

March 15, 2010

Charlene M. Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Room 309-G  
Hubert Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-0030-P  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

<b>Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program (75 Fed. Reg. 1844, January 13, 2010)</b>
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Dear Acting Administrator Frizzera:

On January 13, 2010, the Centers for Medicare and Medicaid Services (CMS) published the above-captioned proposed rule in the *Federal Register* implementing certain provisions of the American Recovery and Reinvestment Act of 2009 (Act) to increase the use of health information technology (HIT).<sup>1</sup>

Section 612 of the Regulatory Flexibility Act (RFA) requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.<sup>2</sup> Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

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<sup>1</sup> Pub. L. No. 111-5.

<sup>2</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. § 612(a).

As Acting Chief Counsel for Advocacy, I am submitting comments on this matter because this regulation is expected to have an impact on a significant number of the health care providers and hospitals in this country, and because my office has been contacted by numerous health care providers and their representatives that are required to comply with various provisions of the Act. I believe there is merit to bringing the following comments to the attention of CMS as the vast majority of these entities are considered small pursuant to SBA size standard definitions.

## **I. Background**

According to the proposed rule's preamble, the regulation would provide incentive payments to eligible professionals (EPs) and eligible hospitals (EHs) participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology. The proposed rule provides the initial criteria an EP and EH would have to use in order to qualify for incentive payments designed to encourage EHR technology.

CMS states that the proposed rule will be economically significant and will have an impact on virtually every EP and EH and other affected health entities.<sup>3</sup> CMS believes that most EPs using EHR systems will require significant changes to achieve certification and/or the EPs will have to make process changes to achieve Meaningful Use (MU).<sup>4</sup> Per CMS there are approximately 624,000 healthcare organizations (EPs and eligible hospitals) that will be affected by the incentive program.<sup>5</sup> Also, CMS estimates that the incentive program will cost EPs approximately \$54,000 to purchase a certified EHR and \$10,000 annually for ongoing maintenance.<sup>6</sup> The agency estimates that it will cost eligible hospitals \$5 million to purchase a certified EHR and \$1 million annually for maintenance.<sup>7</sup> CMS rightfully states that for RFA purposes it is assuming that all affected providers are small based on SBA size standards.<sup>8</sup>

Advocacy commends CMS for appreciating the extent to which this rulemaking will impact the health care industry in the United States, and for complying with §603 of the RFA that requires agencies that conclude that a rule will have a significant impact on a substantial number of small entities to complete an Initial Regulatory Flexibility Analysis (IRFA). While CMS correctly included a discussion of alternatives in its IRFA (as required by §603(c) of the RFA), CMS asserts that it has no discretion with respect to the

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<sup>3</sup> 75 Fed. Reg. 1973 (January 13, 2010).

<sup>4</sup> Id., "Meaningful use" is a term defined by CMS that describes the use of HIT that furthers the goals of information exchange among health care professionals.

<sup>5</sup> 75 Fed. Reg. 1974 (January 13, 2010).

<sup>6</sup> Id.

<sup>7</sup> Id.

<sup>8</sup> Id.

Act's provisions regarding incentive payments or payment reductions.<sup>9</sup> However, CMS believes it does have some discretion on how best to meet the requirements of the HITECH Act.<sup>10</sup>

My office has received several verbal and written communications from physicians, clinical laboratory health providers, and their representatives, who enthusiastically support the public policy underlying this proposed rule. However, they are concerned that some of the rule's provisions may result in unintended consequences that will have a significant negative economic impact on their professions. Advocacy encourages CMS to utilize its discretion and consider the alternatives/comments suggested by the stakeholders that contacted Advocacy concerning this rule. This will improve the transparency of the rule and result in encouraging health care providers to use EHR, which is consistent with the public policy underlying this regulation and the Act. Advocacy presents CMS with the following comments based on our review of the proposed rule and the concerns brought to our attention by affected stakeholders.

**I. Physicians, through the American Medical Association (AMA), suggest that CMS is moving too aggressively in Stage 1 of the rule and that certain changes are needed that will minimize its potential economic impact on their profession.<sup>11</sup>**

The AMA is particularly concerned that the aggressive implementation requirements of Stage 1 will have an especially negative impact on smaller physicians' practices, increasing the chance that they will not be able to meet Stage 1 incentive program measures. AMA's position is consistent with CMS' concern that some providers may have difficulty meeting the proposed rule's objectives.<sup>12</sup> As such, the AMA recommends that CMS should:

1. Remove the "all or nothing" approach that requires physicians to meet all 25 objectives and measures contained in the proposed rule, as well as the reporting requirements that involve the use of numerators and denominators particularly when it would involve manual data collection by the provider. In its place the AMA recommends that physicians should only have to meet 5 of the rule's 25 objectives and measures.<sup>13</sup>
2. Eliminate objectives and measures that were not germane to EHR adoption (i.e. practice management functions) and others that the AMA feels are not ready for Stage 1 due to the lack of electronic exchange readiness (e.g. reporting immunization data).

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<sup>9</sup> 75 Fed Reg. 1974.

<sup>10</sup> Id., Title XIII of Division A of Act, may be cited as the Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act." The incentive payments for adoption and meaningful use of HIT and qualified EHRs are part of a broader effort under the HITECH Act to accelerate the adoption of HIT and utilization of qualified EHRs.

<sup>11</sup> Because of the short time frame for implementation provided by the HITECH Act for providers to begin using EHR technology, CMS proposes to adopt a phased approach to the requirements outlined in the rule. Stage 1, as provided for in this rule outlines the initial Meaningful Use criteria.

<sup>12</sup> 75 Fed Reg. 1854.

<sup>13</sup> Please refer to the AMA's comment letter to CMS for an outline of the 5 suggested objectives and measures.

3. Revise the proposed definition for hospital-based physicians to broaden eligibility; and only require EPs to attest that they have selected three clinically relevant quality measures, if appropriate, and have downloaded and reviewed the Level 1 (human readable) measure specifications for these measures.
4. Only require EPs to attest that they have selected three clinically relevant quality measures, if appropriate, and have downloaded and reviewed the Level 1 (human readable) measure specifications for these measures.

**II. The College of American Pathologists (CAP) believe that the proposed rule will not adequately address the need for pathologist and laboratory support of MU efforts, and therefore EPs will not be able to comply with many MU requirements that rely on laboratory data.**

The CAP recommends that:

1. Based on the Act, laboratories are not considered EPs and do not qualify for MU incentives. In defining “hospital-based” EP, CMS should take into consideration whether a pathologist has or will be required to contribute funding towards an EHR. Those EPs who are required to contribute funding should not be considered hospital-based, as they are not provided full access to the “facilities and equipment of the hospital including the hospital’s qualified EHR.” This will reduce the possibility that EPs that do contribute funding will suffer a negative economic impact while complying with the spirit of the EHR regulation.
2. Under the Act, a hospital-based EP is an EP who furnishes ninety-percent or more of his or her covered professional services in the calendar year proceeding the payment year in a hospital setting. A setting is considered a hospital setting if it is identified by the codes used in the HIPAA standard transactions that identifies the site of service as an inpatient hospital, outpatient hospital, or emergency room. Because of the ninety-percent threshold, small changes in a pathologist’s service mix could result in his or her meeting the definition of hospital-based in one year and not the next. The proposed rule is silent as to how such providers should be treated. CAP recommends that in the final rule CMS explicitly address the treatment of providers whose status may change from year to year.
3. Under the proposed rule, pathologists, who performed *less* than 90 percent of their professional services in any inpatient or outpatient setting in the prior year would be considered an EP pursuant to §495.100 of the Act, and would be subject to the requirements of the regulation. As such, all EPs would be required to report specified Health IT Functionality Measures that include several functions that pathologists do not usually perform, such as transmitting at least 75 percent of all permissible prescriptions electronically using certified EHR technology, or maintaining active medication and medication lists and allergy lists. Further, all EPs have to report on all Core Measures (i.e., preventive care and screening regarding tobacco use, blood pressure measurement, and drugs to be avoided by the elderly) and a subset of clinical measures that are most appropriate to the

physician's specialty. Given the nature of pathology's scope of practice, none of these Core Measures could be met by pathologists in their day-to-day practice. Additionally, the proposed rule's specified specialty group measures –cardiology, pulmonology, endocrinology, oncology, proceduralist/surgery, primary care, pediatrics, obstetrics and gynecology, neurology, psychiatry, ophthalmology, podiatry, radiology, gastroenterology, and nephrology -- are also not applicable to pathology.

4. To ensure that pathologists, who are currently defined as EPs, are not penalized for the failure to meet measures they have no way of meeting in their normal scope of practice, the CAP recommends that CMS consider pathologists as “non-qualifying” eligible providers, exempt from future MU penalties. The CAP appreciates CMS' acknowledgment that certain physicians will not be able to report any specialty MU measures. However, the CAP believes that the exemptions process should be further defined. Specifically, the College recommends clarifying:
  - 1) key terms necessary to support such an exemption process,
  - 2) the exemption process itself, and
  - 3) how and if exempt physicians would be protected from the financial penalties.
5. Several necessary definitions appear to be omitted from the regulation text. CAP is concerned with the omission of the term “specialist.” This definition is not only necessary to identify what and who a specialist is, but who would qualify for the exemption. In addition, while referenced on several occasions in the preamble of the regulation, the key term “qualified EP” was not clearly defined; nor did CMS formally provide a definition for a “Non-Qualifying EP.”<sup>14</sup> Taken as a whole, the preamble and regulation text seem to define any EP who cannot report any specialty group **and** core measures as essentially a “Non-Qualifying Eligible Provider.” For example, pathologists cannot report any measures, specialty or core. CMS should more clearly define or adopt the above-suggested language for “Non-Qualifying EPs” thereby exempting the non-qualifying physicians from potential financial penalties, starting in 2015, for non-compliance with the MU regulation.

Further, based on the suggested definition, the CAP recommends that CMS create a structured regulatory-defined process for the “Non-Qualifying Eligible Provider,” to “attest” as to the “inapplicability of selecting and/or reporting any specialty group or core measures,” and that pathologists be presumed to be “Non-Qualifying EPs.” Lastly, as long as a specialist's specialty could be identified as pathology (through an analysis of the preponderance of their submitted billing

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<sup>14</sup> CMS seems to imply a definition for Non-Qualifying EP on page 1891 of the rule by requiring EPs to select a specialty group on which to report all applicable cases for each of the measures in the specialty group, or to certify to CMS or the State that they should be exempt from selecting and reporting on a specialty measures group.

codes), they would not need to attest on an individual basis, but could be presumed to be exempt by virtue of being a pathologist.

CAP supports the MU objectives and measures for EPs, eligible hospitals and critical access hospitals contained in §495.6 of the Act, and the incorporation of clinical lab-test results in EHRs. However, CAP observes that this is a rigorous goal that may be difficult for many EPs to meet. As such, the measure may require modification. Therefore, the CAP recommends that the MU requirement that *“at least 50 percent of all clinical lab tests results ordered by the EP ..... are incorporated in certified EHR technology as structured data,”* be modified to clarify its specifications and that CMS consider the effects of the requirement on laboratory competition, particularly given the importance of small laboratories to many rural and underserved communities.

6. CAP recognizes that the proposed MU rule is focused on ordering physicians, particularly primary care doctors and the specialties listed in the rule. However, laboratory data is essential to the achievement of MU by EPs since many measures rely on laboratory data. Specifically, as noted above, labs will need to harmonize their HIT systems (i.e. LIS) with qualified EP EHR systems. Such support and data exchange is supported by the CAP and advances the goal of care coordination, achievable through the bidirectional EHR communication between the “Qualifying” and “Non-Qualifying Eligible Provider.” However, as the Exchange Subcommittee of the ONC HIT Policy Committee recognized in a December 15, 2009, presentation, these interfaces often cost from \$5,000 to \$25,000 each (these numbers are for results systems only; the cost would be considerably higher for Computerized Physician Order Entry interfaces where they are even possible in the ambulatory environment) and the cost (except for low-volume customers) is usually borne by the lab. Therefore, the CAP suggests that CMS, in concert with ONC, identify a funding stream to help underwrite the cost of these interfaces. If no such funding stream is available under the Department’s current legal authority, we recommend that HHS request such authority given the centrality of lab data to the achievement of MU. While the refinement of standards will bring the cost of these interfaces down over time, the market for laboratory services may experience heightened concentration before this cost reduction can occur.
7. The CAP looks forward to working with CMS as it implements the additional stages provided for in this proposed rule. In Stage 2, CMS anticipates requiring that pathology reports be reported as structured data. Pathologists will be essential to the achievement of this MU goal. Pathologists can play an important role in coordinating care with primary care and other clinicians, both inside and outside the hospital setting. However, to do so they need access to complete EHRs that includes the necessary software integration with electronic LIS infrastructures. Pathologists, regardless of practice setting, utilize LIS and anatomic pathology information systems (APIS) that enable them to order and track tests as well as monitor a patient’s disease state. However, by itself the

LIS/APIS does not provide enough information for a pathologist to track a patient's disease state. This information is stored and managed in the EHR. LIS/APIS systems only have the ability to work with a limited subset of patient data. Pathologists need to have direct access to the patient's electronic health record, not indirectly through their LIS/APIS system. Without access to robust EHRs, pathologists cannot access the clinical information necessary to determine appropriate testing, test interpretation and follow-up care.

### **Conclusion**

In summary, Advocacy requests that CMS use its discretion and give consideration to the issues raised by the affected stakeholders herein. Advocacy believes there is value bringing these industry positions to CMS' attention in an attempt to balance industry concerns with the agency's regulatory policy. Advocacy encourages CMS to better analyze the possible effects of this regulation on the affected industries. Advocacy appreciates being given a chance to provide CMS with these comments. If you have any questions or concerns, please do not hesitate to contact me, or Assistant Chief Counsel Linwood Rayford, at (202) 205-6533.

Sincerely yours,

Susan M. Walthall  
Acting Chief Counsel Advocacy

Linwood L. Rayford, III  
Assistant Chief Counsel for Food, Drug  
and Health Affairs

cc: Cass R. Sunstein, Administrator, Office of Information and Regulatory Affairs