March 13, 2009

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0033–P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS-0033-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule (Vol. 75, No.98), January 13, 2010

Dear Ms. Frizzera:

On behalf of the Healthcare Billing and Management Association (HBMA), we are pleased to submit these comments for CMS' consideration.

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

HBMA is very concerned that many of the objective/measures outlined in the proposed rule will have a disproportionate impact on different providers depending upon their geographic location or medical specialty.

While certain medical specialties will have little difficulty meeting most or all of these objectives/measures outlined in the proposed rule, this will not be the case for all medical specialties. Further, rural providers may find it more difficult to achieve some of the criteria – particularly those involving patients and the assumption of patient access to electronic communications.

For example, Objective 4 stipulates that in order to qualify, "At least 75% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology." While the EP may have an EHR system that has the ability to transmit a prescription electronically, it is quite possible that the EP does not have a local pharmacy that can accept that electronically generated prescription.

Similarly, Objective 13 seeks to promote electronic communication with the patient and would establish a benchmark that states that "Reminder sent to at least 50 percent of all unique patients seen by the EP that are 50 and over." As with the prescription drug requirement, this seems to presume that at all or substantially all of the providers' patients have the ability to receive electronic follow-up reminders.

Many rural communities are not as "well wired" as urban and suburban communities and sending and receiving large, complex documents electronically can be very time consuming. As a consequence, you do not see the level of penetration of electronic communication in rural communities experienced in more populated areas. Asking EPs to achieve a standard over which they have little or no control will result in thousands of providers being judged ineligible for the incentive payments and not only jeopardizing this initiative but also jeopardizing the economic viability of a practice that is depending upon those incentive payments to recoup at least a portion of the costs of implementing and EHR.

This lack of uniform effect across specialties and geographic areas causes great concern because the proposed rule stipulates that if a provider fails to meet all of the meaningful use criteria, the provider would be ineligible for incentive payments for that year. This type of "all-or-nothing" approach to be considered a meaningful user of EHR puts the provider at substantial financial risk and could cause many to forgo the adoption and use of a qualified EHR system.

Many providers have compared this to their experience with the PQRI incentive payments where the provider invested a significant amount of time and resources into complying with the PQRI criteria only to find that they fell just shy of the thresholds and thus were ineligible for the incentive payments. Similarly, providers will be concerned that after investing a considerable amount of time, money and other resources, the provider will find that he/she failed to meet one of the criteria and thus lose out on the incentive payments.

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.

CMS has proposed a series of objectives and measures that Eligible Professionals (EPs) must meet in order to qualify for the EHR incentive payments. Failure to meet any of the 25 measures would result in the provider being disqualified from receipt of the incentive payment for that year.

In reviewing the Objectives/Measures proposed by CMS we believe that there too many measures in general and that some of the measures are unnecessary or inappropriate for some medical practices or sites.

General Recommendations:

1. The number of measures should be reduced in the aggregate from 25 to 20.
2. Providers should have some flexibility in Stage 1 with respect to meeting most, but not all of the objectives. A provider meeting 80% (16) of the 20 objectives should qualify for EHR incentive payments in Stage one.
3. The thresholds for demonstrating achievement of a particular objectives should be revised in Stage 1 in order to ensure more EPs are able to meet the objective.

Specific Issues:

In addition to the general observations and recommendations made above, we have specific comments and recommendations on certain Measures identified in the proposed rule.

Objective (1): Use CPOE
Measure: CPOE is used for at least 80 percent of all orders.

Comments:

Computerized Physician Order Entry (CPOE) has been an internal capability of hospital software systems for decades. Obviously, in an internal, closed system with only one protocol for entering orders it is relatively straightforward for a hospital to implement and mandate use of CPOE. Some hospital systems are capable of supporting remote access to the hospital's system (still a "closed" system) so that providers are able to utilize CPOE from their office or other locations. We are aware, anecdotally, that many physicians practicing in hospitals with CPOE capability rely on hospital staff (nurses, technicians, medical assistants, etc.) to enter the orders for them, whether the physician personally "signs" the order or the hospital employee performs that function as well.

It is not unusual for community-based and academic physicians to practice in more than one hospital; in urban settings the number of hospitals to which physicians issue orders can be as many as ten. While the number of hospital system vendors is far fewer (under 50) than medical practice management systems (over 350) or EHR systems (450+), the likelihood that all of the hospitals where a physician orders services will all have the same software systems is almost zero.

Not all hospital software systems are capable of receiving CPOE from external systems. This will leave providers with no way to meet the 80% requirement, particularly if the hospital without CPOE capability is the ONLY hospital to which orders are sent, or that hospital represents a statistically significant volume of a practice's orders.

EHR systems and their users will face developing and maintaining a vast array of interfaces and communication protocols, data formats and specifications, authentication and verification processes and a host of other elements in order to establish and maintain CPOE connectivity with

hospitals. We are concerned that the costs of creating and maintaining these interfaces and protocols have not been anticipated or accounted for in anyone's historic analysis of the acquisition, implementation or operating costs of EHR systems for EPs.

The study listed below highlights the challenges outlined above:

> **Inpatient Computerized Provider Order Entry (CPOE)**
> Findings from the AHRQ Health IT Portfolio (January 2009)
> Prepared for: Agency for Healthcare Research and Quality
>
> U.S. Department of Health and Human Services
> http://healthit.ahrq.gov/images/jan09cpoereport/cpoe_issue_paper.htm

Hospitals are not the only entities to whom physicians issue orders; pharmacies, private and commercial clinical laboratories, imaging centers, DME providers, IDTFs, SNFs, and a host of other providers are regularly asked to provide services ordered by physicians. While many of these providers are computerized, not all of them are, and most utilize different systems, some of which are proprietary. Far fewer of these entities currently support CPOE in any format and those that do are typically only supporting one format.

Connecting a practice's privately acquired and operated EHR to a CPOE is a far more complex undertaking, given that each receiver of orders must be capable – and willing – to receive electronic orders from hundreds and hundreds of competing EHR systems. In the marketplace, volume will have an enormous effect on who is accommodated and who is not. This has the probable result of CPOE-capable EHR systems being shunned by hospitals, laboratories, imaging centers and other testing and order-based service providers due to low volumes (as measured by the receiving party, not by the sending party) of requests.

There are no technical standards for CPOE. Each CPOE system is unique and is often highly customized for each hospital client. EHR software vendors will find it difficult and extraordinarily expensive to customize their product to enable each individual EP to connect to each unique CPOE. These costs will not be absorbed by the vendors and cannot realistically be borne by the EP.

EPs that implement CPOE will be significantly burdened with manually tracking and counting all items ordered in order to know the denominator of total orders. Since CPOE will, at best, provide a total of orders sent (the numerator) the only way to know the denominator is to track them by hand. In practices with a high volume of orders due to the clinical specialty, the high acuity of its patient population, prerequisites imposed upon "gatekeeper" physicians to authorize and order tests and a host of other reasons, this burden could be significant, tedious and costly.

In general, we respect the proposed Objective as a desirable long-term (5 – 10 year) goal for users of EHR systems. However, as we highlight above, the fact that this Objective is not only unrealistic in the current marketplace, EPs that might attempt to achieve this Objective will find it technically, operationally and/or economically impossible.

In addition, the proposed Measure of 80% of all orders is impossibly optimistic, even if the Objective is achievable within 5 – 10 years. As noted above, many – and sometimes all – orders issued by a practice are not sent to any hospital and the likelihood that non-hospitals will seek, find, implement and utilize a CPOE capability is extremely limited now and we do not believe this will change appreciably during the period planned for government supported adoption of EHRs.

Objective (1) Recommendations:

1. This Objective and Measure should be deleted.
2. Alternatively, the Measure should be modified to reflect a requirement to utilize CPOE for:
   - A. 75% of all orders for services and products issued to sources capable of receiving CPOE; and,
   - B. Where the annual number of orders issued to that source exceeds 1,200. [Note: we are proposing a 100/month threshold in order to establish a minimum volume that would make such an effort justifiable.]; OR,
   - C. An attestation of "None Available" will be acceptable for meeting these criteria.

Objective (3):	Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-cm or SNOMED CT®
Measure:	At least 80% of all unique patients seen by the EP have at least one entry or an indication of none recorded as structured data

Comments:

HBMA understands the importance of physician documentation of specific encounter information. However, we believe this measure, as stated, is inappropriate for physicians, does not address myriad coding and reimbursement issues, and will be outdated by October 2013.

SNOMED CT® is designed for facility, not physician reporting. The CORE (Clinical Observation Reporting and Encoding) outcome is to capture data at the summary level, i.e. patient problem lists, discharge diagnoses, etc. This data is not synonymous with diagnostic specific information that is reported through the use of ICD-9-CM codes. Although a process is in development to create a reimbursement based mapping rule, this will be extremely difficult given the significant difference in granularity, purpose and intended use of the two very different systems.

This complexity is compounded by the fact that hospital inpatient and physician diagnosis coding conventions currently have different reporting guidelines, as published by Coding Clinic, the authoritative instruction for ICD-9-CM. For example, unconfirmed diagnoses may be reported by facilities for inpatients, but not by physicians providing the professional services and discharge lists may not include all of the diagnoses the physician addressed during the episode of care. The difficulty of developing any meaningful reimbursement mapping will be exponentially increased with the transition to ICD-10-CM and ICD-10-PCS for hospital inpatients.

The ICD-10-CM effective date is October 2013. The measure currently does not include that transition as an option for reporting or meaningful use. Because ICD-10-CM replaces rather than

updates ICD-9-CM, the "up to date list" of diagnosis codes will be completely different after the effective date. However, the fact that the diagnosis codes are different does not mean the problem(s) are new or different. Current problem lists may include both ICD-9-CM and ICD-10-CM codes depending on the problems addressed at a particular visit or encounter. We believe the measure should include both ICD-9-CM and ICD-10-CM and that current and active diagnoses may be reported using either set of coding conventions.

Objective (3) Recommendation:

This Objective should be removed and considered for inclusion in Stage 3.

Alternatively, if the Objective is not removed, we recommend that SNOMED CT® NOT be included in the Eligible Professional (EP) meaningful use Objectives or Measures.

Objective (7): Record demographics.
Measure: At least 80 percent of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

Comments:

Computerized medical records must have absolute reliability and integrity in the identification of the subject patient. Many families have family and/or cultural traditions of naming children, grandchildren and great-grandchildren (etc.) with the same or very similar names. In ethnic communities it is common for many residents to have identical or very similar surnames, first names, etc. Providers are regularly faced with selecting the correct chart for a patient from among many charts for individuals with identical or similar names, dates of birth, etc. We agree that EHRs should incorporate sufficient demographic information to assure that the right patient record is used for every patient encounter.

The "structured demographic data" described in the proposed measures includes four elements that are all static (gender, race, ethnicity, and date of birth) and these would contribute to the correct identification a patient. A fifth element – preferred language – is somewhat static, although over a period of years this might change, particularly among immigrant populations who gradually learn the provider's spoken language.

An EHR is a medical document and it is not a financial document. Office-based practices that utilize paper charts have generally not, as a matter of practice, included any financial information in the medical record. There are a variety of compliance concerns raised by recording or storing patient financial information in the medical record, including how such information might improperly influence the assignment of CPT, HCPCS and/or ICD-9 CM codes. Many chart auditors are critical of storing or recording financial information in a clinical document.

The sixth demographic element listed in the IFR, "insurance type" is highly changeable and subject to the aforementioned compliance risks as well as other potential biases, such as prejudicial perception of a patient's coverage by Medicaid, lack of any health insurance, coverage by an

insurer with which the practice has an active dispute, etc. In addition, as a highly volatile data element, maintenance of this information can be more problematic for a medical record than it would be for the practice's appointment scheduling, registration and billing system(s).

So-called "practice management" (billing) systems have been available to medical practices since the late 1970s. As noted earlier, there are more than 350 of these billing systems, many of which have matured and evolved over decades of development and user input. One of the more sophisticated and complex elements of these systems is the classification, sub-classification, sub-sub-classification and unique registry of a patient's primary, secondary, tertiary and alternative insurance coverage(s). A simple example would be a male adult patient with a group health plan with secondary coverage through his spouse's group health plan, in addition to worker's compensation coverage through his employer and auto insurance coverage for injury-related treatment. There are complex, over-lapping and often pre-empting plan and coverage rules which are often "designed in(to)" billing software but are not part of conventional EHR systems.

We believe the proposed objective and measure reveal an overly simplistic and, perhaps, naïve perception of how medical insurance coverage and the requisite billing processes function and proposes adding a data element to patients' medical records that is inadequate, at least, and, at worst, wholly improper.

This proposed objective and measure are obviously linked to the (assumed) need for insurance information in a medical record if the medical record is to be used for the verification of insurance coverage, the billing function(s) [electronic claims], and, possibly, the transmission of electronic prescriptions. We have prepared comments on these related proposals and will not repeat those comments here. In short, we have found and continue to believe that EHRs are ill-equipped – or are not equipped at all – to perform the financial functions implied by the recording of "insurance type."

The term "insurance type" is vague and is not an industry-standard term, nor is there a chart, list, table or other reference in common use that is widely accepted as a standard definition. "Insurance type" cannot be found within CCHIT standards. The IFR offers no proposed definition of this term. As a result, there is no logical way for an EP or a software developer to anticipate how this term will be defined in order to accommodate it, what function(s) it is expected to perform, or how it is expected to be used if the term is incorporated into final standards.

Objective (7) Recommendation:

Objective (7) and the Measure for this Objective should be modified and "insurance type" should be deleted.

Objective (15):	Check insurance eligibility electronically from public and private payers.
Measure:	Insurance eligibility checked electronically for at least 80 percent of all unique patients seen by the EP.

Comments:

Unless new legislation requires all citizens to have insurance, the HITECH changes to HIPAA allow patients to pay without use of their insurance. So if a patient doesn't want a provider to verify/ file a claim, any EP that verifies insurance and/or uses such information to file a claim with the insurance company could be in violation of new HIPAA Privacy regulations.

According to a recent poll of HBMA members, only 19% of respondents indicate that 80% or more can be checked. Insurance changes on a frequent basis, due to employer choices, patient employment changes, and other variables. In addition, this is not a unique patient issue, it is an every visit need. The measure really does not make sense because the fact that you checked it this visit will not be relevant to all future visits. The insurance industry as a whole is currently not able to actually verify eligibility so an authorized attempt or query is virtually meaningless at this time.

This measure might be more appropriate at a later stage in the EHR implementation process (i.e. Stage 3) when more insurance companies are able to respond to an electronic request for eligibility. To mandate this in Stage 1, requires the provider to undertake a task for which we know that an electronic response is not likely and therefore requires the provider to engage in a meaningless activity.

Objective (15) Recommendation:

This objective should be removed.

Objective (16): Submit claims electronically to public and private payers.
Measure: At least 80 percent of all claims filed electronically by the EP.

Comments:

Computerized medical record systems are not billing systems and billing systems are not electronic medical record systems. As noted in our comments on demographic information, EHR systems are largely not designed nor sold as capable of performing billing functions and the billing functions required for successful submission of electronic claims is a very sophisticated and complex activity. We found this implied assumption – the all EHR systems perform billing functions – to be naïve and grossly inaccurate.

There are some integrated products that combine a separate billing system with an integrated (or interfaced) EHR system and a very few "all-in-one" products that offer (or purport to offer) a "complete" system that is capable of supporting both functions. Our members have reported that there are EHR system vendors that have overstated, exaggerated, and/or misrepresented (deliberately or otherwise) the capabilities of one or the other, or both of the separate capabilities of such systems. In some cases this has led to significant financial catastrophe for the practices, including bankruptcy.

We do not believe that the proposed standards reflect the state-of-the-industry and reveal a lack of awareness of the array of products in the marketplace today.

The state of electronic claim submission is widely misunderstood and, once again, simplistically stereotyped. The statement in the IFR that ". . . nearly all public and private payers accept electronic claims" is ignorant of the facts and is contradicted by the experience of professional billing organizations. Many, but not all public insurers (Medicare, Medicaid, TriCare, etc.) accept electronic claims but far less than 80% of private insurers accept electronic claims. A recent study by The Cooperative Exchange (the professional association for claims clearinghouses) revealed that the present level of insurers' compliance with the HIPAA Transaction Code Set is dramatically less than 80% and that is for claims generated by conventional billing systems which ALL have the ability to produce an electronic claim or the equivalent for a clearinghouse to process.

In preparation for submission of these comments, HBMA surveyed its membership and learned that there is significant disparity in claims production capabilities among the EHR systems utilized by our members' client practices. Many of the EHR systems do not support claims submission (electronic or otherwise) at all, while others have rudimentary claims capabilities and only a few are fully capable of generating compliant electronic claims.

Despite the long-standing availability of electronic submission of many claims to many insurers, there remains a requirement by almost every insurer that some claims be submitted on paper. This is most often true of certain types of acute care services, such as Critical Care, major surgeries – in general, as well as a wide variety of services that are commonly subjected to pre-payment medical necessity review. These manual claim requirements are found among Medicare and Medicaid plans, as well as private plans. In addition, submission of paper claims is almost universal among workers compensation and auto insurers. Depending on the service mix and insurer profile of a specialty, it will not be unusual for some providers to have as many as half of their claims submitted on paper in order to meet insurers' submission requirements. This would, of course, cause the provider to fail the EHR standards.

The probability of electronic claims becoming 100% of all claims submitted is, in our considered professional opinion, nearly zero within the next five years. While the implementation of the HIPAA 5010 transaction standards offers the possibility of diminishing or – eventually – eliminating paper claims via electronic attachments, the establishment of standards merely opens the door for implementation it does not assure that insurers will, in fact, fully implement those standards. CMS' long-standing record of non-enforcement of the HIPAA 4010 and 4010(a) standards does not suggest that the 5010 standards will be enforced either.

As with many of the other proposed standards, it will be a significant burden for EPs to assemble the data required to know whether they can, or have, met the proposed 80% submission threshold. Claims will have to be logged and/or counted manually, inasmuch as very few systems – billing or EHR – perform an automatic tally of claims prepared for submission (the denominator).

The Meaningful Use Proposed Rule definitions do not include how a "claim" would be counted to meet the proposed standards. Would only "initial" (first) claims be counted, but resubmissions would not be counted? Would "secondary" claims (to successive insurers) be counted, or not?

Would “rebills” (resubmission at the request of the insurer) be counted, or not? Would submission of paper claims to fulfill a data request from an insurer be counted, or not?

An EP should not be held responsible for a payer that cannot receive electronic claims or their attachments, so long as the EP is making a good faith attempt to submit electronically (by submitting to a clearinghouse who may then convert a claim/attachment to paper, as may be required by a payer). Clearinghouses with pooled claims leverage will have greater influence on non-compliant payers.

Stated most simply, EHR systems are not, nor should they be expected to be, fully functional billing systems, any more than billing systems ought to be expected to be medical records systems. There is no basis for expecting an effective EHR product to be capable of creating a claim – whether electronic or paper.

Objective (16) Recommendation:

This Objective and Measure should be should be deleted.

Alternatively, this measure should be changed to 80 percent of all claims filed electronically, either to a third party clearinghouse or to the payer directly, by the EP.

Conclusion

On behalf of the Healthcare Billing and Management Association, we appreciate the opportunity to provide these comments. Please do not hesitate to contact our Executive Director, Brad Lund (866-640-4262) if you have any questions or need any additional information.

Sincerely,

Scott Everson, CHBME
President
HBMA