



March 11, 2010

Submitted electronically at www.regulations.gov

Charlene Frizzerra
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program [CMS – 0033—P; RIN 0938 – AP78]

Dear Administrator Frizzerra:

As President and Executive Vice President/CEO of the Academy of Medicine of Cleveland & Northern Ohio (AMCNO) a regional organization representing more than 5,000 physicians, we are writing on behalf of the physicians we represent to offer our comments on the Centers for Medicare and Medicaid Services (CMS) *Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs* Notice of Proposed Rule Making (NPRM) published January 13, 2010.

CMS is charged with ensuring that physicians are a key component of the effort under the American Recovery and Reinvestment Act of 2009 (ARRA) to promote health information technology and its use to transform medical practice and the health care delivery system. Our comments focus on our support for a program that allows as many eligible physicians as possible to participate and that creates trust and buy-in from physicians on the value of that participation and the fairness of the process.

The Academy of Medicine of Cleveland and Northern Ohio makes four key recommendations to CMS as follows:

- CMS should limit the definition of hospital-based professionals ineligible to participate in the EHR Incentive programs to ensure broad physician participation in Meaningful Use.
- CMS should scale back the measures, make the thresholds for the objectives and quality metrics more realistic, and allow achievement of meaningful use on something less than an “all or nothing” basis.
- CMS should allow eligible professionals to demonstrate meaningful use through substantial compliance with the measures and objectives in Stage 1.
- CMS should streamline that administrative burden on physicians so that physicians can easily create the compliance documentation needed.

1. CMS should limit the definition of hospital-based professionals ineligible to participate in the EHR Incentive programs to ensure broad physician participation.

The NPRM definition of “hospital-based eligible professional” is too restrictive considering the statutory language and Congressional intent of the HITECH Act. This definition also is ambiguous given the current status of EHR technology in the ambulatory setting and inconsistent with the incentive payment rules for eligible hospitals. A restrictive approach to defining “hospital-based eligible professional” may delay or even curtail the development, implementation and meaningful use of ambulatory EHR systems. As a result, this definition may do more to

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thwart, rather than enhance, the meaningful use of EHR by physicians, despite the overall goals of the HITECH Act to expand physician use of EHRs and transform the existing health care delivery system.

The HITECH Act contains language intended to clarify the determination of “hospital-based eligible professional.” The HITECH Act defines a “hospital-based eligible professional” as:

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. The determination of whether an eligible professional is a hospital-based eligible professional *shall be made on the basis of site of service and without regard to any employment or billing arrangement between the eligible professional and any other provider.* HITECH Act at §4101 (emphasis added).

The italicized language should be read to limit the definition to those professionals providing substantially all services in a hospital setting. While the term “hospital setting” is not defined in the HITECH Act, Congress clearly intended that “hospital setting” have its plain and ordinary meaning, which simply is the traditional hospital setting (e.g., inpatient and ER) and not ambulatory care sites (e.g., clinics, provider-based outpatient settings, and care rendered by non-emergency physicians in observation units).

This Congressional intent is reflected in the conference committee report, which provides several common examples of qualifying eligible professionals that are not hospital-based eligible professionals. These professionals include physicians employed by hospitals to work in ambulatory clinics. This Congressional intent is further reflected in recent letters from members of Congress to the Secretary and CMS explaining that physicians furnishing ambulatory care services should not be included in the definition of hospital-based eligible professional.

This Congressional intent is also reflected if the meaningful use of EHR systems is viewed as a choice made by hospitals and eligible professionals. Physicians have a choice of using an EHR system or not. The HITECH Act reflects Congress’s clear intent to create an “incentive” to make the former choice. With this objective, “hospital setting” and the “EHR of the hospital” must refer to practice settings where a professional has no choice with regards to an EHR system separate from the hospital’s inpatient EHR system. The examples of such settings set forth in ARRA are consistent with this concept - anesthesiology, pathology, and emergency care are typically practice settings that are invariably a part of a hospital where the physician has no choice with regards to an EHR system.

This concept of differentiating ambulatory care services from services rendered in the “hospital setting” is further supported by the various quality measures for “eligible professionals” in the NPRM. As to physicians, the plain and ordinary meaning of “hospital setting” should include only those physicians who base almost all their practice in the hospital *and* use the hospital’s qualified electronic health records, i.e., do not have or need an EHR for an ambulatory practice, regardless of the point of service codes reported by said physicians. The physician specialties referenced in the statutory definition (pathology, anesthesiology, or emergency medicine) are classic examples of physicians that practice in a hospital setting and do not generally maintain an ambulatory practice or have a need for an EHR separate and apart from the hospital EHR. CMS has even included radiologists as a specialty recognized in the NPRM quality measures, a recognition that these specialists may indeed have an ambulatory practice despite the point of service as hospital-based as proposed in the NPRM. It is our strong belief that physicians of every specialty should be considered outside the scope of “hospital based” and qualify for incentive payments to the extent that the physician adopts a qualified EHR system and otherwise meets the definition of meaningful use.

The NPRM definition of “hospital-based eligible professional” is inconsistent with the statutory definition and the goals of ARRA to promote adoption. CMS assumed that, for purposes of the definition of “hospital-based eligible professionals,” physicians furnishing services in an inpatient or outpatient hospital setting are using the hospital EHR system(s). For inpatient hospital settings, this assumption may be valid. Physicians in certain specialties

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(e.g., cardiovascular surgery, neurosurgery) may provide their professional services primarily in a hospital setting but also use a separate ambulatory EHR for their practice.

In many instances, however, physicians practicing in an integrated health system or academic medical center will primarily use a separate EHR system or module specifically developed for the provision of ambulatory care. An ambulatory EHR system is significantly different than an inpatient EHR system. Ambulatory EHR systems are designed and integrated differently and generally contain various add-on modules and components not found in inpatient EHR systems.

Ambulatory and inpatient EHR systems are typically distinct modules with separate sets of resources for implementation timelines, strategies, teams, and costs. The needs, functionalities, and specifications of inpatient EHR systems are markedly different from those of ambulatory EHR systems owing in large part to the different nature of the care that patients receive in inpatient and ambulatory settings. Ambulatory EHR systems include features such as schedules and referral management, health maintenance alerts, results routing, immunization management, prescription medication lists, problem lists, histories, and other items that help the continuity of care between physicians and often drive an outcome of clinical care or a requirement to see a clinician. In contrast, inpatient EHR systems are different in that patients for which an EHR is maintained are markedly more ill and health maintenance is not as important, but clinical best practice alerts are immensely important. Consequently, while ambulatory and inpatient systems may be capable of integration, using both systems in the same care setting at relatively the same time is hard, if not impossible, due to the distinctly separate system set-ups, mocks and specifications for inpatient care and ambulatory care.

Physicians in all settings may have contributed to the purchase of the ambulatory EHR system, which in those instances should be considered as part of their practice. *See* Letter from Am. Hospital Assn. (Dec. 11, 2009). This result seems contradictory given that, per the statutory definition, a hospital-based eligible professional must furnish services through the use of the facilities and equipment, including qualified EHRs, *of the hospital*.

Take for example, a hospital owned outpatient clinic for which the hospital has yet to implement an inpatient EHR system. An inpatient EHR system is not a component of the workflow for the physicians furnishing services at the clinic. By the definition in the NPRM, the clinic physicians are hospital-based eligible physicians excluded from the eligible professional EHR incentives even though they do not use any EHR system of the hospital. Even if the hospital maintains an inpatient EHR system, the hospital will still need to implement some form of ambulatory EHR system for its clinic. More importantly, the clinic physicians have absolutely zero incentive under the HITECH Act to advocate for, or even contribute financially to, the implementation and use of an EHR system. The clinic physicians would not be eligible for incentive payments even if they, not the hospital, purchased the EHR system. Likewise, the clinic physicians would not be subject to any reduction in their fee schedule amounts as a result of them not being meaningful users of EHR by 2015.

Applying the point of service rules proposed under the NPRM definition of “hospital-based eligible professional” will result in most, if not all, provider-based physicians of all specialties being deemed “hospital-based eligible professionals” and not eligible for the incentive payments. This is the case even though most provider-based physicians maintain an ambulatory practice and use a qualified ambulatory EHR despite reporting outpatient hospital point of service codes for billing purposes. We strongly believe that CMS must reconsider this proposal and interpret the term “hospital setting” in its plain and ordinary meaning to avoid such a restrictive result.

The assumptions behind the definition of “hospital-based eligible professionals” and the strict point of service determination will isolate physicians practicing in integrated health systems and academic medical centers from the common pathway to meaningful use for eligible professionals and hospitals. By using POS codes as a proxy for hospital-based and including outpatient and provider-based settings, CMS is excluding an important aspect of our nation’s health care delivery system.

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The definition of hospital-based eligible professional in the NPRM may also delay, or even curtail, the development, implementation and meaningful use of ambulatory EHR systems. Even with the incentive payments, resources are limited for both hospitals and eligible professionals to implement and meaningfully use EHR systems. Hospitals and eligible professionals must thus make significant financial and business decisions to allocate resources appropriately to receive the best result possible.

CMS estimates that more than one-quarter and almost one-third of otherwise eligible professionals will be categorized as hospital-based and thus not eligible to receive direct incentive payments. While the estimated figure is startling, even more startling is that these “re-categorized” professionals are affiliated directly with hospital-owned outpatient facilities/departments. The financial impact on physicians in Northeast Ohio is significant. Many physicians in Northeast Ohio are affiliated with and/or practice at large integrated health systems with many outpatient departments, facilities, clinics, etc. According to one of the major hospital-owned integrated health systems, the financial impact on its affiliated physicians could be between \$30,000,000.00 and \$44,000,000.00. Using this figure as a benchmark, we believe the total financial impact on physicians in Northeast Ohio could exceed \$100,000,000.00. Since this financial impact would otherwise help spur the meaningful use of EHR systems in Northeast Ohio, there can be little doubt that the proposed definition of hospital-based eligible profession will hamper and stymie EHR meaningful use, especially in the provider-based setting.

Physicians in Northeast Ohio providing services in provider-based settings are at the forefront of technology, especially EHRs development and implementation. They should be incentivized to meaningfully use it. Hospitals and integrated systems partner with their affiliated professionals to further their technology goals. Moreover, the research, development, testing, and advancements in ambulatory EHR systems have resulted in more efficient and affordable ambulatory EHR systems across the board. This has made the implementation of ambulatory EHR systems at the grass roots level possible.

Physicians practicing in integrated health systems and academic medical centers have no financial incentive under the NPRM to partner with hospitals for meaningful use considering that the proposed point of service rule eliminates direct incentive payments to the physicians, which is neither justified nor desirable. There is no “double dipping,” considering that the meaningful use of an ambulatory EHR system by professionals furnishing services at outpatient facilities/departments (regardless if provider based for reimbursement purposes) will have little to no affect on hospital patient discharges, the variable component of the hospital EHR incentives. The hospital incentive programs for Medicare and Medicaid consider only the inpatient volumes in computing their applicable incentive payments.

The overall result is a significant delay or curtailment of the development of ambulatory EHR systems and their integration with hospital-based care. This delay extended even further, significantly hampers the development of health information exchange across care settings and the interoperability of inpatient and ambulatory EHR systems going forward. While meaningful use of specific EHR systems is the first step in achieving the transformation of the nation’s health IT network, the ultimate goal, one which is stated in the HITECH Act, is the interoperability of all EHR systems and health information exchange so that the health records of individuals are freely accessible and transferable across all spectrums of care. Without robust and effective ambulatory EHR systems in place, this ultimate goal could be in jeopardy.

CMS should limit the specialties included in the definition of hospital-based to those commonly and traditionally considered hospital-based (anesthesiology, pathology and emergency medicine). AMCNO recommends that CMS address the concerns over the definition of “hospital-based eligible professional” by eliminating from the point of service rules the point of service code for hospital outpatient (Point of Service Code 22). Elimination of this code will go a long way to cure any ambiguities and inconsistencies with the application of the definition of “hospital-based eligible professional” to those professionals that maintain and practice in an ambulatory setting. In addition or in the alternative, CMS should narrow the scope of the outpatient hospital point of service code so that it only applies to instances in which the otherwise eligible professional is strictly furnishing services through and using the inpatient EHR system of a hospital. This approach should be capable of easy implementation from a practical

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standpoint considering that inpatient and ambulatory EHR systems are vastly different and physicians reporting a Point of Service Code 22 are highly unlikely to furnish services using an inpatient EHR system of a hospital.

2. CMS should make the thresholds for the objectives and quality metrics more realistic and allow achievement of meaningful use on something less than an “all or nothing” basis.

We are concerned that the selection of such an extensive number of objectives and measures makes meaningful use daunting to the physician. We are concerned that the breadth and number of measures and the requirement that core measures and specialty measures be met at 100% compliance will discourage physicians from participating in the EHR incentive programs.

AMCNO has members working solo, in smaller groups that have not adopted EHR systems, as well as some of the nation’s most sophisticated institutions. Physicians in both settings desire to qualify for the EHR incentive programs. But making the achievement of Stage 1 objectives unrealistic for small physician practices will create a digital divide and serve to make healthcare delivery and referrals more disconnected and fragmented. AMCNO is a stakeholder in the Northeast Ohio Regional Extension Center application to Ohio Health Information Partnership (OHIP) and will support that role in helping smaller physician practices adopt and meaningfully use certified EHR technologies. The reality is that those who are at the beginning of the adoption cycle still have a long way to go to implement the functional technology and develop the capabilities.

Given the tight timeframes, CMS should focus its priorities. We believe that at least in Stage 1, the laundry list of quality measures should be scaled back to an achievable level with only a few straightforward, achievable measures clearly identified for each specialty. Those measures should be evidence-based measures having full endorsement by the respective medical specialty societies and at the level of maturity where implementation specifications have already been developed. Maintaining and attaining achievement of dozens of measures is far too complex for each physician to administer. At most, physicians should be responsible for 3-5 quality measures in Stage 1.

The criteria for meaningful use also should be scaled back. We believe that requiring physicians to directly enter 80% of their orders for ancillaries is far too high. For Stage 1, a more flexible approach should be considered for CPOE providing sufficient lead time for physicians to achieve the criteria. Obtaining 50% of all lab results in the EHR creates the need for many lab interfaces at this early juncture of HIT interoperability. Requiring e-prescribing for 75% of permissible prescriptions is too high given the various levels of adoption in the pharmacy world, the difficulties with the DEA restrictions on scheduled drugs and the other competing measures included in the NPRM.

3. CMS should allow eligible professionals to demonstrate meaningful use through substantial compliance with the measures and objectives in Stage 1.

In addition to scaling back the thresholds and the number and variety of measures, CMS should reconsider the “all or nothing” approach to the measures and objectives. EHR implementations may experience delays or the need to change priorities based on legitimate and uncontrollable events, so flexibility in the roadmap to Meaningful Use should be designed into the incentive programs.

One solution for this problem would be to allow Eligible Professionals to achieve meaningful use through “substantial compliance” or in a quantitative approach, by allowing deferral of a set number of objectives and measures, as recommended by the federal Health IT Policy Committee. In addition, physicians need to be able to demonstrate meaningful use in something less than a full year if they experience uncontrollable events, vendor changes, and system upgrades.

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4. CMS should streamline the administrative burden on physicians so that physicians can easily create the compliance documentation needed.

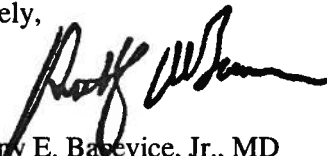
We are very concerned about the undue compliance burden for physicians. CMS estimates that Eligible Professionals will need to be directly involved in the reporting and submission of meaningful use objectives and measures and estimates eight hours for these tasks. An additional hour is estimated for quality measures and attestation. These estimates are low given the breadth and variety of measures and the difficulties expected in tracking and reporting data where manual computations are involved (e.g., if 80% of all orders must be placed through CPOE, the practice will need to manually track and count the orders placed outside the EHR). Physicians are also concerned about the scope of the attestation and hope that CMS can limit the certification that physicians must make. Physicians should be able to rely on the ONC-designated EHR certification process for matters of technology and be protected from False Claims Act liability for good faith certifications.

Finally, we also ask CMS to consider a Medicare reconsideration process for reviews of contractor determinations of eligibility, similar to that established for Medicaid. Physicians need to know that the EHR incentive program will be administered fairly, and if mistakes are made or if additional documentation is needed from the physician, a process has been put in place to ensure fair and accurate determinations.

Conclusion:

On behalf of the physicians of Cleveland and Northern Ohio, AMCNO appreciates this opportunity to comment on the NPRM. Please feel free to contact Elayne Biddlestone, Executive Vice President at (216) 520-1000 should you have any questions.

Sincerely,



Anthony E. Basevich, Jr., MD
President
Academy of Medicine of Cleveland
& Northern Ohio



Elayne Biddlestone
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cc: Northern Ohio Congressional Delegation