

May 7, 2012

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0044-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

**Re: CMS-0044-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2 Proposed Rule (Vol. 77, No.45), March 7, 2012**

Dear Administrator Tavenner:

As the nation's premier voice for medical group practices the Medical Group Management Association (MGMA) is very supportive of physician practice adoption of health information technology (HIT). However, we are very concerned about the direction proposed for the Medicare and Medicaid electronic health record (EHR) incentive program. We believe that if the program logistics and meaningful use requirements proposed in the above entitled rule are not substantially modified, this could result in a failure to meet the goals outlined in the American Recovery and Reinvestment Act of 2009 (ARRA) and a missed opportunity to transition large numbers of medical practices to HIT.

MGMA-ACMPE is the premier association for professional administrators and leaders of medical group practices. Since 1926, the Association has delivered networking, professional education and resources, advocacy and certification for medical practice professionals. The Association represents 22,500 members who lead 13,600 organizations nationwide in which some 280,000 physicians provide more than 40 percent of the healthcare services delivered in the United States.

The objective of HIT is to improve healthcare quality, control growth in costs, enhance the efficiency of healthcare administration, stimulate innovation, and ensure the privacy and security of patient information. ARRA sets out broad requirements for the incentive program and it is clear that the overarching goals of the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) should be to develop a flexible set of supporting regulations with the goal of fulfilling this statutory mandate. We assert that in order to fulfill the objectives outlined in the underlying legislation, the meaningful use requirements must be achievable and verifiable without creating an undue burden on eligible professionals (EPs) and their administrative staff. This is especially critical in the first two stages of the incentive program.

With this Stage 2 proposed rule, CMS has increased emphasis on interoperability, patient engagement, and more extensive quality measure reporting, creating an extremely demanding set of requirements that will correspond to a significant step up in capability and effort for all EPs. While ARRA outlines that the successive stages of the program are to be "more stringent," we assert that this proposed rule goes well beyond the legislative intent.

### **Summary of Key Issues and Recommendations**

- Medical groups are, in general, very supportive of the adoption of EHRs
- Meaningful use EHR incentive program must be fully harmonized with the e-prescribing (eRx) and Physician Quality Reporting System (PQRS) incentive programs
- CMS must fully evaluate Stage 1 to before developing Stage 2 requirements
- Stage 2 objectives and measures must be reasonable and not act as a disincentive for EPs to participate in the incentive program
- CMS should avoid significantly increasing measure thresholds
- No Stage 2 objective must require actions on the part of patient in order for the EP to successfully participate in the program
- “Full year” reporting definition should be flexible
- No incentive program payment adjustment should be assigned in one year for activity in a previous year
- MGMA supports the proposed hardship exemptions and encourages CMS to create additional hardship categories
- MGMA applauds CMS for its provider outreach efforts and encourages a continuation of these efforts for the second stage of the program

### **Meaningful Use Stage 2 as an Incentive for EHR Adoption**

With the vast majority of private practice EPs still not participating in the meaningful use program, we remain concerned that raising the bar too high will discourage clinicians to acquire and use EHR technology. Although the proposed rule maintains that the number of core and menu measures (20) is with the same as in Stage 1 of the program, the actual requirements themselves have significantly expanded in complexity.

In particular, we are very concerned with the Stage 2 requirements in the area of patient engagement. While EPs should be encouraged to engage patients and their families in the care delivery process, the proposed rule requires the patient to take specific actions, such as e-mailing their EP and accessing their health information via an Internet portal. We believe it is inappropriate to require patients to take certain actions that are beyond the control of the EP being measured.

It is important to note that in *Health Affairs* (April 2012 online) researchers funded by the Office of the National Coordinator for Health Information Technology (ONC), examined data from the Centers for Disease Control and Prevention's National Ambulatory Medical Care Survey from 2002 through 2011. For five years, the survey asked whether providers used "any EHR," but in 2007, the study began asking

questions about specific EHR functions to determine whether providers were using a so-called “basic” EHR.

According to the researchers, by 2011, 24.2 percent of physicians in solo or two-physician practices had adopted a basic EHR, compared with 37.1 percent of groups of three to nine physicians and 60 percent of physicians in groups of 10 or more. Similarly, rural physicians trailed their urban counterparts in EHR adoption as well, with 34.2 percent of physicians outside of metropolitan statistical areas having basic EHRs in 2011, while 39.4 percent in metropolitan areas did. Further, specialists were slower to adopt EHRs than their primary-care physician counterparts, with the gap for adoption of a basic EHR widening since 2007. Specialists, according to the researchers, had basic EHR adoption rates of 12.4 percent in 2007 and 30.9 percent by 2011. Primary-care physicians, meanwhile, had basic EHR adoption rates of 17.1 percent in 2007 and 40.2 percent in 2011.

With these data as the backdrop, we believe it is critical that the second stage of this incentive program not be crafted in such a way to a deter clinicians, especially specialty physicians and those practicing in smaller and rural settings, from adopting these important technologies or EHR vendors from developing the supporting software.

### **Fully evaluate Stage 1 before developing Stage 2 requirements**

It is critical that prior to finalizing the Stage 2 objectives and measures, the agency should understand how the Stage 1 requirements were met by successful EPs and also understand the experience of those participating EPs who failed to meet or just barely met the requirements. Before moving a measure from the Stage 1 menu set to the core set for Stage 2, or prior to adding new core measures for Stage 2, CMS should take all appropriate steps to ensure that the impact will not act as a disincentive to EP participation or result in EPs failing to attest.

### **MGMA Research**

MGMA conducted member research in April 2012 to determine the ability of medical groups to meet the Stage 2 meaningful use requirements and qualify for EHR incentives. The more than 430 respondents were asked a series of questions that included their plans to participate in the incentive program, and their reaction to the proposed Stage 2 meaningful use criteria. The results from this research are below.

As seen in Table 1, a very large percentage (88.6 percent) of respondents of this study said they currently have an EHR.

Table 1

<b>Does your practice currently have an electronic health record (EHR) system?</b>	
<b>Answer Options</b>	<b>Response Percent</b>
Yes	<b>88.6%</b>
No	11.4%

When asked about program participation, 21 percent said *all* of the EPs in their practice have attested and received meaningful use EHR incentive program payments. About 14 percent said some of their EPs have attested and received program payments, and over 60 percent said some or all of their EPs plan to participate in the meaningful use EHR incentive program (see Table 2).

Table 2

<b>Which of the following best describes how the eligible professionals (EPs) in your practice plan to participate in the Meaningful Use EHR incentive program?</b>	
<b>Answer Options</b>	<b>Response Percent</b>
None plan to participate	5.3%
Some plan to participate	10.5%
All plan to participate	<b>49.8%</b>
Some have attested and have received Meaningful Use EHR incentive program payments	13.5%
All have attested and have received Meaningful Use EHR incentive program payments	20.9%

### **Comments and Recommendations**

We offer the following recommendations for developing a program that promotes widespread adoption of EHRs and furthers the development of a national HIT infrastructure that will meet the needs of a complex and diverse healthcare system.

#### **Recognition of the impact of other federal mandates**

There are numerous current and pending regulatory HIT mandates impacting physician practices that are competing with meaningful use for human and financial resources. The challenge of complying with these additional federal programs should be taken into account when finalizing Stage 2 of the EHR incentive program. These overlapping initiatives include but are not limited to implementation of the new HITECH privacy requirements, HIPAA 5010 electronic transactions, administrative simplification provisions in the Patient Protection and Affordable Care Act of 2010, including operating rules for patient insurance eligibility verification and claim status, standards and operating rules for electronic funds transfer/electronic remittance advice, health plan identifier, electronic claims attachments, and the potential implementation of ICD-10.

In developing objectives, measures and program timelines, it is critical that CMS recognize the additional challenges facing EPs in the coming months and years, which will draw on the same human and financial resources necessary to meet the EHR incentive program requirements.

#### **Harmonization between incentive programs**

Harmonization of federal programs is critical to the future of quality measurement and reporting. The burden on practices is immense and harmonization will enable practices to focus on increasing quality in the healthcare system. CMS efforts to harmonize quality measures among incentive programs have been modest at best. The Government Accountability Office's (GAO) February 2011 report, "CMS Should

Address Inconsistencies in Its Two Incentive Programs That Encourage the Use of Health Information Technology" clearly articulated this sentiment. In the report, GAO encourages CMS to eliminate the duplication of capturing data over multiple CMS-administered programs, which currently causes significant administrative burden on group practices.

While, CMS proposes to align its clinical quality measure (CQM) reporting options with the PQRS and the Medicare Shared Savings Program, the true extent of this measure and reporting alignment remains to be seen. In Stage 1, CMS used measures developed and utilized by other programs but maintained slightly different measure specifications in some instances. As a result, providers needed to capture these measures differently, creating significant administrative burdens. Additionally, the reporting methods between the PQRS and the meaningful use program lack alignment. For example, the meaningful use program requires a quality measure to be calculated within the certified EHR technology, whereas for PQRS EHR reporting, the EHR vendor may be a 'designated PQRS EHR Vendor,' and raw data is sent to a data warehouse with the measure being calculated outside the physician's EHR system." It is critical that CMS acknowledge and repair these discrepancies.

Similar issues impact the CMS electronic prescribing (eRx) incentive program. There is significant overlap between the Medicare eRx initiative and the Medicare EHR incentive program. Both seek to encourage EP adoption of eRx technology, yet both have vastly different reporting requirements. In addition, despite the more stringent eRx reporting requirement contained in the meaningful use incentive program, attestation by an EP for meaningful use does not eliminate the potential of their incurring a payment adjustment for "non-participation" in the duplicative eRx incentive program. This issue has led to considerable confusion and consternation within the provider community.

Further exacerbating the problem, CMS has historically been unable to provide feedback to providers on their eRx activity until the year following their participation in the program. It has proven to be extremely challenging for providers to determine if they have qualified for one or both of these incentive programs in a timely manner. Thus, it is expected that many EPs will apply for both the eRx and EHR incentive programs in 2012 and beyond. As EPs are not eligible to receive payments from both programs, it is critical that CMS accurately and quickly ascertains if an EP has successfully completed all requirements for either program, and expediently report the results.

Further, those EPs who have attested to being a meaningful user should not be required to submit a eRx hardship exemption form. As CMS is clearly requiring the interoperability of provider systems, the agency itself should develop the internal system interoperability necessary to capture and process provider information to and from multiple CMS-administered incentive programs. We strongly recommend that CMS develop the functionality to identify those EPs who successfully participate in the meaningful use incentive program and automatically deem them as successfully participating in the eRx and PQRS incentive programs.

CMS has expanded the definition of a qualifying eRx system so that EHR technology under the Medicare/Medicaid EHR incentive program can be recognized as a qualifying system under the eRx program. For the purposes of reporting the current eRx quality measure during 2011 for incentives and for avoiding the 2012 eRx penalty, CMS has indicated that nothing precludes EPs (or a group practice) who already have certified EHR technology that meet the four functionalities described above from using that technology for the eRx Medicare incentive program. CMS further indicates that if it finalizes the proposed rule later this year, using certified EHR technology will be acceptable for eRx in future reporting years even if the certified EHR does not meet the four specific functionalities.

We strongly support CMS' proposal to recognize EHR technology certified under the Medicare/Medicaid EHR incentive program as a qualifying system under the eRx incentive and penalty programs. This

recognition is an example of the importance of synchronizing the overlapping eRx and EHR programs so that EPs do not have to purchase an eRx system just to avoid penalties, and can invest in certified EHR technology that does more than just enable eRx. However, we strongly encourage the expansion of this provision to include the purchase in 2012 of EHR technology certified under the Medicare/Medicaid EHR incentive program to either qualify for the eRx incentive program bonus in 2012 and/or avoid the 2012 payment adjustment.

It is critical that CMS adopt the GAO's recommendations and pursue reasonable, achievable requirements aligned with those for the various incentive programs currently underway to simplify the process for all EPs, and coordinate educational outreach efforts. CMS should expedite efforts to remove the overlap in reporting requirements for physicians who may be eligible for incentive payments or subject to penalties under CMS-administered programs.

### **E -prescribing of controlled substances**

The Drug Enforcement Administration (DEA) has not yet released a final rule on the eRx of controlled substances. Thus, physicians are forced to employ two separate workflows within their organization for processing prescriptions. This has proven to be particularly onerous for EPs who prescribe a large percentage of controlled substances. We encourage CMS to work with the DEA to expedite the publication of a final rule, permitting vendors to produce the supporting software and physicians to implement it.

### **CORE and MENU Objectives**

Respondents to MGMA's research were asked to provide feedback on the proposed CORE and five menu meaningful use objectives. For each objective they were asked to indicate if the measure was too low, too high or correct, and also to indicate if they felt the objective should be removed or moved to the menu objective set. A number of these results warrant attention (see Table 3 below).

Table 3

<p>In this proposed rule, most of the Stage 1 CORE and MENU objectives have been retained for Stage 2. However, CMS is proposing different thresholds for each objective, often significantly higher. Using your best judgment, please provide your feedback on the following 17 proposed CORE (required) meaningful use objectives for EPs. More than one response per objective is permitted (i.e., indicate that the objective threshold is too high and should be moved to the MENU (optional) set).</p>					
Answer Options	Stage 2 Measure Too Low	Stage 2 Measure Too High	Stage 2 Measure Correct	Stage 2 Objective Should be Removed	Stage 2 Objective Should be Moved to MENU set
Implement clinical decision support interventions related to five or more clinical quality measures at a relevant point in patient care - Stage 1 Measure Threshold: 1; Stage 2 Measure Threshold: 5	0.3%	<b>66.7%</b>	20.5%	9.4%	8.7%
Patients provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EPs discretion to withhold certain information - Stage 1 Measure Threshold: 10% (MENU set); Stage 2 Measure Threshold: more than 50%	0.3%	<b>60.3%</b>	21.3%	14.3%	15%
Patients or their authorized representatives to view, download, or transmit to a third party their health information - Stage 1 Measure Threshold: New; Stage 2 Measure Threshold: more than 10%	0.7%	33.2%	<b>36%</b>	21.7%	14.3%
Clinical summaries provided to patients - Stage 1 Measure Threshold: 50%, time period 3 days; Stage 2 Measure Threshold: more than 50%, within 24 hrs	1%	<b>55.9%</b>	31.6%	12.8%	5.2%

A secure message was sent using the electronic messaging function- Stage 1 Measure Threshold: New; Stage 2 Measure Threshold: more than 10%	1.4%	<b>32.5%</b>	42.7%	15.4%	14%
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### Clinical decision support

- **Proposed Objective:** Use clinical decision support (CDS) to improve performance on high-priority health conditions.
- **Proposed Measures:** EPs, eligible hospitals, and critical access hospitals (CAHs) must satisfy both measures in order to meet the objective.
  - Implement five CDS interventions related to five or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period.
  - The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

For Stage 2 based on the HIT Policy Committee recommendations, each CDS intervention must enable the provider to review all of the following attributes of the intervention: developer of the intervention, bibliographic citation, funding source of the intervention, and release/revision date of the intervention. The agency contends that this will enable providers to review complete information including any potential conflict of interest for the decision support intervention(s), if they so choose.

Although CMS leaves it to the provider’s clinical discretion to determine the relevant point in patient care when such interventions will be most effective, the interventions must be presented through Certified EHR Technology to a licensed healthcare professional who can exercise clinical judgment about the decision support intervention before an action is taken on behalf of the patient.

Finally, CMS proposes that CDS intervention must be related to five or more of the clinical quality measures that the agency will finalize for EPs and on which they will be expected to report. By relating CDS interventions to one or more clinical quality measures, providers are necessarily focusing on high-priority health conditions. Drug-drug/drug-allergy checks have been moved to this objective as well.

### MGMA Comment:

We are concerned that Stage 1’s single CDS rule has been changed in the proposed regulation to five rules, with the rules needing to be related to the finalized clinical quality measures. Additionally, we will see a number of additional certification requirements that will likely make the rules more challenging to build.

Many argue that CDS is still not fully mature. As the Agency for Healthcare Research and Quality states on the homepage for their CDS Initiative: “Despite thoughtful efforts over the last three decades to translate clinical guidelines into CDS rules, there has not been widespread and successful use of such rules to improve patient care” ([http://healthit.ahrq.gov/portal/server.pt/community/ahrq-funded\\_projects/654/clinical\\_decision\\_support\\_initiative/13665](http://healthit.ahrq.gov/portal/server.pt/community/ahrq-funded_projects/654/clinical_decision_support_initiative/13665)). Of course, this limited success so far does not necessarily mean that CDS will not be beneficial in the future. In addition, there is a wide range of sophistication in systems that might be called CDS, and which would in part satisfy the meaningful use requirements.

The CDS Stage 2 objective is to “use clinical decision support to improve performance on high-priority health conditions.” The associated Stage 2 measure as proposed is to, “Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care”, including enabling and implementing drug-drug and drug-allergy interaction checks. The drug-related functionality is intended to provide information to “advise the provider’s decisions” in prescribing drugs to a patient.

The “advice” component of CDS is a particularly challenging issue because the quality of the advice provided is a critical element in any CDS system. It is here that the degree to which the EP should rely on that advice becomes a critical part of how CDS should be used, and, just as important, how it will actually be used. It is important to note that many CDS systems include disclaimers and associated assertions that the clinician must not necessarily rely on the advice provided by the system, but rather they should use their own professional judgment.

There are a number of ways in which CDS may produce inaccurate information for the clinician. The underlying information for which the advice is based on has errors; the underlying information is correct, but the software is flawed; and the health condition of the individual patient may require alternative information or require an alternative treatment approach.

The Stage 2 proposed rule requires that each CDS intervention must enable the provider to review all of the following attributes of the intervention:

- Developer of the intervention
- Bibliographic citation
- Funding source of the intervention
- Release/revision date of the intervention

This suggests, correctly, that the advice provided by the CDS therefore cannot be fully relied on, nor can or should it be a substitute for the judgment of a qualified clinician. It is also interesting to note that the proposed rule observes that while the agency hopes clinical improvement will be the outcome of this objective, it does “not propose to require the provider to demonstrate actual improvement in performance on clinical quality measures” through using a CDS.

The requirement to implement five CDS interventions related to five or more clinical quality measures would be particularly difficult for certain specialists and sub-specialists to meet. These clinicians would need to implement numerous CDS interventions for their particular patient populations given the specific type of care that they provide. As a result, we believe that EPs should only be required to implement two CDS rules during the reporting period for Stage 2. In addition, we recommend that the threshold remain at 30 percent, and that EPs be provided with the option to use Computerized Physician Order Entry (CPOE) for any combination of laboratory, radiology, and medication orders.

### **Online information to patients**

- **Proposed Objective:** Provide patients the ability to view online, download, and transmit their health information within four business days of the information being available to the EP.
- **Proposed Measures:** The proposed rule outlines two measures for this objective, both of which must be satisfied in order to meet the objective:
  - More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within four business days after the information is available to the EP) online access to their health information subject to the EP’s discretion to withhold certain information.

- More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.
- **1<sup>st</sup> Measure (provide access)**
  - Denominator: Number of unique patients seen by the EP during the EHR reporting period.
  - Numerator: The number of patients in the denominator who have timely (within four business days after the information is available to the EP) online access to their health information online.
  - Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.
- **2<sup>nd</sup> Measure (access achieved)**
  - Denominator: Number of unique patients seen by the EP during the EHR reporting period.
  - Numerator: The number of unique patients (or their authorized representatives) in the denominator who have viewed online or downloaded or transmitted to a third party the patient's health information.
  - Threshold: The resulting percentage must be more than 10 percent in order for an EP to meet this measure.
- **Exclusions**: Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures. Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission (FCC) on the first day of the EHR reporting period may exclude only the second measure.

This objective replaces the Stage 1 core objective that requires EPs to “provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request,” and the Stage 1 menu objective for EPs to “provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, and allergies) within four business days of the information being available to the EP.”

The rule explains that transmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.). However, the relocation of physical electronic media (for example, USB, CD) does not qualify as transmission although the movement of the information from online to the physical electronic media would be a download. In order to make the information available to patients online consistent with the information provided during transitions of care, CMS seeks to align the information required to meet this objective with the information provided in the summary of care record for each transition of care or referral.

**MGMA Comment:**

Various Stage 1 requirements are now incorporated into this new online access EP requirement. The threshold from Stage 1's has increased from 10 percent to 50 percent for Measure 1 (providing the online information) and moved to the core requirements. We contend that this could prove to be a significant barrier to successful participation in the program. Measure 2 (10 percent of patients access the information) is particularly concerning. This introduces the element of patient action in order for the EP to meet the requirement. As stated in the rule, “While this is a departure from most meaningful use measures, which are dependent solely on actions taken by the EP, we believe that requiring a measurement of patient use ensures that the EP will promote the availability and active use of electronic health information by the patient or their authorized representatives.”

This requirement has the potential of negatively impacting a number of EPs in different clinical settings. Those EPs practicing among underserved populations with limited access to electronic technology would be hard pressed to meet this requirement. Also, those EPs with a patient-base comprised of large percentages of elderly or those in certain medical specialties such as psychiatry, Alzheimer clinics and others may be severely challenged to have sufficient numbers of their patients electronically access their records. Further, many medical specialties typically see a patient only one time, with little or no need for follow-up care. Again, these patients may be less likely to access their records electronically. Finally, this requirement will disproportionately and negatively impact those EPs practicing in rural environments. It is important to note that many practices participating in Stage 1 of the program, especially those in rural or underserved areas, received few or no requests from patients for an electronic copy of their medical record.

We encourage the agency to develop a number of options for EPs to meet this objective, and include “provide an electronic copy of the medical record to those patients that request it within 72 hours” as an alternative for meeting this requirement. In addition, we strongly urge CMS to remove the requirement that 10 percent of patients access the information and align this objective and measure with the current Stage 1 approach and require the EP offer this service to their patients.

In terms of the proposed exclusion: “Any EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures. Any EP that conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC on the first day of the EHR reporting period may exclude only the second measure,” we have concerns regarding the ability of EPs to accurately access and assess this level of FCC data.

As Table 4 indicates, when we asked our research respondents how difficult it would be to meet the “view, download or transmit” requirement, 56.8 percent of respondents said extremely difficult, and an additional 24.6 percent said very difficult.

Table 4

<b>CMS is proposing a meaningful use measure that requires more than 10 percent of patients to “view, download or transmit” a patient record to a third party health information system by “hosting a patient portal, contracting with a vendor to host a patient portal, connecting with an online PHR or other means.” This is the first meaningful use measure which is dependent solely on actions taken by a patient. How difficult to you think it will be to meet this requirement?</b>	
<b>Answer Options</b>	<b>Response Percent</b>
Extremely difficult	<b>56.8%</b>
Very difficult	24.6%
Somewhat difficult	14.7%
Not very difficult	2.8%
Not at all difficult	1.1%

We urge CMS to provide additional guidance on this issue and permit flexibility in how EPs will be able to apply and account for this exclusion.

### **Providing patients with an electronic copy of their record**

As discussed above, we believe that the measure providing patients with a copy of the health information upon request is reasonable and should be retained as one method of achieving the “view, download and transmit” requirement. However, we have serious concerns with the requirement that those records must be made available within 48 hours and in an electronic format to 80 percent of the patients that request them. Current HIPAA regulations permit providers up to 30 days to compile a patients’ medical record and make it available to the patient. There are several reasons why this timeframe is required:

- Records are often stored in multiple systems and potentially multiple locations, even those in an electronic format
- Records are often stored in multiple formats and require time to consolidate into a single format for the patient
- Under HIPAA, providers are permitted to review the medical record and redact any information that they believe could be harmful to either the patient or someone else

By accelerating the timeframe that the provider has to compile and produce the medical record, the proposed rule is placing an undue burden on the physician and the practice’s administrative staff.

### **Summary care record for transitions of care**

- **Proposed Objective:** The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral.
- **Proposed Measures:** EPs, eligible hospitals, and CAHs must satisfy both measures in order to meet the objective:
- **1<sup>st</sup> Measure:** The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals.
  - **Denominator:** Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.
  - **Numerator:** The number of transitions of care and referrals in the denominator where a summary of care record was provided.
  - **Threshold:** The percentage must be more than 65 percent in order for an EP, eligible hospital, or CAH to meet this measure.
  - **Exclusion:** Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.
- **2<sup>nd</sup> Measure:** The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.
  - **Denominator:** Number of transitions of care and referrals during the EHR reporting period for which the EP or eligible hospital’s or CAH’s inpatient or emergency department (POS 21 or 23) was the transferring or referring provider.

- Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was electronically transmitted using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender.
- Threshold: The percentage must be more than 10 percent in order for an EP, eligible hospital or CAH to meet this measure.
- Exclusion: Any EP who neither transfers a patient to another setting nor refers a patient to another provider during the EHR reporting period is excluded from both measures.

To meet the second measure of this objective an EP must use Certified EHR Technology to create a summary of care document with the required information according to the required standards and electronically transmit the summary of care document using the transport standards to which its Certified EHR Technology has been certified. No other transport standards beyond those proposed for adoption as part of certification would be permitted to be used to meet this measure.

Additionally, in order to foster standards based-exchange across organizational and vendor boundaries, CMS proposes to further limit the numerator by only permitting electronic transmissions to count towards the numerator if they are made to recipients that are — (1) not within the organization of the transmitting provider; and (2) do not have Certified EHR Technology from the same EHR vendor.

The rule proposes to eliminate the objective for the exchange of key clinical information for Stage 2 and instead include such information as part of the summary of care when it is a part of the patient's electronic record.

All summary of care documents used to meet this objective must include the following: patient name; referring or transitioning provider's name and office contact information (EP only); procedures; relevant past diagnoses; laboratory test results; vital signs (height, weight, blood pressure, BMI, growth charts); smoking status; demographic information (preferred language, gender, race, ethnicity, date of birth); care plan field, including goals and instructions; and any additional known care team members beyond the referring or transitioning provider and the receiving provider.

In addition, all summary of care documents used to meet this objective must include the following: an up-to-date problem list of current and active diagnoses; an active medication list; and an active medication allergy list. In order for the summary of care document to count in the numerator of this objective, the EP or hospital must verify these three fields (problem list, medication list, and medication allergy list) are not blank, and include the most recent information known by the EP or hospital as of the time of generating the summary of care document.

CMS notes that the inclusion and verification of these elements in the summary of care record replaces the Stage 1 objectives for "Maintain an up-to-date problem list," "Maintain active medication list," and "Maintain active medication allergy list."

**MGMA Comment:**

The Stage 2 proposed rule increases the Stage 1 requirement of 50 percent for Measure 1 (provision of summary care document) to 65 percent; and various new data elements are required in the clinical summary. Measure 2 (electronic exchange of the summary care record for 10 percent of transitions) introduces an entirely new area for EPs. While we agree that there may be some advantages for EPs having the ability to exchange data with distinctive vendors and organizations, the current healthcare environment is such that not all transitions and referrals will necessarily be with a care setting that has a certified EHR, let alone a certified EHR on a different vendor's system. The administrative burden of

attempting to discern what EHR software is being utilized by a particular care setting will be significant. Further complicating this issue is the fact that Authorized Testing and Certification Bodies (ATCBs) have certified multiple EHR products from a single vendor. In addition, this requirement will prove particularly challenging for those EPs serving underserved populations and located in rural settings. We are also concerned about the cost to EPs for implementing this feature.

We recommend moving this requirement from the core to the menu set. In addition, we urge CMS to recalibrate the numerators and denominators to include only those transitions of care in which the receiving setting is capable of accepting the electronic file. In addition, we recommend eliminating the requirement to exchange with a care setting using a different vendor's product.

### **Provide clinical summary**

- **Proposed Objective:** Provide clinical summaries for patients for each office visit.
- **Proposed Measure:** Clinical summaries for more than 50 percent of office visits.
  - Denominator: Number of office visits conducted by the EP during the EHR reporting period.
  - Numerator: Number of office visits in the denominator where the patient is provided a clinical summary of their visit within 24 hours.
  - Threshold: The resulting percentage must be more than 50 percent in order for an EP to meet this measure.
  - Exclusion: Any EP who has no office visits during the EHR reporting period.

CMS proposes to require the following information to be part of the clinical summary for Stage 2:

- Patient Name
- Provider's name and office contact information
- Date and location of the visit
- Reason for the office visit
- Current problem list and any updates to it
- Current medication list and any updates to it
- Current medication allergy list and any updates to it
- Procedures performed during the visit
- Immunizations or medications administered during the visit
- Vital signs and any updates
- Laboratory test results
- List of diagnostic tests pending
- Clinical instructions
- Future appointments
- Referrals to other providers
- Future scheduled tests
- Demographics maintained by EP (gender, race, ethnicity, date of birth, preferred language)(new requirement for Stage 2)
- Smoking status (new requirement for Stage 2)
- Care plan field, including goals and instructions (new requirement for Stage 2)
- Recommended patient decision aids (if applicable to the visit)(new requirement for Stage 2)

CMS also proposes to maintain several other policies from Stage 1. For purposes of meaningful use, an EP may withhold information from the clinical summary if they believe substantial harm may arise from its disclosure through an after-visit clinical summary. An EP can choose whether to offer the summary

electronically or on paper by default, but, at the patient's request, must make the other form available. The EP can select any modality (for example, online, CD, USB) as their electronic option and does not have to accommodate requests for different modalities. CMS does not believe it would be appropriate for an EP to charge the patient a fee for providing the summary.

**MGMA Comment:**

The Stage 1 requirement to provide the clinical summary to 50 percent of patients within three business days has been proposed to increase to 50 percent within 24 hours. This is a significant shortening of the timeframe EPs have to provide this information to the patient and we believe it is unreasonable. The timeframe of three days should remain, the 50 percent threshold decreased significantly or, preferably, both should occur.

Physician practices require enough time to complete a clinical summary following a patient visit. Forcing EPs to adopt this approach could significantly alter office workflow and reduce the amount of time a clinician spends with their patient. A printed copy of the clinical summary is not necessary for every patient encounter and it is best left to the discretion of the physician whether one is appropriate for that patient and for that encounter. With such a high threshold, EPs will most likely have to print a summary for virtually every patient, regardless of its necessity, just to meet the program requirement.

We also oppose the CMS proposal to prohibit EPs from charging the patient a fee for providing the clinical summary. The HIPAA Privacy rule permits the practice the right to charge the patient a reasonable cost-based fee for a copy of their health information or a summary or explanation of such information. It costs the practice time and materials to produce these summaries and we feel it is appropriate to recoup the costs for their production.

**Secure patient messaging**

- **Proposed Objective:** Use secure electronic messaging to communicate with patients on relevant health information.
- **Proposed Measure:** A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen by the EP during the EHR reporting period.
  - **Denominator:** Number of unique patients seen by the EP during the EHR reporting period.
  - **Numerator:** The number of patients in the denominator who send a secure electronic message to the EP using the electronic messaging function of Certified EHR Technology during the EHR reporting period.
  - **Threshold:** The resulting percentage must be more than 10 percent in order for an EP to meet this measure.
  - **Exclusion:** Any EP who has no office visits during the EHR reporting period.

**MGMA Comment:**

As we outlined above with the issue of online access, we are concerned about the ability of certain providers to meet the requirement of sending a secure message using the electronic messaging function of Certified EHR Technology to more than 10 percent of unique patients seen by the EP during the EHR reporting period. As we described, certain medical specialties and care settings will find it extremely challenging to meet this requirement, especially when they must rely on actions taken by their patients, many of whom may not have access to the appropriate technology.

We recommend that the final rule eliminate the requirement that 10 percent of a EP's patients utilize this service and substitute it for 50 percent of patients who request communication via secure electronic messaging.

### **Security risk analysis**

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

This measure is the same as in Stage 1 except that CMS specifically addresses the encryption/security of data that is stored in Certified EHR Technology (data at rest). Due to the number of breaches reported to HHS involving lost or stolen devices, the HIT Policy Committee recommended specifically highlighting the importance of an entity's reviewing its encryption practices as part of its risk analysis. CMS argues that this is an area of security that appears to need specific focus. Recent HHS analysis of reported breaches indicates that almost 40 percent of large breaches involve lost or stolen devices.

CMS argues that had these devices been encrypted, their data would have been secured. It is for these reasons that we specifically call out this element of the requirements under 45 CFR 164.308(a)(1) for the meaningful use measure. CMS does not propose to change the HIPAA Security Rule requirements, or require any more than would be required under HIPAA. CMS only emphasizes the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure.

CMS proposes this measure because the implementation of Certified EHR Technology has privacy and security implications under 45 CFR 164.308(a)(1). A review must be conducted for each EHR reporting period and any security updates and deficiencies that are identified should be included in the provider's risk management process and implemented or corrected as dictated by that process.

### **MGMA Comment:**

Maintaining the privacy of patient health information and the security of electronic health records is one of the foundations of our healthcare system and has been outlined clearly through the legislative and regulatory processes. As such, providers, as covered entities, are required to conduct risk analyses and mitigate any real or potential security vulnerabilities. Requiring an eligible professional to conduct a security risk analysis that is already required under HIPAA is duplicative and adds an unnecessary reporting burden.

While highlighting the importance of encryption is a laudable goal, it is important to remember that this method of protecting patient data is an "addressable" issue under the HIPAA Security rule. We encourage CMS to work with the Office for Civil Rights (OCR) in development of guidance and educational materials to assist physician practices understand and implement encryption should it be determined by the organization to be an appropriate solution.

Creating an additional challenge to this objective has been the imprecise definition of "risk analysis." The HIPAA Security regulation outlines the process an organization must go through, but does not specify the exact steps, milestones and outcomes of that analysis. As a consequence, compliance with this requirement of the rule and fulfillment of this meaningful use objective has proven very difficult,

especially for smaller practices that have limited in-house expertise in this area. Should this objective continue to be required as part of the meaningful use incentive program, we strongly encourage CMS to work with the OCR to develop guidance and education on the issue of risk analysis and risk mitigation.

### **Measure thresholds**

CMS has indicated that the majority of EPs attesting in 2011 to meaningful use exceeded the minimum measure threshold requirements. We strongly encourage the agency to avoid seeing this as an opportunity to significantly increase measure thresholds. We contend there are several major reasons for this. First, we believe many of those EPs who attested in 2011, these early adopters, are existing EHR users well-acquainted with their technology and the reporting of data. As we move further into the program, EPs starting to utilize EHRs will be seeking to participate in the program. Second, CMS proposes a full-year reporting period-much more challenging than the first year 90-consecutive day reporting period. Finally, arbitrarily increasing measure thresholds could result in a significant number of EPs failing to meet the program requirements.

### **Group Practice Reporting**

The group practice reporting method helps eliminate redundant measure reporting by multiple providers in the same practice treating a single patient. Lowering the burden of data collection activities associated with quality measurement will increase the efficiency of physician measurement. MGMA applauds the three group-reporting options in the proposed rule as alternatives to the current individual reporting method for CQMs used by eligible professionals beginning in 2014. The array of CQM group reporting options under evaluation provides CMS an opportunity to better align multiple incentive programs currently underway.

One of the group reporting options proposed by CMS for reporting CQMs is to define a Medicare EHR Incentive Group as Medicare EPs that successfully report under the Physician Quality Reporting System (PQRS) Group Practice Reporting Option (GRPO) using a certified EHR. CMS changed the definition of a group practice in the 2012 final Medicare Physician Fee Schedule (MPFS). The new definition defines a group practice as 25 or more EPs (previously two or more EPs defined a group practice under the GPRO). Under the new definition of a group practice under the PQRS, a significant percentage of EPs will no longer be able to utilize the GPRO as they participate in the EHR and PQRS incentive programs. Currently, 66 percent of MGMA members are from practices of 25 providers or less. These practices are now unable to participate in the GRPO. This is a step backwards. CMS should seek ways to simplify physician participation by aligning the PQRS and meaningful use definition of a group practice.

CMS also proposes to allow Medicare EPs within a single group practice to report core and menu objective meaningful use data through a "batch file" process in lieu of individual Medicare EP attestation through the CMS Attestation website. The purpose of the group reporting option is to provide administrative relief to group practices that need to attest to meaningful use. Nonetheless, each EP would still have to meet the required meaningful use thresholds independently. This requirement is counterproductive and adds significant administrative burden to the eligible professional's data collection process. With the proposed batch file process, EPs will still be measured at the individual level unlike the CQM group reporting options. We urge CMS to employ group reporting options, at the aggregate group practice level, for all meaningful use requirements (both CQMs as well as core and menu objective data).

We believe that adding effective group reporting options will help drive up participation in the meaningful use incentive program. When we asked MGMA members their level of support for the ability to report all meaningful use requirements at the aggregate group practice level versus the individual EP

level, as seen in Table 5, nearly 66 percent of respondents indicated that they strongly support or somewhat support reporting at the aggregate level.

Table 5

**CMS proposes to allow EPs within a single group practice to report meaningful use data through a “batch file” process in lieu of individual EP attestation. However, each EP would still have to meet the required meaningful use thresholds independently. Please indicate your support for the ability to report all meaningful use requirements at the aggregate group practice level versus the individual EP level.**

<b>Answer Options</b>	<b>Response Percent</b>
<b>Strongly support</b>	<b>41%</b>
<b>Somewhat support</b>	24.4%
<b>Neither support or oppose</b>	21.9%
<b>Somewhat oppose</b>	8.8%
<b>Strongly oppose</b>	3.9%

As noted earlier, CMS proposes three group reporting options to allow EPs within a single group practice to report CQM data on a group level beginning in 2014 if all EPs in the group are beyond the first year of Stage 1. Currently, for the first year of Stage 1 compliance EPs may report CQMs through attestation. CMS is considering an “interim submission” option for EPs who are in their first year of Stage 1 and participate in PQRS. These EPs will submit the PQRS CQMs for their 90-day EHR reporting period. After that, EPs will report the remainder of their CQMs data by the deadline specified in the PQRS. We support the interim submission option for EPs and urge CMS to implement this option. Offering robust and numerous group reporting options will act as an accelerant for small, medium and large groups to participate in the EHR program.

### **Clinical Quality Measures**

MGMA is committed to quality improvement and patient focused care. We look forward to the day when automated quality reporting through an EHR provides reliable information that can inform our quality improvement efforts and the public. However, developing and testing measures for automated reporting takes time and it is essential to ensure that vendor products, once installed and in use, produce scientifically valid and reliable data.

Major challenges have already been identified in Stage 1 in collecting, calculating, and reporting measures. Overall, it will be a challenge for practices to both check all the boxes they need to cover and to make sure that they put in place the change management, processes, and clinical decision support that will improve care. The Stage 1 regulations required EPs to report on six CQMs. In Stage 2, CMS proposes a

significant uptick in CQM reporting, with EPs required to complete 12 of the 125 CQMs over six domains.

The large number of proposed measures will impose a substantial burden on many EPs. EPs have begun the process of converting from their current manual approach of quality reporting (heavily dependent on chart abstraction) to one where the measures must be based on data captured in the EHR. Adding measures unnecessarily increases the administrative burden. In addition, the large volume of quality measures already developed for claims-based reporting but not readily available in EHRs, makes the current measure sets and timeframes unrealistic to meet the desired goals.

As seen in Table 6, over 60 percent of MGMA members responded regarding the proposal that the increased requirement of CQM reporting will result in a significant administrative burden for their practices. The increased number of measures, in addition to their added complexity will create an extreme burden for many EPs, especially smaller practices that may already lag behind in adoption.

Table 6

<b>CMS is proposing 12 total clinical quality measure (CQM) reporting requirements for EPs (up from six in Stage 1). Please indicate the expected administrative burden on your practice of meeting this increased requirement.</b>	
<b>Answer Options</b>	<b>Response Percent</b>
Not applicable	0.7%
Not sure	5.6%
No increase	1.8%
Slight increase	4.6%
Moderate increase	28.1%
Significant increase	<b>59.3%</b>

Additionally, many specialists will face a significant challenge finding measures that are applicable to their practices. Therefore, we urge CMS to reduce the number of CQMs required for reporting in order to enhance participation in the program. Moreover, exemption categories should be created for specialists so that an EP may opt out of a measure if the measure has little relevance (not just a zero denominator) to the EP's practice. We urge CMS to provide an exemption for EPs from the CQM requirements of the EHR meaningful use rule until measures have been tested and vendors have shown they have met the certification requirements for the specific EHR technology being utilized by the EP. It is imperative that CMS actively test whether the measures are, in fact, feasible to calculate before they are finalized.

CMS proposes to align the CQMs with the quality reporting requirements of other CMS and national quality measurement programs, such as the PQRS. We support CMS's efforts to align quality measures across the various programs; however, we strongly believe that if an EP successfully meets the CQM requirements for the meaningful use program they should be deemed as successfully meeting all the requirements for the PQRS program, instead of the other way around.

## **Program Logistics**

Similar to other Medicare incentive programs, the success or failure of the incentive program will depend on the logistics of the program. The more providers are presented with significant challenges in the collection and reporting of data, the higher the likelihood of failure. As many physician practices leverage their expected incentive payments in their EHR contracting process, they need assurances that they will qualify for the incentives prior to their purchase. Should they not receive these types of assurances, many may choose not to participate in the incentive program. Streamlined and efficient program logistics will provide increased assurance to the EP of successful participation.

### **Extension of Stage 1 through 2013**

We support the agency's proposal to extend Stage 1 of the program one year and begin Stage 2 in January 2014. This affords additional time for those EPs who have begun the program in 2011, attested in year one, and will need to modify their EHR software to accommodate the revised Stage 2 requirements. Similarly, EHR software vendors will be given more time to develop, test and deploy software to physician practices.

### **Reporting "year"**

The statute defines the EHR reporting period in the following manner: "The ... term 'EHR reporting period' means, with respect to a payment year, any period (or periods) as specified by the Secretary." With this statutory flexibility, we assert that CMS should consider revising meaningful use incentive program definition of "reporting period." Currently, an EP participating in meaningful use for the first time is required to report on 90 consecutive days. Subsequent participation years require the EP to report data for the entire calendar year. We believe that this is unreasonable and should be modified.

There are numerous scenarios where EPs would be unable to meet the requirement of the full year reporting. For example, the EHR vendor they selected for Stage 1 (ATCB certified) may decide not to certify their product for Stage 2 of the program. Other vendors may stop supporting their product after the beginning of the reporting year, forcing EPs to hire outside consulting help to retrofit and/or maintain their current software, or move to another vendor's product.

Other potential issues that would shut down use of an EHR for a period of time include environmental (i.e., bad weather leading to power outages), infrastructure problems (i.e., Internet down, hardware failures), vendor-related (i.e., slow response times for updates or repairs), and human resource issues (i.e., key practice personnel leaving the organization). Each of these issues could lead to the EHR being unusable for some period of time during the reporting year.

To avoid situations where an EP participating in meaningful use would fail to meet the reporting requirement due to unforeseen circumstances, we strongly recommend that CMS adopt a more flexible reporting period process. Options for achieving this flexibility include:

- "All year" reporting could be modified for each reporting year to mirror the 90-day reporting requirement for the first year of program participation.
- The definition of "all year" reporting could be modified to be "a minimum of 200 days."
- "All year" reporting could permit a 20 percent "down time" calculation to reflect issues out of the control of the EP that would prevent using the EHR and/or reporting data.

### **Good faith program participation**

We urge CMS to exhibit flexibility for EPs who participated in the meaningful use incentive program in good faith, but encountered problems in their reporting of objectives. This flexibility will be particularly important should the agency require complete full year reporting. It would be unfair to not only prevent an EP from achieving the incentive, but potentially penalizing them as well, for failing to report even a small amount of data.

During the attestation process and prior to incurring a payment adjustment, EPs and group practices should have the opportunity to explain that they participated in the incentive program in good faith but were unable to meet the program requirements due to data submission errors. These EPs and group practices should be permitted additional time to submit the appropriate data to qualify for the incentive and/or be exempt from the payment adjustment.

### **Establishment of an appeals process**

The proposed rule outlines the establishment of an appeals process that permits the filing of three types of appeals: (1) eligibility appeals; (2) meaningful use appeals (disputes involving thresholds); and (3) incentive payment appeals. There would be two levels in the appeals process: an informal review and a final reconsideration. The administrative review and appeals process would have to be exhausted prior to seeking review in federal court.

We support this approach and urge disseminating guidance documents to assist EPs seeking to appeal a meaningful use decision. We urge the development of an appeals process that would be automated and streamlined to the greatest degree possible and permit EPs to submit appeal requests by phone, in writing, and directly via a web portal. We also recommend that practices with multiple EPs appealing the same issue be permitted to submit one appeal covering all impacted EPs in the group.

In addition, we recommend that CMS provide EPs the right to petition for a change in their hospital-based status when there is a material change in their organizational affiliation (i.e., a physician leaving a hospital-based practice to join an outpatient physician practice). Finally, we urge CMS to engage the provider community during the development phase of the appeals process to assist in producing the appropriate logistics, tools and supporting resources.

### **Payment Adjustment Issues**

The proposed rule states, "...we believe the payment adjustment should be applied primarily to assure that those who have a large volume of prescribing do so electronically, without penalizing those for whom the adoption and use of an electronic prescribing system may be impractical given the low volume of prescribing." While we concur with the idea that low volume prescribers should not be penalized, we also believe that CMS should exercise additional flexibility in assigning penalties. For example, a higher volume prescriber may be located in a geographic area where the local pharmacies do not have eRx capabilities.

Similarly, certain medical specialties experience a high volume of controlled substance prescribing. While the DEA has issued an interim final rule permitting the eRx of controlled substances in certain circumstances, the regulation has not been finalized as of this writing and presents numerous barriers that prevent the wide use eRx for controlled substances. CMS should, therefore, carefully review the individual practitioner's circumstances prior to assigning any penalties.

### **2015 payment adjustments based on 2015 reporting**

We strongly recommend not imposing payment adjustments in 2015 and 2016 for 2014 meaningful use activity. For purposes of the 2015 incentive program and payment adjustment, the reporting period should be Jan. 1, 2015 to Dec. 31, 2015, or alternatively, Jan. 1, 2015 to Oct. 31, 2015. Just as the incentive program payments are assigned retroactively, the payment adjustments can be assigned in same manner. We urge the agency to impose payment adjustments starting Jan. 1, 2016 for failing to meet the 2015 meaningful use requirements. We believe this is the appropriate interpretation of the statute's requirement that payment adjustments begin in 2015. Modifying the reporting periods will also provide additional time for CMS, trade associations and professional societies to educate EPs on program requirements.

### **Harmonization of incentive program payment adjustments**

In the 2011 Medicare Physician Fee Schedule final rule CMS states that "...although earning an incentive payment under the EHR incentive payment program precludes an EP from earning an eRx incentive payment. The eRx criteria vary significantly between the two programs and it does not preclude the EP from being subject to the eRx penalty. In order to avoid the eRx penalty, an EP participating in the Medicare EHR incentive program still must meet the relevant eRx penalty criteria for being a successful electronic prescriber." We contend that if CMS has determined that an EP is a "meaningful user of EHR" no eRx penalties should be assigned.

EPs seeking to qualify for the payments must have certified systems (including eRx capability) and thus should not be subject to eRx penalties. It is unreasonable to expect EPs to purchase and implement complicated and expensive stand-alone eRx systems to avoid penalties in 2012, only to replace those systems with complete and certified EHRs to meet the EHR incentive program requirements. We strongly encourage the agency to reexamine these proposed penalties and synchronize the eRx and EHR incentive programs to ensure that "meaningful EHR users" are not subject to eRx penalties.

### **Alternative 2014 reporting period**

Should the agency not adopt a payment adjustment process that synchronizes the payment adjustment year and the activity year, we believe that CMS must revisit and revise the 2014 reporting period itself. The proposed rule states that for purposes of the 2015 payment adjustment, EPs in their first year of demonstrating meaningful use would be required to fulfill a reporting period that ends at least three months before the end of CY 2014. In addition, the EP would have to actually successfully register for and attest to meaningful use no later than the date that occurs three months before the end of CY 2014. This provides the agency with 90 days to make a determination of whether an EP is subject to the 2015 payment adjustment.

CMS identifies a "successful" EP meaningful user in year one as one who completes the reporting requirements for any 90-day consecutive period within a calendar year. It appears patently unfair to impose an eRx payment adjustment in 2012 on an EP who was a fully successful e-prescriber (through meaningful use) in 2011 and potentially in 2012 as well. We therefore recommend that if the agency does not utilize a 2012 reporting period for purposes of determining the 2012 eRx payment adjustment, at a minimum, the agency should extend the reporting period for purposes of the 2012 payment adjustment from Jan. 1, 2012 - June 30, 2012 to Jan. 1, 2012 - Dec. 31, 2012. Payment adjustments can always be calculated in 2012 and applied retroactively in 2013 based on actual 2012 payments.

## **Payment Adjustment Issues**

We strongly encourage the agency to closely review the implementation of the Medicare eRx incentive program's payment adjustment process and apply lessons learned from that program to the meaningful use incentive program. The following are the proposed exceptions to payment adjustments and our comments.

### **Insufficient Internet access**

#### **Regulatory language:**

*First, we propose that the Secretary may grant an exception to EPs who practice in areas without sufficient Internet access. This is in keeping with the language at section 1848(a)(7)(B) of the Act that a significant hardship may exist "in the case of an eligible professional who practices in a rural area without sufficient Internet access." It also recognizes that a non-rural area may also lack sufficient Internet access to make complying with the requirements for being a meaningful EHR user a significant hardship for an EP.*

*Because exceptions on the basis of insufficient Internet connectivity must intrinsically be considered on a case-by-case basis, we believe that it is appropriate to require EPs to demonstrate insufficient Internet connectivity to qualify for the exception through an application process...The hardship would be shown for the year that is 2 years prior to the payment adjustment year.*

*We also encourage EPs to apply for the exception as soon as possible, which would be after the first 90 days (the earliest EHR reporting period) of CY 2013. If applications are submitted close to or on the latest date possible (that is, July 1, 2014 for the 2015 payment adjustment year), then the applications could not be processed in sufficient time to conduct an EHR reporting period in CY 2014 in the event that the application is denied.*

#### **MGMA Comment:**

We support the inclusion of the hardship exception for EPs practicing in areas without sufficient Internet access. We also believe that the administrative burden on the EP to "demonstrate" this insufficient Internet connectivity should be minimal. We encourage CMS to develop a simple approach for EPs to confirm that this hardship applies in their case and urge creating multiple methods of confirmation, including mail, phone, and fax. Further, although we concur that EPs should be encouraged to submit their hardship exception request as quickly as possible, we assert that, at a minimum, the deadline for these applications should be Dec. 31, 2014 to apply toward the 2015 payment adjustment.

### **Newly practicing EPs**

#### **Regulatory language:**

*Secondly, we propose to provide an exception for new EPs for a limited period of time after the EP has begun practicing. Newly practicing EPs would not be able to demonstrate that they are meaningful EHR users for a reporting period that occurs prior to the payment adjustment year. Therefore, we are proposing that for 2 years after they begin practicing, EPs could receive an exception from the payment adjustments that would otherwise apply in CY 2015 and thereafter.*

*We note that, for purposes of this exception, an EP who switches specialties and begins practicing under a new specialty would not be considered newly practicing. For example, an EP who begins practicing in*

*CY 2015 would receive an exception from the payment adjustments in CYs 2015 and 2016. However, as discussed previously, the new EP would still be required to demonstrate meaningful use in CY 2016 in order to avoid being subject to the payment adjustment in CY 2017. In the absence of demonstrating meaningful use in CY 2016, an EP who had begun practicing in CY 2015 would be subject to the payment adjustment in CY 2017. We will employ an application process for granting this exception, and will provide additional information on the timeline and form of the application in guidance subsequent to the publication of the final rule.*

**MGMA Comment:**

We support the inclusion of the hardship exception for EPs practicing for a limited period of time. We encourage this exception to be expanded to five years after they begin practicing in recognition of the particularly challenging economic times that EPs face and allow them additional time to identify, acquire and implement the most appropriate EHR technology. In addition, we recommend that the exception be expanded to include those EPs who have changed specialties. In these cases, the exception should apply to EPs changing specialties to two years after they begin practicing. We strongly encourage the development of a simplified hardship exception application process and recommend that multiple application submission options be implemented including mail, fax and online capabilities.

**Extreme circumstances**

Regulatory language:

*Thirdly, we are proposing an additional exception in this proposed rule for extreme circumstances that make it impossible for an EP to demonstrate meaningful use requirements through no fault of her own during the reporting period. Such circumstances might include: a practice being closed down; a hospital closed; a natural disaster in which an EHR system is destroyed; EHR vendor going out of business; and similar circumstances. Because exceptions on extreme, uncontrollable circumstances must be evaluated on a case-by-case basis, we believe that it is appropriate to require EPs to qualify for the exception through an application process.*

*We would require applications to be submitted no later than July 1 of the calendar year before the payment adjustment year in order to provide sufficient time for a determination to be made and for the EP to be notified about whether an exception has been granted prior to the payment adjustment year. This timeline for submission and consideration of hardship applications also allows for sufficient time to adjust our payment systems so that payment adjustments are not applied to EPs who have received an exception for a specific payment adjustment year.*

*The purpose of this exception is for EPs who would have otherwise be able to become meaningful EHR users and avoid the payment adjustment for a given year. Therefore, it is not necessary to account for circumstances that arise during a payment adjustment year, but rather those that arise in the two years prior to the payment adjustment year (that is in the calendar year immediately prior to the payment adjustment year, or the calendar year that is 2 years prior).*

**MGMA Comment:**

We support the inclusion of the hardship exception for EPs who experience extreme circumstances that make it impossible for an EP to demonstrate meaningful use requirements through no fault of their own during the reporting period. We encourage expanding this exception to five years after they begin experiencing extreme circumstances.

When asked about three of the proposed categories EPs would have to meet to justify an application for a hardship exemption, the response from MGMA members was overwhelmingly in support of each (Table 7). 67.9 percent said they support or strongly support the hardship exemption due to insufficient Internet access two years prior to the payment adjustment year of 2015. 73.1 percent either support or strongly support the exemption of a new practice that opens fewer than two years prior to 2015. Finally, 93.3 percent of respondents either support or strongly support a hardship exemption due to extreme circumstances such as an unexpected office closure, a natural disaster, or an EHR vendor going out of business.

Table 7

The proposed rule outlines three categories for EPs that justify an application for a hardship exemption. Please indicate your level of support for each of these:					
Answer Options	Strongly support	Support	Neither support or oppose	Oppose	Strongly oppose
Insufficient Internet access two years prior to the payment adjustment year of 2015	34.3%	33.6%	20.5%	9.9%	1.8%
A new practice opens fewer than two years prior to 2015	36.7%	36.4%	17%	7.1%	2.8%
Extreme circumstances such as an unexpected office closure, a natural disaster, or an EHR vendor going out of business	61.6%	31.7%	5.6%	0.7%	0.4%

### Specialty exceptions

#### Regulatory language:

*Finally, we are soliciting comments on the appropriateness of granting an exception for EPs meeting certain criteria. These include--*

- Lack of face-to-face or telemedicine interaction with patients, thereby making compliance with meaningful use criteria more difficult. Meaningful use requires that a provider is able to transport information online (to a PHR, to another provider, or to a patient) and is significantly easier if the provider has direct contact with the patient and a need for follow up care or contact. Certain physicians often do not have a consultative interaction with the patient. For example, pathologist and radiologists seldom have direct consultations with patients. Rather, they typically submit reports to other physicians who review the results with their patients;*
- Lack of follow up with patients. Again, the meaningful use requirements for transporting information online are significantly easier to meet if a provider immediate contact with or follows up with or contact patients; and*
- Lack of control over the availability of Certified EHR Technology at their practice locations.*

*We do not believe that any one of these barriers taken independently constitutes an insurmountable hardship; however, our experience with Stage 1 of meaningful use suggests that, taken together, they may pose a substantial obstacle to achieving meaningful use.*

**MGMA Comment:**

We support the inclusion of the hardship exception for EPs who have a lack of face-to-face or telemedicine interaction with patients, a lack of follow up with patients, and a lack of control over the availability of Certified EHR Technology at their practice locations. This is particularly important for certain medical specialties (i.e., radiology and pathology) that utilize inpatient EHRs yet may bill using outpatient or ambulatory surgical center place of service (POS) codes. Hospital-located professionals whose services include more than 10 percent in POS 22 find themselves reliant on hospitals for the technology that would enable them to successfully participate in the EHR incentive program. Hospitals are not required to facilitate the meaningful use compliance of these professionals and many have chosen not to, leaving these EPs with no way to participate and subject to payment adjustments beginning in 2015.

When asked about this potential fourth hardship category made up of three criteria, the respondents to our research questionnaire were asked about their level of support for separating these three categories and treating each as individual hardship exemptions. As shown in Table 8, 66.4 percent support or strongly support this idea.

Table 8

What is your level of support for treating each of these three criteria as individual hardship exemptions?	
Answer Options	Response Percent
Strongly support	32.5%
Support	<b>33.9%</b>
Neither support or oppose	22.6%
Oppose	8.1%
Strongly oppose	2.8%

Regulatory language:

*One option is to provide a time-limited, two year payment adjustment exception for all EPs who meet the previous criteria. This approach would allow us to reconsider this issue in future rulemaking. Another option is to provide such an exception with no specific time limit. However, we note that even under this less restrictive option, by statute no individual EP can receive an exception for more than five years. As discussed earlier, we believe the proliferation of both Certified EHR Technology and health information exchange will reduce the barriers faced by specialties with less CEHRT adoption over time as other providers may be providing the necessary data for these specialties to meet meaningful use. We particularly request comment on how soon EPs who meet the previous criteria would reasonably be able to achieve meaningful use. We believe that EPs who meet the criteria listed previously face unique*

*challenges in trying to successfully achieve meaningful use. However, we encourage comment on whether these criteria, or additional criteria not accounted for in the meaningful use exclusions constitute a significant hardship to meeting meaningful use. For the final rule, we will consider whether to adopt an exception based on these or similar criteria, and, if so, whether such an exception should apply to individual EPs or across-the-board based on specialty or other groupings that generally meet the appropriate criteria.*

**MGMA Comment:**

We do not believe that these exemptions should be time-limited. Should an EP qualify for this “specialty exception,” it will be because they do not have an opportunity to participate in the current meaningful use incentive program. While we agree that it is likely there will be advancements in the areas of CEHRT and HIEs, it is unlikely that these advancements will either occur in time for these specialty EPs to participate in the meaningful use incentive program, or materially alter the environment in which these EPs practice.

**Additional recommended hardship exceptions**

We believe that it is unfair to require participation in this incentive program for those EPs who are eligible for social security benefits. Meeting the requirements of meaningful use requires considerable expenditures of both human and financial capital. It is expected that the return on investment of an EHR installation will require several years of operation. Thus, we contend that these older EPs should be granted a hardship exception and not be subject to any Medicare payment adjustment.

**Submission of the hardship request**

Should CMS not adopt the more reasonable approach of utilizing 2015 meaningful use activity to determine the 2015 payment adjustment, we strongly encourage the agency to extend the time period in which EPs and group practices can submit hardship requests to Dec. 31, 2014.

In the proposed rule, CMS proposes a July 1, 2014 deadline for submission of hardship requests to avoid the 2015 payment adjustment. We disagree that a full six months is required to capture the data and determine what EPs would be subject to the penalty. As a reference point, CMS permitted EPs to submit a hardship request via a Web-portal tool until Nov. 8, 2011, for the 2011 eRx incentive program.

Further, CMS should permit EPs to submit their hardship requests by phone, in writing, and web portal. In addition, we support the proposal to limit the information that an EP or group practice would be required to include in an exemption application. It appears reasonable to require identifying information (e.g., TIN, NPI, name, mailing address and e-mail address of all affected eligible professionals), selection of one or more of the significant hardship exemption categories that apply, a brief justification statement and an attestation of the accuracy of the information provided. We also recommend that once CMS has completed its review of the EPs request for an exemption, that it notifies the EP or group practice within two weeks.

In addition, we strongly encourage CMS to develop a process that permits EPs and group practices to designate an individual responsible for submission of all submit hardship exemption applications for multiple EPs at once.

## **Additional Issues**

### **Continued monitoring of the EHR marketplace**

Section 3007 (a) of the ARRA legislation states that the “National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 3000) consistent with subsections (b) and (c), and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.”

We encourage the close monitoring of the EHR marketplace by ONC to ensure that appropriate and cost-efficient products are being offered in a timely manner to physician practices, especially small practices with limited financial resources. We also encourage the early recognition by the ONC of marketplace failures and the subsequent requirement for the deployment of low-cost alternative software.

We recommend that CMS, in partnership with ONC, should continue to aggressively and comprehensively monitor the industry to ensure: (a) that there are sufficient certified EHR products to meet the needs of all segments of the eligible professional industry; (b) that bottlenecks and order backlogs caused by delayed software development or certification are not preventing eligible professionals from obtaining and implementing appropriate products in a timely manner; (c) that vendors of complete EHRs and EHR modules that have been certified for participation for Stage 1 of the program will be certifying for Stage 2 as well, and (d) that product pricing is not preventing large numbers of eligible professionals from participating in the incentive program, thus triggering the ARRA provision requiring the HHS Secretary to develop alternative products. In addition, we urge HHS to aggressively scrutinize the EHR vendor sector, establishing toll-free telephone numbers and a website allowing physician practices and others to report problems, issues, and unfair business practices.

### **Physician practice communication and education**

The success of the ARRA incentive program will rely in part on effective outreach to the physician practice community. We applaud both CMS and ONC for their willingness to perform significant outreach to the physician community. CMS has done an excellent job communicating timelines, definitions, program modifications, updates, and the application processes to potential incentive recipients. In particular, we want to thank the agencies for convening regular provider conference calls and addressing questions and issues.

We recommend that CMS and ONC continue their multi-pronged communication outreach plan that includes:

- Regularly updated websites with comprehensive FAQ sections
- Toll-free telephone numbers to provide accurate information
- Regularly-scheduled “open door” webinars to provide updates and address participant questions
- Participation by HHS officials at industry conferences and forums
- Direct outreach to provider professional associations

## **Conclusion**

In conclusion, we strongly support adoption of HIT in ambulatory care settings. However, in order to best achieve the goals set out in the legislation, MGMA encourages CMS to significantly modify this rule as proposed.

In order to maximize the success of the program, we also believe that a workable and practical definition of meaningful use must be developed, reasonable and specialty-appropriate measures required, and program logistics created that reduce administrative burden on participating practices. Should the qualifications for participation in these incentive programs be overly stringent or the process too onerous, the government runs the risk of excluding a large percentage of physician practices from participation.

This is a historic opportunity to reform and revitalize the nation's healthcare system. However, considerable work must be accomplished in order to make effective HIT widely available. We look forward to working with the government to facilitate the physician practice transition to EHRs, and make the promise of improving the nation's healthcare system through technology a reality.

We appreciate the opportunity to offer our comments on this important issue. Should you have any questions, please contact Robert Tennant at [rtennant@mgma.org](mailto:rtennant@mgma.org) or 202-293-3450.

Sincerely,

A handwritten signature in black ink that reads "Susan Turney". The signature is written in a cursive, flowing style.

Susan Turney, MD, MS, FACP, FACMPE  
MGMA president and CEO