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March 15, 2010

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW
Washington, DC 20201

Comments submitted electronically at <http://www.regulations.gov>

Re: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology (RIN 0991-AB58)

Dear Dr. Blumenthal:

We submit these comments on behalf of more than 27,000 oncology practitioners who belong to the American Society of Clinical Oncology (ASCO). Our members represent all oncology disciplines (medical, radiation, and surgical oncology) and subspecialties, and include physicians and health-care professionals participating in approved oncology training programs, oncology nurses, and other practitioners with a predominant interest in oncology. ASCO's members set the standard for patient care worldwide and lead the way in carrying out clinical research aimed at improving the prevention, diagnosis, and treatment of cancer.

ASCO appreciates the opportunity to comment on the Interim Final Rule published on January 13, 2010 specifying the initial set of standards, implementation specifications and certification criteria for electronic health record (EHR) technology, RIN 0991-AB58 (Federal Register Vol. 75, No. 8, p. 2013).

This comment letter addresses issues of concern to our members as they seek to implement certified EHR technology and meet the requirements of meaningful use. In it, we make a number of recommendations based on our comments to

the Centers for Medicare & Medicaid Services (CMS) on its proposed rule on the Medicare and Medicaid EHR Incentive program.

ASCO has made a number of recommendations to CMS on ways to modify the proposed meaningful use objectives. Attached is a copy of our letter to CMS for your reference. We remain hopeful that CMS will respond to our comments by making significant changes to the meaningful use criteria. If that happens, ASCO urges ONC to make corresponding changes to the IFR and publish a final rule on certification criteria and standards that correspond to CMS' final rule on the Medicare and Medicaid EHR Incentive Programs as quickly as possible.

EHR vendors and open source developers will need the maximum amount of lead time to bring certified products to market, which physicians and other eligible professionals (EPs) will then need to implement expeditiously if they hope to meet the tight timeframes for meaningful use.

1. Certification of the generation of HIT functionality measures.

ASCO believes that the certification criteria included in the ONC final rule should explicitly specify that certified EHR technology must be capable of performing the calculations and generating all numeric HIT functionality measures required to demonstrate meaningful use of the technology. CMS states in its NPRM (p. 1903), that the agency does “not believe that demonstration of meaningful use should require use of certified EHR technology beyond the capabilities certified” through the federal certification process.

To reduce reporting burden for EPs, ASCO recommended a number of modifications to the HIT functionality measures proposed by CMS. In many cases, ASCO recommended replacing percentage measures with a simple count of the number of times an EP had done something. For example, rather than demonstrating the 75 percent of permissible prescriptions had been placed through e-prescribing, ASCO recommended that CMS require EPs to report that they had used e-prescribing at least 25 times in a reporting period, consistent with the requirements under the current Medicare e-prescribing incentive program.

However, even if CMS accepts our recommendations, a number of percentage measures will remain, such as the percent of unique patients with a structured problem list, the percent of unique patients with a medication list, and the share of patients who have asked for an electronic copy of their health information and gotten it.

ASCO recommends that ONC include certification criteria for the generation of all measures in the final meaningful use rule from CMS that require a percentage or numeric response. Without automated measure generation, we fear that EHR users will be forced to undertake burdensome, manual activities to prove that they have become meaningful users of electronic technology.

We also believe that certification of measure generation will help ensure the validity and reliability of the reporting from vendor products. Furthermore, CMS asks as part of the meaningful use rule that providers attest to the accuracy of data reported from their EHRs. Knowing that all EHR vendors are meeting the same criteria to generate the measures will

improve providers' confidence in the reporting tools for demonstrating meaningful use embedded in their certified EHRs.

2. Removal of certification criteria for administrative transactions.

ASCO recommended that CMS **remove** two proposed meaningful use objectives:

- **Check insurance eligibility electronically from public and private payers (measure: 80 percent of unique patients)**
- **Submit claims electronically to public and private payers (measure: 80 percent of unique patients)**

These objectives describe administrative activities that are already addressed under the HIPAA Administrative Procedures regulations and overseen by CMS. Physicians are performing these activities through existing claims processing systems, which are almost always integrated with clinical EHR systems, although they are rarely part of an EHR vendor product. Including administrative activities in the meaningful use objectives would result in a requirement that physicians replace existing, functional systems with new products that have been certified through the federal EHR certification process. Such a requirement would create unnecessary work and expense.

ASCO is also concerned that these measures hold physicians accountable for the actions of public and private payers over which they have no control. Small physician offices can have difficulty establishing electronic connectivity with insurers, particularly when their patients have many different forms of coverage. Including this objective risks penalizing physicians for the actions of others, which would be unfair.

We strongly recommend that CMS remove the electronic claims submission and electronic insurance eligibility verification objectives, and recognize alternate electronic claims strategies including parallel software systems.

3. Certification Criteria for Quality Reporting

ASCO has a deep and abiding concern for the quality of cancer care. Over time, ASCO has built a strong infrastructure to develop, test, and collect measures of the quality of cancer care, with 90 measures currently in use. ASCO supports scientific development of quality measures, use of performance measures to assess and improve quality, and the collection of quality data for practice improvement, primarily through its Quality Oncology Practice Initiative (QOPI®).

One of the meaningful use objectives is reporting on clinical quality measures through certified EHR technology. ASCO is concerned that the quality measures are not yet ready for automated reporting. Before such reporting can occur, the measures must be re-specified for an electronic process. After that, the measures must undergo scientific testing to ensure that automated reports maintain measure integrity, and provide valid and reliable results. Field-testing is also needed to ensure that physician offices can enter needed data for quality measurement and calculate the measures without undue burden. Even after all of that testing is completed, EPs will not be able

to attest that the data are accurate, only that the data are accurate to the best of their knowledge and belief.

The certification process, if done correctly, could increase providers' confidence in automated calculations of quality measures by vendor products. Therefore, the certification process should include testing of the validity and reliability of the actual quality measure calculation by vendor products. This can be done through the use of "dummy datasets" that test whether vendor products generate the expected values for various quality metrics or other tests of reliability and validity.

ASCO urges ONC to include specific certification criteria related to the accuracy of quality measure generation in its final rule and specify a process for testing the accuracy and reliability of measurement based on dummy data or an alternative approach. At a minimum, the first certification criterion under quality reporting should read: "1. ACCURATELY calculate and electronically display quality measure results as specified by CMS or states."

In closing, the oncology community is committed to the widespread use of EHRs and believes that it will lead to significant improvements in the care of cancer patients. Our recommendations are targeted at ensuring that certified vendor EHRs support EPs as they adopt and use EHRs.

If you have questions on any of these comments or need more information, please contact Nickol Todd at nickol.todd@asco.org or 571-483-1655.

Sincerely,

A handwritten signature in black ink, appearing to read "Peter Paul Yu". The signature is fluid and cursive, with a long, sweeping tail on the final letter.

Peter Paul Yu, MD
Chair, ASCO EHR Workgroup
Member, ASCO Board of Directors