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March 15, 2010

Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
Attn: CMS-0033-P  
7500 Social Security Blvd  
Baltimore, MD 21244-1850

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

**Ref: CMS-0033-P**

Dear Ms. Frizzera:

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 Notice of Proposed Rule Making (NPRM) entitled Medicare and Medicaid Programs; Electronic Health Record Incentive Program, published by the Centers for Medicare and Medicaid Services (CMS) in the Federal Register on January 13, 2010 [CMS-0033-P]. This program provides much-needed funds to support the transition to an e-enabled health care system. Although clinical oncologists have not yet adopted EHRs in large numbers, they share the Administration's vision of a health care system where widespread use of interoperable EHRs will improve quality by better coordination of care, the exchange of data to eliminate errors, and automated capture of quality measures.

ASCO has demonstrated its commitment to widespread adoption of EHRs by the oncology community by working with members and others to facilitate that process. For example, ASCO has:

- Published a comprehensive Field Guide to assist oncologists in the evaluation, selection and implementation of EHRs with oncology-specific functionality;
- Hosted two EHR Symposia to disseminate the most recent developments in HIT technology and public policy to the oncology community;
- Partnered with the National Cancer Institute (NCI) and others to define the functional requirements of an oncology-specific EHR, which will form the basis for a planned certification effort by CCHIT; and
- Published, in its Journals, a number of articles on the benefits of EHRs to support specific oncology practices, such as safe chemotherapy administration, and participation in clinical research.

As the Administration has well articulated, ASCO understands the important opportunity that adoption of EHRs presents for transforming health care. This comment letter focuses on those aspects of the NPRM that touch oncology directly.

## **Background**

The American Recovery and Reinvestment Act (ARRA) authorized Medicare and Medicaid incentive payments to physicians and hospitals that are “meaningful users” of certified electronic health records (EHRs). For physicians and other “eligible professionals” (collectively referred to as “EPs”), the incentive programs begin on January 1, 2011.

For EPs, a total of \$44,000 in Medicare payment incentives can be earned over five years. Physicians that cannot demonstrate meaningful use of EHRs face financial penalties beginning in 2015; the penalties increase through 2017. The Medicaid incentive program provides greater incentives (maximum of \$63,750 over 6 years) and includes no penalties. To qualify, however, physicians must care for a patient population that includes at least 30 percent of those patients covered by Medicaid.

## **Definition of Meaningful Use**

The proposed rule defines meaningful use of certified EHR technology through three two-year stages, with the expectation that the requirements will increase over time. The NPRM further specifies that for Stage 1, to be considered a “meaningful user” and receive incentive payments, eligible professionals must meet 25 EHR and health information exchange (HIE) objectives. These objectives include, for example, maintaining problem and medication lists, using e-prescribing, providing a clinical summary for each visit, and giving patients electronic access to their health information. CMS will specify the requirements for both Stages 2 and 3 in future regulations, but the NPRM indicates that the later stages will include significant increases in the scope and complexity of the EHR.

CMS proposes that, to be eligible for the incentive payments, EPs must:

- Use an EHR certified through a yet-to-be-established federal process;
- Meet all 25 objectives of meaningful use;

- Report on all 24 “HIT Functionality Measures” of meaningful use that often require meeting specific thresholds of use; and
- Report quality data on 3 core measures and a set of specialty-specific measures (which, for oncology, include 6 proposed measures).

As currently proposed, the rule takes an “all-or-nothing” approach, which means that if a provider fails to meet even one objective, missing a threshold by a small amount, or making a mistake in quality reporting, the provider would not receive an incentive. We propose a gradual progression towards full compliance of the various stages. For example, an EP would meet 80% of the Stage I meaningful use requirements in 2011 and 2012, and in 2013 100% of Stage I and 80% of Stage II.

For clinical oncologists and other health professionals just beginning the process of EHR adoption, we believe that, taken together, these objectives are too ambitious. We also believe that the “all-or-nothing” approach discriminates in particular against small and medium-sized physician practices without the resources and infrastructure to implement complex clinical information systems. We are particularly concerned that setting the bar too high will discourage oncologists and other EPs from adopting EHRs at all.

We are concerned that the aggressive set of requirements and timeframe presented for the EHR incentive program will lead to rushed implementations that risk failure and could pose patient safety concerns, particularly for oncology, which involves complex workflows with highly toxic medications. There is growing literature on the unintended adverse consequences of EHRs, including errors accidentally imbedded in e-prescribing and CPOE tools.<sup>1</sup> A careful approach to implementation, that includes ongoing monitoring for unintended consequences, is needed.

We also note that physicians failing to adopt EHRs by 2015 will be subject to significant payment cuts. As will be discussed further below, few EHRs available today support the unique needs of oncologists, and those that are available have not been certified. Those systems that support oncology will need more time to meet certification requirements. We do not believe that oncologists choosing to wait for certified products that meet their needs should be penalized or receive less than the full incentive payment.

**We recommend, therefore, that to prevent potentially calamitous drug order entry errors with high risk medications, CMS apply standards for successful use of EHR for chemotherapy that preserve essential patient safeguards such as pharmacy re-verification prior to drug entry. CMS provide a more gradual transition to achieving meaningful use, whereby physicians are expected to achieve a percentage of the proposed meaningful use objectives in Phase I.**

This approach would allow physicians to take a more incremental approach to adoption and give them flexibility in deciding how best to increase the functionality and information sharing capabilities of their EHRs. **We also believe that the punitive approach taken in ARRA**

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<sup>1</sup> DF Sittig; DC Classen. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *JAMA*. 2010; 303(5):450-451.

**should be modified through legislative action to eliminate the payment reductions in 2015 and later years.**

### **Concerns with Specific Objectives and Measures**

**1. CPOE.** CMS proposes to require that EPs use CPOE for 80 percent of “all” orders. In recognition of the limited information exchange infrastructure available to physicians, CMS does not propose to require actual transmission of orders other than medications to another party to fill. They could, instead, be printed and given to the patient. We appreciate that recognition.

We appreciate the intent behind this requirement and believe that CPOE is an important automated clinical tool that conveys safety and efficiency benefits. However, we are concerned that physicians just adopting EHRs will have difficulty achieving this objective. And, since the actual transmission of orders is not yet possible, we are not certain why this objective is required in 2011. **ASCO believes that, in Phase I, CMS should focus on achieving more widespread use of e-prescribing. CPOE is more appropriate for Phase 2, when greater information exchange is possible. There is some value in recording the ordering of tests and consults, even if that order cannot yet be transmitted by most systems, in that it documents a part of the plan of action. However, since it is not a functionality that most health systems can take advantage of, a much lower threshold is appropriate, perhaps 20% so that EP begin to get comfortable with a future new workflow.**

We are also very concerned with the proposed CPOE measure. Although the NPRM provides examples of what CMS means by “orders” (mentioning, for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services), no precise definition is given. **We recommend that CMS provide a specific definition of orders that is limited to consultations, lab tests, and imaging studies.**

We also note that the 80 percent measure is impossible to calculate without manual chart review to calculate the denominator of orders placed through both CPOE and other means. And, given that the proposed measure applies to all patients, physicians would be forced to conduct reviews of all charts to determine the share of all orders placed through CPOE. In the NPRM, CMS discusses an alternative approach, which would require a set minimum number of orders entered through CPOE (such as 50) as the metric. EPs that met the minimum level of reporting would be assumed to continue their use of CPOE. That approach will provide assurance that the EP is using CPOE without requiring burdensome chart reviews.

**If CMS chooses to keep the CPOE objective, we strongly recommend the alternative metric of the number of orders entered through CPOE, with a minimum requirement of 50 orders.**

**2. Drug-drug, drug-allergy, drug-formulary checks.** Drug-drug and drug-allergy checks are an important safety and quality benefit of using an EHR and should be maintained. We are concerned, however, about the drug-formulary checks. In the context of ambulatory care, EPs see patients with many different types of insurance and drug coverage. It may not be possible, or even advisable, for a physician to maintain real-time electronic connections to the formularies of

all insurance plans to which his or her patients belong. Indeed, some plans may not provide electronic access to their formularies. **For this reason, we ask CMS to clarify that the measure requires only that the drug-formulary check functionality is enabled, and not that it is used for all patients.**

**3. e-Prescribing.** Oncologists in clinical practice routinely prescribe narcotics and other drugs that the DEA considers non-permissible for e-prescribing. Many cancer patients receive multiple prescriptions at a single visit, including both permissible and non-permissible medications. This situation creates a need for dual processes within the oncology office, where some prescriptions can be transmitted electronically, whereas others must be printed and given to the patient. This creates workflow issues for the office and inconvenience to the patient. ASCO members who have become routine e-prescribers report that this is a significant issue for them. **We encourage CMS to work closely with the DEA to provide a methodology for e-prescribing narcotics and other classified drugs as quickly as possible.**

As with CPOE, the proposed e-prescribing measure would require burdensome manual chart review to determine the percent of permissible prescriptions transmitted electronically using the certified EHR technology. The burden is likely greater for oncologists than most physicians in community practice due to the need to distinguish between permissible and non-permissible prescriptions. In addition, ASCO members report that the 75 percent threshold, while laudable, is not possible to achieve given current levels of interoperability. Patients often prefer pharmacies that do not currently accept electronic transmission of prescriptions; also, some patients simply have a preference for written prescriptions, for a variety of reasons.

Under the current e-prescribing incentive program, CMS determines physician use of e-prescribing by requiring that a certain number of prescriptions be transmitted electronically and reported on claims (currently 25). This approach has been working and is the result of modifications made to reduce reporting burden.

**Therefore, we recommend that CMS continue to measure physician use of e-prescribing by requiring a minimum count of claims on which the EP has reported transmitting prescriptions electronically.**

**4. Clinical-lab tests incorporated into the EHR as structured data (Measure: at least 50 percent of lab data is incorporated into the EHR as structured data).** Including the results of clinical lab tests in the EHR requires establishing an interface with reference labs that is expensive and can be outside the control of the physician. General experience indicates that each interface costs at least \$10,000 and sometimes higher by an order of magnitude, and each requires considerable time and effort to establish. Physicians in smaller offices have noted that the lab companies often put them “at the end of the queue” for creating electronic links. In addition, as currently constructed, the measure for this objective would require manual review of 100 percent of charts and extensive effort to calculate.

**In the face of these difficulties, we recommend that CMS change the measure for this objective to read: At least 50 percent of clinical-lab test results incorporated into the EHR are recorded using structured data.**

This approach will allow the measure to be calculated directly from the EHR. In addition, it will not penalize physicians who work with multiple labs that may not undertake the establishment of interfaces in a timely manner.

**5. Send reminders to patients per patient preference for preventive/ follow up care (measure: Reminder sent to at least 50% of all unique patients seen by the EP that are age 50 or over).** This objective is not applicable to oncology, as clinical oncology professionals do not generally conduct preventive care. Furthermore, screening for unrecognized disease is inappropriate for patients with advanced malignancy. **Therefore, we recommend that CMS apply this objective only to primary care physicians, or modify the requirement so that CMS advocates for preventive and follow up care to be offered to those for whom it is medically appropriate. Within an oncology practice, for example, this might be confined to patients who have completed a course of adjuvant treatment.**

If CMS chooses to keep this objective, we recommend changing the measure to limit the reporting burden. As currently specified, measurement would require review of all patient charts to first identify those patients over 50, then count the number of reminders sent. **We strongly recommend that CMS change this measure to a count of patients who have received reminders for follow-up care, with a minimum requirement of 50 patients.**

**6. Clinical decision support.** Clinical decision support is a key electronic tool for improving the safety and quality of patient care. We strongly support the use of clinical decision support, and are working as a specialty society to define best practices for oncology that can be the basis for clinical decision support tools. We are concerned, however, with the ambiguity of the requirement laid out in the proposed rule and the implication that CMS will determine whether a particular decision rule is relevant to a given specialty.

The measure reads: “Implement 5 clinical decision support rules relevant to the clinical quality metrics the EP is responsible for as described [elsewhere in] the proposed rule.” We do not believe that CMS should decide a priori what decision rules are of benefit to a given provider, or make an after-the-fact judgment on the applicability of a decision rule that has been chosen.

**We recommend that CMS change the measure to read “Implement 5 clinical decision support rules relevant to your practice.”**

**7. Electronic claims submission and insurance eligibility verification.** These objectives describe administrative activities that are already addressed under the HIPAA Administrative Procedures regulations and overseen by CMS. Physicians already face a financial penalty for submitting paper claims. Duplicative regulation of these functions under the EHR Incentive Program is unnecessary and could result in considerable confusion.

In addition, 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 during Stage I.**

**8. Provide patients with an electronic copy of their health information (Measure: At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours).** This objective goes beyond the legal requirements for sharing of health information and should be modified. The ARRA amended the HIPAA statute to require that providers give patients an electronic copy of health information “maintained in electronic form.” During the transition from paper to electronic charts, it is not reasonable to ask for electronic copies of information that is not held in electronic form, as that would necessitate transforming paper records into electronic records. In addition, the time period required (48 hours) is too short and more prescriptive than HIPAA requirements. Clinicians must review information in the medical record, ensure that they have received all test results, and verify that they have discussed sensitive results with the patient before release, per CLIA and state laws. In addition, office staff must be available to receive and fulfill requests. For physicians in both small offices and clinic settings, staff may not be available on weekends and holidays, making it impossible to meet the 48-hour timeframe.

**ASCO recommends that CMS revise this objective to require provision of an electronic copy of health information “maintained in electronic form,” in a manner consistent with the new ARRA provisions on sharing electronic medical records.**

**9. Provide patients with timely electronic access to their health information (measure: At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information).** ASCO believes strongly in engaging and informing patients about their care. However, we believe that this objective will be extremely difficult for physicians just adopting EHRs to achieve. EHR adoption requires major changes to workflow, and must be installed for some time before a base of patient data can be built. This requirement implies establishing a patient portal that is always up to date, which is almost always a second-tier capability. Patient portals are an added capital and maintenance expense that many small practices will have trouble covering.

**ASCO recommends that CMS defer this objective to Stage 2.**

**10. Provide clinical summaries for patients for each office visit (measure: clinical summaries are provided for at least 80% of all office visits).**

This objective implies a tremendous change in physician office workflow that should be studied carefully before it is required. To meet this objective, physicians will have to complete their documentation of an office visit while the patient is in the exam room. They will also need to develop a process to ensure that the summary is almost immediately copied electronically or printed and shared with the patient. **Given these uncertainties, we recommend that CMS defer this objective to Stage 2. In the meantime, CMS and ONC should work to better define the contents of a clinical summary, including specialty-specific documents, and study the impact of this requirement on physician office workflows. In principle, items that require a major workflow change should be allowed to be implemented more slowly.**

**11. Provide summary care record for each transition of care and referral.** ASCO has developed tools to document treatment plans and summaries that may form the basis of a summary care record. We are currently working with oncology EHR vendors and CCHIT to have these products imbedded into EHRs. We are also working with CCHIT to develop an oncology-specific module for comprehensive EHR certifications. That will not, however, happen before January 1, 2011. **ASCO and its volunteers have committed considerable resources to develop these tools, which we believe should be considered as meeting this objective. We propose that 50% of episodes of chemotherapy have a treatment plan and summary.**

**12. Automated public health reporting.** The two objectives on providing data to public health (immunization registries and syndromic surveillance data) are not relevant to oncology. Although oncologists verify immunization status, and make recommendations for needed immunizations, they do not consider tracking immunizations to be a core oncology function. Requiring this of oncologists and other specialists could result in overlapping reports on immunization status, leading to confusion. **Therefore, we recommend that these objectives apply only to primary care physicians.**

### **Measurement and Reporting Burden**

As noted in many of the specific comments above, ASCO is very concerned with the burden of reporting the HIT functionality measures proposed by CMS. In our view, the impact analysis included in the NPRM vastly underestimates the likely burden of reporting.

We are also concerned that the NPRM does not include any mention of a testing or pilot process, whereby EPs can submit their data and receive feedback on whether the data are complete and submitted in the appropriate manner. Experience with the Physicians Quality Reporting Initiative (PQRI) program suggests that this kind of testing is essential. Otherwise, EPs risk undertaking a tremendous amount of work to comply with the requirements, yet fail to receive incentive payments due to reporting errors that may otherwise have been quite easily rectified.

To lessen the reporting burden and increase the likelihood of successful implementation, we make the following recommendations.

**1. No measures should include denominators that require calculation across paper and**

electronic systems.

**2. To lessen the reporting burden and ensure consistency in reporting across EPs, EHRs must be able to generate all measures, and particularly those that CMS included in “Set A” of its impact analysis. We recommend the inclusion of the calculation and reporting of HIT Functionality Measures in the certification criteria adopted by ONC. ASCO will provide separate comment to ONC on this issue.**

**3. CMS must establish a process for its contractors to receive reports from EPs and provide feedback on the completeness of reporting and whether it has been done in accordance with requirements. EPs should then be given the opportunity to correct their submissions to provide missing data or comply with reporting requirements.**

### **Certification Concerns**

ASCO is very concerned that the lack of a certification process will delay timely implementation of EHRs by oncologist. ASCO is further concerned that few EHR products currently available meet the needs of oncologists.

ARRA requires the use of EHR technology certified through a federally approved certification process. However, rule-making on the federal process has yet to begin (ONC has not yet released its NPRM). In general, the rule-making process takes a minimum of 180 days between release of a proposed rule and the effective date of a final rule. In the case of certification, a number of additional steps are needed after a rule is effective and before certified products become available: the federal process to accredit certification agencies must be established; certification agencies must apply and be accredited; and vendors must go through the process of revising their products and getting them certified. ONC estimates that “it will generally take 6 to 18 months for commercial vendors and open source developers...to prepare for testing and certification.” (Federal Register Vol. 75, No. 8, p. 2041)

It seems highly unlikely that, given this process, a pool of certified systems will be available before the start of the EHR incentive program on January 1, 2011. In addition, EPs may, rightfully, delay making IT investments until products have received federal certification, putting them behind the curve even at the outset of the incentive program.

For oncology, the situation is even more complicated. To achieve the best outcomes, medical specialties, including oncology, require EHRs that meet their needs. Currently, however, oncologists are challenged by the limited availability of products tailored to support their unique needs. For example, oncologists must document the type and stage of cancer, use computer physician order entry (CPOE) systems designed to support complex chemotherapy order sets that include supportive care drugs, have access to oncology-specific flow sheets, and document chemotherapy treatments that often involve highly toxic medications. The relatively small size of oncology within a large institution’s functional needs, which include medical-surgical departments, pediatrics, emergency departments and operating rooms, limits vendor interest in developing oncology-specific products.

Furthermore, of the handful of niche EHR vendors that have oncology-specific products (identified in a vendor directory at [www.asco.org/ehr](http://www.asco.org/ehr)), none are currently certified by CCHIT. We are very pleased to report that ASCO has successfully petitioned CCHIT to include oncology as a modular certification. ASCO volunteers will be working with CCHIT to inform vendors of the needs of oncology professionals and ensure that products seeking to meet their needs do so reliably. However, the CCHIT oncology certification project is currently in its planning stages and is not likely to result in actual certifications until, at the earliest, mid-year 2011.

Previous federal efforts suggest that new systems are not easily established in short order. For example, the process of enumerating National Provider Identifiers (NPIs) took longer than the initial two years that was planned and was delayed twice, for a total of 12 additional months. The process also included a transition phase, during which providers were allowed to use either their legacy number or the NPI. Other regulatory initiatives requiring information system changes have included considerable transition periods. For example, the use of ICD-10 for claims submission was first proposed by the National Committee on Vital and Health Statistics in November 2003. CMS issued proposed regulations on adoption of ICD-10 in August 2008 and a final rule in January 2009. The final rule provides almost four years of transition time, calling for ICD-10 to be in use by October 1, 2013.

**Given this information, EPs that are early adopters of EHR technology should not be penalized for having systems in place that haven't been given sufficient transition time to upgrade their software to meet the meaningful use criteria. ASCO strongly recommends that CMS provides additional time for EPs that have existing EHR systems to meet the meaningful use requirements.**

### **Hospital-Based Professionals**

Under ARRA, hospital-based professionals are not eligible for the Medicare and Medicaid EHR incentive payments (or penalties in later years). The law defines hospital-based professionals as those who furnish substantially all of their services in a hospital setting (whether inpatient or outpatient) using the facilities and equipment, including the qualified EHR, of the hospital. ASCO believes that the intent of this provision was to prevent “double-dipping” by professionals who use inpatient hospital systems.

In the NPRM, CMS proposes to identify hospital-based eligible professionals as those who furnish at least 90 percent of their services in the inpatient hospital, outpatient hospital, or emergency department setting. CMS also proposed to define outpatient hospital settings to include all types of outpatient care settings in the main provider, on-campus and off-campus provider-based departments of the hospital, and entities having provider-based status. To identify services furnished in a hospital setting, CMS proposes to use the following “place of service” codes on the professional’s claim: 21, Inpatient Hospital; 22, Outpatient Hospital, and 23, Emergency Room, Hospital.

For the Medicare EHR incentive program, CMS proposes to determine hospital-based status by annually assessing an eligible professional’s Medicare claims from the prior year. In the proposed rule, the agency estimates that between 27 and 32 percent of eligible professionals

would be considered hospital-based for Medicare incentive payment purposes. Thus, approximately 30 percent of otherwise eligible professionals would be excluded from the Medicare EHR incentive program.

ASCO is concerned that this broad definition of hospital-based professional will unnecessarily include many professionals offering clinic-based services to Medicare beneficiaries, including many oncologists. As a result, oncologists providing ambulatory services in hospital outpatient departments may be less likely to adopt EHRs, resulting in limited ability to use electronic tools for care coordination and information exchange.

**ASCO recommends that CMS take the following operational steps to ensure that no professionals are unfairly prevented from participating in the EHR incentive program:**

1. CMS has an obligation to make its determination of which professionals are provider-based before the start of the payment year and communicate its determination to all those it has identified as hospital-based. Otherwise, professionals may expend extensive resources in registering for the program and complying with the significant reporting requirements, only to find out later that they were not eligible in the first place.
2. CMS has an obligation to give professionals an opportunity to review the agency's determinations on eligibility and challenge those they believe are in error.
3. CMS has an obligation to provide professionals with a mechanism to petition for a change in their hospital-based status when there is a material change in their organizational affiliations. For example, a physician leaving a hospitalist practice to open a private practice should be able to petition to be eligible for the EHR incentive program in the next payment year. Under the current proposal, professionals would need to wait a year (or even up to 18 months) until their claims data indicate that they are no longer hospital-based.

**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®). ASCO strongly supports CMS' decision to consider proposed quality metrics from a greater number of organizations. The meaningful use of health information technology will necessitate changes in the work process that can lead to improved efficiencies and outcomes. Quality improvement metrics should recognize that complex diseases require multidisciplinary care involving coordination of care delivery components. While each one of these components may not directly lead to improved outcomes, each may be essential to achieving optimal patient outcomes.

One of the meaningful use objectives is reporting on clinical quality measures through certified EHR technology. CMS proposes that EPs report on both a set of three core measures and a set of specialty-specific measures.

The proposed core measures (Table 4, p. 1890) are:

- PQRI 114/NQF 0028 – Preventive care and screening: Inquiry regarding tobacco use
- NQF 0013 – Blood pressure measurement
- NQF 0022 – Drugs to be avoided in the elderly (a. Patients who receive at least one drug to be avoided; b. Patients who receive at least two different drugs to be avoided).

The proposed core measures are primarily primary care measures. However, oncologists generally perform the actions implied by the first two core measures. There are specialty-specific reasons that NQF 0022 may be clinically inappropriate to cancer patients. ASCO is more concerned about the third core measure – drugs to be avoided in the elderly. Due to the unique nature of cancer care, some drugs that would otherwise be avoided in this population are indicated for oncology patients to mitigate the adverse effects of chemotherapy. Therefore, this measure, while reportable, is of questionable value in understanding the quality of oncology care.

The proposed measures for oncology are:

**Measure Group: Oncology (p. 1892)**

<b>Measure Number</b>	<b>Clinical Quality Measure Title &amp; Description</b>
PQRI 71 NQF 0387	<b>Title:</b> Breast Cancer: Hormonal Therapy for Stage ICIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
PQRI 72 NQF 0385	<b>Title:</b> Colon Cancer: Chemotherapy for Stage III Colon Cancer Patients
PQRI 102 NQF 0389	<b>Title:</b> Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low-Risk Prostate Cancer Patients
PQRI 112 NQF 0031	<b>Title:</b> Preventive Care and Screening: Screening Mammography
PQRI 113 NQF 0034	<b>Title:</b> Preventive Care and Screening: Colorectal Cancer Screening
NQF 0032	<b>Title:</b> Cervical Cancer Screening

Of these six measures, three are more appropriate to primary care than oncology:

- Screening mammography (PQRI 112)
- Colorectal cancer screening (PQRI 113)
- Cervical cancer screening (NQF 0032)

In general, patients are referred to oncologists after a cancer diagnosis has been confirmed, not for routine cancer screenings.

**ASCO recommends that CMS drop the three cancer screening measures from the oncology quality measure set. We propose that CMS blend the preventive care measure with the notification measure so that the end-of-treatment care plan generated by the EHR for patients after adjuvant breast or colon cancer treatment satisfy one or both of the requirements.**

The other three measures are appropriate to clinical oncology, although it should be noted that not all oncologists will see patients with each type of cancer measured (breast, colon, and prostate). Additionally, patients with low-risk prostate cancer are also treated by urologists, so this measure is not unique to oncology.

ASCO is concerned that the quality measures are not yet ready for automated reporting. In the NPRM, CMS proposes attestation of quality measures in 2011 and electronic reporting in 2012. EPs would attest that the:

- measure data were generated as output of a certified EHR;
- data (including numerators, denominators, and exclusions for each of the applicable measures) are accurate; and
- data for each measure include all patients to whom it applies.

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**. If a vendor product is flawed and miscalculates a quality measure, EPs are not likely to identify the problem and should not have their incentive payments put at risk for a vendor error.

**ASCO recommends that CMS delay quality reporting requirements until at least 2012 to allow the required measures to be re-specified for automated reporting, tested, and incorporated into vendor products.**

**Registry reporting.** Looking forward, CMS proposes three methods for direct electronic submission of quality data from the EHR in 2012 and later years, including: directly to a CMS-designated portal (primary method); through a Health Information Exchange/Health Information Organization; or through a registry. For HIE and registry reporting, however, the data originally submitted by EP or eligible hospital must be generated from a certified EHR.

ASCO is concerned that the proposed rule is too restrictive in the use of registries to report quality data. ASCO has devoted considerable resources to developing QOPI, which is designed

to promote both quality measurement and practice improvement. Currently, more than 735 oncology practice sites are registered for QOPI. QOPI reports allow oncologists to systematically assess the quality of care they provide and engage in data-driven practice improvement activities. In early 2010, ASCO through the Institute for Clinical Effectiveness, LLC, began to offer formal certification of ambulatory practice sites based on performance on subset of QOPI measures and published site assessment standards. Experience by PQRI demonstrates that, in general, registry reporting is more successful than reporting by individual physician practices.

QOPI has a rich catalogue of 90 measures that cover a diverse range of cancer diagnoses and domains of high quality cancer care. Participating practices submit their data to a secure, central database and receive performance reports which can be compared to their own past performance and to the performance of the national aggregate data for all participating practices. ASCO is working with EHR vendors to support electronic QOPI participation and expects to begin testing the electronic transmission of data in 2010.

**ASCO believes that registries have an important role to play in promoting practice improvement as well as quality reporting. If physicians choose to use a registry for reporting quality data to CMS, ASCO believes they should be able to do so, even when the data are not generated as output of an EHR.**

### **Program Administration**

CMS provides little information on how it plans to operate the EHR Incentive Program. To facilitate compliance, ASCO requests that CMS provide additional information on its operational plans, including:

- The process to apply for meaningful use payments;
- The process to submit meaningful use data;
- The information needed for attestation; and
- The expected timeframe and process for payments.

In addition, we recommend that CMS instate for the Medicare program all of the appeals processes it proposes to require of state Medicaid programs in 495.370 (Appeals process for a Medicaid provider receiving electronic health record incentive payments.) Specifically, to ensure that the program is implemented fairly, providers must have a process to appeal and provide documentation to support the appeal of:

- (1) Incentive payments
- (2) Incentive payment amounts
- (3) Provider eligibility determinations

ASCO is concerned by CMS's proposal that eligible providers maintain evidence of qualification to receive incentive payments for 10 years after the date they register for the incentive program. A retention period of 10 years is too long and would result in significant difficulties in ensuring adequate systems to store and retrieve the information, particularly as technology changes over time. In addition, physicians who change practices may find it challenging to ensure that they have access to documentation from previous locations. Electronic retention for medical records is governed by state laws and is generally five years.

**ASCO recommends that CMS shorten the retention period for evidence of qualification to receive incentive payments to five years.**

Finally, given that this is a new and highly complex program, ASCO urges CMS to provide vigorous and well-planned contractor and provider education, so as to maximize the likelihood of success. Recent experiences with implementations of the e-prescribing incentive program and PQRI highlight the difficulties associated with beginning new programs.

In closing, ASCO appreciates the opportunity to comment on the proposed regulations. The oncology community is committed to the widespread use of EHRs and believes that, with appropriate clinical implementation, they will lead to significant improvements in the care of cancer patients. Our recommendations are targeted at ensuring a smooth adoption process that incentivizes all physicians to adopt and use EHRs.

If you have any questions or need further information, please contact Nickol Todd at [nickol.todd@asco.org](mailto:nickol.todd@asco.org) or 571-483-1655.

Sincerely,

A handwritten signature in cursive script, appearing to read "Peter Paul Yu".

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