

May 7, 2012

Marilyn Tavenner  
Centers for Medicare & Medicaid Services,  
Department of Health and Human Services,  
Attention: CMS-0044-P,  
P.O. Box 8013,  
Baltimore, MD 21244-8013

Re: File Code CMS-0044-P

Dear Ms. Tavenner:

The American Association for Cancer Research (AACR) is pleased to offer comments regarding the draft Stage 2 Meaningful Use criteria issued by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator (ONC). The AACR is the world's oldest and largest professional organization dedicated to advancing cancer research. The membership includes 33,000 laboratory, translational and clinical researchers; health care professionals; and cancer survivors and advocates in the United States and more than 90 other countries.

As a research organization whose mission is to prevent and cure cancer through research, education and collaboration, the AACR values the use of appropriate technologies to create efficiencies in the pursuit of research and improvement in patient care. In an era where digital devices permeate many aspects of daily life, our healthcare system lags significantly behind in the digital revolution. Electronic health records (EHRs) have been available for years, but their prevalence had hovered in the single digits before the Meaningful Use program. The AACR applauds CMS' efforts to promote meaningful use of electronic technologies that have the capability to provide valuable data that can be used to speed new innovations into our healthcare system through a better understanding of diseases.

### **Data Reuse Is as Important as Primary Data Use**

The AACR would like to use our comments to bring attention to the importance of the meaningful use criteria as they relate to secondary data use in research. While many other organizations will undoubtedly focus on the primary data use requirements embodied in the Stage 2 criteria (e.g., the particular quality measures chosen and/or thresholds for quality or reporting metrics), the AACR feels that the most significant outcome of the meaningful use criteria is the digitization of standardized patient health data, along with the infrastructure to share and analyze these data. This paradigm shift, more than any one data field or quality metric contained in the criteria, is the key to creating a knowledge-driven healthcare enterprise, adding rigor to how current therapies are applied as well as how new therapies are discovered. Data use and reuse will be successful only if the appropriate data and standards are incorporated into the current criteria, which the AACR feels that CMS has largely achieved.

In our comments, we discuss the required data elements and functionality first, commenting on a subset of the 22 core and menu data elements and functionalities proposed in the criteria. These have been selected based on their importance to cancer research and the comments are grouped according to themes. We then follow with a discussion of the quality metrics and the importance of data handling capabilities.

## **Data Elements and Functionality**

### **Patient characteristics**

*Record the following demographics (EP, Hosp, Required)*

- Preferred Language
- Gender
- Race
- Ethnicity
- Date of birth

*Record and chart changes in vital signs: (EP, Hosp, Required)*

- Height
- Weight
- Blood pressure (age 3 and over)
- Calculate and display BMI
- Plot and display growth chart for patients 0-20 years, including BMI

*Record patient family health history as structured data (EP, Hosp, Optional)*

*Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach (EP, Hosp, Required)*

The AACR fully supports the collection of datasets rich in individual characteristics that include patient-reported demographic data, co-morbid conditions, vital signs, and family health history. Disease exists not in isolation, but rather within individuals who each have unique characteristics that affect susceptibility and ability to respond to a disease. Elucidating these causal or confounding factors around a disease requires that as much as possible is known about the biological and environmental status of an individual with a given disease. The data and functionality requirements listed above enable the study of subgroups of patients whose shared characteristics may lead to tailored treatment plans that differ from the general population.

### **Smoking**

*Record smoking status for patients 13 years old or older (EP, Hosp, Required)*

The AACR is deeply concerned about tobacco use, as tobacco use causes no less than 18 different types of cancer and is the largest preventable cause of cancer. The collection of smoking status is key to understanding the full scope of the problem, including the impact of continued tobacco use during patient treatment. The AACR therefore strongly supports the collection of smoking status. The AACR further supports the collection of all types of tobacco exposure; however, we recognize the difficulty in collecting this information with the lack of current standards. The scientific community is working toward such standards, and more complete measures of tobacco exposure should be incorporated into meaningful use criteria as soon as standards are developed.

The AACR believes that cessation intervention should be tightly coupled with tobacco use assessment. Quitting tobacco use at any time offers a benefit, and new research shows that quitting even after a cancer diagnosis can significantly improve treatment efficacy and patient outcomes. The AACR's support of screening and intervention is further discussed below in reference to reporting quality measures.

### **Best Practices**

*Use clinical decision support to improve performance on high priority health conditions (EP, Hosp, Required)*

*Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care (EP, Required)*

The goal of medical research is to identify improved interventions that will result in better health for patients. Studies have shown, however, that after research findings point to improved practices, the dissemination of this knowledge is often slow and inconsistent across geographic regions, practice type (academic versus community), and medical specialty. The AACR therefore encourages the use of decision support tools within EHR systems to improve dissemination of proven practices and the latest research findings.

The same EHR functionalities that can provide decision support and identify specific subpopulations of patients for follow up can also be useful for other clinical and research purposes. Clinical trials are one of the last steps in taking an intervention from a laboratory discovery to an accepted clinical practice. This critical step confirms an intervention's safety and efficacy in actual patients; however, recruiting clinical trial participants is very difficult, resulting in only 3% to 5% of adult cancer patients taking part in clinical trials. The difficulty in recruitment results in slower research progress, higher costs, and occasional termination of trials due to a lack of enrollment. While legal and ethical frameworks are also required for recruitment, EHRs have the potential to facilitate markedly improved trial participation through targeted identification of patients that meet eligibility requirements based on their age, disease, genetic profile, etc., combined with automated prompts to physicians making them aware of a patient's eligibility for a given trial and reminding them to invite these patients to enroll in a trial.

The emerging fields of personalized medicine (PM) and patient-centered outcomes research (PCOR) focus on the delivery of the best care to each individual, recognizing that the optimal care may vary from individual to individual based on a variety of patient characteristics ranging from genetic profiles to comorbidities. With the transition toward greater personalization comes increased complexity in decision algorithms that help determine optimal treatments. Like clinical trial recruitment, the practice of PM and PCOR will be facilitated by EHR systems that identify relevant patient information and incorporate it into decision support for personalized care plans.

### **Data standardization**

*Incorporate clinical lab-test results into EHR as structured data (EP, Hosp, Required)*

*Incorporate imaging results and information into Certified EHR Technology (EP, Hosp, Optional)*

The AACR supports developing and requiring the adoption of standardized computable formats for the storage of all relevant clinical data. Research using large datasets to search for causal or correlated relationships holds great promise to help uncover complex health interactions that have proven elusive to find using traditional models that attempt to tie a single cause to a single effect. This type of research requires both a large quantity of data and standardized formats that enable comparison of aggregate data across multiple sources. While the quantity of medical data stored in a digital format is growing exponentially, and will continue to do so regardless of federal policy, the standardization of this data is currently a major obstacle to its utility to researchers.

The AACR also endorses the storage of all relevant clinical data within a patient's EHR. The organization of clinical data around the patient, rather than around clinical departments, will facilitate a more complete analysis of a patient's health and will avoid the problem of trying to match patient data from various departments or data repositories that use different patient identification standards.

### **Patient Privacy and Data Security**

*Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capacities. (EP, Hosp, Required)*

The AACR feels that patient privacy and data security must be maintained within any EHR system and supports the implementation of encryption and other technical measures that will ensure data security while providing authorized access and use by researchers and clinicians. While out of the scope of this solicitation of comments, the AACR has provided extensive comments elsewhere regarding the need to revise the current paradigm of privacy and consent

that is embodied in the Common Rule and the HIPAA Privacy Rule in order to more effectively protect privacy and promote needed research.

### **Public Registries**

*Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice (EP, Hosp, Required)*

*Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice (Hosp, Required)*

*Capability to identify and report cancer cases to a State cancer registry where authorized, and in accordance with applicable law and practice (EP, Optional)*

The AACR supports making health data available to researchers through appropriate public registries. While cancer is not a communicable disease, a number of cancers such as cervical and liver cancer are associated with communicable infections (Human Papilloma Virus (HPV) and Hepatitis respectively). In the case of HPV, vaccinations may, for the first time, prove effective in preventing cancer by preventing the primary infections that lead to tumorigenesis. Providing immunization information to registries will therefore allow researchers to determine the effect of immunizations on cancer prevention.

Cancer incidence and cancer outcomes are also tied to co-morbidities and overall health; therefore, improved reporting and surveillance of cancer incidence and mortality, along with infections and public health metrics, are critical to a better understanding of cancer epidemiology. Cancer and public health registries have provided researchers with valuable epidemiological data, and the AACR supports integrating the automated submission of cancer, laboratory and immunization data to registries and public health officials into the standard functionality of EHR systems.

## **Quality Reporting**

### **Data-handling Capabilities Most Important Aspect of Quality Reporting**

Quality reporting requires two capabilities: 1) the ability to record primary data, and 2) the ability to access the data across patients to mathematically manipulate these primary data (for example by dividing, subtracting, etc.) to arrive at a secondary measure that is compared to a benchmark. For example, measures of both cervical cancer and cholesterol screenings require the EHR system to access recorded demographic information about patients along with standardized procedure codes that indicate the dates and types of services delivered to each patient. To calculate the quality metric, the EHR system must filter patients to create a subgroup

that meets age and sex criteria, and then the number of individuals within that subgroup who have had appropriate interventions is divided by the total number in the subgroup. While the filtering criteria and the services queried are different in each case, the underlying functionality is the same and can be adapted to any number of evaluative exercises.

While the specific quality measurements chosen are important, the AACR is primarily concerned with ensuring that the capability to access, filter and mathematically manipulate primary data, along with the additional primary data necessitated by this requirement is maximized. This capability embodies the concept of “meaningful use” by actually operationalizing data rather than simply replacing paper with pixels as the storage medium for clinical data. Researchers, and practices interested in understanding and improving their performance, will want to create any number of compound measures to evaluate the impact of certain practices on patient health. It is critical, therefore, that the types of permutations used by EHR systems to calculate these measures be flexible and open to user modification. In other words, EHR systems need to contain spreadsheet-like functionality that enables system administrators to filter, combine, and manipulate data fields rather than hard coding a narrow set of rigidly defined quality measure calculations into the EHR.

### **Quality Reporting Requirements**

CMS has requested comment regarding whether the 12 EP quality measures should be comprised of :

- a) 11 core items and 1 menu item, or
- b) 12 menu items.

The AACR acknowledges the rationale for the mandatory reporting of high impact conditions as exemplified by option “a”; however, we are concerned that the list provides too little choice and includes conditions that are not universally relevant to all physician practices. The AACR supports the concept of a “core” and “menu” set of measures; however, we would suggest that a larger proportion of the 12 measures be left to individual physicians to choose from the “menu” set.

Stage 1 core measures deal with tobacco use, obesity, and hypertension, three critical determinants of health. The AACR strongly supports continuing to require these three areas as a Stage 2 core measure set. In particular, tobacco use is the largest preventable cause of cancer, and the AACR feels strongly that the screening and cessation quality measure (NQF 0028) should remain mandatory. The NQF 0028 quality measurement also enables physicians to measure all forms of tobacco use beyond simply cigarette smoking, which will become a core data field as part of Stage 2. CMS noted a struggle with requiring other forms of tobacco use to be recorded as a core data field because of a lack of measurement standards; however, the tobacco quality measure avoids this problem by reporting a metric that is insensitive to the standards of recording tobacco consumption by a patient. In other words, even if each practice records other types of tobacco use (e.g. smokeless, water pipe, etc.) in a different format, it does

not interfere with reporting the percentage of patients who have been followed up with after screening. Furthermore, this quality measure goes beyond simply recording patient behaviors, it also captures the degree of cessation intervention, which is one of the key reasons for querying tobacco behaviors.

While we support continued requirement of obesity screening, we would like to note that the obesity measure in the proposed Stage 2 core set (NQF 0024) only applies to children between the ages of 3 and 17, which leaves out a large segment of the U.S. population. The AACR feels that any core criteria dealing with obesity measurement and intervention should encompass patients of all ages.

As a more general comment with respect to quality measures, the AACR encourages the use of only those quality metrics that measure adherence to guidelines that have been developed according to the process outlined in the Institute of Medicine's 2011 report "Clinical Practice Guidelines We Can Trust." A proliferation of guidelines and a variation in the degree of reliance on expert consensus versus scientific evidence can result in different treatment and screening guidelines being issued by different organizations for the same condition or population. Quality measures and the guidelines upon which they are based must remain up to date and be evidence based; otherwise they risk actually inhibiting best practices rather than promoting them.

## **Future Considerations**

Meaningful use criteria are designed to evolve alongside the growth in the community's adoption and expertise in digital recordkeeping. With this evolution in mind, the AACR would like to suggest two areas that merit consideration for future stages of meaningful use development. The first is a more robust measurement of tobacco use, which was briefly discussed above. As soon as reasonable consensus is reached on data standards, the standardized measurement of all forms of tobacco use should be incorporated into the core data fields.

The second area that we feel merits attention is the increased engagement of the patient. The AACR commends the inclusion of Stage 2 criteria aimed at enabling patients to view, transmit and download their data, but this is still very one-directional, providing patient access to laboratory and clinician-generated data. Stage 2 enables some patient input on data elements like race, ethnicity and family history, but it does not capture the patient's expectations and experience of his or her health and healthcare interventions through the inclusion of patient-reported outcomes (PROs). The patient viewpoint is vitally important to understand the progression of disease and the effectiveness of various interventions in a patient-centered care model, and while the incorporation of PROs is currently difficult due to a lack of standards, future iterations of meaningful use should consider ways to encourage the collection of PROs.

**Summary**

The AACR applauds CMS for driving increased adoption of EHRs through the Meaningful Use program, and working to maximize the utility of this newly created capability. While the creation of criteria, such as those currently proposed as part of Stage 2, can lead to a narrow focus on the details of numbers, timelines and exceptions, needed to “pass the test,” the AACR would like to reiterate the importance of the larger goals of these criteria, which are to enable exchange and reuse of data beyond their primary use. We encourage CMS, EHR vendors, and practices that are implementing EHRs to keep these larger goals as the focus rather than the details of individual criteria. Doing so will ensure that the systems put in place fulfill the full promise of meaningful use.

In addition to the comments offered above, the AACR stands ready to provide any further assistance to CMS and the ONC as additional guidance is developed. If you have questions, please feel free to contact the AACR through Mark Fleury, Ph.D., associate director for science policy, at 215-446-7147 or mark.fleury@aacr.org.

Thank you for your consideration of AACR's comments.

Sincerely,



William S. Dalton, M.D.,  
Chairperson, AACR Science Policy and Legislative Affairs Committee



Margaret Foti, Ph.D., M.D. (h.c.),  
Chief Executive Officer, AACR