DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the National Coordinator for Health Information Technology
Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)
AGENCY: Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Request for Comments.

SUMMARY: This document is a request for comments by the HIT Policy Committee regarding the Stage 3 definition of meaningful use of EHRs.

COMMENT DATE: To be assured consideration, comments must be received by 11:59p.m. ET on January 14, 2013.

ADDRESSES: Because of staff and resource limitations we are only accepting comments electronically through http://www.regulations.gov. Follow the "Submit a comment" instructions. Attachments should be in Microsoft Word or Excel, WordPerfect, or Adobe PDF. Please do not submit duplicate comments.

FOR FURTHER INFORMATION CONTACT: MacKenzie Robertson, Office of the National Coordinator, Patriots Plaza III, 355 E Street, SW., Washington, DC 20201, (202) 205-8089, mackenzie.robertson@hhs.gov.

SUPPLEMENTARY INFORMATION:
Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Background

The Health Information Technology Policy Committee (HITPC) is a federal advisory committee that advises the U.S. Department of Health and Human Services (HHS) on federal HIT policy issues, including how to define the "meaningful use" (MU) of electronic health records (EHRs) for the purposes of the Medicare and Medicaid EHR incentive programs. The HITECH portion of the American Recovery and Reinvestment Act (ARRA) of 2009 specifically mandated that incentives should be given to Medicare and Medicaid providers not for EHR adoption but for "meaningful use" of EHRs. In July of 2010 and August 2012, HHS released that program's final rule defining stage 1 and stage 2 MU respectively strongly signaling that the bar for what constitutes MU would be raised in subsequent stages in order to improve advanced care processes and health outcomes.

The HITPC held a series of public hearings and listening sessions to hear testimony from a wide range of stakeholders regarding current experience with MU, lessons learned, and what thought leaders desire in the future, including how MU should support emerging new models of care. This input helped to inform many hours of public deliberations regarding the future vision of MU. The stage 3 vision includes a collaborative model of care with shared responsibility and accountability, building upon previous MU objectives. While the committee appreciates and recognizes today's challenges in setting up data exchanges, it is the committee's recommendation that stage 3 is the time to begin to transition from a setting-specific focus to a collaborative, patient- and family- centric approach.

To realize this vision, the HITPC used the following guiding principles. To be considered for stage 3, an objective should:

- Support new models of care (e.g., team-based, outcomes-oriented, population management)
- Address national health priorities (e.g., NQS, Million Hearts)
- Have broad applicability (since MU is a floor) to
    - provider specialties (e.g., primary care, specialty care)
    - patient health needs
    - areas of the country
- Promote advancement -- Not "topped out" or not already driven by market forces
- Be achievable – e.g. there are mature standards widely adopted or could be widely adopted by 2016
- Reflect reasonableness/feasibility of products or organizational capacity
- Prefer to have standards available if not widely adopted

The HITPC has developed a preliminary set of recommendations specifically designed to solicit additional public feedback. The goal of sending out this request for comment (RFC) early is threefold.

- Extend the public discussion of future stage MU definitions through a more formal public comment process well in advance of its formal stage 3 recommendations.
- Request input on specific questions.
- Provide some signal to the industry of potential new EHR functionalities that the HITPC may recommend to assist the industry.

Following the analysis of the comments received through the comment period, the HITPC intends to revisit these recommendations in its public meetings in the first quarter of 2013. It is important to note that although the following RFC is being communicated via HHS and the Federal Register, it represents the preliminary thinking of the HITPC and not necessarily HHS or its various agencies.

HITPC Solicitation of Comments

This document is broken into the following sections: Meaningful Use Objectives and Measures, Quality Measures, and Privacy and Security. Details from the HITPC workgroups have been accumulated into these sections for consideration to HHS for stage 3. We want to acknowledge and thank the following workgroups for the tireless hours they have put forth to aggregate these recommendations for comment: Meaningful Use, Information Exchange, Quality Measures, and the Privacy and Security Tiger Team.

Each item that the HITPC is requesting comment on has been given an identification number in order to streamline the accumulation of comments, please use this identification number when submitting comments.

I. Meaningful Use Objectives and Measures

This section includes a grid with items from both the Meaningful Use Workgroup and the Information Exchange Workgroup. Recommendations, concepts, and questions have been organized into 6 sections that include:

1) Improving Quality, Safety, and Reducing Health Disparities
2) Engaging Patients and Families
3) Improving Care Coordination
4) Improving population and public health
5) Information Exchange
6) Overarching MU questions

The grid below includes the following columns: stage 2 objectives and measures (for reference), stage 3 recommendations, proposed for future stage, and questions/comments. The proposed for future stage column includes items that the HITPC believes are important, but may not be feasible for stage 3; therefore comments on the readiness and feasibility of these items are appreciated. The questions/comment column provides a place for the HITPC to describe the thinking behind the objective or ask questions related to these objectives. In an effort to achieve parsimony, there are also items identified as certification criteria. These items are intended to create additional functionality within electronic health record (EHR) systems for providers, but there may not be use requirements associated with them. As a reminder, identification numbers are provided so that commenters can easily reference the objective when commenting. All commenters are encouraged to provide opinions regarding feasibility; we especially encourage commenters to provide feedback with published evidence or with data from their own experience.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments	HITSC/WG Assignment
Improving quality, safety, and reducing health disparities					
		•			

SGRP 104	**EP Objective: Record the following demographics**
	• Preferred language
	• Sex
	• Race
	• Ethnicity
	• Date of birth
	
	EH Objective: Record the following demographics
	• Preferred language
	• Sex
	• Race
	• Ethnicity
	• Date of birth
	• Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH
	
	Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.
		Retire 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
				Do commenters agree with retiring the measure, or should we continue this objective? Continuing the measure would mean an additional number of objectives that providers will need to attest to.	Primary- Clinical Operations WG
					Secondary- Implementation WG

Comments:

- Agree with the retirement of the topped out measures (Original demographic measures)
- Agree with the addition of the new updated demographic measures
- Structured data will be captured and not codified data at this time

- *What is the definition of Disability Status?* Federal definition or patient identification, or otherwise
- Question on how sexual orientation will or can be codified
- Introduce as a general comment about Disability status being included as long as it can be captured
- Date needs to be included as well, Physician in EP setting and the initial assessor in the EH setting????

SGRP 105	**Consolidated in summary of care objective** Maintain an up-to-date problem list of current and active diagnoses	**Certification criteria:** EHR systems should provide functionality to help maintain up-to-date, accurate problem list **Certification criteria:** Use of lab test results, medications, and vital signs (BP, ht, wt, BMI), to support clinicians' maintenance of up-to-date accurate problem lists. Systems provide decision support about additions, edits, and deletions for clinicians' review and action. For example, if diabetes is not on the problem list but hypoglycemic medications are on the medication list: the EHR system might ask the provider whether diabetes should be on the problem list. It would not automatically add anything to the problem list without professional action.	Patient input to reconciliation of problems	The implementation of these criteria will assist in achieving the CDC's goal of using EHR technology features to identify patients meeting criteria for hypertension who are not yet diagnosed and managed for the disorder. How to incorporate into certification criteria for pilot testing?	Clinical Operations WG Implementation WG
				The intent is that EHR vendors would provide functionality to help maintain functionality for active problem lists, not that they supply the actual knowledge for the rules.	Clinical Operations WG

Comments:

- Do we include that type of clinical decision support in Pilot Testing? Our question is how incorporate into certification criteria on using computer logic related to determine problems not on the list based on data like lab findings or medications. For purposes of certifiying this functionality the testing scripts and data sets would have to being clinical relevant and included 'clue data' that would lead to additional problems. This represents advanced software logic.
-
- Not opposed generally, but want to ensure that this is not too restrictive and limiting
  - Chronic nationwide issues are more possible – The point here is that you want straightforward connections between findings (interventions and diagnostics) and a 'problem.)
- Balance needed to allow EPs and EHs to pick a problem that suits their needs without overly burdening the vendor / developer - ????

SGRP 106	**Consolidated with summary of care** - Maintain active medication list	**Certification criteria:** EHR systems should provide functionality to help maintain up-to-date, accurate medication list	**Certification criteria:** Use other EHR data such as medications filled or dispensed, or free text searching for medications to support maintenance of up-to-date and accurate	How to incorporate into certification criteria for pilot testing?	Primary- Implementation WG Secondary- Clinical Operations WG

		Certification criteria: Use of problems and lab test results to support clinicians' maintenance of up-to-date accurate medication lists. Systems provide decision support about additions, edits, and deletions for clinicians' review. For example, an antibiotic (not for acne) has been on the medication list for over say a month, the EHR system might ask the provider whether the medication is a chronic medication. The system will not make any changes without professional approval.	medication lists.	The intent is that EHR vendors would provide functionality to help maintain functionality for active medication lists, not that they supply the actual knowledge for the rules.	Clinical Operations WG

Comments:

- First sentence is alarming to group- We need to be much more specific to our concern
- 105 and 106 should be tied together and the use can be linked together
  - Link the two together so that we understand the difference between filled and dispensed - The concern expressed related to the standards/process to provide the information of a medication being filled then dispensed back to the primary care provider (EP).
- Good idea for long term, but may not be appropriate right now

Comments added 1/9/2013

- Tie into our scenario discussion with the additional decision support
- Additional comment to test CDS in the real world with input from actual providers and workers, before it is added as a testing criteria

SGRP 113	**EP/EH Objective:** Use clinical decision support to improve performance on high-priority health conditions **Measure:** 1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision	**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**	**Certification criteria:** Explore greater specificity for food-drug interactions *Procedure/Surgery/lab/radiology/test prior authorization v.A*: for those procedures/surgeries/lab/radiology/test with clear and objective prior authorization requirements and a structured data prior authorization form is available, clinician fill out the prior authorization form using structured data fields and prior authorization can be granted electronically and in real-time by the payor. *Procedure/Surgery/lab/radiology /test prior*	Ability for EHRs to consume CDS interventions from central repositories The EHR would query (via web services) available databases to identify "trigger event" conditions (e.g., case reporting criteria, drug-drug interactions, potentially relevant trials) based on the patient's health condition, diagnoses, location, and other basic facts. The HITPC is interested in experience from payors that may	Primary- Clinical Operations WG Secondary- Implementation WG, NwHIN PT Implementation WG

	support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency. 2. The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	(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) * This will assist in achieving the CDC's goal of improvements in hypertension control. **Kuperman, GJ. (2007)Medication-related clinical decision support in computerized provider order entry systems a review. *Journal of the American Medical Informatics Association*: JAMIA, 14(1):29-40.	*authorization v.B*: for those procedures/surgeries/lab/radiology/test, for which prior authorization is non-standardized and is highly individualized, a standardized form is created that collects from the clinician text fields answering an agreed upon set of medical necessity questions, standardized form is sent electronically to insurer for review, insurer responds with Approval/Denial (with rationale if denied) using a standardized format text document back to clinician with either approval and/or denial with rationale.	contribute to CDS.	

Comments:

- CDS needs to be congruent with clinician workflow requirements, it needs to be appropriate, tunable, fast and reliable to work in a clinical workflow setting -
- Reporting and follow-up items needs to be managed and handled properly
- If repositories are developed the EP/EH should be able to access those. EPs, EHs, and Vendors should be able to access central repositories but the certification requirements should not assume that they exist in all areas for all 15 of the CDS interventions. There needs to be an alternative to central repositories to meet this requirement.
- Local resources should be available when needed.
- Send the specific question to Ann if input is needed. – This input from Ann was specific to the payor input.

SGRP 118	**MENU Objective: I**maging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR	**CORE Objective:** Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR Technology.		What barriers could be encountered in moving this to core?	Primary- Clinical Operations WG Secondary- Implementation WG

	Technology. **MENU Measure:** More than 10 percent of all tests whose result is one or more images 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.	**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			
Comments: • Cost is a barrier moving this to core. • Definitions of EHRs and the relevance of actual images are barriers as well. • Combination of product, interface and financial interface will be an additional barrier • Considering the necessity of the use of the image, this should be considered only as a menu item. The summary of imaging is always important, the actual image is only sometimes important and can be accessed for clinical purposes as needed without being stored in the core EHR..					
Engage patients and families in their care					
SGRP 204A	**EP Objective:** Provide patients the ability to view online, download, and transmit (VDT) their health information within 4 business days of the information being available to the EP. **EP Measure:** 1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information. 2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a	• EPs should make info available within 24 hours if generated during course of visit • For labs or other types of info not generated within course of visit, it is made available to pts within four business days of info becoming available to EPs • Potential to increase both thresholds (% offer and % use) based on experience in Stage 2 **Note:** Depending on experience in Stage 2, CMS may want to give credit to some providers (e.g. specialists) for view/download/transmit where the patient has requested that they prefer info to be sent to a location they specify (such as another provider portal or PHR), rather than only making available information on the provider's portal. **MENU item:** Automated Transmit*: (builds on Automated Blue Button Initiative (ABBI)): Provide 50%	Building on Automated Transmit: 1a. Create the ability for providers to review patient-transmitted information and accept updates into EHR. 1b. Related certification criteria: Standards needed for provider directories in order to facilitate more automated transmissions per patients' designations.	Explore the readiness of vendors and the pros and cons of including certification for the following in this objective: • Images (actual images, not just reports)	Primary- Implementation WG Secondary- Clinical Operations WG
				• Radiation dosing information from tests involving radiation exposure in a structured field so that patients can view the amount of radiation they have been exposed to	Primary- Implementation WG Secondary- Clinical Operations WG
				Add a MENU item to enable patients to view provider progress notes (re: Open	HITSC

	third party their health information. **EH Objective:** Provide patients the ability to view online, download, and transmit information about a hospital admission 1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.	of patients the ability to designate to whom and when (i.e. pre-set automated & on-demand) a summary of care document is sent to patient-designated recipient** (for example, a one-time request to send information from specialist to primary care, or a standing request to always send an updated care summary when certain events arise, such as a change in medication or the completion of new tests or procedures). *Subject to the same conditions as view, download, transmit **Before issuing final recommendations in May 2013, HITPC will also review the result of Automated Blue Button pilots, in addition to considering public comments received.		Notes: Doctors and Patients Signing On. *Ann Intern Med.* 20 July 2010;153(2):121-125)	
				What is the best way to ensure that individuals access their health information through the view/download/transmit capability are provided with transparency and education about the benefits and potential risks of downloading health information, consistent with the HIT Policy Committee's recommendations of August 16, 2011? Is certification an appropriate vehicle for ensuring such transparency is part of CEHRT? If so, what would the certification requirement look like? If not, what are other mechanisms for ensuring transparency to consumers using the view/download/transmit capabilities?	HITSC
				In its recent final rule, and in response to comments, ONC adopted Level A conformance as the standard for the accessibility web content in accordance with the Web Content Accessibility Guidelines (WCAG). ONC indicated per commenters suggestions that WCAG Level AA conformance would be considered for the next edition of certification criteria. Given that all EHR technologies certified to the view, download, transmit to a 3rd party certification criterion will have met Level A, how difficult would it be for EHR technology to have to meet Level AA conformance?	Primary- Implementation WG Secondary- Clinical Operations WG and NwHIN PT

Comments:

SGRP 204 A - Images

- There is a potential issue that PACS products are not certified products and that getting the images out of the PACS systems into the EHRs could be difficult Radiology Images are currently being uploaded today to inpatient records. Cardiology and other images are in early stages of integration.
- Providers may not have had a chance to look at the direct image when its in PACS, they just view the reports –Eligible Providers and Patients may not have the need or desire to view the image. Concern was expressed over the ability of patients to be able to receive large images.

SGRP 204 A Radiation Dosing

- Who is responsible for providing that information?
  - Vendor or Provider? - The current software applications provide the ability to capture this data and it could be made available to the patient portal. Consideration should be given to the patient's ability to understand and use the data. Radiation dosing is specific to the disease process, patient condition etc and will require the clinical community to engage on effective communication parameters.
- Concerns around patient's ability to use the information correctly and effectively

SGRP 204 A – WCAG

- No one is really knowledgeable enough here to weigh in on A versus AA
- Seek other input from others on workgroup team to get help with this

SGRP 207	**EP Objective:** Use secure electronic messaging to communicate with patients on relevant health information **EP Measure:** A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period	**Measure:** More than 10%* of patients use secure electronic messaging to communicate with EPs	Create capacity for electronic episodes of care (telemetry devices, etc) and to do e-referrals and e-consults	*What would be an appropriate increase in threshold based upon evidence and experience?	Primary-Implementation WG Secondary- Privacy and Security WG

Comments:

- Providers using patient portals are nowhere near 10% threshold
- We do not think the threshold should be increased above 10%. Definitely an ambitious goal to keep in mind

Improve Care Coordination					
SGRP 303	**EP/EH CORE Objective:** The EP/EH/CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides summary care record for each transition of care or referral. **CORE Measure:** 1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals. 2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NwHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network. 3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) conducts one or more successful electronic exchanges of a summary of care document, as part ofwhich is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii)	**EP/ EH / CAH Objective:** EP/EH/CAH who transitions their patient to another setting of care or refers their patient to another provider of care Provide a summary of care record for each site transition or referral when transition or referral occurs with available information Must include the following four for transitions of site of care, and the first for referrals (with the others as clinically relevant): 1. Concise narrative in support of care transitions (free text that captures current care synopsis and expectations for transitions and / or referral) 2. Setting-specific goals 3. Instructions for care during transition and for 48 hours afterwards 4. Care team members, including primary care provider and caregiver name, role and contact info (using DECAF (**D**irect care provision, **E**motional support, **C**are coordination, **A**dvocacy, and **F**inancial)) **Measure:** The EP, eligible hospital, or CAH that site transitions or refers their patient to another setting of care (including home) or provider of care provides a summary of care record for 65% of transitions of care and referrals (and at least 30%* electronically). **Certification Criteria:** EHR is able to set aside a concise narrative section in the summary of care document that allows the provider to prioritize clinically relevant information such as reason for transition and/or referral. **Certification criteria:** Ability to automatically populate a referral form for specific purposes, including a referral to a smoking quit line.		*What would be an appropriate increase in the electronic threshold based upon evidence and experience?	Primary- Implementation WG Secondary- Clinical Operations WG

	(B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or (B) conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period.	**Certification Criteria:** Inclusion of data sets being defined by S&I Longitudinal Coordination of Care WG, which and are expected to complete HL7 balloting for inclusion in the C-CDA by Summer 2013: 1) Consultation Request (Referral to a consultant or the ED) 2) Transfer of Care (Permanent or long-term transfer to a different facility, different care team, or Home Health Agency)			
Comments: • Increase to 65% is extremely ambitious • More information available when a patient is transferred is better (100% should be the goal) • Agreement to raise to 65% is ok, but who will be accountable for receipt • Suggestion that requirement is that data is sent, and the receipt is not factored in the same way • MA will be using a DIRECT based HIE. When an EH or EP places a record in a centralized repository, is the percentage calculated based on successfully placing the record in the repository, or whether it is accessed by the EH or EP it was intended for (or another EH or EP)?					
SGRP 305	**New**	**EP / EH / CAH Objective:** EP/EH/CAH to whom a patient is referred acknowledges receipt of external information and provides referral results to the requesting provider, thereby beginning to close the loop. **Measure:** For patients referred during an EHR reporting period, referral results generated from the EHR, 50% are returned to the requestor and 10% of those are returned electronically* **Certification Criteria:** Include data set defined by S&I Longitudinal Coordination of Care WG and expected to complete HL7 balloting for inclusion in the C-CDA by Summer 2013: Shared Care Encounter Summary (Consultation Summary, Return from the ED to the referring facility, Office Visit) **Certification Criteria**: Include standards for referral	Continue working to close the loop with an acknowledgement of order receipt and tracking for completion.	The HITPC would appreciate comments on the return of test results to the referring provider.	Primary- Implementation WG Secondary- Clinical Operations WG

		requests that require authorizations (or pre-certifications) for procedure, surgery, lab, radiology, test orders *This builds upon the clinical quality measure (CQM) in stage 2 for closing the referral loop,CMS50v1 (NQF TBD)			

Comments:

- Support concept and don't anticipate an issue other than one potentially related to the software computing the calculations and necessary counting needed when files are sent

In addition to the questions above, the HITPC would also appreciate comment on the following questions.

ID#	Questions	HITSC/WG Assignment
MU02	What is the best balance between ease of clinical documentation and the ease of practice management efficiency?	Primary- Clinical Operations WG Secondary- Implementation WG

Comments:

- Not add extra expectations for providers to capture structured data
- CMS should add definitions to ensure legal protection and regulations to ensure providers and hospitals are protected

MU03	To improve the safety of EHRs, should there be a MU requirement for providers to conduct a health IT safety risk assessment? Are there models or standards that we should look to for guidance?	Primary- Implementation WG Secondary- Privacy and Security WG, Clinical Operations WG

Comments:

- Let's not add an additional requirements at this time

	• We do not think this will work right now • Lets not add HealthIT safety requirements today	
MU06	What can be included in EHR technology to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based. This capability will need to support measures that occur in all stages of MU (e.g. there are yes/no measures in stage 1 that still need to be supported). Are there objectives and measures that should be prioritized to assist providers in showing that the capability was enabled during the reporting period?	Primary- Implementation WG Secondary- Clinical Operations WG, Privacy and Security WG

Comments:

- No easy way to capture and prove that intervention and yes / no answer was deployed during entire period
- Looking to determine what technical capability vendor would have to prove that yes/no was in fact deployed
- Ask John to provide further information on the yes/no support

II. Quality Measures

The Health IT Policy Committee, in the October 2010 "Tiger Team Summary Report", the December 2010 Request for Comment, and the August 2011 Transmittal Letter, described the intention to support the development of HIT-sensitive, parsimonious, longitudinal, outcomes-focused CQMs for the EHR Incentive Program. In advance of Stage 2 the HITPC recommended eCQM sub-domains and concepts for development and implementation. In advance of Stage 3, the committee intends to focus more broadly on the measure components (logic and value sets), the environment in which the measures operate and the extent to which the measures support quality improvement.

We understand the fundamental mission of the EHR Incentive Program CQM set is to promote the capabilities of EHRs to capture relevant data and to calculate and report measures used by public recognition and payment programs as efficiently and reliably as possible in order to improve the quality of care and experience of care for providers and patients

1. The measures should leverage, to the greatest extent possible, data routinely captured in the EHR and PHR during the process of care, while minimizing data-collection burden on the part of providers
2. The measures set should address measures for public reporting and quality improvement, and be meaningful at the point of care.
3. CQMs should not be "hard coded" into the EHR. Doing so may negatively impact local workflow.
    - Providers should be able to configure the CQM calculation to use data elements appropriate to local workflow
    - When part of EHR the CQM should calculate automatically.
4. An end goal is to shift quality measurement and reporting from sampled retrospective/human chart reviews/ accounting to concurrent/ machine-automated/ improvement while recognizing that there will remain a place for human abstracted quality measurement.

5. Support for CQM calculations should be flexible and adaptive to future requirements, which may include new measures or changes to measure definitions at minimal cost and resources.

Please use the identification numbers below to comment on the appropriateness of the fundamental mission and five key attributes described above for the stage 3 clinical quality measures.

ID #	Questions	HITSC/WG Assignment
QMWG01	As we propose to expand the features of the eCQM measure set, how can it be done in ways to minimize health care costs and reduces burden on health care providers?	Primary- Clinical Quality WG Secondary- Implementation WG
Comments: • There is a need to make sure we do not dilute by adding additional eCQMs to burden providers and reduce level of care		

A. **Patient Centeredness: Broaden Stakeholder Input**

The HITPC intends to capture insights broadly from providers, patients, lay caregivers and other stakeholder groups across the healthcare landscape that have been previously less engaged in HIT policymaking but actively engaged as providers, purchases and recipients of care.

ID #	Questions	HITSC/WG Assignment

B. **Patient Centeredness: Patient-reported and Patient-Directed Data**

The HITPC recognizes that both patients and providers generate and consume clinical quality data. The committee anticipates that consumer generated and directed data is most useful if the data spans settings and is oriented to outcomes. We appreciate that performance data is important for both quality improvement and for shared decision making. Contributors have challenged the workgroup to develop CQMs that accommodate personal care goals in addition to guideline-directed care goals. This is a commendable aspiration; still significant barriers to integration of patient-generated data with EHR clinical data remain.

ID #	Questions	HITSC/WG Assignment

ID #	Questions	HITSC/WG Assignment

C. **CQM Pipeline: Process and Outcome Measures**

The HITPC Quality Measure Workgroup has previously described, in the October 2010 "Tiger Team Summary Report" and the December 2010 Request for Comment, our intention to support the development of HIT-sensitive, parsimonious, longitudinal outcomes-focused CQMs for the EHR Incentive Program. The HITPC also recognizes that there remains value in developing near real-time, point-of-care, process measures for clinical use that can contribute nuance to performance demonstrated by value-oriented, outcomes measures.

ID #	Questions	HITSC/WG Assignment

D. **CQM Pipeline: Measure Development Lifecycle**

The HITPC is considering recommendations both on the types of measures that are developed on the process for measure development. The QMWG has heard from eCQM measure developers, that "retooling", the process of translating existing quality measures, originally based on administrative and claims data and chart abstraction, into XML code may not fully preserve the original intent of the legacy measures and measure components (logic and value sets). Furthermore, retooled measures often do not take full advantage of the richness of clinical data in the EHR, and do not reach out to collect data from patients that are possible through the use of PHRs. Consequently, the QMWG is considering recommending that HHS efforts shift from retooling paper chart/claims measures to designing de novo EHR-enabled measures. The QMWG supports development of de novo measures that stay faithful to high priority quality measurement concepts.

ID #	Questions	HITSC/WG Assignment

E. **CQM Pipeline: MU Alignment with Functional Objectives**

The HITPC understands that EHRs are a powerful tool with the potential to increase clinical efficiency. However, with EHR adoption and implementation there is also a risk of increasing provider administrative burden as well. The HITPC recognizes that successful attestation weighs an administrative burden on providers and their staff. For Stage 3, the workgroup intends to alleviate administrative burden by further aligning the eCQMs logic and value sets with EHR Incentive Program Functional Objectives. For example, care coordination CQMs can be refined/or designed de novo to better align with the Summary of Care objective.

Our goal is not only to mitigate increased burden but to guide users on leveraging efficient and meaningful use. The HITPC seeks comments to guide our recommendations for Stage 3 in this area. The HITPC continues to support HHS-wide efforts to align CQMs across quality assessment programs (PQRS, MU,IQR, etc).

ID #	Questions	HITSC/WG Assignment

F. **CQM Pipeline: Domains and Exemplars**

The HITPC continues to encourage development and release of eCQMs that cover the six priority domains identified by the National Quality Strategy. The HITPC intends to identify exemplar measures/concepts that both address underrepresented NQS priority domains and leverage the current and near future capabilities of EHRs.

ID #	Questions	HITSC/WG Assignment

G. **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 CQMs for endorsement by NQF because they do not consider themselves to be a measure developer. However, these locally developed measures may be useful to many other organizations in the country.

In order to leverage some of the innovation by health systems in creating measures that leverage data from the EHR, the QMWG has discussed a proposal to allow EPs or EHs to submit a locally developed CQM as a menu item in partial fulfillment of MU requirements (in lieu of one of the existing measures specified in the MU program). Health care organizations choosing this optional menu track would be required to use a brief submission form that describes some of the evidence that supports their measure and how the measure was used in their organization to improve care. The healthcare organization benefits by reporting on something that it feels is important in partial completion of MU qualification. CMS benefits from learning about CQMs developed by EHR users in the field, and may use this pipeline of innovative CQMs as a stimulus for new-measure development.

As the EHR Incentive Program is currently an attestation and not accountability program, we see this program as a valuable opportunity to encourage provider-level CQM innovation and perform provider-level CQM testing. If we can set reasonable criteria, then we can use this program for more developmental and

innovative work. We have received comments that recommend individual providers that have designed/developed their own measures should be allowed to submit these measures and data as part of attestation.

ID #	Questions	HITSC/WG Assignment
QMWG23	For the existing and/or in the proposed expanded institution-initiated CQMs, how can federal agencies better support consistent implementation of measures for vendors and local practices (e.g., test case patients, template workflow diagrams, defined intent of measure and valueset)?	Primary- Clinical Quality WG Secondary- Implementation WG
Comment: • Reduce burden and dilution		
QMWG24	Stage 3 may increase the number of measures EPs and EHs calculate and report. Considering provider burden, is there a limit to the number of measures that a provider should be expected to calculate? Is there evidence to support a limit?	Primary- Clinical Quality WG Secondary- Implementation WG

H. **Quality Improvement Support: Architecture and Standards**

The HITPC recognizes that there is an opportunity, in the next stage of Meaningful Use, to design measures that improve the user experience and leverage technologic capability of certified EHR software to affect quality improvement. The workgroup considers the features below for eCQMs and EHRs to valuable both for users and meaningful in clinical practice.

ID #	Questions	HITSC/WG Assignment

I. **Quality Improvement Support: CQM Population Management Platform**

The HITPC intends to encourage the development and expansion of HIT tools that leverage use of eCQMs for population management. The work group is especially interested in development of CQM population mapping and task-management platforms such as, clinical quality measure dashboard or business

process management software and workflow engines that allow users to respond to actionable data on clinical care gaps and assign tasks both to individual patients and for user-determined cohorts. The workgroup understands that this technology is desired by providers and requests comments on the potential role of the HITPC and HHS in this space.

ID #	Questions	HITSC/WG Assignment
QMWG30	What are the technological challenges to widespread release and adoption? Can the HITPC encourage technology in this area without being prohibitively prescriptive? Should the HITPC and HHS pursue avenues outside of regulation to support this technology: e.g. design open source prototypes, challenge grants, demonstration projects, guidance document, etc?	Primary- Clinical Quality WG Secondary- Implementation WG
Comments: • We need to be in support of pushing innovation so that items are tested ahead of time. Vendors are willing to provide labor, but not labor and lost revenue due to standards that are not set in stone.		

III. Privacy and Security

In September 2012, the HITPC recommended that EHRs should be able to accept two factor (or higher) authentication for provider users to remotely access protected health information (PHI) in stage 3. [1] This included recommending that organizations/entities, as part of their HIPAA security risk analysis, should identify any other access environments that may require multiple factors to authenticate an asserted identity, and that organizations/entities should continue to identity proof provider users in compliance with Health Insurance Portability and Accountability Act (HIPAA). The HITPC would like input on the following questions related to multi-factor provider authentication:

ID #	Questions	HITSC/WG Assignment
PSTT02	How would ONC test the HITPC's recommendation in certification criteria?	Primary- Privacy and Security WG Secondary- Implementation WG

[1] Remote access includes the following scenarios: a) Access from outside of an organization's/entity's private network; b) Access from an IP address not recognized as part of the organization/entity or that is outside of the organization/entity's compliance environment; and c) Access across a network, any part of which is or could be unsecure (such as across the open Internet or using an unsecure wireless connection).

ID #	Questions	HITSC/WG Assignment

In addition to considering provider user authentication, the HITPC has assessed the success of the security requirement included in Stage 1 of Meaningful use and is looking for feedback on the logical next steps. In Stages 1 and 2 of Meaningful Use, EPs/EHs/CAHs are required to attest to completing a HIPAA security risk analysis (and addressing deficiencies): In Stage 2, they are required to attest to specifically addressing encryption of data at rest in Certified EHR Technology.

ID #	Questions	HITSC/WG Assignment
PSTT04	What, if any, security risk issues (or Health Insurance Portability and Accountability Act (HIPAA) Security Rule provisions) should be subject to Meaningful Use attestation in Stage 3? For example, the requirement to make staff/workforce aware of the HIPAA Security Rule and to train them on Security Rule provisions is one of the top 5 areas of Security Rule noncompliance identified by the HHS Office for Civil Rights over the past 5 years. In addition, entities covered by the Security Rule must also send periodic security reminders to staff. The HITPC is considering requiring EPs/EHs/CAHs to attest to implementing HIPAA Security Rule provisions regarding workforce/staff outreach & training and sending periodic security reminders; we seek feedback on this proposal.	Primary- Privacy and Security WG Secondary- Implementation WG

Feedback on standards for accounting for disclosures would also be appreciated. Accounting for disclosures, surveillance for unauthorized access or disclosure and incident investigation associated with alleged unauthorized access is a responsibility of organizations that operate EHRs and other clinical systems. Currently, the 2014 Edition for Certified EHR Technology specifies the use of ASTM E-2147-01. This specification describes the contents of audit file reports but does not specify a standard format to support multiple-system analytics with respect to access. The HITPC requests comment on the following related questions:

ID #	Questions	HITSC/WG Assignment