American Association for Cancer Research

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HIT Policy Committee
Office of the National Coordinator for Health Information Technology (ONC)
Department of Health and Human Services (HHS)
Patriots Plaza III, 355 E Street, SW
Washington, DC 20201

Dear Committee Members:

The American Association for Cancer Research (AACR) is pleased to offer comments regarding the draft Stage 3 Meaningful Use (MU) criteria issued by the Centers for Medicare and Medicaid Services (CMS) and the Policy Committee of 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 improvements 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 MU program. The AACR applauds CMS's 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 MU 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.

Below you will find specific comments in relation to individual criteria.

- ***SGRP104 EP Objective: Record the following demographics…***
  ONC proposes retiring prior demographics objective because it is topped out (achieved 80% threshold).
  Certification criteria:
  - *Occupation and industry codes*
  - *Sexual orientation, gender identity (optional fields)*
  - *Disability status*
  - *Differentiate between patient reported & medically determined*
  - *Need to continue standards work*

We concur with the need to continue standards work, and strongly emphasize the importance of meta-data that would differentiate between patient reported and medically determined data. This distinction in data source is important not only for demographic data, but more widely as discussed below with other variables in the electronic record that are either input directly by patients or corrected by patients.

- ***SGRP109 EP/EH Objective: Record smoking status for patients 13 years old or older***
  Measure: More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data.
  ONC proposes retiring because the objective is 'topped out,' and another quality measure (NQF 0028) is thought to adequately address smoking behavior.

We have concerns about retiring this requirement, even though certain aspects of tobacco use are covered through the NQF 0028 measure as noted. There are, however, major differences between the two measures. The SGRP109 metric starts at age 13, whereas NQF0028 evaluates patients beginning at the age of 18. Almost all (90%) long-term smokers begin smoking before the age of 18, therefore it is important to encourage assessment, cessation interventions and prevention at an early age. In fact, the U.S. Preventive Services Task Force has just released a draft recommendation that encourages interventions to prevent smoking in school-aged children, and the American Academy of Pediatrics has gone further, recommending counseling and interventions in children as young as five years old. Interventions in youth can be facilitated by prompts inquiring about smoking status in electronic medical records systems, but a shift to using NQF0028 would ignore the critical years before the age of 18 when lifelong smoking habits are being formed.

Another difference between the two metrics is that SGRP109 focuses only on smoking, whereas NQF0028 specifies the more broad term "tobacco use," which encompasses more forms of tobacco exposures. We would recommend changing the SGRP109 requirement to measure not just smoking, but one additional catch-all category of "Chews tobacco" (SNOWMED CT 81703003) as well.

Finally, another weakness of SGRP109 is that while clinicians must "categorize" at least 80% of their patients into one of eight smoking categories to meet this meaningful use standard, one of the allowable categories is “unknown.” This would appear to allow a clinician to score 100% on recording smoking status even without asking any of their patients if they smoked by simply entering “unknown” into the field by default. We therefore suggest changing the criterion to requiring a minimum of 80% of patients with a status other than “unknown” entered.

- ***SGRP 113 Objective: Use clinical decision support to improve performance on high priority health conditions***
  Measure:
  1. Implement 15 clinical decision support interventions or guidance related to five or more clinical quality measures that are presented at a relevant point in patient care for the entire EHR reporting period. The 15 CDS interventions should include one or more interventions in each of the following areas, as applicable to the EP's specialty:
    - *Preventative care (including immunizations)*
    - *Chronic disease management, including hypertension* (e.g., diabetes, coronary artery disease)*
    - *Appropriateness of lab and radiology orders*
    - *Advanced medication-related decision support** (e.g., renal drug dosing)*

  2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

  Certification criteria:

  1. Ability to track CDS triggers and how the provider responded to improve the effectiveness of CDS interventions

  2. Ability to flag preference-sensitive conditions, and provide decision support materials for patients.

  3. Capability to check for a maximum dose in addition to a weight based calculation.

  4. Use of structured SIG standards

  5. Ability for EHRs to consume CDS interventions from central repositories (e.g., rules for drug-drug interactions, rules for reporting diseases for public health departments, preference-sensitive care lists)

We strongly support the implementation of clinical decision support (CDS) and application of evidence-based medicine through EHRs as a way to close the loop on converting research into improved patient care and support collection of discrete data to feed back into the research cycle. Certification criterion 5 is especially important to making EHR functionality extensible. This same functionality of being able to accept updated CDSs as they become available could also be used to link granting opportunities to develop CDSs that align with MU requirements and support implementation of best practice cancer care into a clinician dashboard as they become available. Specific examples of cancer decision support could include vaccinations, screenings and tobacco interventions.

- ***SGRP114 Objective: Incorporate clinical lab-test results into EHR as structured data Measure:*** *More than 80% of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data*

We strongly endorse this measure and emphasize the need for standards work that would allow the growing number of cancer-related biomarkers to be entered as discrete data.

- ***SGRP115 EP Objective: Generate lists of patients for multiple specific conditions and present near real-time*** *(vs. retrospective reporting) patient-oriented dashboards to use for quality improvement, reduction of disparities, research, or outreach reports. Dashboards are incorporated into the EHR's clinical workflow for the care coordinator or the provider. It is actionable and not a retrospective report.*

We strongly endorse this measure for its value in facilitating a learning healthcare system.

- ***SGRP116 EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care EP Measure:*** *More than 20% of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference* ***Exclusion:*** *Specialists may be excluded for prevention reminders (could be more condition specific).*

We endorse the increased threshold and the emphasis on implementation of evidence-based medicine. This functionality should include collection of data on how and when reminders are provided, as well as the actions that resulted from those reminders, as this information will help refine our understanding of how to conduct screening effectively and efficiently. Important cancer prevention interventions that could be promoted through this criterion include tobacco cessation, colorectal cancer screening and mammograms.

- ***SGRP118 CORE Objective: Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology. CORE Measure:*** *More than 10 percent of all tests whose result is an image (including ECGs) ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology*

We highly endorse this measure as it represents an especially important change for oncology that will help enable the evaluation of tumor response to therapies. Currently, research that retrospectively evaluates tumor response depends on proxy measures like health utilization rather than actual tumor size, and better access to images will improve the quality of research.

- ***SGRP119 CORE Objective: Record high priority family history data***

CORE Measure: *Record high priority family history in 40% of patients seen during reporting period*
Certification criteria: *Make sure that every appropriate CDS intervention can take into account family history for outreach (need to move that functionality along as part of preventative outreach).*

Family history data are especially relevant in many types of heritable cancer risk factors and structured data allows the implementation of new findings regarding prevention and personalized medicine as they become available. Oncology is leading the medical community in the understanding of the genetic underpinnings of disease, and we strongly endorse this functionality and increased threshold contained in the criterion. Note: This objective is tied closely to SGRP113, and could potentially be combined with that objective.

- ***SGRP204B MENU: Provide 10% of patients with the ability to submit patient-generated health information*** *to improve performance on high priority health conditions, and/or to improve patient engagement in care (e.g., patient experience, pre-visit information, patient created health goals, shared decision making, advance directives, etc.). This could be accomplished through semi-structured questionnaires, and EPs and EHs would choose information that is most relevant for their patients and/or related to high priority health conditions they elect to focus on. Based upon feedback from HITSC this should be a MENU item in order to create the essential functionality in certified EHRs.*

We endorse this objective and encourage the evidence-based implementation of this functionality, including the use of psychometrically validated instruments, timely reminders and appropriate recall periods. The listed objective uses examples of patient-reported data that are qualitative, like recording patient goals and advance directives, but this functionality should also encompass quantitative data such as weight, blood pressure, blood glucose level, pain scales, etc. Patient-reported outcomes (PROs) are used increasingly in cancer research[1], and experiences within the research domain can serve as a guide for wider implementation of PROs in everyday patient care. While the research community utilizes some PRO standards tailored specifically for research, there are a number of standards and tools commonly used in oncology that could be used in clinical care including Patient Care Monitor (PCM)[2], Linear Analog Self-Assessment (LASA)[3], and the MD Anderson Symptom Inventory (MDASI)[4]. As discussed in our comments on SGRP104 above, it is critical that meta-data be attached to any patient-reported data in order to identify the source of the data including, where relevant the tools used for collection.

Further, we encourage the ONC to consult with the newly-formed Patient-Centered Outcomes Research Institute (PCORI), which is focused on patient engagement in the conduct of research and delivery of care. Their extensive work in this area can help inform MU criteria in this domain.

References:

1. *Recommendations for incorporating patient-reported outcomes into clinical comparative effectiveness research in adult oncology, Basch, et al, Journal of Clinical Oncology, 1 December, 2012, Volume 30(34), pp. 4249-55.*
2. *Validation of the Patient Care Monitor (Version 2.0): A Review of System Assessment Instrument for Cancer Patients, Abernethy, et al., Journal of Pain and Symptom Management, October 2010, Volume 40,(4), pp. 545-558.*
3. *On the receiving end—II. Linear analogue self-assessment (LASA) in evaluation of aspects of the quality of life of cancer patients receiving therapy, Coates, et al., European Journal of Cancer and Clinical Oncology, November 1983, Volume 19(11), pp. 1633–1637.*
4. *Assessing symptom distress in cancer patients, The M. D. Anderson Symptom Inventory, Cleeland, et al., Cancer, 1 October 2000, Volume 89(7), pp. 1634–1646.*

- ***SGRP204D Objective: Provide patients with the ability to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record)***

Echoing our comments on SGRP104 and SGRP204B above, we recommend the additional requirement of associating meta-data with these fields in order to distinguish between data which are physician entered and patient entered.

- ***SGRP209 Certification Criteria: Capability for EHR to query research enrollment systems to identify available clinical trials. No use requirements until future stages.***

The ability for EHRs to query available clinical trials would be extremely valuable to the research community. Cancer clinical trial participation is currently below five percent and stands as a major impediment to advancing research in new therapies, so efforts to expand this participation are wholeheartedly endorsed. A great deal of work on standards will be needed to enable this functionality, but due to demand this is a feature that will see rapid adoption. As standards work to interface EHRs with databases like Clinicaltrials.gov advance, care should be taken so that eligibility requirements are interpreted loosely enough to not exclude potential participants. For example, the system should not prevent alerts based on assumptions about the patient's willingness to travel to be a part of a clinical trial.

The proposed functionality should be available not only to the clinician managing the patient's medical record and/or care, but rather it should also be available to the patient. Just as "blue button" functionality allows patients to access and transfer their medical records without relying on someone within the healthcare system to act as an intermediary, this proposed trials query functionality could be employed in a blue-button fashion whereby patients could initiate a clinical trials query based on their records.

While this criterion appears to focus unidirectionally on an EHR's ability to query clinical trials databases, information exchange in the other direction is also important. Many academic cancer centers have systems in place that allow researchers to search patient records in order to locate patients meeting trial criteria. Connecting EHRs and clinical trials databases in

this fashion adds additional requirements, namely that patients must have consented to be recontacted for research purposes. The ONC should consider also including design criteria and standards to facilitate this consent management, as discussed in MU04 below.

Lastly, consideration should be given to ways to indicate within a patient's EHR that he or she is enrolled in a clinical trial. In many cases the details of care received as part of a clinical trial are kept in separate software, but the fact that a patient is receiving treatment outside of the patient's normal network is important information for the patient's normal care team or emergency room personnel to be aware of so as to avoid duplicative or contraindicated care.

- ***SGRP303 Certification criteria: Ability to automatically populate a referral form for specific purposes, including a referral to a smoking quit line***.

We highly endorse the certification criterion that would facilitate autopopulation of tobacco referral forms, but also encourage functionality that will allow feedback from referral services back into the EHR so that the referring clinician is able to fully follow a tobacco user's cessation progress in any external program.

- ***SGRP401B EP/EH Objective: Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations*** *(including immunization events from immunization registries or immunization information systems) as applicable by local or state policy.* ***Measure:*** *Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization*

We endorse this objective; however it seems somewhat redundant with SGRP113 and SGRP116. Furthermore, care should be exercised in the context of the 20% requirement, as the goal of this objective is to insure proper immunization, but the criterion measures delivery of immunization relative to an automatically generated reminder. This could provide the perverse incentive of erring on the side of withholding delivery of immunizations until a later date.

- ***SGRP404 EH/EP Objective: Capability to electronically participate and send standardized (i.e. data elements and transport mechanisms), commonly formatted reports to a mandated jurisdictional registry (e.g., cancer, children with special needs, and/or early hearing detection and intervention) from Certified EHR to either local/state health departments***

We fully endorse this measure, which expands submission of data to additional registries beyond cancer registries. With this expansion, however, it is important that submission to cancer registries remains a core requirement that cannot be fulfilled by submission to a different type of registry.

- ***MU04*** *Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining*

patient consent for sharing certain sensitive health information, including restricting the recipient's further disclosure of such information.

- *How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?*
- *How can MU help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?*
- *Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today's EHRs and HIEs?*

Not only will recording differential consent for different subsets of data within an EHR be important, but it will also be important to have the capability to modify consent over time, since increasingly patients are given the option to withdraw or modify original consent agreements later. This is especially relevant for genomic sequence data.

- ***MU05*** *The HITECH ACT has given a lot of emphasis to EHRs as the central distribution channel for health information, but there may be limits on how much we can add on to EHR technologies. As additional program demands are added onto EHRs, what can be done to foster innovation to share information and receive intelligence from other, non-EHR applications and services that could be built on top of that data architecture?*

  For example, is it possible to create an application programming interface (API) to make available the information defined in a CCDA so that systems can communicate it with each other? Is the information defined in the CCDA the appropriate content for other uses of clinical information? Are the standards used to communicate between EHR systems (e.g., Direct, Exchange) adequate for communication between EHRs and other kinds of systems? What other technologies, standards or approaches could be implemented or defined to facilitate the sharing of clinical knowledge between EHRs and other systems?

Many academic cancer centers have separate, stand-alone research data management systems in which clinical data from consenting patients is held in parallel to the EHR system. Often the data entry is manually duplicated, leading to great inefficiencies. These separate systems also often serve as the clinical annotation system for stored biospecimens. We feel that an API is an absolutely essential expectation of EHRs in order to facilitate efficient data exchange to a wide variety of external systems, including research systems, personalized medicine applications, external clinical decision support, patient/clinician education, matching of clinical trials, populating registries, etc. In the context of making data "liquid," an API is key to unlocking data.

- ***QMWG07*** *Please comment with guidance on how consumer-reported data can be incorporated into CQMs. What examples are there of EHR-enabled quality measures that use data directly entered by patients?*

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- ***QMWG08*** *Please provide examples of how patient-directed data is informing shared decision making. How does the public view the integration of EHR derived data with patient generated data for quality measurement? How important is it to keep this data separate? Should it be separate?*
- ***CQM Pipeline: MU and Innovation*** *The HITPC recognizes that some health systems, ACOs, and other provider networks have developed, tested and deployed locally generated CQMs that address high priority conditions or processes relevant to their local patient population or organizations. Usually, health systems do not submit these self-developed*
- ***QMWG18*** *Please comment on the desirability and feasibility of such an innovation track as a voluntary, optional component of the MU CQM requirement*

Quality and quality measurement is a core aspect of comparative effectiveness research. Many of the current oncology quality metrics focus on patient centered concerns, for example pain or fatigue, but the data are quite often clinician recorded rather than patient entered. We feel that there is an important opportunity for measure/metric development to happen as a part of clinical trials so that PRO-derived metrics can reinforce scientific discovery, and therefore support openness to an "innovation track" for new CQMs.

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,

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Chairperson
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