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March 2, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0033-P
Comments submitted electronically to <http://www.regulations.gov>

Re: Electronic Health Record Incentive Program

Dear Ms. Frizzera:

On behalf of the Association of Community Cancer Centers (ACCC), I welcome the opportunity to submit comments regarding the proposed rule published on January 13, 2010, specifying the criteria that eligible professionals (EPs) and eligible hospitals must meet to qualify for Medicare and Medicaid incentives as meaningful users of certified electronic health record (EHR) technology. ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC's more than 900 member institutions and organizations treat 60 percent of all U.S. cancer patients when combined with our physician membership.

Definitions

For purposes of Medicare and Medicaid incentive payments, CMS proposes to define the EHR reporting period to be any continuous 90-day period within the first payment year and the entire payment year for all subsequent payment years. We strongly support the proposed 90-day reporting period for the first payment year. However, we believe that this policy should not only apply to 2011 but to any "first" payment year for a given EP or eligible hospital. Such a broadened application of the 90-day reporting period would give EPs and eligible hospitals a better opportunity of qualifying for Medicare and Medicaid EHR incentive payments at the earliest opportunity, which we believe was the Congressional intent. Further, it would acknowledge the many difficulties inherent in acquiring, implementing, and meaningfully using certified EHR technology.

Phased Approach to Meaningful Use

CMS envisions a phased approach to defining meaningful use with three stages but the proposed rule only addresses meaningful use criteria under Stage 1. CMS plans to propose the Stage 2 criteria by the end of 2011 (that is, in time for the 2013 payment year) and the Stage 3 criteria by the end of 2013 (in time for the 2015 payment year). For Stage 2 meaningful use criteria, CMS announces its intent to build up several functionality measures, including requiring: (1) the electronic transmission of CPOE-entered orders; (2) the incorporation of the full array of diagnostic test data into EHR as structured data, including radiology and nuclear medicine tests (rather than only clinical lab test results); (3) increased exchange of electronic and structured data (rather than unstructured data); and (4) actual electronic submission of data, such as syndromic surveillance data, to public health agencies (rather than only the performance of a capability test).

As we note below, ACCC believes that the proposed meaningful use criteria for Stage 1 are far too ambitious and we, therefore, urge CMS to re-examine its plans for Stage 2 and Stage 3. Overall, we believe that CMS needs to have more reasonable expectations with respect to the ability of EPs and eligible hospitals to adopt and meaningfully use certified EHR technology. At this point in time, we believe that it would be premature for us to offer more definitive advice about future meaningful use criteria, except to strongly recommend that decisions about such criteria take into account the availability of certified EHR products and the proportion of EPs and eligible hospitals able to meet the final Stage 1 criteria.

Stage 1 Criteria for Meaningful Use

ACCC has a number of concerns with the proposed Stage 1 meaningful use criteria for EPs and the related measures. Overall, we believe there are too many criteria proposed for Stage 1, that some of the proposed criteria are overly demanding, and that the proposed criteria could possibly mean that relatively few EPs would benefit from the HIT-related stimulus dollars approved under the American Recovery and Reinvestment Act.

Further, there appears to be very little assurance that there will be any certified EHR technology available for EPs to acquire, let alone meaningfully use, by 2011, especially given the delays in issuing the proposed rule that is expected to establish the policies for the certification of HIT.

In terms of our concerns regarding specific, proposed criteria, we consider the first criterion, involving use of computerized provider order entry (CPOE), to be ambitious. We would urge CMS to reduce the percentage of CPOE necessary in Stage 1 to be a meaningful user.

Criterion 4 speaks to e-prescribing and, under Stage 1, would be satisfied if at least 75 percent of all permissible prescriptions written by the EP were transmitted electronically using certified EHR technology. We believe that the proposed "75 percent" threshold may be too ambitious, especially given the current requirement in place to qualify for the electronic prescribing bonus.

Criterion 13 would require EPs to send reminders for preventive/follow-up care to at least 50 percent of all unique patients seen by the EP that are age 50 and older. This strikes us as a criterion developed with primary care physicians in mind and one that may not be appropriate for various specialties, including oncology.

Criterion 17 would require EPs to provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, etc.) upon request, and to do so within 48 hours. First, the 48-hour standard appears to ignore the fact that most EP practices are not open 24 hours a day, 7 days a week. Second, this criterion does not take into account that there might be sound and legitimate reasons for not disclosing particular aspects of a patient's health information, electronically or otherwise. This issue was most recently addressed in an article by Epstein, Korones, and Quill, entitled "Withholding Information from Patients —When Less is More," published in the February 4, 2010, issue of the *New England Journal of Medicine*. The authors of this article address the complexities involved with disclosure of information to patients and, among other things, note the following:

[S]ince information can sometimes increase patients' cognitive and emotional burden and lead to greater confusion rather than clarity, the right to autonomy must be balanced with the ethical obligations to do good for patients (beneficence) and not harm them (nonmaleficence)...The emotional nature of some information that is irrelevant to prognosis or treatment choices may result in unnecessary distress...There may be situations in which it is even appropriate to withhold information of potential significance (or to delay its disclosure)...

We see nothing in the proposed rule to suggest that the preceding complexities relating to the disclosure of information to patients have been taken into account.

In a similar vein, criterion 18 would require EPs to provide patients with timely electronic access to their health information (including lab results, problem list, medication list, allergies) within 96 hours of the information being available to the EP. For Stage 1, this criterion would be satisfied if at least 10 percent of all unique patients seen by the EP had been provided such timely electronic access. However, again, we are concerned that this criterion does not appear to recognize that it is not always appropriate for access to such information as test results to be made electronically under some artificial deadline. For example, we would argue that test results indicating a cancer diagnosis or recurrence should typically be provided to a patient during a face-to-face encounter, which might take longer than 96 hours to arrange. Perhaps the "10 percent" threshold reflects some appreciation for this but we cannot be sure and we would certainly oppose any attempt to mandate 100 percent compliance with some artificial disclosure deadline that could prove harmful or disturbing to patients.

Criterion 19 would require EPs to provide clinical summaries for patients of each office visit, through a personal health record, patient portal on the web site, secure

email, electronic media such as CD or USB fob, or printed copy. Under Stage 1, this criterion would be satisfied if such clinical summaries had been provided to patients for at least 80 percent of all office visits. We believe this requirement is unduly burdensome and should be dropped, at least for purposes of Stage 1. Alternatively, this criterion could apply only when the clinical summary is requested by a patient, not automatically for all office visits.

Finally, we note that the above comments apply to any comparable meaningful use criteria and measures for eligible hospitals.

Clinical Quality Measures

In the proposed rule, CMS states that it does not anticipate having the capacity to electronically accept data on clinical quality measures from EHRs for the 2011 payment year. Thus, EPs and eligible hospitals will be expected to use an attestation methodology to submit summary information to CMS on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology. ACCC urges CMS to reconsider its plan to require the reporting of clinical quality information before the agency is prepared to receive such information from EHRs electronically.

For the 2012 payment year, CMS does expect to be capable of receiving clinical quality measure data from EHRs electronically, and thus EPs and eligible hospitals will be expected to submit such data electronically at that time (unless CMS advises otherwise in a future notice in the *Federal Register*). We believe that language found in section 4101 of the American Recovery and Reinvestment Act could be viewed as giving the Secretary sufficient authority to defer quality reporting until 2012 (or later, if CMS is not prepared to receive quality data electronically by 2012). Further, we believe that the proposed, alternative data generation and attestation requirements would be unduly burdensome for EPs and eligible hospitals.

Medicaid Incentives

Under the proposed definition of eligible “acute care hospital” for purposes of Medicaid EHR incentive payments, CMS estimates that there would be 11 eligible cancer hospitals. We urge CMS to ensure that any definition of “acute care hospital” adopted in the final rule maximizes cancer hospital eligibility since the adoption, implementation, upgrade, and meaningful use of certified EHR technology shows great promise of improving cancer care in the United States by, for example, facilitating coordination of care and providing decision support for clinicians in all settings.

With respect to Medicaid incentive payments, CMS also proposes that EPs would qualify for the same maximum payment in year 1 (\$21,250) whether they had adopted, implemented or upgraded certified EHR technology, or were determined to be meaningful users of such technology. In the proposed rule, CMS explains that this policy is intended to avoid disadvantaging those EPs who have already adopted, implemented, or upgraded certified EHR technology. ACCC supports this approach.

Regulatory Impact Analysis

In the proposed rule, CMS estimates that 47 to 79 percent of EPs could face Medicare penalties in 2015 for failing to meet EHR meaningful use criteria. We find this estimate troubling, and we believe it suggests that the meaningful use criteria envisioned by CMS are overly ambitious. In addition, this helps explain why CMS estimates that so few of the stimulus dollars approved by Congress for Medicare and Medicaid incentive payments would actually reach their intended targets.

We urge CMS to re-examine the proposed criteria, taking into account the comments submitted by ACCC and other stakeholders. We remain hopeful that this will lead to adoption of more reasonable Stage 1 criteria and a heightened sensitivity to the challenges EPs and eligible hospitals face in adopting and meaningfully using certified EHR technology.

I hope the preceding input is helpful. If you have any questions regarding our comments or need more information, please contact Matthew Farber, ACCC's Director of Provider Economics & Public Policy at (301) 984-9496, or at mfarber@accc-cancer.org.

Sincerely,

Matthew Farber, MA
Director, Provider Economics & Public Policy
Association of Community Cancer Centers