May 7, 2012

The Honorable Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Attn: CMS–0044–P.
7200 Security Blvd
Baltimore, MD 21244-1850

Dear Acting Administrator Tavenner:

On behalf of the Healthcare Billing and Management Association (HBMA), we are pleased to submit these comments on the proposed EHR Stage II criteria (CMS–0044–P).

HBMA members process medical billing, physician billing, insurance billing, and other claims integral to the healthcare delivery system. HBMA members frequently perform all of the physician's practice management functions, accounts receivable management, medical billing consulting, as well as assistance in the preparation and completion of provider enrollment forms and other practice management services.

HBMA members typically provide services to specialty physician groups and primary care practices and process Medicare, Medicaid, and private health insurance claims. A typical HBMA member processes approximately 20,000 claims per month, totaling $20 million per year; some do much more.

General Comments

Stage 2 meaningful use requirements include new expectations for health information exchange including: more demanding requirements for e-prescribing; incorporating structured laboratory results; and the expectation that providers will electronically transmit patient care summaries to support transitions in care across unaffiliated providers, settings and EHR systems. This incorporation of the interoperability capacity to share information among otherwise unaffiliated providers is an extremely important transition.

HBMA strongly recommends that CMS and ONC monitor this area closely to ensure that it goes smoothly and information exchanged across different platforms moves smoothly and effectively. If this does not go well, then the goal of ensuring that "information follows the patient" will be extremely hard to achieve and the tremendous expense of moving to an EHR could be wasted.

HBMA is very appreciative of the Department's efforts to balance the concerns of specialty physicians with those of primary care providers while also continuing the process of encouraging the adoption and use of Electronic Health Records.

As with Stage I, certain medical specialties will have little difficulty meeting most or all of these objectives/measures outlined in the proposed rule; however, this will not be the case for all medical specialties.

Proposed Delay for moving to Stage II

As we noted in comments HBMA submitted for Stage I in 2009, "successful EHR implementation is a multi-year process that requires significant capital and operating expenditures, investment in personnel and close collaboration with patients and other providers. In the best cases, such an approach requires at least a three-year window from initial project conceptualization to the point where EPs can actually use the systems for patient care. In most cases, the time required is much longer; even relatively smooth-running EHR initiatives can take between five-and-seven years. In addition, EPs will need ample time to test their EHR systems as they are implementing them to ensure that all safeguards are in place."

We stand by that observation and for this reason, we appreciate that CMS is proposing to slow-down the adoption/implementation phase to allow more time for providers to achieve Stage I meaningful use before moving to Stage II.

In the Stage 1 final rule, CMS adopted a policy that any provider who first attested to Stage 1 criteria for Medicare in 2011 would begin using Stage 2 criteria in 2013. This proposed rule delays the onset of those Stage 2 criteria until 2014.

Recommendation:

HBMA supports the delay for beginning Stage II from 2013 to 2014. Along these lines, HBMA believes that it will be necessary to allow additional time for the next phase of the transition and recommends that CMS and ONC adopt as a matter of policy, that each phase of the transition lasts a minimum of 3 years. Stage I would be in place for three years before moving to Stage II (as CMS proposes). Stage II would also be in place for three years before moving to Stage III.

Adding new exceptions for avoiding the EHR MU "payment adjustments"

While much of the focus on the EHR meaningful use has been on the incentive payments, many providers are now confronting the reality of "payment adjustments" for failure to be a meaningful user of EHR. This sensitivity to the "payment adjustment" issue is, we believe, somewhat driven by providers experiencing a "payment adjustment" in Medicare Part B payments for failure to e-prescribe.

CMS proposes 3 reasons why a provider could obtain an "exception" and thereby avoid the "payment adjustment."

1. Lack of availability of Internet access or barriers to obtaining IT infrastructure;
2. A time-limited exception for newly practicing EPs; and,

3. Unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis.

Each of these exceptions makes sense and we believe they are reasonable and appropriate.

In the NPRM, you also ask for comments on a potential fourth category of exception: Due to a combination of clinical features limiting a provider's interaction with patients and lack of control over the availability of Certified EHR technology at their practice locations.

Recommendation:

HBMA supports these exceptions.

HBMA supports an exception that would recognize that certain types of providers (i.e. Radiologists and Pathologists) have limited face-to-face interaction with patients or a providers inability to control his/her access to certified EHR.

HBMA also supports the following proposed changes for Stage II

- Allowing EPs to exclude either height/weight or blood pressure recording – or both – if not relevant to scope of practice.
- Keeping the objective of the "capability to submit electronic syndrome surveillance data to public health agencies" as an "objective" rather than moving it to a requirement in Stage 2.
- Allowing patients seen by a PA or NP under the physician's supervision to be counted by both for Medicaid incentive purposes.
- Requiring encryption of data at rest in the EHR.

HBMA has concerns about the following proposed changes

*A. Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders **directly entered** by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.*

There are two issues here that concern us. One, the requirement that the information be **directly entered** by a licensed healthcare professional and; two, that the person doing the entering of information must be licensed as a condition to make an entry.

In many states, unlicensed staff (i.e. Scribes and Medical Assistants) are utilized to directly enter orders in the medical record. These individuals have often been through some credentialing and/or certification process to assess their qualifications to perform this function but they are often not "licensed" to perform this function. These individuals may literally follow the licensed provider and enter the order in the computerized system but it is the licensed professional who reviews that information and assures it's accuracy prior to transmission to another provider, pharmacy, etc.

Furthermore, although these individuals may not be licensed by the state, they are performing a task they are permitted to perform under relevant state law or state regulatory mechanism. In some states, this task (order entry) is specifically identified, in other states, the authority occurs as part of the broad delegatory authority granted to the physician or other licensed healthcare provider by the state.

If you adopt this standard, you will significantly reduce the productivity of the office. This requirement, in conjunction with the 24 hour turnaround requirement, will effectively preclude the use of a scribe or a medical assistant to work with the physician.

Establishing this standard would be analogous to Congress requiring that the Administrator of CMS personally review every comment submitted in response to this NPRM and personally writing a response to every comment.

Recommendation:

This requirement needs to take into consideration the reality of staff that do the groundwork for a provider and then have the EP be the final authority to transmit the order for medication, imaging or lab services.

B. Proposed EP Objective: Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP. Both of the following measures have to be met:

> *1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 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.*
>
> *2. More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download or transmit to a third party their health information.*

Ensuring that the providers make this option available to patients within the timeframe (4 business days) is reasonable. The provider can control this and holding the provider accountable for this is reasonable.

However, also requiring that "more than 10 percent of all unique patients view, download or transmit to a third party" is unreasonable.

We appreciate the fact that CMS wants the providers to actively engage their patients and encourage them to encourage their patients to utilize the EHR tools available, but you fail to recognize that MANY patients either do not want this feature or will simply not avail themselves of the opportunity.

Holding the provider liable for the failure of the patient to exercise this option is unreasonable.

Recommendation:

CMS should retain the requirement that the EP provide the EHR report to 50% of patients but remove the subsequent requirement that 10 percent of all patients view, download or transmit their information.

C. Proposed Measures: The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals. 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.

The NPRM describes "transitions of care" as follows: "… the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another."

The NPRM goes on to note that "a transition home without any expectation of follow-up care related to the care given in the prior setting by another provider is not a transition of care for purpose of Stage 2 meaningful use measures as there is no provider recipient." In addition, a transition within one setting of care does not qualify as a transition of care.

The NPRM describes referrals as, "… cases where one provider refers a patient to another, but the referring provider maintains their care of the patient as well."

In the concluding paragraph, the NPRM notes, "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 should provide summary care record for each transition of care or referral.''

Recommendation:

We do not have any objections to the intent behind this objective and believe it is reasonable for Stage II and most EPs with a certified EHR should be able to comply with the intent of this objective. We are concerned, however, that the terms "transitions" and "refers" require additional explanation. We encourage CMS to provide examples or clarification of the usage of the terms "transitions" and "refers" as it relates to Meaningful Use.

D. Capability to submit electronic data to immunization registries, reportable lab results to public health agencies, electronic surveillance data to public health agencies and report cancer cases to a cancer registry.

Recommendation:

We recommend that CMS make allowances for situations where states and agencies do not have the ability to receive information into the registry. Further, we recommend you limit specific patient information where possible in order to protect identity.

E. Use of the term relevant.

On various occasions in the NPRM, CMS uses the term "relevant." For example, the document refers to "relevant past diagnoses" in the discussion about the summary of care document. It refers to the fact that it is left up to the EP to determine what additional "relevant" clinical information to include in the summary record.

While we respect and appreciate CMS' desire to provide maximum flexibility to providers, it has been our experience that providing more direction or insight (via examples) will help to ensure that EPs achieve this objective.

Recommendation:

Absent providing examples, at least clarify that what the individual EP considers relevant is sufficient to meet the definition of the term for purposes of EHR Meaningful Use.

F. CMS seeks comments on whether the barriers to collecting information for our proposed denominator would be greater in a hospital or ambulatory setting.

1. CMS welcomes comments on whether laboratory and radiology orders are sufficiently different in the use of CPOE that they would require a different threshold and whether such a threshold should be a lower percentage or a yes/no attestation.

HBMA would favor the yes/no attestation

2. CMS does not believe that OTC medicines will be routinely electronically prescribed and proposes to continue to exclude them from the definition of a prescription. However, we encourage public comment on this assumption.

HBMA would recommend that the Stage II MU continue to exclude OTC from the definition but we encourage you to require information about what OTCs were recommended be included in the patient record.

3 CMS encourages public comment on the burden and ability of including disability status for patients as part of the data collection for this objective. We believe that the recording of disability status for certain patients can improve care coordination, and so we are considering making the recording of disability status an option for providers.

We concur that requiring the collection of data on the patients disability status will, in the long-run, prove beneficial.

4. Proposed EP Measure: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits. Although CMS provided 3 business days to send the clinical summary in Stage 1, you now believe that a faster exchange of information with the patient is not only possible but also encourages better quality of care.

HBMA believes that rather than using the 24 hour time period, the measure should be next business day. This way, if a practice is not open or the visit occurs on a Friday evening and the practice is closed on Saturday, the provider can get the information out Monday.

In addition, we are concerned that some lab information may not be available within 24 hours or one business day. Therefore, inclusion of lab results in a visit summary should only apply to those test results available at the time of the visit.

5. CMS seeks comments on a potential second measure that would encourage the exchange of imaging and results between providers. CMS is considering a threshold of 10 percent of all scans and tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period and accessible through Certified EHR Technology also be exchanged with another provider of care.

CMS appears concerned that this extra measure may be difficult for some EPs to meet and might discourage a significant number of EPs from selecting this objective as part of their menu set. We also solicit comment on whether an exclusion for this second measure should be included for providers who do not typically exchange imaging scans and test results as a normal part of their workflow, and we encourage commenters to provide details about how such an exclusion might be included.

As with many of the objectives, HBMA believes this only works if both sides have EHR capability. The EP who seeks EHR meaningful use should not be punished because the area they practice in does not have this ability. For example, many federally certified RHCs may not adopt and use EHR for some time because of the way the incentives and "payment adjustments" are structured.

Therefore, it is entirely possible that many RHCs will not be able to receive imaging or pathology results electronically.

We do not believe EPs should be punished because they do not have a suitable partner(s) with whom to share information electronically.

G. Conduct or review a security risk analysis, including addressing the encryption/security of data at rest, and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.

We believe it is appropriate to require EPs to conduct a security risk analysis, however, it should be clarified that it is clear that the HIPAA privacy standards are the controlling authority. We are concerned that other areas of ONC regulations may conflict with certain HIPAA security and privacy standards thereby creating confusion on the part of the provider. Do I follow the HIPAA privacy standard or do I follow the ONC security standard?

We share the concern expressed by others that it would be a mistake for each EHR incentive program regulation to emphasize different aspects of the HIPAA privacy and security rules. We understand that these rules may change over time but such changes should be accomplished through separate rulemaking, not as part of the EHR incentive program regulations.

Some have suggested that the Stage II MU standards create a potential conflict between HIPAA and ONC standards. Although we do not see the conflict, in the event there is a real or perceived conflict, any conflict should be resolved in favor of the HIPAA requirements. CMS should not create a conflicting set of obligations or enforcement mechanisms for privacy and security compliance.

H. Establishment of Clinical Quality Measures

HBMA supports the establishment of the Clinical Quality Measures and the effort by CMS to align the CQM with both the PQRS and E-Prescribing criteria. We believe this will be more efficient for providers and help improve the quality of care available to patients.

As we are not a clinical organization, we do not offer an opinion on the actual clinical measures, but we believe this is an important addition. We also appreciate the added flexibility on the denominator for this measure.

We strongly support the move toward automated quality reporting. We believe this can ease the burden on EPs and provide real-time information. In addition, we believe the various reporting measures should be folded into the EHR process so there is no overlapping of the various quality data reporting.

Based on the meaningful use penalties in the statute, it also seems likely that CMS will transition to automated reporting of quality data in the not too distant future. However, CMS has yet to state this in regulation. It is important for CMS to provide clear direction for providers so that the necessary resources for automated quality reporting can be budgeted.

As do others, we believe it is inefficient and wasteful to require providers to submit the same quality data through multiple reporting mechanisms.

We urge CMS to recognize the potential for overlap and take steps through the rulemaking process to better coordinate the various quality/data reporting initiatives.

I. General Observations

Patient Ownership of Personal Health

We think it is also important for CMS to acknowledge that the individual patient is ultimately responsible for his or her health and well-being. Providers can offer suggestions, make recommendations and develop treatment protocols for the patients. But once the patient leaves the office, there is little the EP can do to guarantee that the patient complies. Ultimately it is up to the patient to follow the plan of care.

Recommendation

All measures dependent upon someone other than the physician for compliance should be removed from Stage II. Establishing measures which set minimum patient activity as a condition for compliance are inappropriate. The ability of a physician to meet the meaningful use criteria should not be dependent upon the actions of others.

Application of Penalties for failure to Meaningfully Use EHR

Beginning in 2015, EPs will be subject to a penalty for failure to be a meaningful user of a certified EHR during 2013. We recognize that there must be a time lag between when the provider completes the year in which they are being evaluated and the application of the penalty. We are concerned, however that the time between when a provider must meet the Stage I MU standards (2013) and when the penalty will be applied (2015) will cause tremendous confusion and situations in which providers will not even understand why they are subject to the penalty.

We are concerned that there are no exceptions to the penalties similar to the exceptions that CMS established for e-prescribing. For example, a provider who joins a practice late in 2013 and is unable to meet the Stage I MU standards, could be subject to a penalty in 2015 for failing to meet the Stage I measures. We would be happy to work with CMS to determine what those exceptions should be.

Recommendation:

Eligible Professionals should be provided with as much opportunity as possible to participate in MU prior to the penalties go into effect. And, similar to the e-prescribing criteria, exceptions should be made available, and an appeals and reversals of inappropriately applied reductions.

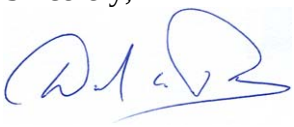
Conclusion

On behalf of the Healthcare Billing and Management Association (HBMA), we that you for the opportunity to submit these comments. Please do not hesitate to contact Bill Finerfrock, the Association's Director of Government Affairs (202-544-1880 or bf@capitolassociates.com) or

Brad Lund, HBMA's Executive Director (877-640-4262 or Brad@hbma.org) if you have any questions or need any additional information.

Your consideration of these comments is greatly appreciated.

Sincerely,



Don Rodden, CPA, CHBME
President
Healthcare Billing and Management Association