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Via Electronic Submission (www.regulations.gov)

January 14, 2013

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: HHS-OS-2012-0007-0001

Dear Dr. Mostashari:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Office of the National Coordinator for Health Information Technology (ONC) *Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)*, available at http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf. The AAMC represents all 141 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 75,000 medical students, and 106,000 resident physicians who deliver over one-fifth of all clinical care in the nation.

AAMC members are engaged in meeting Stage 1 of meaningful use and currently are working diligently to prepare to meet Stage 2 requirements. They understand the important role of the electronic health record (EHR) in improving patient care and have an on-going commitment to devote considerable resources of time and money to adopting EHRs. As intended by Congress, ONC's Stage 3 proposal increases the challenges of meeting meaningful use requirements. The Association continues to caution that as the meaningful use (MU) program moves forward, it is important to maintain a balance between the desire for imposing increasingly difficult measures and the ability of physicians, hospitals, and vendors to meet those measures without impeding patient care.

General Comments and Responses to Select MU Questions

To respond to the ONC proposals we have conducted several teleconferences with our members. These discussions revealed several noteworthy themes:

- All meaningful use measures should be sufficiently flexible. (MU01)

  - On the eligible professional (EP) side, measures should allow for variation in the way physicians practice based on specialty. On the eligible hospital (EH) side, they should allow for differences based on factors such as type of hospital and patient population served.
  - Once the penalty provisions are implemented, there should be a way both for EPs and EHs to avoid a penalty so long as they meet most of the objectives. The AAMC would be pleased to work with ONC and CMS to develop a system that will incorporate this idea.

- Ease of clinical documentation and ease of practice management efficiency (MU02) are only two important factors. Of equal importance is ensuring that documentation is accurate and enhances patient care.
- There should be little or no expansion of the number of measures that rely on actions by others that are wholly outside the control of the EP or EH. Likewise, thresholds for such measures should not be increased absent convincing evidence that current thresholds can be met by large numbers of EPs and EHs.
- Proposals for Stage 3, especially those that rely on transmission of data, should recognize that while some EPs and EHs may be ready for Stage 3 in 2015, it is likely they will be interacting with other EPs and EHs that may only have met Stage 1 or 2 requirements. Stage 3 meaningful users should not be penalized for being unable to meet certain measures, simply because the providers with which they interact have only met an earlier stage and may not be able to accept their data, for example.
- All newly proposed Stage 3 measures should be menu measures and should *not* be placed directly into the core set.
- Stage 2 menu measures should not become core measures for Stage 3 until sufficient evidence exists that all types of providers have been able to meet these requirements.
- The thresholds for Stage 2 core measures should not be increased for Stage 3 until evidence exists that all types of providers have been able to meet current thresholds for Stages 1 and 2.
- For any measures that require attestation, CMS should provide timely and detailed guidance so that EPs and EHs have sufficient notice about what will be required when such measures are audited.

Comments on Clinical Quality Measures

The AAMC appreciates that ONC is seeking stakeholder feedback on the strategic direction and priorities for clinical quality measurement in the meaningful use program, specifically for Stage 3. The Association continues to have serious concerns about the rapid pace of implementation for new stages of MU to date so we believe this is an appropriate time to step back and evaluate the future direction of quality measurement. Hospitals, eligible providers, and vendors are overwhelmed with the additional and continually changing quality reporting and submission requirements for Stage 2, which were only finalized in August of 2012. Data sharing between hospitals, EPs, and the government has not been seamless, which has resulted in additional burden and cost for providers.

Overarching Questions

Before proposing any new guidance for Stage 3 clinical quality measures (CQMs), the AAMC urges ONC to allow hospitals and EPs enough time to ensure that their current systems are fully functional and are capturing and accurately generating quality measure data. One of the AAMC's primary concerns is the readiness of untested e-specifications for measures that are already in the program. We ask that ONC ensure that these e-specified measures are standardized and rigorously tested and validated; otherwise providers will continue to generate data of little value, thus undermining the intended goal of improved healthcare data.

CQM Pipeline: Measure Development Cycle

The AAMC believes that the best EHR measures should parallel the workflow of health care providers. For both CQMs and functional measures, this means that the EHR incentive program needs to thoughtfully consider how the EHR is integrated with care delivery. In general, "de novo" EHR-enabled measures that take full advantage of the structure and available clinical data that EHRs offer would be more effective than retooled measures that were originally designed for claims or chart abstraction. While some progress has been made with new EHR measures, much additional work is necessary to ensure the accuracy and validity of EHR clinical data. The Association supports the creation of a transition period in moving to e-measures and therefore recommends that the pace for adding additional measures in a prior format be significantly slowed.

CQM Pipeline: Process and Outcome Measures

The AAMC supports the use of process measures focused at the point of care and believes that, when done properly, these types of measures have the ability to improve outcomes. However, hospitals and EPs are overburdened with the information currently required for entry in the EHR at the patient's point of care. While some of this workflow is necessary and applicable for all patients, more should be done to encourage a streamlined and natural flow of information. Providers are suffering from alert fatigue in combination with an increase in measures requiring them to "check the box." The AAMC recommends that to increase the effectiveness of point of care measures ONC should take steps to identify and reduce "check-the-box" questions of moderate value. The Association also believes that the focus of measurement should be on building reports, capturing and submitting data, etc. While we agree that the long-term goal of the EHR incentive program should be a transition towards measuring outcomes, ONC should not propose doing so until a means to adequately risk-adjust EHR outcome measures is put into place.

CQM Pipeline: Meaningful Use Alignment with Functional Objectives/ Domains

As we move towards Stage 3, we are also noticing an overlap between the goals of the functional measures and the desired clinical quality measures in particular quality domain areas such as care coordination. In the future, ONC may want to look into taking additional steps to integrate and align the MU functional measure goals with the six clinical quality domains specified for clinical

quality measures. Finally, the AAMC believes that all required quality measures in the MU program should be endorsed by the National Quality Forum (NQF) and approved by the Measure Applications Partnership (MAP). However, we also urge ONC to implement a process that recognizes and credits innovative EHR models and measurement tools at the local level.

Comments on Privacy and Security

The AAMC is a signatory to the letter submitted by the Confidentiality Coalition in response to the ONC Request for Comment (RFC). In this letter we reiterate that given that a final rule has yet to be issued on accounting for disclosures, it is premature for ONC to request comments on any measure related to an accounting for disclosures standard (PSTT 05-08). Any standards related to privacy and security should be consistent with—and not seek to expand—requirements governed by HIPAA regulations.

MU03
The RFC seeks comment on the creation of a MU requirement for providers to conduct a health IT safety risk assessment to improve the safety of EHRs. While the AAMC applauds all efforts to increase patient safety, we seek clarification on ONC's meaning of "the safety of EHRs" and what a "health IT safety risk assessment" would entail. If the ONC is referring to the security of EHR records, we believe that the existing HIPAA Security Rule thoroughly addresses this topic and are not in favor of a further MU requirement for EHR risk assessments.

MU04
The AAMC is a strong supporter of patient health information privacy and confidentiality. We support guidance and standards for managing patient consent and disclosure information, making the sea of federal laws less burdensome. Further, we believe the HITPC could propose working towards a single set of federal privacy laws.

MU05
The AAMC supports allowing non-EHR applications and services the ability to build on top of an EHR's data architecture as long as security is maintained and verified to be at the same level of the original certified EHR.

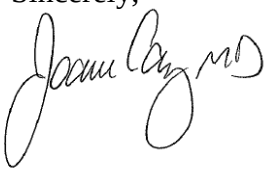
Comments on Specific Measures

Please see the attached Addendum for comments on specific proposed measures.

Conclusion

Thank you for the opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health center community. Please feel free to contact Ivy Baer, J.D., M.P.H., at 202-828-0499 or at ibaer@aamc.org with any questions.

Sincerely,



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Chief Health Care Officer

cc: Ivy Baer, AAMC
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Addendum: AAMC Comments on Specific Stage 3 Proposed Measures

ID#	Objective	Measure	AAMC Concerns
SGRP 130	Use of CPOE for referrals of care orders directly entered by healthcare professional, to create first record of the order	>20% of referrals/transitions of care orders created during EHR reporting period are recorded	• Measure will prove problematic for transitions to care settings that do not have EHRs. • Does not specify *how* referrals /transitions of care orders are to be recorded. • Unclear what this is trying to measure: does not specify whether measure is for referrals/transitions *into* or *out* of the hospital, or both. • Numerator and denominator both require much more clarity.
SGRP 103	Generate and transmit permissible discharge prescriptions electronically (eRx)	**EP:** >50% of permissible prescriptions written by EP are compared to at least one drug formulary (reviewed for generic substitutions) transmitted electronically using CEHRT **EH:** >30% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using CHERT	• Concern with the idea of tripling the threshold for EHs from Stage 2, particularly given that we do not yet have Stage 2 data to determine how reasonable the 10% threshold was. • This measure may not be appropriate for hospitals as they do not have the same relationship with their patients as EPs do. • Measure should clarify how refills are assessed.
SGRPs 104, 108, 109	• Record demographics • Record and chart changes in vital signs	Retire objectives, because measures are "topped out" (achieved 80% threshold)	• Meaningful use thresholds should not increase above 80% because legitimate circumstances can prevent users from reaching higher

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	• Record smoking status for patients 13 years and older		thresholds. • The AAMC supports the concept of removing "topped out" measures to reduce provider burden. However, before taking any actions to retire measures, we recommend that ONC seek input from multiple stakeholders. ONC should consider a number of factors, such as whether the measure has been incorporated into a standard of care or whether quality of care will be affected.
SGRP 113	Use clinical decision support (CDS) to improve performance on high-priority health conditions	Implement 15 clinical decision support interventions or guidance related to 5+ clinical quality measures (CQM) presented at a relevant point in patient care for entire EHR reporting period.	• Difficult to assess appropriateness of the increased CDS requirements given we do not yet have Stage 2 data. • Strong concern about "alert fatigue" with so many required interventions. • The CDS recommendation may be reasonable for EPs if the requirement could be measured at the group practice level, especially for practices that choose to submit CQM data at the group level starting in 2014. • An additional concern for EPs is that the limited number of measures and support tools available could impede specialists and subspecialists from meeting these criteria.

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SGRP 114	Incorporate clinical lab-test results into EHR as structured data	>80% of all clinical lab test results ordered by EP or an authorized provider of the EH during the EHR reporting period whose results are in either a positive/negative or numerical format are incorporated in certified EHR as structured data	• Measure assumes integration between the provider's EHR and the laboratory's information system, which is often not the case. • With such a high threshold, concern that measure would unnecessarily restrict a hospital's choice of laboratory, and that restriction could be to patients' detriment. • Some point of service tests may not be available as structured data.

SGRP 115	Generate lists of patients for multiple specific conditions and present near real-time (vs. retrospective reporting) patient-oriented dashboards for quality improvement, reduction of disparities, research, or outreach reports. Dashboards incorporated into EHR's clinical workflow for care coordinator or provider.	None stated.	• Several terms used in the objective are unclear and require further definition, including:
			  • "Near real-time"
			  • Lists (what is a list: 2 items? 3 items? more?)
			  • Multiple (how many?)
			• Stage 2 also applied to both EPs and EHs, but this draft objective only appears to apply to EPs. Unclear whether this objective would apply to EHs as well.
			• Recommend adding a measure to accompany the objective.

SGRP 116	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care	• >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.	• Measure should *not* be changed to "an office visit" but should remain at "two or more office visits." Two office visits is a minimum threshold to indicate patients have a relationship with their clinician that may require follow-up. • Exclusion should be

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		• Exclusion: specialists may be excluded for prevention reminders (could be more condition specific)	broadened to account for clinicians who perform services where there is no need for follow-up visits.
SGRP 117	Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)	• >30% of medication orders created by authorized providers of the hospital's inpatient or emergency department during EHR reporting period are tracked using eMAR • Mismatches are tracked for use in quality improvement	• Serious concerns about new "mismatch" requirement: • How to define a mismatch? • How is the provider expected to identify the mismatch? There is no existing electronic method of identifying this. Providers currently must identify by hand on a subpopulation, which is *extremely* resource intensive. • Recommend deleting "mismatch" requirement until a practical way of capturing electronically is available.
SGRP 118	Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT	>10% of all tests whose result is an image (including ECGs) ordered by EP or authorized provider of EH during EHR reporting period are accessible through Certified EHR Technology	• Recommend not moving to core set until Stage 2 results are assessed. • Stage 2 measure specifically excluded providers with no access to electronic images. Recommend retaining this exclusion. For example, eye images cannot be inserted into an EHR at this time. • Not clear whether definition of "accessible through CEHRT" would be the same as how it was defined in Stage 2 (i.e., that the CEHRT need not store the images, and a link to them would be

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			sufficient).
SGRP 120	Record electronic notes in patient records	Record electronic notes in patient records for >30% of office visits within 4 calendar days	• Unclear whether proposal is to move the measure to the core or keep it in the Menu set. • For Stage 2, measure only applied to EPs; unclear whether Stage 3 proposal would apply to EHs or remain an EP-only measure.
SGRP 121	Provide structured electronic lab results to eligible professionals	Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for >80% of electronic lab orders received.	• Serious concerns with extreme jump in threshold from 20% to 80%; if measure is moving to core, threshold should *not* increase. • Recommend not moving to core set until Stage 2 results are assessed.

SGRP 122	EHR is able to assist with follow-up on test results	10% of test results, including those which were not completed are acknowledged within 3 days	• Serious concerns about many unresolved issues:
			  • What does "not completed" mean?
			  • Acknowledged by whom?
			  • How must acknowledgment take place?

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			• To what population does the measure apply? • To what does the time frame refer – 3 days of ordering the test or 3 days of receiving a result? • Does measure take into account tests for which no result is available within 3 days (e.g., some tests for cancer patients may take a week or more)? • All other measures require "more than" a certain percentage, not an exact percentage; should this be >10%? • Objective sounds like a certification requirement, but the measure seems to apply to EHs and/or EPs. To whom and what does the measure apply?
SGRP 204A	Provide patients ability to view online, download, and transmit (VDT) health information • EPs: within 4 business days of information being available to EP • EHs: about a hospital admission	• >50% of patients are provided online access (within 24 hours for EPs if generated during course of visit, otherwise 4 days; within 36 hours for EHs) • >5% of patients VDT their information during the reporting period • Potential to increase both thresholds based on experience in Stage 2 • New menu item: Automated transmit,	• Unclear whether new automated transmit requirement would apply to EPs or EHs or both. • Remaining concerns that provider has no way to control patient's actions. Concern about what the new proposed Stage 3 threshold might be. • Some patients have no need to download information after they see the provider • What is "online access"--e-mail? Web portal? Other?

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		i.e. provide 50% of patients the ability to designate to whom and when a summary of care document is sent to patient-designated recipient	
SGRP 204B		Provide 10% of patients with ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care.	• "Ability to submit" language is preferable to a requirement that patients perform a certain action. This gives the patient the opportunity to submit data without holding providers accountable for patient action. • Unclear whether measure is intended to apply both to EPs and EHs. Hospital care is episodic, so may not make sense for EHs. • Unclear whether the measure also requires a new certification component (many current systems do not have separate field for this type of information). • Unclear which or how many of the examples of patient-generated health information would have to be included to meet the measure.

ID#	Objective	Measure	AAMC Concerns

SGRP 204D	Provide patients with ability to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) through VDT in an obvious manner	None stated.	• Any measure should be consistent with HIPAA requirements.
			• Serious concerns about many unresolved issues:
			  • What would the proposed measure be?
			  • Would the measure apply to both EPs and EHs?
			  • What does "in an obvious manner" mean?
			  • How do you document this?

SGRP 206	Use CEHRT to identify patient-specific education resources and provide those resources to the patient	>10% of all unique patients with office visits seen by EP or admitted to the hospital's inpatient department or ED are provided patient-specific education resources identified by the CEHRT; for top 5 non-English languages spoken nationally, provide 80% of patient-specific education materials in at least one of those languages, based on the EPs or EHs local population, where publically available	• Serious concerns about the new non-English language materials requirement, including:
			  • Threshold is extremely high and would impose an immense burden on providers
			  • Unclear what the term "where publicly available" means
			  • Unclear what the term "local population" means
			  • Unclear how requirement would apply when one EH has multiple campuses, all with different language majority populations.
			  • Unintended consequence would be reduction in all patient-specific materials, if so many resources have to be devoted to translation
			• Recommend removing this measure.

SGRP 207	Use secure electronic messaging to communicate with patients on relevant health information	>10% of patients use secure electronic messaging to communicate with EPs	• Concern regarding doubling of threshold, when we do not yet have any data from Stage 2 to know whether 5% was attainable.

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			• Measure should specify "unique" patients.
SGRP 208	Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care	Record communication preferences for 20% of patients (based on how (e.g., the medium) patients would like to receive information for certain purposes (including appointment reminders, reminders for follow up and preventive care, referrals, after visit summaries and test results)	• ONC indicates that this is part of the reminder objective (SGRP 116) but includes it separately here; unclear whether it is intended to be a separate measure or not. • Unclear whether the measure also applies to EHs; all references are to EP activities. • Recommend clarifying that this measure does not apply to EHs.
SGRP 305	When patient referred, EP/EH acknowledges and provides referral results to requestor	50% of referrals generated from EHR are returned to requestor and 10% of those are returned electronically	• This measure is very problematic for EHs; should be an EP only measure. • Requestor may not have ability to receive referral results electronically.
SGRP 302	If receive patient from another setting or believe an encounter is relevant should perform reconciliation for medications, medication allergies, problems	Perform reconciliation for medications for greater than 50% of transitions of care; perform reconciliation for medication allergies and problems for greater than 10% of transitions of care	• The problem list requirement may be problematic for each specialty to verify (and it may be of limited utility). • Is this the correct measure? Is reconciliation what is important or is it important that the correct medicines are being prescribed?
SGRP 303	EP/EH who transitions patient to another care setting or refers patient to another provider must provide summary of care record.	Summary of care record provided for greater than 65% of transitions of care and referrals (greater than 30% electronically)	• Proposed 30% electronic threshold is too high. What if patient transitions to a care setting (e.g., nursing home) that doesn't have an EHR?
SGRP 401B	Capability to receive, generate or access	Implement immunization recommendation system	• This should be an EP only measure. EHs are not primary

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	appropriate age, gender, and immunization history-based recommendations	that establishes baseline recommendations and allow for local/state variations. For 20% of patients receiving immunization, EP/EH practice receives recommendation before giving an immunization	givers of immunizations • Measure seems to reward EPs for receiving a recommendation rather than giving the immunization • This measure may be difficult for those providers that operate in more than one state. Each location may use the same EHR but each EHR would have to have a different CDS based on the requirements of the state in which it is located
SGRP 405	Capability to electronically submit standardized reports to an additional registry beyond any prior MU requirements	Documentation of successful ongoing electronic transmission of standardized reports to a jurisdictional, professional or other aggregation source.	• Not all specialties have registries so some EPs may be unable to meet this measure.
IEWG 101		MENU objective: For patients transitioned without a care summary, an individual in the practice should query an outside entity. The intent of this objective is to recognize providers who are proactively querying.	The AAMC supports a comprehensive and longitudinal EHR system in which EHRs are able to query outside entities for outside records to provide health care providers with comprehensive patient information. As we move into a more robust health information exchange environment, we encourage ONC to identify and test consent management standards to support health information exchange that supports patient privacy and accurately matches patient records. We caution about adopting this as a measure prematurely.
IEWG 102		Certification Criteria: The EHR must be able to	The AAMC is not aware of sufficiently mature standards that

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		query a Provider Directory external to the EHR to obtain entity-level addressing information (e.g. push or pull addresses)	would support these criteria at this time.
IEWG 103	Certification Criteria: Lists requirements for exporting patient records summaries in a standard format.	Q: What criteria should be added to the next phase of EHR certification to further facilitate healthcare providers' ability to switch from using one EHR to another vendor's EHR?	The AAMC fully supports efforts to further facilitate healthcare providers' ability to switch from using one EHR to another vendor's EHR. For the next phase of EHR certification, AAMC encourages ONC to identify or facilitate standards for cognitive status and functional status to help facilitate providers' transitions between EHRs.