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Centers for Medicare and Medicaid Services
Department of Health and Human Services
S–0033–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Attention File Code CMS–0033–P

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program

Dear Ms. Frizzera:

On behalf of the HIMSS Electronic Health Record (EHR) Association, we applaud the huge effort put forth in the development of the NPRM. There are many key areas where we support the proposals identified. There are also areas where we have concerns. Our comments are covered at a high-level in the Summary Comments Section. These high-level comments are supported by more detailed recommendations in the Detailed Comments Section.

Summary Comments

It is essential that CMS reconsider its proposals and these comments in the context of the stated Congressional goal of providing incentives for adoption of interoperable EHRs that actually increase adoption. The incentive structure that has been proposed to be put in place, including the actual dollar amounts, did not anticipate the level of detail for meaningful use, associated compliance costs and compliance-related uncertainties that have emerged over the past several months.

We also ask CMS to take into account the additional challenges facing providers and CMS in the coming months which will all draw on the same resources necessary to

meet the requirements covered by this NPRM, notably the shift to 5010, ICD10, Red Flag, and likely changes related to Health Reform.

We suggest that CMS fine-tune an approach to meaningful use that will incentivize the greatest number of providers to adopt and use interoperable, comprehensive EHRs, recognizing that different users will attach different priorities to specific areas of EHR functionality. As we have seen with recent innovative technologies, users will find "meaningful use" in various ways that enable the most productive use in their local environment beyond the very specific expected value of any given component or application. We ask CMS to shift the balance from highly detailed meaningful use criteria/measures and very aggressive timelines to a baseline set of measures, plus the option for providers to defer a small number of criteria in each of the meaningful use categories. With that in mind, we provide the following summary comments.

Unrealistic Lead Times

The overall process we have been following for the last 12 months, which defines the requirements for meaningful use and related information, and as laid out for the future in the regulation, introduces for too much uncertainty too late in the game. This uncertainty causes a tremendous amount of inefficiency and waste in the vendor community, decreasing our ability to continue to provide innovative solutions to the market. It causes patient safety concerns in provider environments as too many requirements for implementation are being defined much too late relative to qualification dates. More lead time must be built into the process for developers and users to complete their normal processes for rigorous quality testing and workflow redesign.

Given these concerns as they relate to Stage 1, we urge CMS to work closely with ONC to ensure that the new certification process is developed, implemented and applied on an expedited timeframe to allow for available EHRs consistent with the meaningful use start dates.

Not only are the timeframes too short, but the content changes significantly each time information becomes available at various points in the process. A clearly specified, multi-stage glide-path is needed to allow for vendors and providers to plan for requirements.

Too Many Opportunities to Fail

The sheer number of requirements, and the associated complexity, could cause an eligible professional and/or hospital that is really doing everything right to miss the incentives based on small oversights or elements beyond their control. We recommend that CMS consider providing credit for going the right direction and advancing capabilities that are key to improving quality of care. Each individual objective and measure makes sense on its own. However, the combination of all of the requirements creates a very high bar to achievement with too much complexity to be managed in such short timeframes. Even those who are very far along in their implementation of EHRs will find it extremely challenging to achieve these requirements. The focus should be on meeting fewer requirements well instead of spreading implementation across many requirements and making less progress overall.

Clinical Quality Measures

To fulfill the ARRA legislative requirement to report quality measures, the NPRM includes a broad set of quality measures to be reported by Eligible Hospitals (EHs) and Eligible Professionals (EPs). We believe the intent of the rule is to advance quality measure reporting by including measures that can be HIT-enabled as part of the care process, requiring minimum manual effort, with electronic reporting at a summary level, to lay the groundwork for "measures that matter" and that are appropriate to venue and/or specialty.

We have a number of concerns about the quality measures proposed in the NPRM in support of this goal. The sheer volume of measures so late in the process, coupled with the fact that the measures are new, inadequately defined or tested, and not readily available in EHRs, make the current measure sets and timeframes unrealistic to meet the desired goals.

The large number of proposed measures will impose a substantial burden on hospitals that need to convert from a more manual approach to quality reporting, heavily dependent on chart abstraction, to one where the measures must be based on data captured in the EHR. The large number of EP measures will pose similar challenges to multi-specialty groups and IDNs. From a vendor perspective, this large number of measures, along with the absence of EHR specifications, poses a challenge in terms of ensuring that our products are capturing all of the needed data elements in an accurate and efficient workflow.

We ask that CMS substantially reduce the number of quality measures, focusing on those measures that have validated EHR specifications, are selected from other quality measurement and reporting programs, and where the data required for the measure is available within EHRs.

Exclusion of Hospital-Based Eligible Professionals from Incentives

The definition of a hospital-based EP excludes many eligible professionals who practice in hospital settings from qualifying to receive incentives. This broad definition excludes 27% of otherwise eligible professionals from incentives. The group of providers excluded may be those who more likely to be successful with adoption of EHRs. Often the hospital will provide support for the providers associated with the hospital. This support may be in the form of EHR selection, implementation, adoption, help desk or other services. We recommend that CMS substantially reduce the number of excluded professionals by using statutory language that the provider must meet all criteria (both site of service and use of hospital facilities and equipment, including a qualified hospital EHR) in order to be deemed a hospital-based provider.

Certification Modules in Support of Meaningful Use

We recommend that CMS recognize that hospitals and physicians use many systems to support their efforts (e.g. additional software such as report-writers) to meet their administrative, clinical and quality goals. We also ask that CMS reinforce in the Final Rule the points made in the IFR about the need for provider due diligence regarding module interoperability.

Time Requirements and Cost Requirements

CMS presents an extensive analysis of information collection requirements (ICR). We believe many of the ICR cost estimates are significantly understated.

Detailed Comments

Unrealistic Lead Times

Proposal

The NPRM proposes updating the meaningful use criteria on a biennial basis, with the Stage 2 criteria proposed by the end of 2011 and the Stage 3 definition proposed by the end of 2013. *(NPRM - Considerations in Defining Meaningful Use, page 1852)*

Issue

The overall process we have been following for the last 12 months, which defines the requirements for meaningful use and related information, and as laid out for the future in the regulation, provides for too much uncertainty too late in the game. This uncertainty causes a tremendous amount of inefficiency and waste in the vendor community, decreasing our ability to continue to provide innovative solutions to the market. It causes patient safety risk concerns in EP and hospital environments, as there are too many requirements for implementation without enough lead-time for complete testing of products and workflows.

The timeframes from when providers and vendors receive final requirements for Stage 1 and when they need to be generally available to customers is inadequate. Final requirements will not be available until approximately May 2010 or even later. For hospitals who want to pursue 2011 incentives, the software needs to be generally available, then implemented in the hospital as early as October of 2010. For EPs, the applicable date is January 1, 2011. This timeline does not allow adequate time for software development, thorough quality assurance testing, general availability and implementation in hospitals. Given these concerns, we urge CMS to work closely with ONC to ensure that the new certification process is developed, implemented and applied on an expedited timeframe to allow for available EHRs consistent with the meaningful use start dates.

In addition, the timeframes for the NPRM in Stage 2 and Stage 3 of meaningful use repeat the same short timeframes. If new applications or functions are required to be implemented, there will not be enough time to make software changes and implement new software at provider sites to the levels required to meet meaningful use criteria.

We would point out that the HIPAA 5010 transactions implementation timeframes allowed three years and all the ASC X12 5010 transaction standards were published long before the HIPAA Final Rule. The 5010 transactions were version changes, not initial implementation, and were administrative transactions with few patient safety risks. EHR implementation is much more complex, with many more users who must be trained.

Not only are the timeframes too short, but the content has changed significantly each time information becomes available at various points in the process. A multi-stage glide-path is needed to allow for vendors and providers to plan for and implement requirements. Previous to ARRA/HITECH, there was a road-mapping process in place based on the federally- recognized organizations, CCHIT and HITSP. There was 18-months advance notice given on the intent to certify a specific function, using already clearly-defined and federally- recognized specifications for interoperability (from HITSP). This approach provided continuity in direction, which allowed vendors and providers to be

forward-looking and prepare for required functions and implementations of those functions within more realistic timeframes.

The recent ONC strategy for so-called "simplicity" in interoperability introduces so much uncertainty and variability so as to be ineffective. Interoperability is not simple and never will be. It requires precise specifications such as those harmonized by HITSP. Limiting the use of the HITSP body of work for Stage 1 may be understandable, but not including it for Stage 2 is a major program-wide risk. Knowing what is planned with adequate lead-time allows stakeholders to work toward future stages and accelerates progress toward ultimate goals. A high level of confidence that this direction will remain consistent supports forward progress. Uncertainty and ambiguity lead to paralysis, false starts and stops, huge inefficiencies for vendors and providers, and, ultimately, less compliance.

Comments

The 18-month lead-time (as discussed above) would require an NPRM for Stage 2 by November 2010. However, this timeframe might not allow for adequate understanding and experience on Stage 1, which should directly contribute to the requirements for Stage 2. Allowing for adequate lead-time for vendors and providers, while enabling feedback from the current stage, should have a positive influence on the desired result to increase EHR adoption. We suggest that CMS use a focused early assessment of Stage 1 experience, along with comments received on the NPRM, to make needed adjustments. We recommend that the NPRM for Stage 2 be available by the end of 2010 and the final rule by April 2011 at the latest. We also recommend that the NPRM for Stage 3 be available by the end of 2012 and the final rule by April 2013 at the latest.

We also recommend that the Stage 1 Final Rule include a clear signal to the market about the contents of Stage 2. And, that the Stage 2 Final Rule includes a clear signal to the market about the contents of Stage 3.

We also recommend that the 90–day reporting period be in effect for the first reporting years for Stage 2 and Stage 3. For the same reasons that this approach was proposed for Stage 1, this shorter reporting period allows providers to have a chance to learn the requirements for each subsequent stage and have time to ramp up to meet the new requirements.

Too Many Opportunities to Fail

Proposal

The NPRM currently requires:

- EPs and hospitals will report on more than 20 functional measures addressing use of specific health IT capabilities such as recording vital signs, problem lists and demographics, and using CPOE and reminders.
- A large percentage of measures require reporting a number and denominator.
- All reporting is through attestation in the first year, but specific (high) thresholds must be demonstrated and met.
- EPs are required to submit reports of clinical outcomes based on a set of core measures plus a subset of measures most appropriate to the EP's specialty data on the two measure groups.
- Eligible hospitals are required to report up to 43 (at least 35 for Medicare, eight for Medicaid) summary quality measures for applicable cases.

- All objectives and thresholds must be met to achieve the incentive.

Issue

The sheer volume of the reporting requirements, coupled with the complexity of many of the individual objectives, is causing many providers to consider whether the net of the incentives and the penalties are worth the significant cost and effort associated with becoming meaningful users.

Even if a provider strives for meaningful use and is aggressive about achieving every objective, measure and clinical quality measures, a small oversight or element beyond their control could cause them to not qualify for the incentives (e.g., an EP might meet every objective and measure, but come in at 79% for the problem list).

Implementing this large number of objectives and measures will require significant process changes for hospitals and EPs. In the short timeframes laid out, this challenge could introduce too much change in too short a timeframe, potentially causing patient safety concerns.

Comment

We recommend that CMS consider providing credit for going the right direction and advancing capabilities that are key to improving quality of care. Each individual objective and measure makes sense on its own. However, it is the combination of all of the requirements that creates implementation challenges, with too much complexity to be managed in such short timeframes. The focus should be on implementing fewer requirements well instead of spreading implementation across many requirements and making less progress overall. To enable this, we recommend:

- The overall number of requirements should be decreased.
- Measures removed in the NPRM (from the original recommendation from the HIT Policy Committee) should not be added back.
- Eliminate and/or revise measures that require manual capture of numerators or denominators.
- Eliminate and/or revise measures where denominators require capturing data manually outside of the EHR system.
- Some measures that have thresholds should be changed to attestation only.
- Threshold percentages should be reduced on most measures.
- Add flexibility by allowing some requirements to be deferred from Stage 1 to Stage 2, while ensuring that key requirements remain as required for Stage 1.

In addition, the focus of attestation should be on achievement of the measure, as opposed to achievement of the objective and the measure.

Specific recommendations by objective and measure are included directly below.

Meaningful Use Objectives and Measures

CPOE

Hospital Objective

Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP)

Hospital Measure

CPOE is used for 10% of all orders

Hospital Comment

We are concerned that the 10% threshold may be too high as hospitals begin to roll out CPOE on a department-by-department basis. According to HIMSS Analytics data reported in October 2009, fewer than half of US hospitals have implemented CPOE, with only 11% of physicians managing patients in hospitals using it, and less than 5% of hospitals requiring their doctors to use CPOE. As an alternative, we suggest that, for hospitals, CMS focus on an attestation that the hospital has begun to implement CPOE and initiated at least one pilot project. Also, please clarify which types of orders must be included in the numerator and the denominator, as well as the requirements for the authorizing provider to physically enter the information in the CPOE system. We are also concerned with the measurement burden of counting paper orders and other orders that are not included in the EHR.

EP Comment

The 80% threshold for CPOE is too high and should be reduced to 50%. We are also concerned with the measurement burden of counting paper orders and other orders that are not included in the EHR.

Problem List

Objective

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 or admitted to an eligible hospital have at least one entry or an indication of “none” recorded as structured data.

Comment

First, we ask that CMS not use "none" as a potential response as it is not a clinically relevant term. Instead, we suggest that CMS allow such terms as “no known problem” or “no problem”. It is important that the problem list remain focused on being a clinical problem list and not a listing of diagnoses or a tool for administrative purposes.

Feedback from our hospital customers is that the implementation of problem lists is extensive and requires significant process change, similar to CPOE. So, secondly, we ask that the threshold be reduced to 10% for hospitals and 50% for EPs, given measurement uncertainty and the fact that hospital implementation of problem lists requires careful change management. In addition, in the hospital context, problems should not be required to be coded when they are being entered and

utilized as part of the care process.

Third, we ask that CMS clarify, per the approach taken by the HIT Standards Committee, that the specified vocabulary should support interoperability between entities and not only within an entity. Content should be able to be represented in the specified vocabularies and exchanged in the specified standard formats at the boundary between entities, regardless of how it is managed internally. Many methods may potentially be used to achieve interoperability standards (e.g., mapping, external services or native data capture).

Active Medication List

Objective

Maintain active medication list.

Measure

At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.

Comment

Given measurement issues, reduce the threshold to 50% or significantly less to show that the hospital has begun implementation. Also, please clarify that this count applies to patients seen during the reporting period.

Medication Allergy List

Objective

Maintain active medication allergy list.

Measure

At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data.

Comment

Please clarify that this only applies to patients seen during reporting period.

Demographics

Objectives

Hospital: Record demographics, preferred language, insurance type, gender, race, ethnicity, date of birth, date and cause of death in the event of mortality.

EP: Record demographics, preferred language, insurance type, gender, race, ethnicity, date of birth.

Measure

At least 80% of all unique patients seen by the EP or admitted to the eligible hospital have demographics recorded as structured data.

Comment
For hospitals, we recommend that date and cause of death in the event of mortality not be required. This data is not typically managed in hospital EHRs. If used, clarify that this requirement applies only for hospital mortality reporting.

Also, please provide specific guidance for insurance type and race/ethnicity categories. We note that the latter was addressed in the Preamble.

Also, please clarify that the 80% threshold means that 0% of patients have one or more of the required data elements (not all of the data elements).

Vital Signs
Objective
Record and chart changes in vital signs, height, weight, blood pressure. Calculate and display BMI, plot and display growth charts for children 2-20 years, including BMI.

Measure
For at least 80% of all unique patients age 2 and over seen by the EP or admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20.

Comment
We ask that the requirement for growth charts be omitted from the hospital requirements as the creation or maintenance of such charts is not generally applicable for hospitalizations. If this element is retained, we request that the requirement be to capture the data points without data plotting and that, rather than a numerical percentage, the hospital attest that the function is enabled, but don't require a percentage. For EPs, given the complexity of tracking whether a growth chart was plotted, we propose that the measure should focus on *enabled capability* to plot growth charts, rather than on a percentage metric of their actual use.

We also suggest that the recording of BMI not be required, but rather the recording of height and weight, from which BMI can be computed. For growth charts, the standard should be specified relative to plotting the patient's actual growth against standard growth graphs so the doctor can determine a percentile.

This measure seems to indicate that the action of plotting or viewing the growth chart should be recorded. The capability should be required, but the action should not. This measure should be changed to "For at least 50 percent of all unique patients age 2 years or older seen by the EP or admitted to the eligible hospital, record height, weight and blood pressure, and calculate BMI."

Lab-Test Results
Objective
Incorporate clinical lab-test results into EHR as structured data.

Measure
At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.

Comment
Please clarify that this requirement applies only to data received from the lab electronically in one of the specified formats in the ONC Interim Final Rule (IFR). Also, the IFR seems to suggest that a "user intervention" is required. Please clarify that these data should be able to be updated automatically based on provider/hospital preference.

The suggested alternate wording is: “At least 50% percent of all clinical lab tests results ordered by the EP or authorized provider of the hospital during the EHR reporting period whose results are returned electronically as discrete data using the specified standard are incorporated in certified EHR technology as structured data.”

Quality Reporting
Objective
Report ambulatory (hospital) quality measures to CMS or the states.

Measure
For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of this proposed rule For 2012, electronically submit the measures as discussed in section II(A)(3) of this proposed rule.

Comment
CMS proposes a set of 43 quality measures for hospitals in Tables 20 and 21 and 93 measures for Eligible Professionals in Tables 2 and 4, for reporting via attestation in 2011 as part of its general authority to define meaningful use, and for 2012, as part of its statutory authority to require quality reporting from the certified EHR if it can accept quality measures electronically. On page 1871, CMS acknowledges that much work must still be done on the quality measures, and that many of these measures do not yet have EHR specifications completed. Only 16 of the 35 Medicare measures in Table 20 have such specifications indicated (and none on Table 21), and a much smaller percentage of the EP measures have such specifications; many of these have not been widely used or validated. CMS proposes to have such specifications for hospital measures available in April 1, 2010 (with no date proposed for 2011 EP measures specifications and a date of April 1, 2012 for 2012 EP measures).

The timeline proposed for availability of quality measure specifications is simply too short given the need to ensure that both EHRs and provider workflow can capture the applicable data elements and calculate the measures. Moreover, in many cases, we do not believe that adequate measure testing has been done nor is there good evidence to support the conclusion that, for these measures, the right data can be captured in actual practice as a byproduct of the patient care workflow. Fundamentally, the measure specifications need to be valid and reliable at time of release.

We urge that CMS substantially reduce the number of measures to be used for 2011-2012, with a primary focus on establishing a “pipeline” for calculation and submission of quality measures. The primary goal in Stage 1 should be to establish an EHR-based quality reporting process. The number of required measures should be a reasonable number (3-5) for EPs and for EHs. We urge that, to the greatest extent possible, CMS select measures that hospitals must currently report to CMS and the

JCAHO and that EPs must report to CMS, while eliminating measures that fall into the following categories:

- Measures that require standard terminology (SNOMED, RXNORM) not required in Stage 1;
- Measures where the data for the measure is not captured in the certified EHR (text, ER, surgery, critical care/ICU) and requires a manual process or special interface to acquire the applicable data; and
- Measures that would require substantial workflow change.

In addition, we believe that EHR specifications for a measure must be available no later than April 1, 2010, with the measure successfully tested by October 1, 2010. Measures should also be endorsed by NQF.

To ensure the continued progress of EHR-enabled quality measures, CMS should implement a quality measure testing program to ensure feasibility and replicability of the quality measure data. The testing program should include both EP and EH quality measures and the EHR measure specifications, and follow the NQF and PCPI endorsement protocols. The testing process should identify pilot/test sites and require reporting in reasonable timeframe. For measures not successfully tested by October 1, 2010, measures testing should continue with results as soon as possible for Stage 2 reporting requirements.

CMS should also clarify alignment of quality measure reporting requirements for providers participating in multiple CMS quality programs to ensure against undue burden and reporting duplication. If they are currently reporting quality measures manually, EPs and EHs will still have to report manually since they are not going through EHR. But if they are reporting quality measures on meaningful use through their EHRs, then they should, as CMS suggests, not have to report twice. Clarification needs to be provided to provide clarification and avoid further confusion.

We are also concerned that starting with the PQRI XML reporting in Stage 1 and then switching to QRDA in Stage 2 (2013 and beyond) could require duplicative investments. As a result, we suggest retaining an attestation approach for 2011-2012, as well as potentially allowing the optional use of QRDA in 2012.

We agree with the focus on aggregate, computed measures for 2011 through the approach referenced in the proposed requirements. We recommend that the use of aggregate (i.e., population-level data) be retained as an option for 2012 reporting even if CMS moves to direct electronic reporting from the EHR as discussed in Section II (A)(3).

For hospitals, we ask that CMS clarify how Tables 20 and 21 interrelate for Medicaid reporting. Can a hospital report only some of Table 21 measures for Medicaid, or must they report on all? We also urge that states not be allowed to require additional clinical quality measures as part of their discretionary meaningful use criteria. In many cases, adding new measures could, in fact, require functionality above that required by EHR certification. Following the logic that CMS should not allow states to impose additional meaningful use requirements beyond those established for certification, states should also not be able to require additional clinical quality measures. We note that states

already have authority to require reporting; we are simply recommending that states should not be allowed to couple that reporting to the meaningful use incentives.

Reminders to Patients

Objective

Send Reminders to Patients per Patient Preference/Follow-up Care

Measure

Reminders sent to at least 50% of all unique patients seen by the EP that are age 50 or over

Comments

Particularly for the first reporting year, it is not clear how the time period for sending reminders correlates with the time period of reporting. For example, if a practice chooses to report on patients seen from June through August 2011, the reminders for a one-year follow-up would not normally be sent to those patients until nine months later.

According to the NPRM, patient preference refers to the patient's choice of delivery method between internet-based delivery or delivery not requiring internet access. The wording "per patient preference" is not clear. Choices could be delivery method (which is the intended meaning), date of reminder, type of condition or need, etc. Please change the wording to "Send reminders to patients using patient preference for means of delivery for preventive/follow-up care."

Clinical Decision Support

Objective

Implement five clinical decision support rules relevant to specialty or high clinical priority, including diagnostic test ordering, along with the ability to track compliance with those rules.

Measure

Implement five clinical decision support rules relevant to the clinical quality metrics the EP and EH is responsible for as described further in section II(A)(3).

Comments

We agree with the proposed use of five clinical decision support (CDS) rules. Also, we believe that no more than two of the rules should be required to link to the utilized quality measures to allow for EPs and hospitals to focus on other applicable high priority clinical areas. Another reason to only link two rules to quality measures is the fact that not all EP specialties will have measures in one of the defined specialty groups. Finally, we are concerned with the burden associated with the requirement to track responses, given the different types of CDS (e.g., results-based CDS). The need to track such responses can lead to a focus on certain types of alerts and approaches to CDS, stifling innovation and contributing to "alert fatigue" – the tendency for clinicians to ignore alerts based on repetitive or irrelevant rules. Tracking should be moved to consideration for Stage 2.

Eligibility Checking

Objective

Check insurance eligibility electronically from public and private payers.

Measure

Insurance eligibility checked electronically for at least 80% of all unique patients seen by the EP or admitted to the eligible hospital.

Comment

We ask that this objective be eliminated from the meaningful use requirement. While this function is standard in the industry, such functionality is not uniformly standard as part of an EHR.

In addition, if this objective is retained, we ask that the measure be replaced by an attestation of capability or at least have the threshold be substantially reduced, as this metric could be negatively affected by payer capabilities. As this requirement is expressed through certification, there is also the prospect of substantial burden and confusion on providers and their vendors, with vendors primarily focused on practice management/revenue cycle having no focus on ARRA meaningful use and certification issues. If this measure is retained, we ask that CMS clarify that, as stated on page 1863 but not in the actual regulation language, the denominator applies only to unique patients "whose insurer allows for the electronic verification of eligibility".

Electronic Claims Submission

Objective

Submit claims electronically to public and private payers.

Measure

At least 80% of all claims filed electronically by the EP or the eligible hospital.

Comment

We ask that this objective be eliminated from the meaningful use requirement. While this function is standard in the industry, such functionality is not standard as part of an EHR.

In addition, if this objective is retained, we ask that the measure be replaced by an attestation of capability or at least have the threshold be substantially reduced, as this metric could be negatively affected by payer capabilities. As this requirement is expressed through certification, there is the prospect of substantial burden on providers and their vendors and confusion about their responsibilities, with vendors primarily focused on practice management/revenue cycle having no focus on ARRA meaningful use and certification issues. If this measure is retained, claims with payers that do not accept electronic claims should be excluded from the denominator. Finally, it is unclear what application is being certified (revenue cycle applications, clearinghouse, etc.).

Electronic Copy of Health Information

Objective

Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.

Measure

At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours.

Comment

For the reasons outlined below, we propose that this measure be shifted to Stage 2 or replaced by an attestation that the hospital has policies and procedures in place to honor patient requests.

The definition of "health information" is broad and could involve voluminous information. There is a related misalignment between providing a single complete medical record as suggested by the objective and the capabilities of available clinical summary standards. Such a request could require multiple continuity of care documents (CCD, the harmonized standard supported by HITSP), while the continuity of care record (CCR) is not well suited to conveying this level of information and does not include a discharge summary. For hospitals, it will be important to define what must be provided beyond a discharge summary. We ask that CMS clarify its intent, especially on the longitudinal nature of these data, and narrow the scope.

Providers will likely have difficulty tracking requests relevant to this criterion, as it will not always be clear when patients require their "health information."

The ARRA privacy and security requirements (outside of EHR incentive sections) already require that providers furnish such information on request. We have concerns with adding this as a duplicative meaningful use requirement.

We agree with CMS's proposal not to specify "online access" and management of request responses via various electronic media. Associated tracking will be quite burdensome for many providers and many patients may not be prepared to work with such media.

If this measure is retained, we recommend the 48-hour standard be shifted to two-three *business* days to improve administrative feasibility.

Electronic Copy of Discharge Instructions

Objective

Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Measure

At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.

Comment
We believe that this requirement will impose a substantial burden on hospitals relative to the potential benefit during the initial Stage 1 timeframe. In addition to workflow issues, there will be the need for nurses and other personnel to potentially manage multiple media types, including possible needs for data encryption, passwords, etc. Also, there is the burden and uncertainty related to tracking requests in order to compute the performance measure. We also ask that CMS clarify what it means by "procedures", or delete that term from this objective and measure.

Given the issues with this objective, we proposed that it be moved out to Stage 2, or replace the measure with an attestation that a process is in place to honor such requests.

Capability to Exchange Key Clinical Information

Objective

EP: Capability to exchange key clinical information (for example, problem list, medication list, allergies, diagnostic test results) among providers of care and patient-authorized entities electronically.

Hospital: Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results) among providers of care and patient-authorized entities electronically.

Measure

Perform at least one test of certified EHR technology's capacity to electronically exchange key clinical information.

Comment

Given the importance of structured data and the focus on a single test, the required test should be successful and conducted using structured data per allowable standards for patient summary (e.g., CCR or CCD or final standards). In addition, we suggest that CMS clarify that this test should use standards-based interoperability methods in order to be successful.

Medication Reconciliation

Objective

Perform medication reconciliation at relevant encounters and each transition of care.

Measure

Perform medication reconciliation for at least 80% of relevant encounters and transitions of care.

Comment

This measure should focus on using the EHR to track that reconciliation was done. In addition, we believe that the threshold should be reduced to 60%, given measurement issues and the fact that it may be difficult to do an electronic reconciliation with some care transitions. We also recommend that "care transitions" be defined to be *"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."*

Summary Care Record

Objective

Provide summary care record for each transition of care and referral.

Measure

Provide summary of care record for at least 80% of transitions of care and referrals.

Comment

We note that this is a new objective and criterion from the Policy Committee's proposal. We request that CMS reduce the threshold to 50% based on measurement issues.

We also recommend that "care transitions" be defined to be *"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."*

Submission to Immunization Registries

Objective

Capability to submit electronic data to immunization registries and actual submission where required and accepted.

Measure

Perform at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.

Comment

Neither current EHRs nor registries have mature technology to accomplish this objective and it should be moved to Stage 2. In addition, there is a substantial variation in capabilities and approaches required by states to receiving such data. As such, we ask that CMS bring the language from the objective on "required and accepted" into the measure. In addition, we ask that CMS require that there must be available state immunization registries that meet the applicable standards from the ONC NPRM. Also, as with other tests of health information exchange (HIE) capabilities, we propose that the test must be successful.

Finally, this objective and measure appear to require support of each state's Immunization reporting format (i.e., potentially 50+ formats). To minimize the burden on providers, and given the need for certification against national standards, the objective and measure should make clear that they only apply where public health agencies can receive such results using national standards, not just the ability to receive the data electronically.

Capability to Provide Electronic Submission of Reportable Lab Results

Objective

Capability to provide electronic submission of reportable lab results (as required by state or local law) to public health agencies and actual submission where it can be received.

Measure
Perform at least one test of the EHR system's capacity to provide electronic submission of reportable lab results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).

Comment
Fundamentally, this is a function that should be performed by labs and lab information systems, not EHRs. This measure should be deleted as a requirement for meaningful use.

If they remain, this objective and measure appear to require support of each state's public health format (potentially 50+ formats). To minimize the burden on providers given the need for certification against national standards, the objective and measure should make clear that they only apply where public health agencies can receive such results using national standards, not just the ability to receive the data electronically.

Capability to Provide Electronic Syndromic Surveillance Data
Objective
Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

Measure
Perform at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP or eligible hospital submits such information have the capacity to receive the information electronically).

Comment
There is substantial state variation in the capacity and means to receive such data. In addition, the criterion should provide a clear definition of syndromic surveillance and the needed data. For example, how much will be needed beyond lab data? Also, we ask that CMS bring into the measure the language from the objective on "required and accepted".

In addition, this objective and measure appear to require support of each state's public health format (potentially 50+ formats). To minimize the burden on providers given the need for certification against national standards, the objective and measure should make clear that they only apply where public health agencies can receive such results using national standards, not just the ability to receive the data electronically. Finally, the test should have to be successful.

Protect Electronic Health Information
Objective
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.

Measure
Conduct or review a security risk analysis per 45 CFR 164.308 (a) (1) and implement security updates as necessary.

Comment
We are in general agreement with the CMS revision for this objective but ask CMS to emphasize that compliance with HIPAA privacy and, especially, security rules is part of an overall approach to protecting electronic protected health information (PHI) and extends beyond technical means. We also ask that CMS provide additional clarification about the types of acceptable risk analyses, but also remove the duplicative reference to the CFR.

Other Issues

Exclusion of Hospital-Based Eligible Professionals from Incentives

Proposal
CMS proposes to define a hospital-based EP as one who furnishes 90% or more of his or her covered professional services in the calendar year preceding the payment year in a hospital setting. A hospital setting is identified by the place of service codes used in the HIPAA standard transactions that identifies the site of service as an inpatient hospital, outpatient hospital, or emergency room.

Issue
Under this definition, a very large percentage of EPs will be excluded from eligibility for Medicare or Medicaid incentives, well beyond those typically considered hospital-based or anticipated by the Congress in the examples embedded in ARRA. CMS projects that 27% of EPs will be excluded.

Outpatient-focused EPs, even if practicing in a site classified as hospital outpatient by place of service code, are either not using the hospital EHR or are using an extension that is heavily customized for ambulatory use, which will require separate and additional implementation, services and support. Just as ARRA permits incentives to be paid to EPs in a hospital-owned practice located away from the hospital campus, so too should it permit payment for a separate ambulatory-focused EHR, even if it is paid for in whole or in part by the hospital.

If this issue is not effectively resolved, we anticipate several materially negative consequences:

- EHR incentives will not reach nearly one third of EPs, reducing hospital incentives to invest in ambulatory EHRs for affiliated EPs
- Since many less affluent patients go to hospital clinics instead of private practices, this policy will create a wider digital divide, increasing healthcare disparities
- Care coordination and integration will suffer
- This group of providers is especially well positioned to be successful with EHR adoption because of hospital support capabilities
- Hospitals will need to have different processes for areas that are automated and those that are not

Comment
We propose that CMS adopt a far less broad definition of hospital-based eligible professional, consistent with the ARRA statutory language and Congressional intent. In particular, we urge that, as

this category of provider was defined in ARRA, CMS consider the certified EHR the EP is using in addition to place of service code.

Specifically, we propose that a hospital-based EP would be defined as one who provides 90% of their services (agreeing with the 90% criterion), defined as encounters and not as charges (to align best with time spent), in a hospital setting as proposed by CMS, and that they also use the hospital inpatient certified EHR to support the care they are providing in this setting. This approach would mean that, if they were using an ambulatory certified EHR, they would not be considered a hospital-based EP. Eligible professionals, as part of their attestation process, should attest that they are not hospital-based eligible professionals as per the proposed new definition above.

We also ask that CMS, if it continues to look to prior year experience in defining a hospital-based EP, provide an opportunity to appeal if practice circumstances change (e.g., new job, post-resident or fellow, if applicable).

Certification Modules in Support of Meaningful Use

Proposal

CMS proposes to use the certification definitions in the companion Interim Final Rule on standards and certification criteria (p.1992). This IFR sets out a modular approach to certification. On page 2043, the IFR defines a module as "any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary." The IFR goes on to indicate that it is the responsibility of the eligible professional or eligible hospital to perform due diligence to ensure that the selected certified EHR modules are capable of working together to support achievement of meaningful use, and that EPs and EHs should take care to ensure that the certified EHR modules they select are interoperable and can properly perform in their expected operational environment.

Issue

We agree with the concerns raised by ONC regarding the need for disparate modules to be able to work together effectively to support meaningful use and to achieve the functional equivalence of a Complete EHR, as such is likely envisioned by the Congress. We also believe that providers need additional guidance on how they are to implement the modular approach to certified EHR technology.

Also, the addition of the electronic eligibility and billing meaningful use criteria will considerably complicate the certification process, as many providers have stand-alone comprehensive EHRs. In addition, vendors of many stand-alone practice management/revenue cycle products have little familiarity with the ARRA HIT incentives or the EHR certification process.

Comment

We recommend that CMS recognize that hospitals and physicians use many systems to support their efforts (e.g. additional software such as report-writers) to meet their administrative, clinical and quality goals. These systems should not be precluded from supporting efforts to achieve meaningful use and should not require separate vendor certification or require the provider to apply for Site

Certification. We also ask that CMS reinforce in the Final Rule the points made in the IFR about the need for provider due diligence regarding module interoperability.

Attestation Process

Proposal

Claims-based reporting and Online Portal are both mentioned as possible approaches for attestation, but all of the supporting text refers to only the Online Portal option.

Issue

These approaches are vastly different. In addition, there is insufficient detail on both, although various other sections in the rule suggest the Online Portal option. There is a lack of clarity on which vendors and providers might be able determine their ability to support either approach.

Comment

We believe that CMS should adopt the Online Portal option for attestation.

We are also concerned that the proposed overall approach to attestation could create a new administrative burden for Medicare PFFS and MSA plans. (Beginning with CY 2010, PFFS and MSA plans will also be required to begin collecting and submitting administrative HEDIS measures.) Regarding the division of reporting between HEDIS and HITECH, how will the new requirements affect the burden of time spent on attestation? How ready are the vendors to report on HEDIS and/or separate these measures for reporting?

Definition of Encounter

Issue

There is not a clear definition of "encounter".

Comment

There should be a clear definition of the word "encounter", which is used throughout the document. The wording from page 1858 is confusing: "A relevant encounter would be any encounter that the EP or eligible hospital judges performs a medication reconciliation due to new medication or long gaps in time between patient encounters or other reasons determined by the EP or eligible hospital."

Incentives for Eligible Professionals in Health Professional Shortage Areas

Issue

There is inconsistency in the commentary beginning on page 1908 for determining payment of the EP if there is a change in HPSA designation mid year. The HPSA is determined by December 31 of the prior year. If the designation is removed, the EP still gets the 10%. If the designation is added, the EP does not get the additional 10%.

Comment

We recommend this be applied consistently.

CMS Prior Approval of State Medicaid Plans

Issue

CMS proposes specific timing for its approval of stage Medicaid plans.

Comment

The proposed prior approval process for state Medicaid plans seems to be lengthy, with no timeframes specified. For example, there is no proposed timeframe for initial submission from the state to the Department, nor is there a timeline for the approval process from CMS back to the state. There is also no timeline for the implementation of the HIT programs after a state receives approval. Finally, CMS puts the burden for administration of the program on the states but there may not be adequate time to get all of the activities completed by the states to have the infrastructure and processes in place to accept data or attestations from the Eligible Providers and Eligible Hospitals.

Computation of Incentives to Qualifying MA Organizations for MA EPs and Hospitals (page 1923)

Issue

Medicare Advantage incentive computation is inconsistent.

Comment

Sections 3 thru 5 discuss compensation, but the preamble says that the Secretary may substitute a different amount. This discrepancy should be clarified.

Limiting Medicaid Variability

Issue

The NPRM makes a number of recommendations to limit Medicaid variability including:

- HHS needs to approve any additional Medicaid objectives/measures.
- Although we don't recommend that Medicaid be allowed to add any additional requirements, if such are allowed, we recommend that these must be supported by using the certified EHR.
- Hospitals deemed Medicare meaningful users, who also qualify for Medicaid incentives, are automatically deemed Medicaid meaningful users.

Comment

We support these proposals.

Time Requirements and Cost Requirements

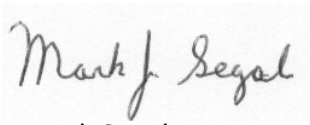
CMS presents an extensive analysis of information collection requirements (ICR) starting on page 1948. We believe many of the ICR costs are under-estimated. For example:

- The overall 0.5 hours estimated burden, which is inclusive of a large number of meaningful use criteria, seems very low. Even if much of this information can be computed using EHR technology, this computation may be complicated by a modular approach to EHR functionality. Given the number of numerators and denominators that require manual effort or other processes, and the substantial compliance implications of these measures as well as the likely need to internally validate them, we suggest that 0.5 hours is significantly low.
- The 0.5 hour estimate for quality reporting seems very low, especially given the large number of measures for hospitals, the need to ensure that measures are relevant for the hospital populations and the effort to ensure that exclusions are appropriately captured.

- The estimate of one hour to manually compute the denominator for CPOE use (and for e-prescribing for EPs) seems exceptionally low, especially given the various types of orders that must be considered. Our customers have identified the issue of CPOE denominator measurement as a major anticipated burden.
- Finally, although the ICRs address both reporting burdens and capital requirements, they do not address the changes that will be needed to comply with the meaningful use requirements (e.g., the process changes needed to implement CPOE or an automated problem list).
- Although we very much agree with CMS that the benefits of EHR use and meaningful use will outweigh the costs, we do think that the discussion in this section and the Regulatory Impact Analysis starting on page 1972 does not give sufficient weight to the initial costs that could offset anticipated incentive impacts, including concerns associated with the likely cumulative impact of reporting and compliance for the very large number of HIT and quality measures.
- Finally, many of the capital costs seem low for hospitals, and may not fully capture the additional costs associated with acquiring and integrating across multiple EHR modules.

In conclusion, the member companies of the EHR Association greatly appreciate the opportunity to provide these suggestions and comments as part of the NPRM process. We look forward to working with CMS staff toward final regulations that support our mutual objectives to encourage the adoption of EHRs toward the overall improvement in healthcare quality and efficiency.

Sincerely,



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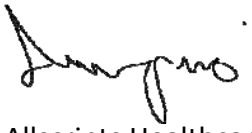

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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit http://www.himssehra.org.