delivery and population health management. While current EHRs can and must be improved, the vision should be to find its proper place in the overall technology environment.

Physician practices and workflows vary by specialty and practice type; however, EHR products have limited flexibility in customizing the user interface, data reporting capabilities, and other requirements. EHRs that learn physician preferences over time and provide more choices regarding data visualization are better suited to an individual physician's workflow.

To improve these systems, EHRs could utilize third party vendors to offer data analytics, or other ‘plug-ins’ that allow for customization of the EHR to meet the needs of the physician practice. Such small data capabilities connect physicians with timely and meaningful insights that are accessible, understandable, and actionable for everyday tasks. By utilizing this approach, the EHR could increase user satisfaction and usability through customized interfaces, built for each encounter, and requiring little cognitive burden. We believe that while some EHR vendors are capable of developing this capability, it is more likely this will require the EHR to integrate with third-party applications.

APIs may provide a way to chart, interact, and customize technology. The recent report from JASON, commissioned by the AHRQ, outlines a health IT framework that does not redefine the EHR itself, but establishes the basis for open interface architecture. While our immediate concern is to improve the usability of EHRs, we believe JASON’s approach could help alleviate physician frustration by allowing for innovative approaches to address many of the problems listed in this document. We agree with JASON’s recommendation that EHR vendors should incorporate open-API technology that:

- Obtains chart or record data for a specified patient;
- Obtains data that can be used by external search and index programs;
- Obtains metadata about what semantic standards are used by the legacy system; and
- Drives the front end of the legacy system (e.g., mouse clicks or command lines) so that better or more convenient user interfaces can be built on top of the legacy system.

Given the above discussion, we recommend the following:

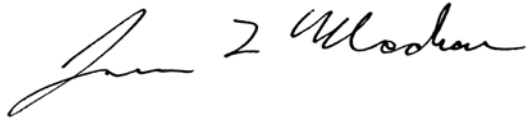
- **Adopt the Health IT Certification/Adoption Workgroup recommendation to revamp the certification program to focus exclusively on: 1) interoperability; 2) quality measure reporting; and 3) privacy/security;**
- **Remove the requirement that only licensed medical professionals and credentialed medical assistants are allowed to enter orders in light of workforce challenges;**
- **Adopt the approach recommended by one of ONC’s SHARPC grantees concerning UCD; and**
- **Incorporate well-developed data management principles to promote consumer choice and EHR flexibility.**

III. Stage 3: Health IT Functionality Requirements – Reaction and Recommendations Associated with HITPC Proposal

We have carefully reviewed the recommendations made by the HITPC. **Attachment 2 provides a summary of our recommendations along with specific examples and additional information describing the challenges and costs of certain measures.** Should you have any questions, please feel free to contact Mari Savickis, Assistant Director, Federal Affairs at mari.savickis@ama-assn.org or 202-789-7414.

Sincerely,

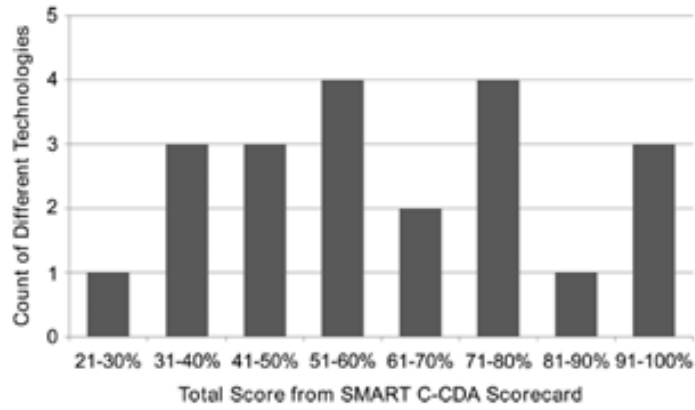
Marilyn B. Tavenner
October 14, 2014
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A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and a stylized "M".

James L. Madara, MD

Attachments

Attachment 1



Source: John D. D'Amore, et al, "Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative," *Journal of the American Medical Informatics Association*, 2014;0:1

ATTACHMENT 2

Justification for Each Measure

	Measure	HITPC Recommendation	Can current technology achieve this?	Additional cost outside of EHR purchase?	Requires multiple interfaces?	Comments / Chief Concerns	Example of Challenges	Our Recommendations
1	Clinical Decision Support (CDS)	<p>CORE.</p> <ul style="list-style-type: none"> Demonstrate use of multiple CDS interventions that apply to quality measures in at least four of the six National Quality Strategy (NQS) priorities. <p>Recommended intervention areas:</p> <ul style="list-style-type: none"> Preventive care; Chronic condition; management (e.g., diabetes, coronary artery disease); Appropriateness of lab and radiology orders (e.g., medical appropriateness, cost-effectiveness - high cost radiology); Advanced medication-related decision support (e.g., renal drug dosing, condition-specific recommendations); Improving the accuracy/completeness of the problem list, medication list, drug allergies; and Drug-drug and drug-allergy interaction checks 	Yes, but it is very immature for many physicians	No	No	<ul style="list-style-type: none"> Support the use of CDS as we believe that it is an important tool for high quality patient care. Yet, the measure is overall too-primary care centric. Recognizing known challenges and lack of measures for certain medical specialties, the HITPC proposal appears arbitrary. Requiring the CDS interventions to relate to quality measures in at least four of the six NQS domains may unnecessarily limit the ability of physicians to comply with this measure. There seems to be a slight disconnect between the six NQS priority areas and the recommended intervention areas. 	<ul style="list-style-type: none"> Otolaryngologist/head and neck surgeons stat that, as specialists who treat non-prioritized conditions and who have little or no access to funding designed to assist in measures development, it is exponentially more difficult to comply with MU criteria that are premised on the existence of such measures. Dermatologists do not have measures in all of the high-priority health conditions. “Appropriateness” of labs and radiology ordering is still very poorly defined for too many conditions without knowing the full clinical context. 	<ul style="list-style-type: none"> Remove the requirement that the CDS interventions cross any minimum number of NQS domains; Continue efforts currently underway to align the standards associated with clinical quality measures and CDS until full alignment and consensus is reached and the standards are fully tested; If there are not applicable measures for a physician, consider allowing them to select/choose their own CDS rule, as long as it falls into one of the NQS domains; and At the very least, provide expansive exception criteria.
2	Record electronic notes in record	<p>CORE.</p> <ul style="list-style-type: none"> Record an electronic progress note, authored by the eligible professional. Notes must be text-searchable Non-searchable scanned notes do not qualify but this does not mean that all of the content has to be character text. Drawings and other content can be included with text notes under this measure 	Yes	No	No	<ul style="list-style-type: none"> Many physicians still dictate and are expected to continue this method for the foreseeable future. They therefore rely on transcriptionists to transcribe their office notes. The requirement that records must be authored and text searchable within four calendar days often conflicts with the typical transcriptionist’s workload. The required four-day timeframe is outside the control of the physician and primarily relies on technology. 	<ul style="list-style-type: none"> A physician who dictates an office note on Friday may not have their audio file transferred to a transcriptionist until the following business day. Depending on the backlog of the transcriptionist, the physician’s office note may not receive attention until Wednesday or Thursday of that week – well past the proposed four calendar day requirement. The delay in transcription may be exacerbated if the transcription work is outsourced to an offsite service. 	<ul style="list-style-type: none"> Allow text searchable notes to be sufficient for this measure; Allow physicians to continue using scanning and faxing to meet this measure; and Remove the four calendar day requirement as the time it takes to transcribe notes is outside the control of the physician.
3	Record demographics	<p>CORE.</p>	Yes	No	No	<ul style="list-style-type: none"> Quality measures typically require some demographic data to identify the relevant patient population for the measure. We appreciate CMS’ and ONC’s attention to data elements that highlight potential disparities in care and identify possible social determinants of health. Based upon PCPI feedback, the demographic information used in this measure is limited to gender and age, which they believe is 	<ul style="list-style-type: none"> There are many known challenges with implementing eCQMs in EHRs; in particular, standards that are not fully tested or are in draft standards for trial use (DSTU) format. The information necessary to capture the data elements resides in a variety of systems that are not necessarily integrated. EHR vendors charge for costly interfaces between the EHR and practice management system. For example, the diagnosis may be in a clinical system and captured as a SNOMED CT or as an ICD code and the Medicaid eligible information is most likely found within an administrative system that is outside of 	<ul style="list-style-type: none"> A thorough environmental scan is needed to assess use of these data elements and standards prior to requiring an EHR to filter on them.

	Measure	HITPC Recommendation	Can current technology achieve this?	Additional cost outside of EHR purchase?	Requires multiple interfaces?	Comments / Chief Concerns	Example of Challenges	Our Recommendations
						reasonable but are still assessing what demographic data are required for the QRDA Category I.	<p>the EHR or clinical system and may not interface with that system.</p> <ul style="list-style-type: none"> • Additional demographic information is often not needed for clinical diagnosis. • It is unclear if some of the data elements, in particular education level and socioeconomic status are regularly captured and if there are existing standards to represent them. • Certain data elements may be specifically relevant to specialties and sub-specialties for eCQMs implementation and/or for population health purposes. 	
4	Patient online access to their information	<p>CORE.</p> <ul style="list-style-type: none"> • Provide patients with the ability to view online, download, and transmit (VDT) their health information within 24 hours if generated during the course of a visit and ensure the functionality is in use by patients. • Threshold for availability: High (i.e., the functionality is available to the majority of patients; it does not require patients to view information online, if they chose not to) Threshold for use: low—Labs or other types of information not generated within the course of the visit should be made available to patients within four business days of information becoming available • Add family history to data available through VDT 	Yes, if a physician has a portal	Yes	No	<ul style="list-style-type: none"> • We respect and understand the need for patients to obtain access to their information in a timely manner. However, we remain very concerned that the Stage 2 requirement to provide patients with access to their information within three business days of their encounter remains an unattainable goal for many physicians. 	N/A	<ul style="list-style-type: none"> • Extend the timeframe physicians have to provide patients with access to their information from 24 hours to between seven to ten business days.
5	Patient view, downloads or transmits their info to a third party		<p>No, for transmit</p> <p>Yes, if a physician has a portal for view and download</p>	<p>Yes, interface needed.</p> <p>Extra costs for VDT depends on data exchange structure (e.g., HISP may charge physician to facilitate transmission of patient data)</p>	No	<p>VDT concerns:</p> <ul style="list-style-type: none"> • Lack of interoperability/readiness of marketplace; • Significant cost; • Patient demand often lacking; • Multiple patient portals that are not connected; • Patients having to manage multiple passwords/ logins; • Functionality does not widely exist to support “transmit” function—primary method used today is DIRECT. Patient would need to know the provider’s DIRECT address and ensure technology requirements that the provider can accept the information. 	<ul style="list-style-type: none"> • Quote from an ACO participant: “The problem with the portal is that it is way harder to get large numbers of patients using a portal than anyone thought. We have persistently gone after getting patients to register over the past year. Currently, we have about five – eight percent of patients seen during a time period registered and using a portal. The high profile theft of credit card information at Target and other places hasn’t helped. And we like our portal. I use it and find it to be very good. We just can’t force patients to use it. It is an unfair requirement.” • Excerpt from Jitin Asnaani, Director of Technology Standards and Policy for EHR Vendor Athena during HIT Policy Committee February 13, 2013 hearing on Transitions of Care and VDT Listening Session: “Particularly for consumers, these problems are not interoperability related, but rather are culture and incentive driven. In fact, after one and a half months of usage of our VDT solution, which is built into our Class #1 ranked patient portal, there have essentially been no requests from patients to use their own Direct address or to send to a specific Direct address. This suggested in the future there are going to be opportunities for other 	<ul style="list-style-type: none"> • Decouple these measures from the requirement that calls for providing patients access to their information within a specific timeframe; and • Make this requirement count as two measures given the effort and cost of complying with these requirements.

	Measure	HITPC Recommendation	Can current technology achieve this?	Additional cost outside of EHR purchase?	Requires multiple interfaces?	Comments / Chief Concerns	Example of Challenges	Our Recommendations
							<p>innovations around PCMH and accountable care that can give the real organic business incentive for providers and other caregivers to influence consumer behavior..."</p> <ul style="list-style-type: none"> 80 physician practice who has met Stage 1 MU 2011-2013, has been using an EHR for the past fifteen years, has had a patient portal for the past five years, is an ACO Medicare Shared Savings Program participant, stated that they are struggling to meet the five percent threshold for Stage 2 because there is little demand in their practice. Many of otolaryngologists work in multiple office settings and need flexibility with the time in which they are required to not only report information, but also have that information available to patients and other health providers. The three-day requirement has proven difficult for otolaryngologists to meet; it is even more unlikely that they would be able to meet the even tighter timeframe of twenty-four hours. In the case of an osteopathic physician who works with nursing home patients, their patients typically cannot respond to the portal and are therefore not meeting this measure. Psychiatrists have expressed concerns about including family history. Since medication and problem lists are crucial to patient safety, they feel the risks associated with privacy violations outweigh the benefits. If family history remains a part of MU going forward, they have concerns that it will have a chilling effect on open communication and honesty with physicians. 	
6	Provide patient with summary of care	<p>CORE.</p> <ul style="list-style-type: none"> Provide office visit summaries to patients or patient-authorized representatives with relevant, actionable information, and instructions pertaining to the visit in the form/media preferred by the patient Summaries should be shared with the patient according to their preference (e.g., online, printed handout), if the provider has implemented the technical capability to meet the patient preference <p>-Threshold: Medium</p>	Yes, user format is very unfriendly	No	No	<ul style="list-style-type: none"> Repeatedly, physicians have emphasized that the summary of care, as structured by Stages 1-2, is of limited use for patients and physicians. Patients find that the information is presented in an unfriendly manner and physicians find that the display is not driven by the physician but by the vendor. 	<p>Quotes from various physicians</p> <ul style="list-style-type: none"> "Not all physicians are able to finish the patient chart while the patient is in the room, making the summary incomplete or inaccurate." "The layout and the data included is not all appropriate patient information. If we could easily customize it, our providers would be more anxious to actually give them to patients." "The biggest issue is the potential need to edit what is in the record so as to be of optimal use to the patient and not cause any harm." 	<ul style="list-style-type: none"> More accurate and meaningful summaries should be prioritized; and Implement a more reasonable timeframe, such as seven to ten business days, except under exceptional circumstances.
7	Provide patient specific education resources	<p>CORE.</p> <ul style="list-style-type: none"> Continue educational material objective from stage 2 <p>- Threshold: Low</p> <ul style="list-style-type: none"> Additionally, use CEHRT capability to provide patient-specific educational material in non-English speaking patient's preferred language, if material is publically available, using preferred media 	Yes	Depends, may have to pay for extra modules in different languages	No	<ul style="list-style-type: none"> Lack of evidence to support only using material generated through an EHR. Inability for physicians to verify accuracy of information provided in another language. 	<p>Quotes from various physicians</p> <ul style="list-style-type: none"> "In our practice, each exam room is lined with patient education resources (exercises for sore shoulder, what does your A1 mean, approach to pre-diabetes...) We also have two drawers in each room with patient handouts that we have curated and continuously update. The nurse or I use our professional judgment and will give a specific handout to a patient (or the patient will help themselves) as the situation warrants. Does this count for meaningful use? My read of the specs says it does not because the health professionals, not the EHR, suggested the patient-specific resources." 	<ul style="list-style-type: none"> Allow physicians to use their discretion to supply patients with information from a variety of sources whether it is from their EHR or elsewhere to meet this requirement; and Forego the additional requirement to provide materials in various different languages.

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		(e.g., online, print-out from CEHRT). – Threshold: Low, this should be a number and not a percentage					<ul style="list-style-type: none"> “Does the computer know better than I that the patient might benefit from quad-set exercises for their sore knee? One of the most impactful handouts we give is about a local nursing home’s fitness center, which has been opened to the public for \$10/month. Does giving this handout count? If so, how do we have to document this for it to count? And again, what type of handout wouldn’t count?” “Our EHR has some handouts available, but the process of accessing them is cumbersome, and the handouts are typically not as good as the ones we have in the room. It takes two seconds to pull off the wall the handout with dietary advice to avoid white carbohydrates. It takes over two minutes to go to the EHR, search for a handout that might fit the situation (there isn’t a good one for this), go through the multistep process to command print, leave the patient and the exam room, walk down the hall, sort through the papers on the printer to find the handout, go back to the exam room and give it to the patient.” 	
8	Secure messaging	CORE. <ul style="list-style-type: none"> No change in objective Patients use secure electronic messaging to communicate with EPs on clinical matters. -Threshold: Low (e.g., 5% of patients send secure messages)	Yes, if a physician has a portal.	Yes	No	<ul style="list-style-type: none"> The AMA sees the value in the use of secure messaging. However, we believe physicians should have the choice to decide whether or not to use it. Medicare does not reimburse for secure messaging, and while many physicians have successfully incorporated it into their workflow, many others do not use it precisely because it is an added workflow burden. 	<p>A <i>Health Affairs</i> August 2013 article, <i>Electronic Communication Improves Access, But Barriers to Widespread Adoption Remain</i>, found:</p> <ul style="list-style-type: none"> “The biggest disadvantage that these medical groups experienced was added work from electronic communication. Providers lamented that electronic communication made the workday longer. As the number of electronic communications with patients increased, several groups tried to cut down on the number of office visits. However, in most cases the number of office visits did not decrease very much. Electronic communication therefore was often added to a full day of office visits.” The article also reported that, “...to their knowledge very few health plans reimbursed for electronic communications.” 	<ul style="list-style-type: none"> Since this measure is outside of a physician’s control and requires substantial effort, physicians who elect to meet this measure should be allowed to count it as meeting two measures.
9	Medication reconciliation	CORE. • No Change	Yes, but requires workflow optimization	No	No			<ul style="list-style-type: none"> We support retaining the Stage 2 medication reconciliation measure for Stage 3, however, the 50 percent threshold should be removed pursuant to our earlier recommendation that all thresholds be removed for Stage 3.
10	Summary of care provided during transitions of care	CORE. Provide a summary of care record during transitions of care. Types of transitions: <ul style="list-style-type: none"> Transfers of care from one site of care to another Consult (referral) request [pertains to EPs only] Consult result note Summary of care may (at the discretion of the provider organization) include, as relevant: <ul style="list-style-type: none"> A narrative that includes a synopsis of current care and expectations for consult/transition or the results of a consult [required for all transitions] Overarching patient goals and/or problem-specific 	Yes	Yes	No	<ul style="list-style-type: none"> The AMA encourages physicians to share information with one another and other health care providers involved with the treatment of their patients. However, we have serious concerns with this measure given the lack of interoperability and other barriers. <p>The AMA participated in a Closing the Referral Loop pilot project which involved physician-to-physician referrals in the ambulatory setting. During the pilot project it was learned that the current vendor systems do not have any functionality to facilitate sharing of patient information, only the ability to request a referral. This is leading to extensive customization (and cost) within each vendor system</p>	<p>Below are quotes from various stakeholders depicting the lack of interoperability and other barriers:</p> <ul style="list-style-type: none"> Quote from Medicare Shared Savings participant: “As part of our next Meaningful Use upgrade with X vendor, we will get access to the X vendor HISP for an annual fee. We will also be required to connect to the X HIE in order to deliver some public health data to the state of X. The X HIE will charge a monthly fee for use of their HIE. They also have a HISP if we want to use it instead. While we have rights to all upgrades from X vendor, they are charging us between \$40,000 - \$60,000 for implementation services for the upgrade. Once the X vendor HISP is available to us, it still remains to be seen if the other entities in the community will be available for us to send and receive records with. We still do not know how much work will be required to set up and administer the HISP addresses in our EMR. We were told that the HISP connections with X vendor would cost \$100 per provider per year. Another \$200 per provider per year goes to X vendor for their Meaningful Use reporting portal. “It really feels to us like everyone is out to make 	<ul style="list-style-type: none"> Retain the measure as drafted from Stage 1 with the exception of the 50 percent threshold, which should be removed pursuant to our earlier recommendation that all thresholds be removed for Stage 3; Given the well-documented technological challenges associated with exchanging summaries of care, which are outside the control of practicing physicians, physicians should only be required to attach documents when sending summary of care information during a transition; and Since this measure is outside of a physician’s control and requires substantial effort, physicians who elect to meet this measure should be allowed to count it as meeting two measures.

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		<p>goals</p> <ul style="list-style-type: none"> • Patient instructions, suggested interventions for care during transition • Information about known care team members (including a designated caregiver) <p>-Threshold: No Change</p>				<p>for a function that should be considered a standard operating practice since it often occurs many times a day.</p>	<p>money off of us with Meaningful Use. To make matters worse, the patient portal requirement alone may prevent a huge number of physicians from meeting MU compliance. So to add injury to insult, the unattainable requirement will cause us to lose money from penalties if the rule is not amended. Patient portal is just way harder than anyone thought and the levels in the rule are simply not attainable except to groups that have been on a portal for many years."</p> <ul style="list-style-type: none"> • "X is actively trying to change how we provide care to a community of patients. To do this well, we need good access to patient information from across our region. One strategy to accomplish this is to implement a HIE. This exchange needs to be able to normalize data and supply the data to analytic systems where it can be leveraged. We have serious doubts about the X HIE being able to do the level of normalization that is needed, and whether they can legally share it with us since they are a public entity. If we build our own HIE, then we will have duplicated some services and added a lot to our total costs." • "Regulation unnecessarily has added to our costs during a time when we should be investing more in transforming the way we provide care to our patients in the value world." • GAO, March, 2014 report (GAO-14-242), found that: "While standards for electronically exchanging information within the EHR programs exist, providers reported that standards may not be sufficient in some areas. Information that is electronically exchanged from one provider to another must adhere to the same standards in order to be interpreted and used in EHRs, thereby permitting interoperability. Several providers stated that they often have difficulty exchanging certain types of health information with other providers that have a different EHR system due to a lack of sufficient standards to support exchange.... one provider noted that there are not sufficient standards to define allergic reactions, and another provider explained that some EHR systems classify an allergic reaction as a side effect... Similarly, an article from the <i>Journal of the American Medical Informatics Association</i> stated that the proper terminology for encoding patients' allergies is complex and that some gaps still exist across existing standards." • Peter DeVault, Director of Interoperability of Epic, testified during the February 13, 2014 Health IT Policy Committee Listening Session on Transitions of Care and VDT, "I think anyone who's done any actual implementation work with Direct understands that it is a new standard and relatively immature. And that we're finding out a lot of things about how the whole ecosystem of EHRs and HISPs [Health Information Service Providers] and other actors need to be coordinated to really make transitions of care work well...I think one of the takeaways that we can apply to Stage 3 is rather than introducing new standards or significantly new workflows around transitions of care, as an example, we should try and shore up some of the gaps and some of the boundaries with the transition of care as they've been specified for Stage 2." • Example from major medical center that has met 	

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							Stage 1 and is preparing for Stage 2 "This really does not seem clinically appropriate to send all labs, especially for longer hospital stays. We definitely risk eating toner and wasting paper at in (sic) offices of our local providers, which will damage our relationships with them."	
11	Care planning / advance directive	NEW MENU. <ul style="list-style-type: none"> Record whether a patient 65 years old or older has an advance directive -Threshold: Medium <ul style="list-style-type: none"> Certification Criteria: CEHRT has the functionality to store the document in the record and/or include more information about the document (e.g., link to document or instructions regarding where to find the document or where to find more information about it). 	Not all EHRs can do but not a significant problem for vendors to create	No	No	<ul style="list-style-type: none"> While we recognize that collecting information on care planning and advance directives can be helpful to patient care, it is not necessarily appropriate for all physicians to have to collect this information. 	<ul style="list-style-type: none"> One of the HITPC workgroups had a meeting with physicians and other providers on the challenges with the care plan. One of the biggest challenges cited by physicians was knowing who was involved in developing the plan of care and whether it was up to date. 	<ul style="list-style-type: none"> We suggest retaining as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
12	Order tracking	NEW MENU <ul style="list-style-type: none"> The EHR is able to assist with follow-up on orders to improve the management of results. Results of specialty consult requests are returned to the ordering provider [pertains to specialists] -Threshold: Low	No	Yes	Yes	<ul style="list-style-type: none"> The AMA is strongly supportive of the functionality to enable order tracking. However, there is a considerable amount of variability with order tracking and we are sensitive to the fact that requiring this functionality for certification could be challenging for vendors to meet. Additionally, this objective is overly prescriptive in that it defines how EHRs should track orders "by date." Interfaces between lab information systems (LIS) and EHRs are costly and any adjustment to meet MU requirements would require added costs and possible system downtime. 	<ul style="list-style-type: none"> Many ambulatory medical practices house at least one diagnostic modality. An established workflow may already be fully functional providing the necessary and timely information at the point of care. If protocols are already utilized by medical practices for orders the requirement of an arbitrary three business day acknowledgment would detract from best practices identified by each facility. Additionally, explicit time requirements are often not necessary as agreements between physicians and labs already exist. 	<ul style="list-style-type: none"> Before this measure is accepted by CMS a well-developed testing scenario should be created that identifies clinically-plausible workflows and aligns with EHR usability; and If adopted, the requirement should be re-worded to say that EHRs should provide the ability to establish "time frame criteria" for orders and consults to be completed. For example, a CBC should be completed within 2 weeks, rather than by a specific date.
13	Unique Device Identifier (UDI)	NEW MENU Record the FDA UDI when a new device is implanted in a patient -Threshold: High	Not currently included as a feature in many EHRs	No	No	<ul style="list-style-type: none"> The AMA recognizes that collected UDI information for some specialists will be helpful in managing their patient's care; however, not every specialist treats patients with devices with a UDI. 		<ul style="list-style-type: none"> This measure should only apply to physicians who see patients with UDIs, and physicians should have flexibility in determining whether or not they have to meet this measure for MU.
14	Patient generated health data	NEW MENU Receive provider-requested, electronically submitted patient-generated health information through either (at the discretion of the provider): <ul style="list-style-type: none"> structured or semi-structured questionnaires (e.g., screening questionnaires, medication adherence surveys, intake forms, risk assessment, functional status) 	Yes, if just using the patient portal as opposed to something like using a smart phone	Depends on the source of the data. Could be an interface (e.g., from a doctor's EHR to stand-alone PHR) or a portal.	No	<ul style="list-style-type: none"> The AMA supports the notion that the data is being requested by the provider as opposed to unsolicited information being sent by the patient. It is important to note that the use of structured and unstructured data is very helpful and highly recommended. However, we do not believe a prescriptive requirement should be placed on the vendor to develop the structured data capability. If they are already providing secure messaging and a patient portal 	<ul style="list-style-type: none"> The HITPC has called for including medication adherence surveys. This would require the CEHRT to access medication fill information from a pharmacy benefit manager (PBM). This is potentially problematic as many prescriptions are filled that do not touch the patient's health plan. This is due to the fact that many generics are offered at a rate lower than the patient's co-pay. If it then becomes a requirement for the pharmacies to transmit "fill" information back to the physician, then there is a transaction fee involved that currently is incurred by the pharmacy. This is why many pharmacies do not submit fill information to the practice, as there is no value to them. If required, who will incur the cost of transmitting 	<ul style="list-style-type: none"> The decision to accept patient-generated data should be left to a physician; and For physicians who elect to meet this measure, how the data is received and formatted should be a decision made between the physician and his or her vendor.

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		or secure messaging. -Threshold: Low				then patient information can be shared. It should be up to the vendor to decide if they want to provide capability for a patient to share data in a structured format. This means physicians should not be required to have to accept structured information.	this information? <ul style="list-style-type: none"> As we move to outcomes measures and payment adjustment based on quality of care provided, patient reported outcomes (PROs) are critical to understanding patient care. Instruments have been developed for patients to collect outcomes data in their homes (e.g., blood pressure; joint swelling counts) and then transmit them to their health care provider. This requirement provides a critical channel for experiential information that can be used to monitor both clinical condition and quality. 	
15	Receive immunization history	NEW CORE Receive a patient's immunization history supplied by an immunization registry or immunization information system, allowing healthcare professionals to use structured historical immunization information in the clinical workflow <ul style="list-style-type: none"> Threshold: Low, a simple use case 	No	Yes	Depends – if you are treating patients in more than one state	<ul style="list-style-type: none"> Not applicable to all specialties; Many states still do not have registries; Requires costly interfaces; and Lacks evidence to support patient improvement in care. 	<ul style="list-style-type: none"> Quote from Medicare Shared Savings participant: “The X HIE connection to send our immunizations looks to cost in the neighborhood of \$150 - \$250 per provider per year.” An example of a state immunization registry's lack of readiness is Texas' ImmTrac, which physicians find still struggling with bi-directional interfaces with many ambulatory vendors. Physicians must log out of their EHR and onto the portal through a separate browser to submit and retrieve patient-specific immunization information, creating significant workflow interruptions 	<ul style="list-style-type: none"> We recommend that physicians have discretion in deciding whether they want to accept this information; and Establish a broad exception for physicians who do not generally review immunization data.
16	Send data from EHR to registry	MENU Electronically transmit data from CEHRT in standardized form (i.e., data elements, structure and transport mechanisms) to one registry <ul style="list-style-type: none"> Reporting should use one of the following mechanisms: <ol style="list-style-type: none"> Upload information from EHR to registry using standards Leverage national or local networks using federated query technologies 	Very spotty	Yes, both interface and data exchange costs	Yes	<ul style="list-style-type: none"> The ability to transmit clinical data to national clinical registries using standardized data definitions will assist physicians and health care systems move to a more advanced state of quality measurement. Without the use of a standard format for data definitions, physicians are incurring added costs of middleware vendors to map and transmit the data when physicians have already purchased the EHR. This is an added cost without any added value. Furthermore, many of these registries are utilized for certain CMS coverage decisions and for PQRS. 	<ul style="list-style-type: none"> The current certification requirements fail to address the need for bi-directional exchange for national clinical registries or clinical data standardization for any other purpose. Cancer and immunization registries, while helpful, are primarily used for surveillance, epidemiology, and point of care information transfer. In comparison, national clinical registries can be used for quality improvement support (e.g., reporting and benchmarking) or other related activities. Bi-directional connectivity allows CEHRTs to not only send data to registries, but also for the CEHRT to accept information from registries. As an example, in CDS, registry data can be combined with CEHRT data to show the risk of various approaches to treatment, individualized to the characteristics of individual patients. Transmitting registry data to the CEHRT also improves physician workflow by eliminating the need to switch back and forth between the CEHRT and the registry. EHR vendors charge providers a cost to map and transmit data from an EHR to a registry. 	<ul style="list-style-type: none"> National clinical registries are often used for quality improvement (e.g. reporting and benchmarking); therefore, physicians who participate in a national clinical registry or QCDR should receive credit for meeting the quality requirements of MU. This would also further the goal of aligning the MU program with PQRS. Instead of developing their own interoperability standards, registries should accept data from EHRs using national data standards, e.g., those used in the QCDR program (CMS-approved XML format, QRDA category III format). This requirement should be expanded to include bi-directional connectivity based on those same national standards (i.e., transmit data from CEHRT to a registry, and from a registry to CEHRT). ONC should require EHR vendors to provide clinical data in a standard format that is backed by standardized data.
17	Computerized Physician Order Entry (CPOE)	REMOVE	Yes	No	No	<ul style="list-style-type: none"> While the HITPC has recommended removing this measure, we urge that CMS retain this measure to expand physician reporting options. The HITPC also considered doubling the measure threshold, something that would be extremely challenging for most physicians since many are already struggling with workflow issues and other barriers to meet the current CPOE threshold, such as longer times to enter orders due to EHR usability issues and the inability to use non-licensed medical professionals to enter 	<ul style="list-style-type: none"> Ophthalmologists tell us they have challenges with the requirement to use CPOE for 30 percent of radiology orders. The majority of ophthalmologists do not realize that “radiology orders” was defined to include ophthalmic examination and office-based low risk ophthalmic imaging studies. Requiring CPOE for in-office ophthalmic imaging presents significant workflow challenges because CMS requires orders to be entered by “certified medical assistants,” but many ophthalmology offices do not have formally certified technicians or assistants. The high volume of low-risk imaging tests ordered in ophthalmology also makes it extremely burdensome and unrealistic for offices to comply with the Stage 2 CPOE requirement for radiology orders as it is currently defined. 	<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommendation to expand the number of measures from which physicians have to choose for Stage 3 and capping the total number of reportable measures at no more than 10. If retained the CPOE measure should remove any percentage thresholds and be split into three different measures – one for eprescribing, one for imaging, and the last for laboratory orders. The measure should also remove the requirement that only a licensed health care professional or medical assistant can enter orders.

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18	ePrescribing ¹	REMOVE	Yes	Yes, SureScript charges a nominal fee per prescriber	No	<ul style="list-style-type: none"> orders. ePrescribing is mandated under HITECH, therefore, it is unclear how it could be removed without a change to the law. While ePrescribing is generally one of the easier measures to meet for physicians there are still some challenges. 	<ul style="list-style-type: none"> Letter to CMS from the Medical Society of Virginia dated February 14, 2014 stated: "Many of the e-prescribing concerns involve military and government pharmacies, including Tricare, only accepting printed prescriptions since they currently do not have the capability of receiving e-prescribing from practicing physicians...In one instance, a Virginia physician saw 344 individual Tricare patients over multiple visits in one year, resulting in 3,818 written prescriptions. These physicians are severely challenged in meeting these Meaningful Use requirements." ePrescribing of controlled substances was included in the Medicare ePrescribing program but not in MU. If added as an option, this could help more physicians meet the requirement. 	<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3. Allow controlled substances to be counted if a physician so chooses. The exception laid out in Stage 2 should be retained.
19	Record vital signs	REMOVE	Yes	No	No			<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
20	Record smoking status	REMOVE	Yes	No	No		<ul style="list-style-type: none"> This requirement in Stage 1 and 2 has not been well aligned with the PCPI quality measure on tobacco screening and cessation, which applies to any type of tobacco (e.g., chewing), and not just smoking. 	<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3. The measure should also be broadened to include smokeless tobacco.
21	Incorporate lab results into EHR as structured data	REMOVE	No	Yes	Yes	<ul style="list-style-type: none"> This objective was included in the committee's draft recommendations. We remain concerned as the draft recommendations proposed the threshold be significantly increased to more than 80 percent. This objective is also problematic because many labs do not have interfaces with EHR systems. Cost remains a challenging barrier. 		<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3 and removing the percentage threshold.
22	Generate lists of patients by specific conditions	REMOVE	Yes	No	No			<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
23	Send reminders to patients	REMOVE	Yes	Yes	No			<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
24	Submit electronic data to immunization registries	REMOVE	No	Yes	Yes	<ul style="list-style-type: none"> This measure is another way to demonstrate the value of the use of registries. Immunization registries, while helpful, are primarily used for surveillance, epidemiology, and point of care information transfer. In comparison, national clinical registries can be used for quality improvement support (e.g., reporting and benchmarking) or other related activities. 	<ul style="list-style-type: none"> Interface costs persist. The readiness of many state immunization registries is lacking. 	<ul style="list-style-type: none"> We suggest retaining as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.

¹ Not recommended for inclusion by the HITPC, however, it is mandated by HITECH.

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25	Conduct security risk assessment	REMOVE	No	Yes	No	<ul style="list-style-type: none"> Physicians seek to protect patient privacy. Given that an increased amount of protected health information (PHI) is being stored and moved digitally, and that physicians are being required to rapidly adopt EHRs and other technologies, there is a strong need for an education campaign for physicians to employ best practices to protect patient information. The level of education and training needed is substantial as most physicians do not have intricate knowledge of digital security. 		<ul style="list-style-type: none"> We suggest retaining as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3. We strongly urge CMS, ONC, and other agencies to develop and deploy training across the country to help physicians better prepare for protecting and securing PHI.
26	Making imaging results available through EHR	REMOVE	Yes	Yes	Yes			<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
27	Record patient and family history	REMOVE	Yes	No	No	<ul style="list-style-type: none"> Patient history and family history are critical data elements frequently used in quality measures. This information can also help inform genetics and personalized medicine. We support standardize data capture for this type of information to guard against care fragmentation. 		<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3. CEHRT should support distinguishing between first degree and non-first degree relatives so that the EHR could correctly calculate the numerator as only looking for first degree relatives, not just any family history.
28	Provide electronic syndromic surveillance data to public health agencies	REMOVE	No	Yes	Yes			<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
29	Cancer registry reporting	REMOVE	No	Yes	Yes	<ul style="list-style-type: none"> Cancer registries, while helpful, are primarily used for surveillance, epidemiology, and point of care information transfer. In comparison, national clinical registries can be used for quality improvement support (e.g., reporting and benchmarking) or other related activities. Certification needs to strengthen bi-directional data transfer between CEHRT and all registries. 		We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.
30	Non-cancer registry reporting	REMOVE	No	Yes	Yes	<ul style="list-style-type: none"> For reasons stated in our earlier comments we prefer recommendations that strengthen bi-directional data transfer between CEHRT and all registries. 		<ul style="list-style-type: none"> We suggest retaining this measure as part of our recommended framework for expanding the number of measures from which physicians have to choose for Stage 3.