CARDIOLOGY ADVOCACY ALLIANCE

National leadership on issues that affect cardiovascular patients and their physicians 202.505.2221 ▪ cardiologycaa.com

May 7, 2012

Marilyn Tavenner, MHA
Acting Administrator
Chief Operating Officer
Centers for Medicare & Medicaid Services
Attention: CMS–0044–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Tavenner:

Subject: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2: Proposed Rule

Dear Sir or Madam:

On behalf of the 3,000 cardiologists in private practice and within integrated organizations across the country that we represent, the Cardiology Advocacy Alliance (CAA) submits the following comments on the proposed rule for the second stage of the meaningful use program for the Medicare Electronic Health Record Incentive Program. CAA's mission is to support the sustainability of the cardiovascular professional regardless of practice setting. CAA represents the common interests of the cardiovascular patient and professional on such issues and encourages its members to advocate for their patients and their practices. CAA member practices devote themselves to continuous quality improvement and use benchmarking data and other tools to ensure that they are offering the highest quality care to their patients.

As we made clear in our comments on the first meaningful use proposed rule, CAA fully supports the need for a nationwide health information infrastructure and the use of Electronic Health Records (EHRs) to increase patient safety, improve efficiency and promote access to patient medical information across the health care spectrum. However, CAA is uncertain for our members' success to achieve Stage Two as we believe that the Agency greatly overestimates the number of medical professionals that have or preparing to deploy EHRs and the consistency of EHR use across specialties, sites of service, geography and venders.

Our concerns are supported by the results of an informal survey taken at a recent meeting of MedAxiom, Inc., a network that provides detailed feedback on how practices compare to their peers for more than 300 cardiology practices, representing over 5,500 cardiologists. The survey of conference participants showed that 51.1% of respondents were still working on achieving Stage One, were not yet ready for Stage One or were in the process of buying an EHR.

We also remind the Centers for Medicare & Medicaid Services (CMS) that today, cardiology practices are struggling with numerous implementation considerations such as the adoption and use of 5010 and ICD-10. Like with meaningful use implementation, CAA member practices rely on their venders to meet and exceed the standards within the deadlines established by Congress, CMS and other government agencies. However, these venders are not held accountable to the same level of compliance as CAA member practices. Instead, all compliance concerns are borne by the medical practice or health plan. Therefore, CAA strongly urges CMS to add clearinghouses and software venders to be within the scope of the covered entities that must comply with this proposed rule, the standardized health care data sets and electronic transaction standard regulations. This change encourages the universal accountability and engagement of the entire health care community in the establishment, updating and sun-setting of these standards.

Below, please find CAA's specific comments to the Agency's solicitation for feedback.

Definition of Meaningful User (77 FR 13702)
CMS proposes to define "meaningful user" in 42 CFR 495.4(3) as follows: "To be considered a meaningful EHR user, at least 50 percent of an EP's patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with certified EHR technology" (emphasis added). The Agency also clarifies in the preamble (77 FR 13707) that "[t]he determination of whether an EP is hospital-based or not occurs prior to the application of this policy, so only non-hospital based eligible professionals are included. Furthermore, this policy, like all meaningful use policies for eligible professionals (EPs), only applies to outpatient settings (all settings except the inpatient and emergency department of a hospital)."

CAA appreciates the modification and clarification; however, these statements are simply not supportive of how medical care is rendered in America now or in the future. CAA discusses later in the Hospital-Based Eligible Professionals section our strong beliefs regarding the definition of hospital-based professionals and urge CMS to address how specialty care is rendered in the hospital setting.

CAA agrees with and supports CMS's clarification that certified EHR technology may be accessed as (1) a permanent installation at the satellite or hospital site; (2) on a portable computing device; or (3) remotely using computing devices at the satellite or hospital site. 77 FR 13707

Changes to Stage One Criteria for Meaningful Use (77 FR 13704)
CAA supports the proposed alternative denominator of the number of medication orders created by the EP or in the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period. For the purpose of achieving the measure percentage, **CAA seeks clarification on how medication orders should be counted and the order definition itself.** For example, are refills of prescriptions originally prescribed outside of the reporting period considered a medication order? Are refills of a prescription ordered during the reporting period considered a unique prescription and thus counted individually as a medication order? Also, are prescription samples provided to evaluate a prescription regime considered a medication order? CAA appreciates this clarification and looks forward to the Agency's guidance on this important reporting issue.

Proposed Measure: Use computer provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who enter orders into the medical record per state, local and professional guidelines to create the first record of the order (77 FR 13708-9)
CAA appreciates the opportunity to respond to the Agency's request for public comment on whether CPOE can be expanded to include non-licensed health care professionals such as scribes. **CAA strongly believes that non-licensed professionals such as scribes are an integral part of the care team and should be enabled to enter CPOE orders under the direction of a licensed health care professional.** Notably, non-licensed professions are under the direction of the EP and are authorized for such actions under current state and local law and other professional guidelines. **Therefore, CAA supports CMS to modify the measure for Stage Two to support the EP spending more time on direction patient care**, such that the measure states: "use CPOE for medication, laboratory and radiology orders created by the EP or authorized providers who enter orders into the medical record that is licensed under state, local and professional guidelines or under the direction of such a licensed health care professional to create the first record of the order" (emphasis added). "Authorized providers" would be defined as licensed and non-licensed health care professionals, including scribes.

CAA also supports that this clarification be included in Stage One CPOE measures to permit scribes to enter medication, laboratory and radiology orders in 2013.

Proposed Measure: More than 60 percent of medication, laboratory and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE (77 FR 13709)
As noted above, **CAA recommends that this measure be inclusive for non-licensed professionals, such as scribes**. The measure should be modified to state: "More than 60 percent of medication, laboratory and radiology orders created by authorized providers of the EP or an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.

Proposed Objective: Use clinical decision support to improve performance on high-priority health conditions (77 FR 13714)

CAA supports the inclusion of clinical decision support tools for clinical quality measures as a Stage Two objective. However, we believe that our member cardiology practices would struggle to achieve implementation of five interventions for five or more quality measures. Simply, the time it takes to agree on the measure and train EPs on how to use the tool in such a way to facilitate sufficient reporting information would be prohibitive. **CAA recommends that in addition to drug-drug and drug-allergy interaction checks that EPs, eligible hospitals and CAHs implement three clinical decision support interventions related to three or more clinical quality measures.**

Proposed Objective: Incorporate clinical lab-test results into certified EHR technology as structured data (77 FR 13717)

CAA is concerned about the raising of the 40 percent Stage One threshold to 55 percent for Stage Two. We greatly appreciate the clarification that structured data is preferred with scanned lab-test results rather than manual entry that may result in key-stroke errors in the data. However, the significant increase in objective threshold when the industry has not standardized electronic transaction of lab-test results is very daunting. **CAA recommends that for Stage Two the objective be increased from 40 to 50 percent.**

CAA appreciates the opportunity to comment on the individual accounting of lab-test results. For Stage Two, CAA agrees that the current prevalence of labs ordered by panel or group prohibit accurate accounting of individual results. This is exacerbated as most certified EHR technology is being implemented with an associated practice management system which would be unable to bill for unbundled labs. Further, private lab companies such as Quest and LabCorp define each panel differently making data entry and individual accounting even more difficult. The use of these companies are required for lab coverage by Medicare Advantage products offered by Aetna and UnitedHealthcare. Thus, the policies of these companies effect Medicare patient lab orders.

In light of the industry's current status, CAA supports flexibility in Stage Two of having panels either count as one test or individually where the system permits data entry or electronic transmission. CAA recommends that CMS and the Office of the National Coordinator work with the medical societies and other stakeholders to standardize lab panels such that the lab-test result entry process can be automated and individual results counted in Stage Three.

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 (77 FR 13718)

CAA believes that this Objective could be strengthened for Stage Two. The Stage One Objective is much clearer as it is measured by the number of patient requests. Here, the Objective is vague in the measurement as it is passive to the patient's wishes. Therefore, and in the spirit of the Stage One Objective, **CAA recommends that the denominator and numerator for the first measure of this Objective be appropriately modified to be the number of patients seen by the EP that have requested online access to their health information.**

Many patient portal software venders interpret patient privacy protections as requiring the patient to enroll first before any health information may be pushed to the secure website. CAA seeks clarification if this process where health information for a patient could be made available but they are not yet enrolled, and not yet posted online, would qualify as providing "patients the ability".

Likewise, CAA's second point can be made into the following cliché: "you can lead the patient to the online portal, but you can't make them use it." CAA has no evidence that this feature of health care information is being requested at any level let alone by 10 percent of patients. To increase participation, an EP could employ common marketing techniques to increase patient access to the online health information portal for viewing, download or transmission of their information. For example, patients could enter a drawing to win a spa weekend if they only registered for the online portal and then logged in. But any incentive that most consumers find worthwhile would be considered a kick-back by Medicare and Medicaid. Likewise, the objective is limiting patient interaction on the site to only viewing, downloading and transmitting their information. Many patients do not need their health information but find value in web portals for other uses. Common uses that may better meet a patient's individual health needs include requesting a refill; completing new patient forms; adding additional health information such as other care providers or allergy information; or scheduling an appointment. For these reasons, **CAA strongly urges CMS to delay implementation of the second measure for this objective. If the measure remains, CAA recommends that the measure be modified to state "more than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) <u>that requested online access to their health information that log into the secure portal atleast once during the EHR reporting period</u>."**

Proposed Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) (77 FR 13721-2)
CAA appreciates the clarification provided in the preamble of the Stage One final rule (75 FR 44362): "We clarify "transition of care" as 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." Yet, CAA seeks further clarity and requests specific sample scenarios of transitions of care, especially when the patient may not have left a geographic location but is transitioning between categories. An example would be a patient who is first seen by an ambulatory cardiology practice that is hospital owned and on the hospital campus, is transferred through the emergency department to an inpatient stay and then the bed converts to a skilled nursing stay. Another scenario is when a patient is in an inpatient stay and being seen by a private practice cardiologist on rounds – would the cardiologist be responsible for a transition of care summary transmission when the patient transitions to home health or a rehabilitation facility?

Proposed Objective: The EP, eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides a summary care record for each transition of care or referral (77 FR 13722)
CAA applauds the rationale for this lofty Objective. However, this Objective is not easily achievable. **CAA therefore recommends that for Stage Two any transition of care or referral that is initiated in an emergency situation or after business hours should be excluded.** Thus, only planned transitions of care or referrals would qualify for this measure.

Proposed Measure: More than 40 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 are accessible through certified EHR technology (77 FR 13727)
CAA greatly appreciates the flexibility afforded by the Agency in how digital scans may be accessible through the certified EHR technology which may include "an indication in [the] certified EHR technology that the image and accompanying information are available for a given patient in another technology and a link to that image and accompanying information." Many CAA members use Picture Archiving and Communication Systems for digital image archival and transfer. We believe that this measure's flexibility will permit industry innovation and not reinvent existing systems.

The Agency seeks feedback on whether a second measure would discourage EPs from selecting this objective. The proposed measure is "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." CAA strongly believes that this second measure is difficult to achieve, especially if images ordered or rendered in the hospital outpatient setting (POS 22) were excluded from the measure. Therefore, **CAA recommends that the measure be revised to include image exchanges where the order or technical component take place in POS 22.**

Proposed EP Objective: Use secure electronic messaging to communicate with patients on relevant health information (77 FR 13728-9)
CAA supports this Objective and the patient-driven nature of electronic messaging outreach initiation. **CAA recommends that the numerator of the measure be modified to include a patient's representative.** We believe that this addition is consistent with one of CMS's stated goals for the objective: "ensuring that each person/family is engaged as partners in their care" 77 FR 13728. Further, we seek clarification on whether messages sent to a member of the EPs staff, such as a registered nurse or social worker, would qualify as sending a secure electronic message to the EP. Also, if messages to staff under the direction of the EP qualify, would messages to non-licensed health care professionals qualify? In the later scenario, the secure messaging may not be directly related to care coordination but may include billing and clarification on coverage of services which directly impacts a patient's course of care.

Proposed Clinical Quality Measures for Eligible Professionals Beginning With CY 2014 (77 FR 13746-7)
We welcome the addition of Option 2 for EPs that participate in the both the Physician Quality Reporting System (PQRS) and the EHR Incentive Program to satisfy their clinical quality measures reporting requirement. This added flexibility will provide more options for CAA members who already submit data through the PQRS program.

Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning With CY 2014 (77 FR 13758)

As noted above, CAA supports the inclusion of PQRS for satisfying individual or group practice reporting requirements. We also support the flexibility in Stage Two for group practices under a single TIN of two or more EPs to report their quality measures as a group. CAA however seeks clarification on the Agency's rationale for excluding the group reporting option for EPs in Stage One in 2014.

Group Reporting Option of Meaningful Use Core and Menu Objectives and Associated Measures for Medicare and Medicaid EPs Beginning With CY 2014 (77 FR 13765)

CMS conveniently provided a list of topics for public comment. CAA addresses many of them below:

What should the definition of a group be for the exercise of group reporting?

CMS is seeking guidance on whether the PQRS definition of a group should be used which is 25 or more eligible professionals who have reassigned their billing rights to the tax identification number (TIN). **For the purposes of core and menu objective reporting, CAA supports the definition of a medical group as noted above for the non-PQRS reporting options which define a group as "two or more EPs, each identified with a unique NPI associated with a group practice identified under one TIN."**

Should there be a self-nomination process for groups as in PQRS or an alternative process for identifying groups?

For consistency in the program and with PQRS and for flexibility of a group practice to choose to report individually, **CAA supports self-nomination**.

Regarding the availability of certified EHR technology across the group, should the group be required to utilize the same certified EHR technology?

More than half of our member practices have integrated with a hospital or health system in the past three years, with another 25 percent pursuing integration discussions. This massive loss of private practice cardiology is due to declining Medicare payments and the uncertainties of future Medicare payment levels. As integrations occur, many practices keep multiple EHR systems active while identifying and planning the streamlining to one or more systems. **Therefore, CAA does not support that a group should be required to use the same certified EHR technology.**

Should a group be eligible if certified EHR technology (same or different) is not available to all associated EPs at all locations?

CAA supports CMS's proposal in at 77 FR 13707 that a group should be able to facilitate EP accessibility to certified EHR technology by (1) a permanent installation at the satellite site; (2) on a portable computing device; or (3) remotely using computing devices at the satellite or hospital site. If they cannot achieve this accessibility, group EPs then have the option to report core and menu objectives individually.

Should a group be eligible if they use multiple Certified EHR Technologies that cannot share data easily?

As noted at the beginning of our letter, CAA strongly believes that this issue is not one to be borne by the EP. Instead, venders must be accountable for interoperability and the ease by which medical providers may share data. **CAA strongly urges CMS to add clearinghouses and software venders to be within the scope of the covered entities that must comply with this proposed rule.**

With respect to EPs who practice in multiple groups or in a group and practice individually, how should meaningful use activities be calculated?

CAA recommends that the EP's covered services be calculated as a whole and percentages be assigned to each TIN that services were billed. Take the example of a cardiologist who works at a large urban medical practice for part of the week, a solo office on Friday and twice a month at another group in a rural location. Using the physician's National Provider Identifier on submitted claims, the Agency could assign the TIN mix: 85% urban practice; 12% solo practice; 3% rural practice.

As the HITECH Act requires all meaningful users to be paid 75 percent of all covered services, how should the covered services performed by EPs in another practice be assigned to the group TIN?

As noted above, **CAA supports that the covered services would be limited to the services rendered at the specific group practice.**

How will meaningful use activities performed at other groups be included?
See the example above.

Should these services be included in the attesting group, or should CMS just ignore this information or account for it in other ways?
Using the example above, **CAA believes that CMS should limit the information for covered services rendered by the group.** If the concern is that in data aggregation CMS cannot associate TINs with NPIs that should be a technology issue the Agency can easily overcome and should not be the burden of the medical group.

How should the government address an EPs failure to meet a measure individually?
If the group is reporting as a group, the individual EPs performance is not being evaluated. **Therefore, CAA believes that the government should not address an EPs individual performance if the group has elected group reporting.**

If an EP chooses not to participate in a particular objective should they be a meaningful EHR user under the group if their non-participation still allows group compliance with a percentage threshold?
Yes. CAA members report great inconvenience by the PQRS requirement that all physicians must participate in the program for group reporting to be available. Thus, so long as the group may still be able to meet the thresholds, they should be able to participate as a group.

Some EPs in a group participate in Medicaid while others participate in Medicare; what covered services should the meaningful use calculation capture?
CAA members participate in the Medicare program and may vary their participation in Medicaid. Thus, **Medicare should be the main source for meaningful use calculation capture**.

Should the incentive payment be reassigned to the group automatically or does the EP still need to assign it to the group at registration?
CAA recommends that incentive payment assignment should be part of the process to self-nominate as a group.

How should covered services for EPs who leave a group during an active EHR reporting period be handled?
See the example above.

How should payment adjustments for Group reporting be handled?
CAA does not believe that payment adjustments for services rendered reporting period will be significant for incentive payments received a year later. In instances where fraud and abuse are confirmed after the incentive payments are received for services rendered during the reporting period, any monies received should be included as part of the Medicare recovery in the criminal proceeding.

Hospital-Based Eligible Professionals (77 FR 13766)

The Agency seeks feedback on the definition of hospital based professionals. Specifically noting that "we have been asked about situations where clinicians may work in specialized hospital units, the clinicians have independently procured and utilize EHR technology that is completely distinct from that of the hospital, and the clinicians are capable, without the facilities and equipment of the hospital, of meeting the eligible professional (for example ambulatory, not in-patient) definition of meaningful use. These inquiries point out that such situations are uncommon and might not be generalized under the uniform definition used by place of service codes."

As CMS is acutely aware, cardiologists like other specialists, are able to bill for services rendered while patients are admitted to a hospital or in the emergency department as a Part B service on the CMS1500/837. These services, such as rounds and other visits, are documented in the EHR of the individual cardiologist and not the hospital. For surgical procedures, the physician is again able to bill for the services rendered separately and while a note may be generated through the hospital system, this hospital note is supplemental to the documentation the surgeon keeps on record, pursuant to state and federal law and licensing requirements. Again, CMS acknowledges that certain services may be considered included as part of an inpatient stay or surgery. The preamble of this rule clarifies that a patient encounter is "any encounter where a medical treatment is provided and/or evaluation and management services are provided. This includes both individually billed events and events that are globally billed […]" 77 FR 13707. CMS must appreciate the fact that the split between Part A and B dollars has created a system that supports the separation of medical documentation. This burden is disproportionality borne by specialty physicians rendering medical services in the hospital setting.

Further, as noted above, many of our members have retained their own stand-alone certified EHR technology in the majority of integrations. These systems are better equipped to document cardiac procedures rather than many hospital systems designed for inpatient stays and possibly operational aspects of surgical procedures. Using the discussion above, the rule for how the group may access the certified EHR technology as (1) a permanent installation at the satellite site; (2) on a portable computing device; or (3) remotely using computing devices at the satellite or hospital site. CAA strongly believes that the issue here is not about internet access or electricity or other aspects; it is about the certified EHR technology and distinct nature of the system. Specialists who have arranged for these solutions should be applauded for their efforts rather than being lost in the scope of the regulation.

CAA also recommends that CMS modify its definition of hospital-based EP to recognize physicians that use certified EHR technology in private practice and hospital settings. The HITECH Act provides CMS this flexibly and clarifies legislative intent by stating that "the term 'hospital-based eligible professional' means […] an eligible professional, such as a pathologist, anesthesiologist or emergency physician, who furnishes substantially all of such services in a hospital setting (whether inpatient or outpatient) and through the use of the facilities and equipment, including qualified electronic health records, of the hospital." HITECH Act §4101(a); 42 USC 1395w-4(o)(1)(C)(ii). **Therefore, CAA recommends that the definition of hospital-based EP at 42 CFR 495.4 be modified to state: "Hospital-based EP is an EP (as defined under this section) who furnishes 90 percent or more of his or her covered professional services in a hospital setting, using the hospital facilities and equipment, and documents 90 percent or more of his or her covered professional services using the hospital's certified EHR technology in the year preceding the payment year."**

Exception to the Application of the Payment Adjustment to EPs in CY 2015 and Subsequent Calendar Years (77 FR 13769-70)

CAA agrees with and supports the proposed two year hardship exception for newly practicing EPs. However, the way the hardship is described, "the new EP would still be required to demonstrate meaningful use in CY 2016 in order to avoid being subject to the payment adjustment in CY 2017," affords that the hardship is only one year. **CAA supports the hardship being two full years to allow one year for implementation and one year for testing before the payment adjustment would apply.** Thus, the EP would not need to demonstrate meaningful use until CY 2017 for a new physician who started in CY 2015. CAA also seeks clarification for physicians that begin practice in the middle or later in a calendar year when the hardship would begin. Additionally, how does CMS define the date when a new EP begins practice? Is it on the date where Medicare or Medicaid enrollment is approved?

Conclusion

Although the EHR incentive program is focused more for the primary care provider than the specialist, cardiovascular disease is our nation's number one killer. Cardiologists provide life-saving services to a significant number of Medicare patients. We hope that CMS appreciates the role of the specialist as this rule is finalized and finds opportunities to bolster collaboration between primary care providers and cardiac care professionals.

Thank you for this opportunity to comment on this proposed rule. Our members and staff are available as resources to you as you examine and address the recommendations outlined above. Please feel free to contact Jen Searfoss, Executive Director, at 202-505-2221 or jen@cardiologycaa.com for any assistance.

Sincerely,

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