Improving quality, safety, and reducing health disparities

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P101	**Eligible Provider (EP) Objective:** Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines **Eligible Hospital (EH) Objective:** Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines **EP/EH Measure:** More than 60 percent of medication, 30 percent of laboratory, and 30 percent of radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	**Objective:** Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order. CPOE for medications includes drug-drug interaction (DDI) checking for "never" combinations as determined by an externally vetted list. **Measure:** More than 60% of medication, laboratory, and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE **Certification Criteria:** EHR must be able to consume an externally supplied list of "never" DDIs, using RxNorm and NDF-RT standards along with a TBD DDI reactions value set. **Certification Criteria for EPs** • EHR must have the ability to transmit lab orders using the lab order and results Interface guidelines produced by the S&I Framework Initiative.	Seeking externally maintained list of DDIs with higher predictive value	

SUMMARY OF PUBLIC COMMENT:

- Overall support for the objective
- Varied opinions on increasing and decreasing the thresholds
    - More leaned towards not increasing, particularly for labs and rads
    - Concerns about the concept of external DDI checking

SUMMARY OF HITSC COMMENTS:

Agree with deferral for future stages. The "externally vetted list" must be better defined before it can be standardized, and methods to reduce false positives - to avoid alert fatigue - should be developed.

Kaiser has a carefully developed, operational list.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P130	New	**Objective:** Use computerized provider order entry for referrals/transition of care orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order. **Measure:** More than 20% of referrals/transition of care orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded.		

SUMMARY OF PUBLIC COMMENT:

- General support
- Great deal of confusion as to whether this proposal simply required the recording of the referrals/transition of care orders created by the EP or whether it actually required the electronic transmission of these orders.
    - For actual electronic transmission, commenters were most concerned about the lack of interoperability and standards
    - Need to factor differences between EP and EH

SUMMARY OF HITSC COMMENTS:

Unclear how referral order workflow would work. Would an order initiate an X12 administrative referral/auth transaction, send a clinical message to the next provider of care, and initiate a closed loop referral management process etc?

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P103	**EP/EH Objective:** Generate and transmit permissible prescriptions electronically (eRx) **Measure:** More than 50% of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT. **EH MENU Objective:** Generate and transmit permissible discharge prescriptions electronically (eRx) **EH MENU Measure:** More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology	**EP Objective:** Generate and transmit permissible prescriptions electronically (eRx) **EP Measure:** More than 50% of all permissible prescriptions written by the EP are compared to at least one drug formulary **(reviewed for generic substitutions)** transmitted electronically using Certified EHR Technology. **EH Objective:** Generate and transmit permissible discharge prescriptions electronically (eRx) **EH Measure:** More than **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 Certified EHR Technology	Advanced medication reconciliation to check for formulary compliance. Medication formulary checking: • If Rx is formulary-compliant, transmit to pharmacy. • If Rx is not formulary compliant, prescriber presented with alternatives (if available through formulary database) or provided a structured prior-authorization form to complete before Rx transmitted. Capability for automatic approval of prior-auth should be available.	How to include formulary checking into EHR and connection to formulary sources (e.g., PBMs)?

SGRP103, continued

SUMMARY OF PUBLIC COMMENT:

- Commenters were not in agreement with this proposal
- Clarifications, concerns and revisions were suggested
- Standards for pre-authorization and formularies were suggested

SUMMARY OF HITSC COMMENTS:

NCPDP Formulary And Benefit Standard Implementation1 Guide Version 3.Ø (ANSI approval Jan 28, 2011) plus editorial corrections published April 2012, or perhaps v4.0 (recently published, ANSI approval pending) formulary standard is recommended for transmission to EHRs. At the same time flexibility in the basis for generic substitution, i.e. allowing reasonable alternatives to formulary restrictions as proposed in the measure, argues against strict adherence to a rigid formulary standard.

Checking of the patient's "formulary" in the outpatient setting will require formulary developers to provide their formularies in standard, electronic form—something many currently decline to do.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments

SGR P104	**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.

SGRP104, continued

SUMMARY OF PUBLIC COMMENT:

- 337 Comments
- Retiring the demographics objective
    - Commenters were fairly evenly split on retiring, though many who support retirement do so with reservations
        - Many requested clarification on what 'retirement' and ‘topping out’ really mean
        - Concerns that retiring would encourage providers to no longer collect the data, leading to disparities and quality loss
        - Commenters suggested a number of additional data elements
        - Requests for additional specificity on race/ethnicity
- Certification criteria: Occupation and industry codes
    - Commenters overwhelmingly support adding
        - Some would like there to be an MU requirement so that practices actually capture this information
        - A few commenters opposed these data elements due to the cost of maintaining, updating EHR systems to capture it, and the complexity of system development
- Certification criteria: Sexual orientation, gender identity
    - Most commenters agreed with inclusion, but want more specificity regarding data standards, definitions and how data will affect other parts of EHR systems

SUMMARY OF HITSC COMMENTS:

Disagree. Although a high level of demographic data recording has been achieved, discontinuing the requirement could diminish collection of foundational data. Sensitive data such as sexual orientation and disability status should be omitted.

No other sector would consider 80% to be optimal performance on an important quality measure, nor should healthcare.

- 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 of disability status and inclusion of functional status should be included

Note: CMS has established HCPCS and modifier coding requirements for reporting functional status and degree of impairment for therapy services claims, and explicitly requires them to be documented into the medical record. Any CMS requirement for that kind of information for meaningful use Stage 3 should take that into account and leverage it at least where the two requirements overlap – not impose additional requirement. The CMS claims requirement impacts all manners of therapy services providers including hospitals and physicians

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P105	**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? 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.

SUMMARY OF PUBLIC COMMENT:

- 101 Comments
- Overall, commenters were concerned that this item, as written was too vague
- A number of commenters suggested integrating this requirement with CDS, indicating that it is duplicative

SUMMARY OF HITSC COMMENTS:

Recommend against standardizing at this time. Best practice advisories, alternative recommendations, and alerts should qualify as helpful tools but should not be mandated. Patient input could be used e.g. to reconcile problem list but introduces new issues in data integrity and validity.

The diabetes example is based on knowledge. How would this work otherwise? In any case, this functionality is not well enough characterized to be a certification criterion.

- Our question is how incorporate into certification criteria on using computer logic related to provide assistance in determining 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 – The point here is that you want straightforward connections between findings (interventions and diagnostics) and a 'problem.
- Limit the certification criteria and therefore pilot testing to high importance, low ambiguity cases.
- Chronic nationwide issues are most feasible. Consider limitation to the top 10
- Nothing in making this a certification criteria that prevents vendors from adding this functionality into their system without this requirement
- The Healthcare industry as a whole may not be ready for this functionality right now
- This type of requirement will create significant challenges with the test scripts.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP106	**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 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.	**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 medication lists.	How to incorporate into certification criteria for pilot testing? 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.

SUMMARY OF PUBLIC COMMENT:

- 84 Comments
- Many commenters expressed support for this additional functionality, while others equally expressed concern
- Concerns about the vagueness of the certification criteria, potential for alert fatigue, and additional costs and complexity for providers

SUMMARY OF HITSC COMMENTS:

Recommend against standardizing at this time, see above response on Problem List. Integration of external data sources e.g. for fill status introduces new concerns with data validation that need to be resolved first.

- Expansions of the measures as explained in certification criteria is of concern due to physician workflow, varying vendor functionality and clear definitions of timelines and factors related to the triggering events.
- 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
- Consider testing CDS in the real world with input from actual providers and workers, before it is added as an expanded measure.
- Great for the future, but difficult to do right now
- More clarity can be added with the use cases to produce adequate testing and then the establishment of certification criteria

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P107	**Consolidated with summary of care -** Maintain active medication allergy list	**Certification criteria:** EHR systems should provide functionality to code medication allergies including its related drug family to code related reactions.	Contraindications that could include adverse reactions and procedural intolerance.	The intent is that EHR vendors would provide functionality to help maintain functionality for active medication allergy lists, not that they supply the actual knowledge for the rules.

SUMMARY OF PUBLIC COMMENT:

- 66 Comments
- Commenters generally supported recommendations
    - Need for a clear and precise certification criteria and standards (some recommendations provided).
    - Suggested inclusion of other allergens and the need to differentiate allergy intolerances and adverse reactions.
    - A few commenters were concerned about alert fatigue and costs

SUMMARY OF HITSC COMMENTS:

See comments on SGRP 105, 106. Advisories and alerts should qualify as helpful tools but should not be mandated. Patient supplied data could be helpful but would introduce new issues with data validity, reliability, and integrity.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P108	**Objective: Record and chart changes in vital signs:** • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI **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 blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data	Retire measure because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0018		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.

SUMMARY OF PUBLIC COMMENT:

- 99 comments
- Approximately 43 or so commenters agreed with retiring the measure, while about 46 or so disagreed with retiring the measures for various reasons.
    - Some comments were not relevant, repetitive, or did not express a clear preference.

SUMMARY OF HITSC COMMENTS:

Agree with retiring the measure.

SUMMARY COMMENT: Retiring this measure makes sense because attestation is of limited use at this stage of MU, but measures should demonstrate the use of such data, not its collection. In general, retiring attestation measures is reasonable provided the intent is that the data is transitioning to data use.

Comments:

Floyd: This objective should be a requirement for the EHR to automatically report the frequency of each item among all visits rather than a requirement for attestation. There is no certification requirement for EHRs to perform functional process utilization. While there should be such a requirement, without it the objective remains an attestation element and adds to unnecessary work on the part of providers.

- Continue blood pressure and BMI with increasing performance standard (to 95%) over 3 years. Perform evidence review regarding the age up to which growth-chart calculation is clinically important.
- Agree with retiring

Discussion:

- Ideally would capture the actual values for the measure – if you wouldn't do that then there is no reason to retain
- Healthcare is the only place where 80% would be "topped out"
- BP is measured in one of the MU2 measures—BMI is also covered for some patients therefore probably not needed
- Only BP would be measured if this is eliminated
- This measure looks at capture of data—not USE of data—need to move beyond capture to utilization

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P109	**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	Retire measure because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0028		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.

SUMMARY OF PUBLIC COMMENT:

- 103 Comments
- Many commenters expressed support for this additional functionality, while others equally expressed concern
- Concerns about the vagueness of the certification criteria, potential for alert fatigue, and additional costs and complexity for providers

SUMMARY OF HITSC COMMENTS:
Agree with retiring the measure

SUMMARY COMMENT: Retiring this measure makes sense because attestation is of limited use at this stage of MU, but measures should demonstrate the use of such data, not its collection. In general, retiring attestation measures is reasonable provided the intent is that the data is transitioning to data use.

Comments:

- This objective should be a requirement for the EHR to automatically report the frequency of each item among all visits rather than a requirement for attestation. There is no certification requirement for EHRs to perform functional process utilization. While there should be such a requirement, without it the objective remains an attestation element and adds to unnecessary work on the part of providers.
- Continue measure with increasing performance standard (to 95%) over 3 years.
- Agree with retiring

Discussion: See discussion for SGRP 108

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P112	**EH MENU Objective: R**ecord whether a patient 65 years old or older has an advance directive **EH MENU Measure:** More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.	Ensure standards support in CDA by 2016 **EP MENU/EH Core Objective:** Record whether a patient 65 years old or older has an advance directive **EP MENU/EH Core Measure:** More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.		

SUMMARY OF PUBLIC COMMENT:

- 81 Comments
- Commenters generally supported recommendations
    - Need for a clear and precise certification criteria and standards
    - Need to differentiate allergy intolerances and adverse reactions
    - Concerns about alert fatigue and costs

SUMMARY OF HITSC COMMENTS:

Agree with need to ensure standards support in CDA by 2016.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
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 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.	**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) * 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.	**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 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.	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 contribute to CDS.

SUMMARY OF PUBLIC COMMENT:

- 157 comments
- Approximately the same number expressed favor/opposition to increasing to 15 interventions
    - Concerns included: alert fatigue, lack of CDS interventions relevant to specialty practice (especially ones related to the CQMs).
    - Clarification needed regarding whether the 15 interventions are to be at the practice/group level or the provider level (which could be burdensome for larger organizations).

SGRP 113, continued

- Comments were varied about the tie to CQMs and focus areas
    - Some opposed, viewing it as too burdensome or not enough relevant CQMs available
    - A few contended that the links and focus areas were "too arbitrary" and detracted from targeted QI
    - A few suggested that ONC focus on outcomes and let providers pick what CDS they need to improve CQMs
- Most opposed the DDI requirement (noted as a source of alert fatigue)
- Many expressed concern that standards will not be available for structured SIG
- Few commenters were in favor of tracking provider responses to CDS
- Clarification was requested related to preference-sensitive conditions and vendors indicated concern about modularity of patient versus provider-facing CDS
- The criterion for the ability to consume CDS interventions was generally met with support
    - Concern about readiness of standards and the cost of content subscriptions to providers.
- There were only a couple of comments related to food-drug interactions and were concerned about the specificity of information likely to be available in an EHR.

SUMMARY OF HITSC COMMENTS:
Defer or reconsider in are areas of certification criteria. Central repositories of CDS interventions do not exist and the standards for representation of rules and data for rules are immature. More tracking, flagging, and alerts may make CDS more detrimental than useful. Recommend instead a more flexible acceptance of tools that are adaptable to different practice patterns and that allow established clinical workflows. A multi-year workplan is needed for research and for standards development.

Proposed certification criterion #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)” dictates design (central repository). Certification criteria should specify what the EHR needs to do and not how it should be implemented within an enterprise. A central rules repository is just one way of implementing CDS. Suggest change to “Ability for EHRs to consume CDS rules as structured data using xxx standard” (standard TBD)

- 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 -
- 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.
- Reporting and follow-up items need to be managed and handled properly
- Payor experience that may contribute to CDS should be solicited from the payor community via hearings, town halls or surveys

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P114	**EP/EH Objective:** Incorporate clinical lab-test results into Certified EHR Technology as structured data **Measure:** More than 55 percent 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 affirmation or numerical format are incorporated in Certified EHR Technology as structured data	**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		

SUMMARY OF PUBLIC COMMENT:

- 73 comments
- Most agreed with the increase in threshold to 80%
    - Clarify if this measure is menu /core.
    - Evaluate experience in stage 2 prior to increasing threshold
    - Consider exclusion criteria

SUMMARY OF HITSC COMMENTS:

Clinical Ops WG: Increased threshold should be workable with existing standards.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P115	**EP CORE Objective:** Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach **EP CORE Measure:** Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.	**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.		

SUMMARY OF PUBLIC COMMENT:

- 98 comments
- Generate lists of patients for multiple specific conditions
    - Most commenters agreed with the intent of this measure, but requested specificity on the number of lists, what they should include, and when they should be used
- Present near real-time (vs. retrospective reporting) patient-oriented dashboards
    - Commenters requested clarity, as the language was not specified well-enough to offer recommendations
- Dashboards are incorporated into the EHR's clinical workflow
    - Commenters were divided on this measure and requested more specificity around the type of information presented and where it fits into clinical workflow
    - Uncertainty around how this would be measurable as proposed
- Actionable and not a retrospective report
    - Commenters were evenly divided on whether this should be included - requested a definition of actionable

SUMMARY OF HITSC COMMENTS:

Need to specifically define near-real-time, and "actionable" to assist standards selection.

As a form of presentation layer, dashboards are fundamentally limited—to a static set of just a few elements. Dashboards should not be specified in certification or elsewhere.

Apt EP Objective: Present to EPs (and other clinicians) usable, actionable patient-specific information in time to improve care processes.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P116	**EP Objective:** Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder per patient preference. **Measure:** More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available	**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).		

SUMMARY OF PUBLIC COMMENT:

- 77 comments
- Agreement on increasing the threshold, but disagreed with decreasing the time to period
    - Specify requested regarding 'clinically relevant', definition of reminder and patient preference , whether core/menu.

SUMMARY OF HITSC COMMENTS:

This should be an initial percentage increasing over several years to 95% of patients for whom a preventive/follow-up reminder is appropriate being sent a reminder via their preferred communication channel. (Many will have moved and be effectively impossible to reach.)

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P117	**EH Objective:** Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR) **Measure:** More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using eMAR.	**EH Objective:** Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR) **Measure:** 1) More than 30% of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR. 2) Mismatches (situations in which a provider dispenses a medication and/or dosing that is not intended) are tracked for use in quality improvement.		

SUMMARY OF PUBLIC COMMENT:

- 52 comments
- Commenters agree with increasing the threshold to 30%
    - Commenters generally agreed with tracking mismatches, but wanted more specificity

SUMMARY OF HITSC COMMENTS:

Increasing to 95%.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P118	**MENU Objective: I**maging results consisting of the image itself and any explanation or other accompanying information are accessible through Certified EHR 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 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		What barriers could be encountered in moving this to core?

SUMMARY OF PUBLIC COMMENT:

- 88 comments
- Commenters do not agree with moving this to core. Numerous barriers were detailed that included:
    - Cost of interfaces and availability, especially to EP
    - Type of images have been expanded beyond RIS/PACS which widens scope
    - Evaluation needed of networking, transmission, and storage impact of large image files
    - Lack of control over getting images from the various image systems
    - Lack of high resolution displays may compromise adequate result viewing

SUMMARY OF HITSC COMMENTS:

Reframe objective as an HIE objective to share images, in a stage subsequent to MU3. Clarify that EKGs are not images but could be useful to caregivers. The ability to access images is not a core EHR function, but can be enabled by linked access to imaging systems, image archives, by image exchange/sharing functions or by other means.

- Cost of achieving interoperability with image source should be recognized. Definitions of image within the EHRs, and the relevance of actual images to the clinician are barriers..
- Considering the necessity of the use of the image, this should be considered only as a menu item.
- The summary/report 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.
- Continue this as a menu measure with a 10% threshold.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P119	**MENU Objective:** Record patient family health history as structured data **MENU Measure:** More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives	**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).		

SUMMARY OF PUBLIC COMMENT:

- 91 comments
- Commenters disagreed with moving to core, increasing the threshold, and the change in wording to 'high priority' (this caused confusion)
- Commenters requested clarification on certification criteria for CDS intervention to have the ability to take family history into account. Many thought this would be more appropriate in the CDS measure.

SUMMARY OF HITSC COMMENTS:

Retain as menu set (offset to recommendation to retain demographics, etc.) and need to define "high priority data" based on an explicit value case analysis.

It is critically important that the family history required is evidence-based, in the sense that it is validated in a clinical trial as informing improved patient care. Whether or not each datum involves a first-degree relative is irrelevant to this.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P120	**EP/EH MENU Objective:** Record electronic notes in patient records **EP MENU Measure:** Enter at least one electronic progress note created, edited and signed by an eligible professional for more than 30 percent of unique patient office visits. Notes must be text-searchable. Non-searchable scanned notes do not qualify but this does not mean that all of the content has to be character text. Drawings and other content can be included with text notes under this measure. **EP MENU Measure:** Enter at least one electronic progress note created, edited, and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period. Electronic progress notes must be text-searchable. Non-searchable, scanned notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with text notes under this measure.	Record electronic notes in patient records for more than 30% of office visits within four calendar days.		

SUMMARY OF PUBLIC COMMENT:

- 72 comments
- 2/3 of the commenters wanted additional specificity before supporting, the remaining mostly agreed with the proposed changes.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P121	**EH MENU Objective:** Provide structured electronic lab results to ambulatory providers **EH MENU Measure:** Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received	**EH CORE Objective:** Provide structured electronic lab results to eligible professionals. **EH CORE Measure:** Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 80% of electronic lab orders received.		

SUMMARY OF PUBLIC COMMENT:

- 59 comments
- Most commenters disagreed with moving to core increasing the threshold.

SUMMARY OF HITSC COMMENTS:

Why not require LOINC by name? It is clearly mature enough and has been recommended for this by HITSC.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P122	**NEW**	**Objective:** The EHR is able to assist with follow-up on test results **Measure:** 10% of test results, including those which were not completed are acknowledged within 3 days **Certification Criteria:** • EHRs must have the ability to identify abnormal test results and to to notify the ordering providers when results are available or not completed by a certain time. • EHRs must record date/time test results are reviewed and by whom		

SUMMARY OF PUBLIC COMMENT:

- 64 Comments
- Commenters were equally divided regarding including this measure. Many requested clarification on terms in order to support (e.g. timing, abnormal)

SUMMARY OF HITSC COMMENTS:

Is this 3 working days? Three week days? If 72 hours is meant, we should say that. Increasing to 95% over time

Engage patients and families in their care

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP204A	**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 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.	• 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% 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.	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) • 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 • Add a MENU item to enable patients to view provider progress notes (re: Open 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? 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?

SGRP204A, continued

SUMMARY OF PUBLIC COMMENT:

- 124 comments
- VDT: A few commenters were concerned about the threshold increase, while others asked for the threshold to be even higher
  - A large number of commenters expressed concern about providers being accountable for patient actions
  - A large number of commenters were concerned about accelerating the timing to 24 hours and 4 days for labs while others (a few thought the timing was too long)
- ABBI: Overall commenters supported, but there were a number of areas of concern (e.g. provider liability, privacy and security risks (42 CFR Part 2 data needs to be clearly identified))
- Very few comments related to the proposed future stage recommendations , those who commented were supportive
- Imaging and Radiation Dosing: Most commenters were supportive of including imaging and/or radiation dosing, but had a few concerns (e.g. availability of standards, educating patients on radiation dosing, providing a link to PACS to avoid bandwidth issues).

SUMMARY OF HITSC COMMENTS:

Allow innovative and flexible approaches in addition to ABBI.

Suggest adding dosing information as a requirement for radiology reports.

Agree [MENU item to enable patients to view provider progress notes] could be a menu item

Careful testing required. This data will be incomplete and therefore deceptive for the foreseeable future. Evidence-based recommendations would need to be validated.

SGRP 204 A - Images

- Images as currently required in Stage 2 are being currently implemented in EHRs. Comments on the expansion of this requirement are contained in the next two bullets.
- Radiology Images are currently being uploaded today to inpatient records. Cardiology and other images are in early stages of integration.
- –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

- 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

- A cursory examination of the AA requirements identifies issues that indicate significant challenges with the standard as written.
- A thorough evaluation could lead to exclusions/exceptions to the AA conformance that would make this requirement acceptable.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 204B	**New**	**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.		Readiness of standards to include medical device data from the home? What information would providers consider most valuable to receive electronically from patients? What information do patients think is most important to share electronically with providers? How can the HITECH incentive program support allowing doctors and patients to mutually agree on patient-generated data flows that meet their needs, and should the functionality to collect those data be part of EHR certification? Please provide published evidence or organizational experience to support suggestions.

SUMMARY OF PUBLIC COMMENT:

- 135 comments
- The majority supported this item, but clarifications were requested:
    - Definition of high priority health conditions
    - Both EP and EH measure
    - Concerns about providers being accountable for patient actions
    - Availability of standards to differentiate between provider and patient data
    - Concerns about burdening providers with too much information
    - There was a wide disparity in comments related to the timing of this measure, some wanted it pushed to core, others thought menu was appropriate, and still others thought it should be pushed out to a future stage.
- Most commenters were concerned that standards will not be available to include medical device data.

SUMMARY OF HITSC COMMENTS:

Multiple issues.

1. Applicable device messaging standards must mature further before being mandated.
2. Device ID is needed first, before including device data standards in MU. Defer home device data until after FDA UDI final rule and align MU dates with UDI implementation for Class III devices.
3. Processes and policies for incorporation of external device data is needed and not sufficiently mature.

Need to define “high priority health conditions” (e.g. cancer, diabetes, heart disease ?) in order to define relevant standards. Standards and policies are immature and this should be a multiyear work plan item for HITSC.

This is too immature and fluid for specification. Evidence of the usefulness of the information must be factored in with patient and clinician preferences.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP204D	**New**	**Objective:** Provide patients with the 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.		

SUMMARY OF PUBLIC COMMENT:

- 95 comments
- The majority supported this item, but clarifications were requested
  - Many suggestions to define "in an obvious manner", documentation requirements, whether or not the provider must accept all amendments, and what parts of the record could have amendments submitted
  - Need to differentiate between patient and provider data and notify patients if amendment is not accepted
  - Many sought clarification on what the measure and threshold would be

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP205	**EP Objective:** Provide clinical summaries for patients for each office visit **EP Measure:** Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.	The clinical summary should be pertinent to the office visit, not just an abstract from the medical record.		What specific information should be included in the after visit summary to facilitate the goal of patients having concise and clear access to information about their most recent health and care, and understand what they can do next, as well as when to call the doctor if certain symptoms/events arise?

SUMMARY OF PUBLIC COMMENT:

- 88 comments
- Commenters were supportive of evaluating this measure to ensure that the clinical summary is pertinent to the office visit.
- Many commenters provided lists of items that should be included, one common theme was to provide information to patients that facilitates concise and clear access to information about their most recent health and care, and understand what they can/should do next.
- Commenters were concerned about the current format of many vendor summaries and included: summaries being too long, not in plain language, and language limitations.
- Quite a few commenters were confused and wanted clarification on what 'pertinent to the office visit" actually meant

SUMMARY OF HITSC COMMENTS:

To identify standards please clarify that clinical summary content should include only specific pertinent visit information – i.e. what was done, what patient needs to do, any tests to be done by specified dates, patient instructions related to goals and follow up care. Also need to ensure this is not duplicative of care plan requirements, progress note requirements, etc.

S: patient-reported signs and symptoms (including those prompting the visit)
O: clinician observations (including test results
A: clinician's assessment of the patient's clinical situation
P: the care plan negotiated by the patient and clinician (short-term and long-term)

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P206	**EP/EH Objective:** Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient **EP CORE Measure:** Patient specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period **EH CORE Measure:** More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient- specific education resources identified by Certified EHR Technology	**Additional language support:** For the top 5 non-English languages spoken nationally, provide 80% of patient-specific education materials in at least one of those languages based on EP's or EH's local population, where publically available.		

SUMMARY OF PUBLIC COMMENT:

- 101 comments
- Many supported this recommendation, but suggested changing the non-English language from the top 5 national to the top 5 local. Other concerns included:
    - Many non-English speaking patients may not be able to read materials or the materials may be printed at too high of a reading level

Others also encouraged adding visual/pictorial materials and Braille

SUMMARY OF HITSC COMMENTS:

95% of patients are offered to usable, useful electronic messaging. (The percent of users varies in research, depending on the patient's perceived need and access to electronic communications.)

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P207	**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?

SUMMARY OF PUBLIC COMMENT:

- 117 comments
- Most commenters did not support increasing the threshold until we learn from stage 2
    - Many commenters recommended including family, and caregivers in the measure
    - Concerns about providers being held accountable for patient actions.

SUMMARY OF HITSC COMMENTS:

We recognize that this measure is intended to motivate EPs to encourage their patients to use secure electronic messaging. But we have no evidence or experience that might inform what an appropriate increase in threshold might be.

- 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
- Current threshold is 5 and recommend leaving the threshold at 5%.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P208	**Not included separately (in reminder objective)**	**EP and EH Measure:** 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).		

SUMMARY OF PUBLIC COMMENT:

- 76 comments
- Most commenters support this requirement to document communication preferences and agree that it is a necessary requirement in order to ensure people receive information in a medium that engages them.
    - Many suggested constraint around the menu of communication types to avoid workflow challenges and suggested that certification criteria be developed to specify the menu of options for “preferences” and “purposes”.

SUMMARY OF HITSC COMMENTS:

Increasing to 95%. Include updating annually.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P209	**New**	**Certification Criteria:** Capability for EHR to query research enrollment systems to identify available clinical trials. No use requirements until future stages.		The goal of this objective is to facilitate identification of patients who might be eligible for a clinical trial, if they are interested. The EHR would query available clinical trial registries and identify potentially relevant trials based on patient's health condition, location, and other basic facts. Ultimately, the EHR would not be able to determine final eligibility for the trial; it would only be able to identify possibly relevant trial opportunities.

SUMMARY OF PUBLIC COMMENT:

- 65 comments
- Commenters see the value in the EHR being able to query clinical trials database and the intent of this criteria to improve enrollment in trials but a number of concerns were noted.
  - Implementation challenges, including the complex functionality that would be required to query multiple sources
  - Lack of specification about what fields to query
  - Lack of standards or a defined use case; workflow challenges; a lack of broad applicability to practitioners (more relevant to specialists)

SUMMARY OF HITSC COMMENTS:

Building a sophisticated parsing algorithm could limit the quality of information by applying too many filters. May not be applicable to many patients in any case. A low impact approach would simply enable access to "clinicaltrials.gov" from the EHR.

Before this was made a measure, evidence would be needed that it improves the patient's care or health.

While I support the intent of this proposed criterion, implementation would require knowledge of the service interfaces of all relevant research enrollment systems (since we can't impose MU standards on them). I think that may be unrealistic. On the other hand, if EHRs implemented a standard service interface to query clinical trials system, developers of these trials system would be encouraged to conform to those standards. So I recommend that ONC sponsor the development of a service interface standard to enable EHRs to query clinical trials systems. (Perhaps CDISC could lead this development?)

Improve Care Coordination

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P302	**EP/EH CORE Objective:** The EP/EH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation. **EP/EH CORE Measure:** The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)	**EP / EH / CAH Objective: The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform reconciliation for:** - medications - medication allergies - problems **EP / EH / CAH Measure:** The EP, EH, or CAH performs reconciliation for medications for more than 50% of transitions of care, and it performs reconciliation for medication allergies, and problems for more than 10% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23). **Certification Criteria:** Standards work needs to be done to adapt and further develop existing standards to define the nature of reactions for allergies (i.e. severity).	Reconciliation of contraindications (any medical reason for not performing a particular therapy; any condition, clinical symptom, or circumstance indicating that the use of an otherwise advisable intervention in some particular line of treatment is improper, undesirable, or inappropriate) **Certification Criteria:** Standards work needs to be done to support the valuing and coding of contraindications.	Feasibility to add additional fields for reconciliation e.g. social history? Is anyone currently doing reconciliation outside of meds, med allergies, and problems and what has the experience been?

SUMMARY OF PUBLIC COMMENT:

- 97 comments
- Overall, commenters were supportive of this measure. There were concerns about the ability to measure outcomes, differences of opinion on the percentage needed to obtain the objective, and requests for clarification.
    - Most comments asked for a higher threshold for the reconciliation items
    - Many commenters asked for additional items to be reconciled (e.g. caregiver names and numbers), while others were not supportive of providing additional items

Concerns regarding how this will actually be measured and readiness of standards

SUMMARY OF HITSC COMMENTS:

Defer this item. Allergy and problem reconciliation is immature and should be further developed, with a value case. More work needs to be done to define medication allergies and problems in relation to reconciliation as well as the vocabulary for contraindications for certain medication therapies, allergy severity, etc.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P303	**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 of which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii) (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.	**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. **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)		*What would be an appropriate increase in the electronic threshold based upon evidence and experience?

SGRP303, continued

SUMMARY OF PUBLIC COMMENT:

- 119 comments
- Strong support for the intent of this objective, however commenters expressed concern regarding the burden imposed by the objective, the lack of existing standards, and the lack of experience from Stage 2 MU.

SUMMARY OF HITSC COMMENTS:

- The increase in functional requirements in Stage 3 are themselves a challenge requiring changes in workflow and perhaps job definitions for clinical personnel. It will be a substantial achievement to implement the new functionality at the 50% level already required for Stage 2. Also upping the measure to 65% may be perceived as an unnecessary addition to the workload for Stage 3. Likewise, the proposed stage 3 rule eliminates the option of satisfying the requirement for electronic transmission by testing with CMS-designated test sites. This is a substantial challenge for many EPs or hospitals. Upping the measure from 10% to 30% significantly compounds the difficulty in implementation and risk that an EP or hospital fails to meet MU measures due to difficulty working with organizations not directly impacted by MU requirements.
- More information available when a patient is transferred is better (100% should be the goal)
- Suggestion: that requirement is that data is sent, and the receipt is not factored/calculated in the same way
- 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)?

Transitions for which this is appropriate should be rationalized, and a threshold should depend on new classification and definitions of transitions. Need to ensure the definition of numerator and denominator for transitions allows for shared patient records and shared case management tools shared by all care team members (e.g. multiple specialties and primary care), not only for fragmented physician record scenarios that may require transmission of data.

95%

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P304	**New**		**EP/ EH / CAH Objective:** EP/ EH/CAH who transitions their patient to another site of care or refers their patient to another provider of care For each transition of site of care, provide the care plan information, including the following elements as applicable: • Medical diagnoses and stages • Functional status, including ADLs • Relevant social and financial information (free text) • Relevant environmental factors impacting patient's health (free text) • Most likely course of illness or condition, in broad terms (free text) • Cross-setting care team member list, including the primary contact from each active provider setting, including primary care, relevant specialists, and caregiver • The patient's long-term goal(s) for care, including time frame (not specific to setting) and initial steps toward meeting these goals • Specific advance care plan (Physician Orders for Life-Sustaining Treatment (POLST)) and the care setting in which it was executed. For each referral, provide a care plan if one exists **Measure:** The EP, eligible hospital, or CAH that transitions or refers their patient to another site of care or provider of care provides the electronic care plan information for 10% of transitions of care to receiving provider and patient/caregiver. **Certification Criteria:** Develop standards for a shared care plan, as being defined by S&I Longitudinal Coordination of Care WG. Some of the data elements in the shared care plan overlap content represented in the CDA. Adopt standards for the structured recording of other data elements, such as patient goals and related interventions.	How might we advance the concept of an electronic shared care planning and collaboration tool that crosses care settings and providers, allows for and encourages team based care, and includes the patient and their non-professional caregivers? Interested in experience to date and the lessons learned. Think through these priority use cases: 1. Patient going home from an acute care hospital admission 2. Patient in nursing home going to ED for emergency assessment and returning to nursing home 3. Patient seeing multiple ambulatory specialists needing care coordination with primary care 4. Patient going home from either hospital and / or nursing some and receiving home health services What are the most essential data elements to ensuring safe, effective care transitions and ongoing care management? How might sharing key data elements actually improve the communication? Consider health concerns, patient goals, expected outcomes, interventions, including advance orders, and care team members. What data strategy and terminology are required such that the data populated by venue specific EHRs can be exchanged. How might existing terminologies be reconciled? What are the requirements (legal, workflow, other considerations) for patients and their identified team to participate in a shared care plan? Is it useful to consider role-based access as a technical method of implementing who will have access to and be able to contribute to the care plan? How will such access be managed?

SUMMARY OF PUBLIC COMMENT:

- 89 comments
- Generally commenters noted the objective is broad as written, suggestion for focused, defined approach and the need to define terms clearly
- Some concerns regarding over specification, lack of standards, lack of experience and burden on providers
- Several commenters recommended combining SGRP 303 and 304
- Several commenters recommended soliciting more feedback on this objective possibly through a HITPC working group sessions or other format

SGRP304, continued

SUMMARY OF HITSC COMMENTS:
Goals for the clinical documents should be more specifically defined, additional data collection by caregivers should be justified, and existing data should be reused to the extent possible. To encourage team based care unnecessary and burdensome data transmission should be avoided and shared information tools or shared document solutions should be enabled and developed.

Today the most essential information elements are problems, medications, allergies, and current labs. Other items are immature.

SUMMARY COMMENT:
Standards development is necessary to ensure consistent and reliable capture of data elements for care transitions. S&I framework should be involved in recommendations on care transitions. Parsimony is a critical consideration.

Longitudinal care plan should be fundamentally different from short term or simple care plans and would be expected to span time, discipline, and care team member which adds to the challenge of collecting and coordinating such data. This data clearly exists in some space between the hospital and EP care—all members of the team should be involved in creation of the care plan. It may not be reasonable at this time to expect SNF/outpatient care facilities to achieve this level of coordination but there should be action toward that aim.

For the first stage, a simple list of essential elements is reasonable:

1. Patient goals identified for > 50% of health concerns identified in the transition summary
2. Expected outcomes identified for > 50% of interventions identified in the transition summary
3. Advance orders (or recommended orders) with identification of the related health concern for > 50% of such advance orders

Metadata might be used to record the responsibilities and roles of the individual team members, but at this time it is not a reasonable request of the electronic record. Care team members might object to the inclusion of this level of responsibility electronically but it is clinically and quality-wise extremely important.

Comments:

- In the absence of a standard definition for care plan and management of health concerns, this element is too expansive. It might be more reasonable to identify essential functions that the EHR should accomplish (certification) and that should occur in clinical practice using the EHR (by measuring elements on transition of care documents if they can be structured) for:
    1. Patient goals identified for > 50% of health concerns identified in the transition summary
    2. Expected outcomes identified for > 50% of interventions identified in the transition summary
    3. Advance orders (or recommended orders) with identification of the related health concern for > 50% of such advance orders
- Stages should be part of diagnoses (e.g., “CKD Stage 3”) Would need validated terms for patient preferences and goals. Parsimony needed—e.g, ADLs (and IADLs) may belong in accessible database, not this data set, patient goals should be limited to high-level (e.g., “for cure”, “for prevention of complications,” “for symptom control.” Scan for standard terms for psychosocial support. EPs should know and document key care-team members, e.g., PCP, care manager, consultants, but could not know many of the team.
- Measure: What percent of the specified data must be provided 10% of the time? 80%?
- Strongly encourages ONC to include provision of care plan information as part of its criteria for meaningful use Stage 3, rather than delaying implementation of such a requirement. By the time Stage 3 requirements begin to be implemented, it will be 2016 – the last year that eligible professionals may begin participating in the Medicaid EHR Incentive Program. As technology continues its rapid evolution and as providers search for even more ways to achieve greater efficiencies in order to counter ongoing fiscal challenges. There will be an increase in the use of software solutions like those offered by LTPAC IT companies. With so many factors driving LTPAC providers toward greater IT adoption, there should not be any lag in LTPAC HIT-readiness to dissipate by 2016, which it is urged that ONC to include LTPAC in several of the Stage 3 meaningful use criteria.
- In the Request for Comment notice, respondents are asked “to think through these priority cases,” and yet the most common patient discharge case requiring provider follow up – the case of a patient who is discharged from a hospital to a nursing facility, home care agency or other LTPAC setting after an acute care episode – is not listed among the so-called “priority cases.” To correct for that oversight it is recommended changing this objective to include transfer to or from the LTPAC setting among the priority cases.

SGRP304, continued

- NASL also recommends that the SGRP 304 measure for Stage 3 be similarly amended to read, "The EP, EH or CAH that site transitions or refers patients to,or receives from an LTPAC setting or provider of care provides the electronic care plan information for 30% of transitions of care to receiving provider and patient/caregiver."
- In addition, it is recommended that the standards for a shared care plan should follow the S&I Longitudinal Coordination of Care Framework. S&I Framework's Transitions of Care Workgroup agrees that functional status and cognition, along with skin issues, are key determinants of safe and efficient care transitions.
- There is value in shared care planning and collaboration and direct ONC's attention to the existing standardized assessment tools, which offer evidence of this value. As stated above, functional and cognitive status are essential elements of the patient's care record and are captured in the Continuity Assessment Record and Evaluation (CARE) tool. Given the variety of standard assessment tools already used by LTPAC. LTPAC Associations like the National Support of Long Term Care (NASL) believe that ONC should explore how to leverage LTPAC expertise in providing longitudinal care to promote shared care planning and greater collaboration across care settings and providers. NASL would welcome the opportunity to discuss how we might assist ONC in this capacity.

Discussion:

- Important to determine validated terms for functional status and ADLs. Certainly should attempt to record the care team members but this is very challenging in that the care team is dynamic and might be difficult to capture without disturbing workflow.
- Care transitions and goal are not well defined in practice. See above for hypothesized goals.
- There is not really good guidance for how to use the data even when it's captured. Floyd's examples above are very reasonable.
- Need the care plan and should reference what the long term care plan committee has identified as critically important. It is necessary to reference the S&I framework when responding to this question. Unclear how data is or would be transmitted back to the hospital.
- All of the comments find consensus that there needs to be greater identification of elements.
- Using the term care plan can be interpreted differently by different care team members. Care plan coordination must include clear roles for each member and it is unclear whether that can be done at this stage in any consistent or meaningful way. The S&I framework might address this moving forward. Ultimately the care plan would include the responsibilities and roles of care team members.
- Might be asked to implement the care plan after the hospital discharge—might be inappropriate to allow hospital to determine long term care plan because they might not have the same level of knowledge of the patient's long term care situation.
- Working towards MU3 voluntary care plan measures—in the QMWG they have been looking at criteria that could be examined in the long term care setting.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P305	**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 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)	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.

SUMMARY OF PUBLIC COMMENT:

- 97 comments
- Overall, commenters were supportive of this measure. There were concerns about the ability to measure outcomes, differences of opinion on the percentage needed to obtain the objective, and requests for clarification.
    - Most comments asked for a higher threshold for the reconciliation items
    - Many commenters asked for additional items to be reconciled (e.g. caregiver names and numbers), while others were not supportive of providing additional items
    - Concerns regarding how this will actually be measured and readiness of standards

SUMMARY OF HITSC COMMENTS:

- Support measure.
- Will need to ensure the software computing functionality now required performing these types of calculations and how to count when files are sent, be included in the certification testing.

For some results this is critical; for others it is minimally useful (tests which require specialist interpretation).

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP127	**New**	**New**	Ability to maintain an up-to-date interdisciplinary problem list inclusive of versioning in support of collaborative care	

SUMMARY OF PUBLIC COMMENT:

- 54 comments
- Overall, most commenters supported this objective, pending further development and clarification and definitions of the terms versioning and interdisciplinary
- Some commenters thought the measure would have limited benefit.

SUMMARY OF HITSC COMMENTS:

Need further description about how this would work. Do we expect that external sources of problem list data would be incorporated into the EHR? If so, we have data integrity concerns, as described in SGRP 105,106

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P125	**New**	**New**	Medication reconciliation: create ability to accept data feed from PBM (Retrieve external medication fill history for medication adherence monitoring) Vendors need an approach for identifying important signals such as: identify data that patient is not taking a drug, patient is taking two kinds of the same drug (including detection of abuse) or multiple drugs that overlap. **Certification criteria:** EHR technology supports streamlined access to prescription drug monitoring programs (PDMP)data. For example: ▪ Via a hyperlink or single sign-on for accessing the PDMP data ▪ Via automated integration into the patient's medication history Leveraging things like single sign on or functionality that could enable the linkage between PDMPs and prescribers and EDs?	

SUMMARY OF PUBLIC COMMENT:

- 83 Comments
- Majority of commenters supported the additional requirement to create the ability to accept data feeds from PBM
- Come caveats included:
  - Data sources must be highly accurate/up-to-date
  - MU measure should have a low threshold and be a menu item
  - Concerns about additional burden on providers

SGRP125, continued

- Commenters suggested additional requirements that should be considered such as including feeds from external (i.e., non-PBM feeds) data sources. Commenters also listed a number of concerns for the HITPC to take into consideration.
- Majority of commenters were supportive of a new certification criterion for EHR technology to support streamlined access to prescription drug monitoring programs (PDMP)
- A majority of those supporters recommended accelerating the proposed certification criteria into Stage 3 to encourage provider access to and use of PDMP data

SUMMARY OF HITSC COMMENTS:
See SGRP 105,106

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 308	**New**	**EH Objective:** The EH/CAH will send electronic notification of a significant healthcare event in a timely manner to key members of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required. **EH Measure:** For 10% of patients with a significant healthcare event (arrival at an Emergency Department (ED), admission to a hospital, discharge from an ED or hospital, or death), EH/CAH will send an electronic notification to at least one key member of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required, within 2 hours of when the event occurs.		

SUMMARY OF PUBLIC COMMENT:

- 82 Comments
- While there was support for this measure, there was a great deal of concern identified:
  - Many felt the 10% threshold was too low
  - Some commenters thought the two hour window was too short
  - Many commenters were concerned with privacy implications and the patients role in consent
  - Further clarification needed regarding the definition of "significant."
  - Some commenters were concerned with there being inefficient technological infrastructure to support this measure.

SUMMARY OF HITSC COMMENTS:
For certification criteria, a specific event would need to be specified (i.e. inpatient admission) to ensure the appropriate standards are available.

Improve population and public health

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 401A	**EP/EH Objective:** Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice **EP/EH Measure:** Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period	**EP/ EH Objective:** Capability to receive a patient's immunization history supplied by an immunization registry or immunization information system, and to enable healthcare professionals to use structured historical immunization events in the clinical workflow, except where prohibited, and in accordance with applicable law and practice. **Measure:** Documentation of timely and successful electronic receipt by the Certified EHR Technology of vaccine history (including null results) from an immunization registry or immunization information system for 30% of patients who received immunizations from the EP/EH during the entire EHR reporting period. **Exclusion:** EPs and EHs that administer no immunizations or jurisdictions where immunization registries/immunization information systems cannot provide electronic immunization histories. **Certification criteria**: EHR is able to receive and present a standard set of structured, externally-generated, immunization history and capture the act and date of review within the EP/EH practice.	**EP/EH Objective:** Add submission of vaccine contraindication(s) and reason(s) for substance refusal to the current objective of successful ongoing immunization data submission to registry or immunization information systems.	

SUMMARY OF PUBLIC COMMENT:

- 93 Comments
- Most commenters supported, with concern about readiness
    - A number of commenters sought clarification on the wording/intent
- Several commenters recommended including vaccine contraction(s) and reason(s) for refusal" into Stage 3, rather than a future stage, as many EHRs are already submitting this data
- A few commenters proposed merging 401A and B

SUMMARY OF HITSC COMMENTS:

At present there is not a vocabulary standard for describing adverse events/contraindications, but the Standards Committee agrees this is an important gap to resolve.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 401B	New	**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. **Exclusion:** EPs and EHs that administer no immunizations. **Certification criteria:** EHR uses a standard (e.g., national, state and/or local) rule set, plus patient age, gender, and prior immunization history to recommend administration of immunizations; capture the act and date/time of recommendation review.		

SUMMARY OF PUBLIC COMMENT:

- 83 Comments
- Commenters were fairly even split on their support for or against
    - There were a number of concerns about readiness and the complexity to implement
    - Concerns about another CDS requirement
    - Clarification on the definition of ‘receipt’
    - A few commenters proposed merging 401A and B

SUMMARY OF HITSC COMMENTS:

At present there is no standard to represent immunization rules

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 402A	**EH Objective:** Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice **Measure:** Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period.	**EH Objective (unchanged):** No change from current requirement for electronic lab reporting which generally is sent from the laboratory information system		

SUMMARY OF PUBLIC COMMENT:

- 56 Comments
- Most commenters agree to keeping this measure unchanged although the standards and Implementation Guide for this measure should be updated to reflect current Public Health requirements.
    - Most agree with keeping as core, but some felt that Laboratory functions should not be part of Meaningful Use and that this requirement should be removed
    - Many commenters also mention that capacity at the state level is still an issue and that states require additional resources to ensure that they can receive this data

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGRP 402B	New	New	**EP Objective:** Capability to use externally accessed or received knowledge (e.g. reporting criteria) to determine when a case report should be reported and then submit the initial report to a public health agency, except where prohibited, and in accordance with applicable law and practice. **Measure:** Attestation of submission of standardized initial case reports to public health agencies on 10% of all reportable disease or conditions during the entire EHR reporting period as authorized, and in accordance with applicable state/local law and practice. **Certification criteria:** The EHR uses external data to prompt the end-user when criteria are met for case reporting. The date and time of prompt is available for audit. Standardized (e.g., consolidated CDA) case reports are submitted to the state/local jurisdiction and the data/time of submission is available for audit. Could similar standards be used as those for clinical trials (SGRP209)?	

SUMMARY OF PUBLIC COMMENT:

- 56 Comments
- Majority of commenters support the inclusion of this objective in either Stage 3 core set or the future stages of Meaningful Use
    - Concerns expressed about the readiness of public health agencies to receive this data electronically and the maturity and availability of content and vocabulary standards
    - Why weren't EHs included?

SUMMARY OF HITSC COMMENTS:

See SGRP 105,106

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P403	**EP MENU Objective:** Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice **EH Objective:** Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice **EP/EH Measure:** Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period	No change from current requirements.		

SUMMARY OF PUBLIC COMMENT:

- 56 Comments
- Most commenters agree that this measure should remain per the recommendations unchanged, concerns that standards are still not mature, especially for EPs
- Many states are not ready and need additional funding to implement

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P404	**EP only MENU Objective:** Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice. **EP only MENU Measure:** Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period	**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, except where prohibited, and in accordance with applicable law and practice. This objective is in addition to prior requirements for submission to an immunization registry. **Measure:** Documentation of ongoing successful electronic transmission of standardized reports from the Certified EHR Technology to the jurisdictional registry. Attestation of submission for at least 10% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice. **Certification criteria:** EHR is able to build and then send a standardized report (e.g., standard message format) to an external mandated registry, maintain an audit of those reports, and track total number of reports sent. **Exclusion:** where local or state health departments have no mandated registries or are incapable of receiving these standardized reports		

SUMMARY OF PUBLIC COMMENT:

- 82 Comments
- Commenters disagreed with the expansion of the scope beyond cancer registry
    - Commenters did not want the scope expanded to include other registries
    - Commenters wondered at the impact on the cancer registry from the expansion to include EH, many of whom already have established reporting mechanisms in place
    - A uniform reporting standard needs to be adopted prior to including other registries

SUMMARY OF HITSC COMMENTS:

Standards to submit data from an EHR to a registry are not yet mature. Need to clarify what a "mandated" registry means

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P405	**EP only MENU Objective:** Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice. **EP only MENU Measure:** Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period	**EP Objective**: Capability to electronically submit standardized reports to an additional registry beyond any prior meaningful use requirements (e.g., immunizations, cancer, early hearing detection and intervention, and/or children with special needs). Registry examples include hypertension, diabetes, body mass index, devices, and/or other diagnoses/conditions) from the Certified EHR to a jurisdictional, professional or other aggregating resources (e.g., HIE, ACO), except where prohibited, and in accordance with applicable law and practice. **Measure:** Documentation of successful ongoing electronic transmission of standardized (e.g., consolidated CDA) reports from the Certified EHR Technology to a jurisdictional, professional or other aggregating resource. Attestation of submission for at least 10% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable state/local law and practice. **Certification criteria:** EHR is able to build and send a standardized message report format to an external registry, maintain an audit of those reports, and track total number of reports sent.		

SUMMARY OF PUBLIC COMMENT:

- 83 Comments
- Commenters support the Stage 3 changes but requested specificity regarding the following:
  - Will this remain menu or move to core
  - Commenters recommended a standard format for reporting be defined
  - Specificity requested regarding which registries qualify under this objective

SUMMARY OF HITSC COMMENTS:

Need to clarify what a "non-mandated" registry means. It may be very difficult to certify products to support this criteria since "non-mandated" registries are likely to be niche/non-standard.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P407	**New**	**EH Objective:** Capability to electronically send standardized Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) using a common format from the Certified EHR, except where prohibited, and in accordance with applicable law and practice. **Measure:** Documentation of successful electronic transmission of standardized healthcare acquired infection reports to the NHSN from the Certified EHR Technology. Total numeric count of HAI in the hospital and attestation of Certified EHR electronic submission of at least 10% of all reports during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice. **Certification criteria**: EHR is able to sending a standard HAI message to NHSN, maintain an audit and track total number of reports sent.		

SUMMARY OF PUBLIC COMMENT:

- 82 Comments
- Commenters disagreed with the expansion of the scope beyond cancer registry
    - Commenters did not want the scope expanded to include other registries
    - Commenters wondered at the impact on the cancer registry from the expansion to include EH, many of whom already have established reporting mechanisms in place
    - A uniform reporting standard needs to be adopted prior to including other registries

SUMMARY OF HITSC COMMENTS:

Hospital Acquired Infection content standards are low maturity

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
SGR P408	**New**	**New**	**EH/EP Objective:** Capability to electronically send adverse event reports (e.g., vaccines, devices, EHR, drugs or biologics) to the Federal Drug Administration (FDA) and/or Centers for Disease Control and Prevention (CDC) from the Certified EHR, except where prohibited, and in accordance with applicable law and practice. **Measure:** Attestation of successful electronic transmission of standardized adverse event reports to the FDA/CDC from the Certified EHR Technology. Total numeric count (null is acceptable) of adverse event reports from the EH/EP submitted electronically during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice. **Certification criteria:** EHR is able to build and send a standardized adverse event report message to FDA/CDC and maintain an audit of those reports sent to track number of reports sent (Common Format).	

SUMMARY OF PUBLIC COMMENT:

- 64 Comments
- Comments were mixed on this measure
- Comments in favor of this cited that this function was already in place and operating within some EHRs and aligns with federal goals of decreasing HAIs.
- Those opposed, noted that determining an HAI by NHSN criteria was not a simple function for an EHR and that it usually involved manual review of data and a chart audit
    - Multiple comments also felt it was premature as the pilot of electronic transmission to NHSN is currently only conceptualized

SUMMARY OF HITSC COMMENTS:

At present adverse event reporting systems, and not EHRs support this functionality. Unclear if EHR workflow would support such a function.

Information Exchange

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
IEWG 101	**New**	**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. **Certification criteria:** The EHR must be able to query another entity for outside records and respond to such queries. The outside entity may be another EHR system, a health information exchange, or an entity on the NwHIN Exchange, for example. This query may consist of three transactions: a) Patient query based on demographics and other available identifiers, as well as the requestor and purpose of request. b) Query for a document list based for an identified patient c) Request a specific set of documents from the returned document list When receiving inbound patient query, the EHR must be able to: a) Tell the querying system whether patient authorization is required to retrieve the patient's records and where to obtain the authorization language*. (E.g. if authorization is already on file at the record-holding institution it may not be required). b) At the direction of the record-holding institution, respond with a list of the patient's releasable documents based on patient's authorization c) At the direction of the record-holding institution, release specific documents with patient's authorization The EHR initiating the query must be able to query an outside entity* for the authorization language to be presented to and signed by the patient or her proxy in order to retrieve the patient's records. Upon the patient signing the form, the EHR must be able to send, based on the preference of the record-holding institution, either: 1. a copy of the signed form to the entity requesting it 2. an electronic notification attesting to the collection of the patient's signature **Note:* The authorization text may come from the record-holding EHR system, or, at the direction of the patient or the record-holding EHR, could be located in a directory separate from the record-holding EHR system, and so a query for authorization language would need to be directable to the correct endpoint.		Should the measure for this MENU objective be for a number of patients (e.g.25 patients were queried) or a percentage (10% of patients are queried)? What is the best way to identify patients when querying for their information?

IEWG 101, continued

SUMMARY OF PUBLIC COMMENT:

- 102 Comments
- Many commenters expressed support for the inclusion of this objective in Stage 3.
- Quite a few commenters seemed confused about the focus and scope of this objective. Many seemed to think it was focused on requiring providers to utilize a HIO leading to concerns about the level of access to fully functional HIOs.
- Quite a few commenters expressed the need to complete additional work around the privacy and security implications of this objective.
- A number of commenters stated that HIE/HIOs should be able to support providers in achieving this objective.
- *Measure*: The majority of those who commented on the measure suggested it should be based on a percentage. Requested additional detail on how the measure will be calculated.
- *Patient matching*: A few commenters on this objective requested ONC establish explicit standards to support patient matching. A few commenters felt it was important to establish a national patient identified to support correctly matching patients for this objective.

SUMMARY OF HITSC COMMENTS:

The workflow required here is a labor-intensive, paper-based workflow that barely works in a paper-based environment. I don't think it's reasonable to attempt to replicate this workflow electronically. The EHR receiving the query should mediate the request and then tell the querying system what documents are available to them. The receiving system should then protect those documents i.a.w. its own policy and the patient's preferences. We need to think through how this should happen in an electronically connected world -- not how to replicate a paper workflow electronically. For increased convenience, reduced complexity, and easier comprehension, I suggest a measure that enables a provider to obtain a patient's privacy preferences from another provider or third party service. This would enable a patient to register her preferences once, and then simply provide a pointer to those preferences for subsequent encounters with other providers. A number of providers and HIEs already are implementing such a service, making the need to specify a standard service interface (e.g., RHex) and coding more urgent.

Unfortunately no universal patient health identifier exists, and the lack of a reliable means of identifying patients is broadly viewed as a significant challenge to care quality. The proposed model involving the use of demographics to identify patients is not sufficiently reliable to support query for individual patients' information. Multiple efforts currently under way are addressing the challenges around "directed query" (i.e., query for a specific patient's information) through the use of a voluntary identifier, and we think it is important that regulations allow progress to continue to be made in this area. Lacking standards to support either the positive and unequivocal identification of patients or query for a specific patient's information, we urge the ONC not to include in regulation a detailed description of how directed query is performed. Policy and standards around trustworthy identity proofing and authentication are rapidly evolving, and should provide a strong foundation for trusted query. We encourage the ONC to continue to support the development of new models for using voluntary or other high-quality identifiers and authentication methods.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
IEWG102	**New**	**Certification criteria**: The EHR must be able to query a Provider Directory external to the EHR to obtain entity-level addressing information (e.g. push or pull addresses).		Are there sufficiently mature standards in place to support this criteria? What implementation of these standards are in place and what has the experience been?

SUMMARY OF PUBLIC COMMENT:

- 62 Comments
- Most commenters agreed that there are not sufficiently mature standards in place to support this criteria at this time.
- Comments were fairly evenly split on if the criterion should be kept in Stage 3.

SUMMARY OF HITSC COMMENTS:

Directories typically are integrated into other services, such as secure communications and enterprise security services, and not an independent capability. Indeed, the two existing EHR standards for secure communications (Direct and Exchange) each has its own integrated directory technology – each of which is supported by a very mature directory standard (DNS and UDDI respectively). We think it would be inappropriate to externalize directory services by creating a separate certification criterion. We therefore recommend that the proposed certification criterion be omitted from the final regulation.

Directory query is only one way this could be done. MU should not dictate how a provider wants to make its contact information available to patients, as doing so would constrain operational choices and thwart innovation. Recommend omitting this measure.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	Questions / Comments
IEWG 103	**Certification criteria**: Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s): (i) *Encounter diagnoses.* The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3); (ii) *Immunizations.* The standard specified in § 170.207(e)(2); (iii) Cognitive status; (iv) Functional status; and (v) Ambulatory setting only. The reason for referral; and referring or transitioning provider's name and office contact information. (vi) Inpatient setting only. Discharge instructions.			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?

SUMMARY OF PUBLIC COMMENT:

- 56 Comments
- The majority of commenters felt this criterion was important and that further progress needed to be achieved around data portability.
- Requests for a variety of data elements to be added common themes were to ensure new data elements included in Stage 3 be added to this criterion and that any historical data required to calculate Stage 3 CQMs be included as well.
- A number of commenters felt this criterion was unnecessary or duplicative of other criteria.
- A few commenters questioned if this criterion would add significant value as substantially more data would need to be migrated to maintain continuity.

SUMMARY OF HITSC COMMENTS:

Privacy & Security WG: The primary focus for criteria to support a switch from one EHR to another should be on migrating the longitudinal EHR data so that if a provider chooses to change EHR products, patient data can be moved with its integrity preserved. However, even considering just the patient data, it is unclear exactly what data elements should be exported or how longitudinal elements should be represented. Deciding what data must be migrated always will involve trade-offs between sufficient and perfection. We recommend the ONC support work to define a standard specifically for the purpose of exporting and importing patient longitudinal data from one product to another. This work should start by exploring the possibility of extending current standards for CEHRT. The Canadian Infoway has performed work in this area with respect to the transfer of records from province to province, and the UK National Health Service (NHS) has performed similar work regarding the transfer of records from provider to provider; this effort may benefit from their experiences.

Clinical Ops WG: The idea that a Consolidated CDA document could represent information needed by a provider for switching from one EHR to another vendor's EHR is flawed. Today CCDA represents a point in time snapshot that is useful for episodic care, it is not a longitudinal record that is needed to build a patient chart in another EHR system. Fundamental rework of the standard may be required to support this idea, which would require a multiyear work plan item.

NwHIN PT: The scope of certification criteria in this area should be limited to the migration of patient data.

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

ID#	Questions
MU01	Currently, providers have to meet all MU criteria to receive incentives. Is there flexibility in achieving a close percentage of the objectives, but not quite achieving all of them? What is the downside of providing this additional flexibility? How will it impact providers who are achieving all of the MU criteria? If there is additional flexibility of this type, what are the ways this can be constructed so that it is not harmful to the goals of the program and advantageous to others?

SUMMARY OF PUBLIC COMMENT:

- 75 Comments
- Most commenters urged the HITPC to recommend more flexibility in the MU program.
- We urge CMS to exhibit flexibility for EPs who participated in the meaningful use incentive program in good faith, but encountered problems in their reporting of measures. This flexibility will be particularly important should the agency require complete full year reporting. It would be unfair to not only prevent an EP from achieving the incentive, but potentially penalizing them as well, for failing to report even a small amount of data.
- Need for additional flexibility in the program. We would recommend that the menu set items be continued, and that providers be considered in compliance if they meet 75 percent of the objectives.
- The Association believes that eligible hospitals and eligible providers should not have to use valuable resources to collect measures that are not meaningful for the populations they serve. Although the case number threshold established in Stage 2 was a step in the right direction, it remains far from an ideal solution.
- Give specialists alternate requirements for core measures; do not overburden them with non-value added work.

SUMMARY OF HITSC COMMENTS:

Desirable flexibility could be achieved by designating more items as menu items and fewer as core items. Other modes of flexibility introduce measurement problems, issues of fairness, etc.

ID#	Questions
MU02	What is the best balance between ease of clinical documentation and the ease of practice management efficiency?

SUMMARY OF PUBLIC COMMENT:

- 59 Comments
- Most commenters favored improvements in overall usability that could be expected to make this balance more manageable. One specific form of usability improvement, natural language processing (NLP), had a small but clear following. After improvements in usability there was an expectation that changing the Meaningful Use requirements to accommodate the growing burden of documentation is a viable answer. Another highly favored solution was a reallocation of the practice workflow to more evenly distribute the work and increase overall practice efficiency. Although statements to that effect were equal in number ere were as many statements providing no recommendation in recognition of the increased burden of documentation.
- It should be noted that there were a number of statements that the question was beyond the scope of the Meaningful Use program, and slightly more than that did not respond.

SUMMARY OF HITSC COMMENTS:

Natural language processing, computer assisted coding, and advanced terminology systems all can ease the burden in this area but they do not belong in Meaningful Use.

- Not add extra expectations for providers to capture structured data. Practice management efficiency and clinical documentation are eased by ensuring that the data capture is part of the normal course of patient care delivery not captured as a part of documentation templates created solely for the purpose of data capture.
- CMS should add definitions to ensure legal protection and regulations to ensure providers and hospitals are protected

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- 63 comments
- Overwhelming opposition to a MU requirement as premature, but support for the need for EHR users to do a safety assessment.
- We believe that doing so could have a chilling effect, since EPs and EHs are already challenged by other meaningful use requirements. We instead urge the Department to continue to pursue other initiatives, such as dissemination of best practices regarding HIT use, mining adverse event reports for useful information and making it easier for clinicians to report patient safety events and risks using EHR technology, incorporating safety into certification criteria for HIT products (as was done with the Stage 2 certification criteria relating to user-centered design and quality management systems), and funding relevant research and pilot projects. We believe these alternatives would be more fruitful in the near-term than imposition of yet another regulatory requirement.

SUMMARY OF HITSC COMMENTS:

- Additional requirements for a health IT safety risk assessment are not prudent at this time.
- It is prudent to fund relevant safety projects/pilots and research to develop the standards and approach for this type of assessment.

This is an evolving area that should be the subject of a multiyear work plan for future development.

We think it would be reasonable and useful to include a MU requirement for providers to conduct a health IT safety risk assessment. We believe safety should be an integral component of a more comprehensive health IT risk assessment, that also includes security. However, the primary methods used for safety risk assessment (e.g., fault-tree analysis, reverse Petri-net analysis) are geared toward devices and control systems and would not be appropriate for EHR systems. Safety risk assessment for EHR technology would be similar to security risk assessment, except it would be driven by hazardous conditions that threaten human lives vs. threats to information confidentiality, integrity, and availability. Unfortunately, HIPAA risk assessment addresses only risks associated with the security of PHI, and much of the data related to patient safety, such as clinical guidelines and clinical decision support rules, do not involve PHI. We suggest including a general MU requirement to perform safety risk assessment in Stage 3 and to allow the standards and certification criteria to evolve over time.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- 74 comments received
- ***Question 1:*** ***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?***
  - Approaches suggested include:
    - Metadata tagging
    - Data segmentation , such as…
      - Data Segmentation for Privacy Initiative
      - VA/SAMHSA
      - SATVA
  - Concerns expressed:
    - The necessary segmentation capabilities do not exist today
    - It is better to focus on identifying and punishing inappropriate use of data
    - Use PHR to give patients control of their data
- ***Question 2:*** ***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?***
  - Create and adopt standards to improve the capacity of EHR infrastructure
  - Create standardized fields for specially protected health information
  - Require all certified EHRs manage patient consent and control re-disclosure
- ***Question 3:*** ***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?***
  - Many comments call attention to segmentation-related initiatives that might be leveraged , such as:
    - S&I Framework's Data Segmentation for Privacy Initiative (DS4P WG)
    - HL7 confidentiality and sensitivity code sets
    - SAMHSA/VA pilot
    - eHI developed the "eHealth Initiative Blueprint: Building Consensus for Common Action"

MU04, continued

SUMMARY OF HITSC COMMENTS:

The entire area of access control – including both enforcing legal protections on special categories of clinical information, and applying rules captured in patient-specified privacy consents – needs to be addressed to develop appropriate policy and technology standards for an electronic health environment that spans multiple institutions and multiple state jurisdictions. The solution is not likely to replicate what is on paper. Enforcing legal protections is quite analogous to the problem that is well known in the field of security engineering as "mandatory access control (MAC)", while enforcing rules based on choices made by patients is analogous to "discretionary access control (DAC)," and solutions should capitalize on well established approaches to MAC and DAC – namely, enforcing security policies based on labels representing MAC categories and within those categories, business rules based on identity, role, and context (e.g., patient consent). The primary challenges that need to be addressed are policy challenges and adapting existing technical solutions for the healthcare context.

The foundational work within Veterans Health Administration (VHA) has demonstrated that a limited set of the HL7 confidentiality and sensitivity vocabulary is adequate to label specially protected clinical data; in fact, this vocabulary already is used in the Exchange transport standard required for Stage 2. However, we lack standard mapping between the vocabulary coding and privacy and security policies (federal/state rules or organizational policies) to be enforced. Work is needed in both EHR and security technology areas – EHR technology needs to be able to electronically identify specially protected types of information, and security systems need be able to electronically enforce policies based on metadata tags.

We also lack standards for coding, managing, interpreting, and exchanging patient consents across organizations, and for workflows that take advantage of trust relationships within a network. We recommend the ONC support the development of a set of common use cases that address the management, interpretation, and enforcement of consumer-consent rules across organizations.

The ultimate solution must enforce access rules based on both clinical labels and individual consents, must support logical and intuitive workflows, must engender trust for both providers and consumers, and must be scalable at a national level.

I think an effective solution can be achieved through the combined use of metadata tagging of special categories of information and the management of patient permissions through a service interface, similar to what was recommended in the PCAST Report. How I envision this working is that the organization that generates the data would attach appropriate metadata indicating special categories of information that by law require special protections. These categories could be the superset of all special categories that require protection by state and/or federal law. HL7 sensitivity codes could be used for this purpose. Of course, as with any exchange, the holder of the information would then need to conform to the state policy under which it operates. The second part – management of consumer preferences through a service – would enable a consumer to select who they wanted to hold their permissions (in most cases, this would probably be their primary care provider or HIE), and then would enable the consumer to provide a pointer to that service instead of having to fill out a form each time he/she received care from another provider. The service provider would manage each consumer's permissions, including notifying the consumer when their permissions needed to be renewed. Then, whenever a data holder received a request for an individual's health information, he or his EHR could just query the service to determine whether the consumer had authorized the requested use or access. Consent revocation and communicating limitations on re-disclosure would be addressed by the fact that before any holder of a consumer's information could make it available to another party, the holder would need to query the service for the permissions currently in effect. In this way, the service would be responsible for managing permissions, and the holder of information would be responsible for managing data in compliance with the permissions in force at any given time. This approach would greatly simplify the consent process for consumers, and also would make it much easier for them to understand and keep track of the permissions they had selected. It also would reduce cost and risk for providers. The service could be accessed using a secure REST protocol or the eHealth Exchange protocol. Permissions could be exchanged using the XACML standard.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

SUMMARY OF HITSC COMMENTS:

"EHR Technology" has been broadly defined to include everything relating to the collection, use, and exchange of electronic health information. So it's unclear to me what's being asked here. For example, what "other kinds of systems" are they asking about?

API development is currently immature. Further development is needed before this can be given any consideration in Meaningful Use.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- 48 Comments
- Commenters (mainly providers) generally agree that EHRs should be able to track usage for yes/no measures. Many suggested that the audit log would be an appropriate functionality for tracking usage and that providers should have only "read-access" to the log. Commenters equally noted the difficulty in tracking activities that occur in (or partially within) the EHR technology and those that occur outside the EHR technology (or partially outside the EHR technology).

SUMMARY OF HITSC COMMENTS:

- Recognition should be given that the technology to capture and prove that intervention and yes / no answer was deployed during entire period is not currently used in mainstream implementations with the exception of custom built audit logs.
- Recommend that EHR vendors being engaged to create innovative solutions to capturing the utilization metrics currently required for yes/no questions.

It would be premature and unwise to consider an audit function for this level of detailed EHR capability in Meaningful Use.

This problem should be addressed case-by-case for each attestation measure for which a basis of evidence is needed. In some of the cases, the audit trail as routinely configured will provide the needed evidence. In other cases, the audit trail may need to be configured to collect additional system information; however, we caution that using the audit trail in this way runs the risk of overburdening the system while providing little to no value other than to "prove" meaningful use. We recommend giving priority to those attestation measures where audit trails, in their standard configuration, can be used for this purpose. Whatever mechanism is used to collect evidence support attestations, make sure the mechanism is not overbearing the system with little or no real benefit to care.

I. 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
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?

SUMMARY OF PUBLIC COMMENT:
While few commenters recommended specific measures to the HITPC, **suggestions focused on care coordination (5 comments), preventive care (2) and behavioral health (3).**

- Key Points
  - Include the ADA Dental Quality Alliance's Pediatric Oral Healthcare measures
  - Add Tuberculosis measures
  - Fostering greater cooperation and coordination around the transitions of care is critical, we recommend that ONC focus on one or two person-centered quality measures – such as falls – that can be measured across the spectrum of care.
  - Expand behavioral health measures beyond depression

SUMMARY OF HITSC COMMENTS:
SUMMARY COMMENT: A person-centric (or patient-centered) focus is critical to moving forward with electronic quality measures. Measures ought to take into account the workflow and clinical decision support from the outset—if prior measures cannot support these aims they should be reconsidered. Prior measures have not adequately considered the processes of care but have focused on the population or the quality concept. Care processes should be a major focus of MU3.

QMWG01, continued

Need to consider how changing a prior measure impacts its performance but shouldn't disregard all the prior work on the existing measures that are not electronic.

Harmonization of quality measures and elimination of duplicate measurement will also positively impact workflow. Agree with move to eliminate or unify similar measures from different programs. Similarly value set harmonization will improve workflow and ease of implementation.

Ultimately prioritization should go to items that align with clinical decision support. Need for unified data model is critical to moving forward with this alignment.

Should adopt the standards work in this space—using HQMF2 would enable local workflow and still automatically calculate the hard data from the measure.

Comments:

- Develop CQMs de novo based on data that should be available in any certified EHR and avoid retooling any measure developed for a different data platform. Also work directly with real practices and vendors to develop mechanisms to standardize the capture and definition of more elusive data elements.
- focus on quality measures that have a direct alignment with implementable decision support functionality (IE: direct changes in clinical care), and not on retrospective assessment of general care activities. Think order sets, documentation of critical elements, provision of tests and procedures.
- Determine a common data model to that covers governmental data expectations and make sure CQMs are defined based on the data model selected. The data model should be broad enough to cover data needed for all health care operations.
- Eric Rose, M.D.: One important impediment to efficiency and effectiveness in ambulatory quality management derives from the fact that patients usually get care from multiple providers who are often not in the same practice. One provider may not be aware that a quality-relevant service (e.g.a screening test) has been performed by another provider involved in the patient's care, and this may result in unnecessary duplication of services. Conversely, a provider may be aware that that service has been performed and thus (appropriately) not perform it, resulting in quality measures suggesting inferior care quality than is really being provided.
- To address this impediment will require interoperability standards and capabilities among ambulatory providers for quality-relevant data. ONC is in a position to hasten the development and implementation of such standards and capabilities.
    - Focus on measures that would support the greatest QALY gains in the population, 2) commission rigorous studies of usability, effectiveness, and safety of proposed solutions.
- We should work with the quality measure groups including CMS and NQF to standardize and harmonize eQM across the spectrum of care. Most of today's eCQMs are episodic and are facility focused. They do not include all provider sites as the HITECH Act does not include skilled nursing facilities, assisted living facilities, Home and Hospice Care Agencies. They should be person centric and take into consideration chronic care. Today, there are many different quality organizations establishing quality measures and also many requiring that providers adhere to their quality measures. With multiple quality measures a person could be normal in one provider site and abnormal in another site because they are not harmonized across the spectrum of care. Multiple quality measures that are similar require a great deal of administrative costs and cause confusion especially if there is a penalty associated with the measure.

Discussion:

- Would not retool existing measures—should create de novo measures
- De novo seems an extreme term—should focus on reusing terms that exist and
- Technically redeveloped measures actually are new content because once the data used is changed, there is not evidence that they should perform or measure the same concept.
- Need to identify measures that not only can still provide important clinical quality data but need to start aligning with clinical decision support.

Given the agreement that developing the process and technology to incorporate new measures into a clinical setting is time consuming and expensive, the most economic/effective way to minimize cost and burden is multi fold. Add measures that can be captured as part of the 'normal' care provision process. A second approach would be to harmonize the measures with quality measures currently required by the myriad of federal/regulatory/ national associations that currently require specifications that are similar but not the same. Consideration should be given to remaining focused on the current set of measures, refining those definitions and researching the clinical care impact of the current measures. There should be a uniform place of introduction for new e-measures across CMS programs that takes as informative what is done for Hospital Value Based Purchasing – measures are used for the Hospital Inpatient Quality Reporting program for one year prior to their inclusion in VBP. PQRS and IQR could both look to MU certification as evidence of EHR based e-measure capability, maybe meaningful use is the place to introduce new e-measures since they will have to be explicitly certified for before they can be reported by any given EHR involved in e-submission.

ID#	Questions
QMWG02	Furthermore, when considering the finite resources available to technology developers, what measures, types of measures or attributes of measures should be a high priority?

SUMMARY OF PUBLIC COMMENT:

- Types of measures
  - Defer to the National Quality Strategy and the Measure Applications Partnership (MAP)
  - The AAP suggests that evidence based measures that relate to the health and safety of vulnerable populations be of high priority.
  - Development of eMeasures that have the greatest impact on quality of care, those that can be fully captured electronically in the common workflow, and that are currently defined in standard nomenclatures
  - Concerns about physician specialties and sub specialties
    - **Re-evaluate the value and purpose of exclusions** in the measure design. These effectively constitute hidden EMR requirements. Few organizations can accurately, consistently, and automatically apply these exclusions
    - The current eCQM requirements pose unique challenges for specialists, who much choose from a limited number of applicable measures within the six quality domains.
- Attributes
  - The AADA **: advance cautiously, spend time building the technical infrastructure** and prospectively addressing standards for data transport and patient identification
    - Testing of these specifications should be completed in a test system environment using test data to assess the measure logic
  - Ensure that technology developers create and enable the functions and capabilities necessary for capturing information required to populate measures of **patient engagement, care coordination, functional status, longitudinal (delta) measures, wellness and health promotion, and population-based measures include health information exchange, calculation of measures using multiple data sources, and integration of patient-generated data**.
  - Reuse **components of existing** i2b2 processor
  - We also encourage **early publication of new requirements for the Data Element Catalog, individual measure specifications and related value sets and value set information.**
  - "As EHR developers, we prioritize development of measures based on the **suitability of the data elements required to capture in our EHR** and on feedback from our EHR users".
- Frameworks and approach:
  - We suggest three guiding principles in prioritizing measures, types of measures or attributes of measures.
    - The focus should be on measures that have **direct impact on increased quality** of care, dependent upon specialty (i.e., the populations seen by the eligible providers and eligible hospitals).
    - To move toward meaningful use of EHR, **measures that are uniquely captured by EHR** (vs. administrative) data **should be prioritized** in Stage 3.
      - use data that are already captured: vital signs, medications, etc.
- There are several additional input channels we suggest, along with measures to success:
  - Data Community Assembly: "Listen and Learn" Open Assembly including all stakeholders.
    - Number of participants attending the "Listen and Learn" Assembly
    - Number of suggestions presented to the HITPC for consideration
  - Open Input Portals to industry who are developing the latest technologies and strategies to improve patient care quality, cost, and patient satisfaction. This is a valuable resource if utilized to its greatest potential.
    - Adaption of resource enhancing combined outcomes of quality, cost, and patient satisfaction
  - Public Data Sub-committee with a wide variety of providers, patients, organizations and societies to solicit input. Build collaboration between stakeholders through data intelligence.
    - Number of industry concepts submitted to HITPC for a continuous consumer advocacy offering

QMWG02, continued

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

- Measures need to be more patient-centric and lead to measurable outcomes using validated outcome measures.
- Measures need to use available data and not have a high workflow or cost burden to collect.
- Should try to follow care processes across settings and providers.

Comments:

- Measures of EHR usage should be a direct output of the EHR. See response to SGRP108. Measures for 2016 should be about outcomes of care determined by valid markers (lab results or examination findings) or validated instruments of status that can be completed directly by patients, their caregivers or non-physician personnel. Processes should be kept to a bare minimum to avoid excess burden of data collection and complexity of measure logic.
- Note: if exceptions or exclusions are to be continued, they should be derived from existing clinical data, or directly from patients (or their caregivers). Such a requirement would greatly enhance provider purchase and use of patient facing applications. Those with such applications will have data on exceptions (or exclusions) that those without such applications will not have the data. To be sure of compliance, the provenance of the exception (or exclusion) data element is essential (i.e., that it cam from the patient).
- Types of patient data: Problem lists/conditions, drugs, allergies, procedures. CQMs that focus on ordersets, and potentially documentation templates.
- Quality measure differ in the degree to which they leverage data that is already captured through established processes of care documentation, as opposed to requiring data entry activities that only serve the purposes of automated quality measurement. It is appropriate that some such data entry be required, all other factors being equal, priority should be given to measures that minimize this burden. One example of measures that are difficult to support without a great deal of extra data-entry burden are those which deal with complex time relationships, particularly with regard to initiation of outpatient medication regimens (e.g. a requirement that a patient be seen for follow-up within a certain time frame after initiating treatment with a particular drug). CMS and ONC could arrange for objective assessment of candidate CQMs for the degree to which they would impose an extra burden of data entry for EHR users.
- Measures that would support the greatest QALY gains in the population.
- In order to encourage transitions of care and care coordination we should start with one or two quality measures that can be person centric and measured across the spectrum of care. Examples could be falls and pressure ulcers. The current quality measure organizations should be asked to work together on harmonization. CMS is working on harmonization of eligible hospitals and eligible physicians. This should be expanded to LTPAC providers.

See discussion above

ID#	Questions
QMWG03	Are there innovations or technological capabilities for measure development or specification that the HITPC could support that would reduce the burden on technology developers?

SUMMARY OF PUBLIC COMMENT:

- The greatest number of comments suggested alignment of measure specification components (12), collaboration among stakeholders early in development (7), field testing of data elements and data-driven selection of logic and value sets (5). Finally, multiple commenters request inclusion of patient entered data and suggested data elements which may be suitable.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

- A unified data model is key to certainty in the development of more sophisticated health records that can be exchanged. It is critical to determine the data elements that will be captured before any measure is accepted or developed. In addition, the need for and impact of new data elements should always be approached with caution; however, the need for clinically warranted new data elements should not hold a measure up if that data does not already exist.
- Improvements in the tool to create measures is required to do ongoing measure development.
- The community should participate in a discussion of the types and content of data to be recorded. This buy-in will greatly improve the quality of data and the satisfaction of the community with the MU program.

Comments:

- Standardization of the data model is essential as is clear education of measure developers to be sure the model is correctly used in designing measures. Feasibility of data elements defined within the model should be assured before any data elements can be used within a new measure. An infrastructure to support such data element feasibility is essential. Also, an open source measure authoring environment is needed with clear guard rails established by an online community.
    - A common data model that all these efforts adhears to, so any implementation can map to that model and have less work implementing a specification based on the model. 2) Tools for measure developers to build better measures – MAT 2.0 – that is based on the publicized data model from #1. 3) Easily accessible standards-based value sets aligned with the CQMs that are openly discussed and vetted.
- In view of recent evidence, HTN may be a poor example, but yes. “High-priority” would be better expressed as “supporting the greatest QALY gains in the population.”
- There is variation from measure to measure for data that is already being captured as compared to data which is specified for the performance of the measure. Preference should be given to data which exists in the record already.
- ONC should vet the requirements and burden of additional data collection that does not already exist. There may be data which is important that is necessary, but for example, the MU1 mental health measures required time data that was almost impossible to obtain.

Discussion:

- Generally focused on eliminating barriers to good measure development.
- Suggestion that alternate data models should be considered.
- Recommend better data element selection and curation.
- More training or unification in methodology among developers or a smaller pool of developers.
- Don’t let the tail wag the dog.

ID#	Questions
QMWG04	Meaningful Use program has used menu objectives and menu CQMs to provide flexibility for providers. Should there be core CQMs for high priority health conditions, such as controlling hypertension?

SUMMARY OF PUBLIC COMMENT:
Generally comments suggested retaining the core versus menu approach to CQMs (6) or allowing providers to flexibly choose which measures are higher priority for their individual practice (8). Comments also suggested that HHS programs align their core measures / harmonize their core set of eCQMs across the department.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
There was not consensus in the CQWG regarding a topic such as hypertension. There may be some topics such as functional status or pain management that can and should cross all specialties. It is unclear where the greatest value would be when comparing the creation of more specialist measures versus focusing on vulnerable patients versus higher priority conditions. Likely some compromise is needed between these competing priorities.

Comments:

- Yes, there should be core CQMs but specific to type of practice. E.g., an orthopedic practice would not be expected to manage hypertension, but such expectation is valid for Family Practice and Internal Medicine (perhaps OB/GYN). Core measures should address outcomes (i.e., the hypertension is fully controlled or improves over time, not merely that a single blood pressure is in normal range. Core measures by type of practice might be workable.
- Yes, under the constraints noted above – prioritize based on potential impact on devastating disorders. I would not focus on common conditions unless the payoff is greatest. I do not think that getting “all clinicians” to use CQMs is the best way forward. Focus on high-priority high payoff conditions.
- I believe this is probably not a good idea unless it is limited to EPs in primary care specialties. The EHR incentive/”MU” program has sought to offer opportunities for participation for EPs of all types, including specialists. If every EP were required to report on certain “core” CQMs, the result could be that for a single patient, multiple physicians trying to manage the same condition. Imagine a frail elderly patient whose family physician, cardiologist, pulmonologist, ophthalmologist, physiatrist, and neurologist were all trying to manage his hypertension. Many of us have seen the results of this and they can be as costly, and as harmful to patients, as too little attention to a chronic condition.
- Yes, and simple low hanging measures like falls and pressure ulcers

Discussion:

- High priority health conditions really relate more to the primary provider but create problems for specialty providers—the GI doc would not be concerned with high blood pressure as much as the management of GI conditions.
- It may not be necessary to create measures for each and every specialist. There is danger to try and collect information that it is unclear what the impact is. Recent studies looked at the impact of anticoagulation in afib (vfiB?) that had no other comorbidities was negative or of no benefit in some age groups. Some measures would not necessarily benefit large numbers of patients but might be much more valuable.
- This is a controversial topic.
- When there is more than one provider involved in care, there might be the opportunity to assign some tasks to some providers but the current state does not allow that electronically.

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
QMWG05	How can the HITPC and QMWG capture input from a wide variety of providers, patients, organizations and societies?

SUMMARY OF PUBLIC COMMENT:

- **Stakeholder Engagement-**Nearly all commenters encouraged the HITPC and QMWG to actively seek input from stakeholders. They suggested:
- **Professional societies**- including nursing, pharmacy, specialty societies
- **Patient/consumer groups**- including Special Interest Groups for those with disabilities, advocates for the ageing, survivors of violence, breast feeding advocates
- Employers
- Public Health

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
State-wide efforts and local efforts are widespread at this stage but poorly aligned with federal efforts. Collaboration with the local and state health agencies could occur with ONC's leadership and impetus. It is important to remember that providers are also getting pressure from other agencies and regulators outside of MU. Broader participation from more stakeholders in hearings and the targeted use of semi-structured interviews might be higher yield methods of getting feedback. Other electronic crowd-based methods might also lead to broader participation.

Comments:

- The general measure concepts discussed are just that – concepts. Without clear understanding of the required data elements it is unreasonable to expect consensus on feasibility. An evaluation process for detailed measures already exists and it involves consensus form a wide variety of providers and other stakeholders. HITPC and QMWG should more effectively use the National Quality Forum to use only endorsed measures developed for the EHR platform within MU.
- I would give consideration to reaching out to state departments of health. In many states, including my own home state of Washington, collaborative statewide efforts involving providers, the state, and other entities are under way to measure and manage quality, particularly in hospitals. The Washington Surgical Care and Outcomes Assessment Program (see www.scoap.org) is one such example. A national convergence of these efforts would be a positive thing, as long as it allows for appropriate state-specific approaches, and HITPC is in a position to open the channels of communication toward that end.
- Semi-structured interviews with key stakeholders with transparent analytics and reporting to HITPC would broaden input while lowering the cost.
- Hold a one day roundtable of all organization decision makers working on quality measures. Ask them to work out a strategic plan with short and long term goals to harmonize quality measures based on person centric electronic longitudinal care coordination.

Discusssion:
State-wide efforts and local efforts are widespread. Collaboration with the local and state health agencies could occur with ONC's leadership and impetus. It is important to remember that providers are also getting pressure from other agencies and regulators outside of MU.

ID#	Questions
QMWG06	What additional channels for input should we consider?

SUMMARY OF PUBLIC COMMENT:

- The majority of the responders agreed that increased patient input is necessary to improve quality measurement
- **Active Outreach Strategies for Stakeholder Engagement** – many felt the RFC and open meetings are a great start to active outreach, but encouraged the committee and workgroup to go farther utilizing strategies such as:
    - Social media
    - Webinars, open forum
    - **Outreach to professional societies and patient advocacy groups**
    - Establishing an "emeasure steering committee" (federation of American Hospitals)

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

- The current channels for feedback are inadequate; for example, a 5 minute comment period in public hearings does not allow all potential stakeholders to have a chance to respond. The community cannot be expected to take on the burden (time, cost, effort) of providing feedback without additional channels and greater regulatory efforts to reach out. More methods and attention should be given to additional channels of feedback (e.g., electronic) and more effort should focus on outreach.

Comments:

- A forum for data element feasibility is essential. Before a measure can be constructed for electronic reporting a list of feasible data elements must be available from which it can be created. This should be an open forum to allow input from as large of a group as possible. Vendors cannot be relied upon to determine real data use.
- make it easier for implementers to comment and suggest changes to MU CQM elements and value sets – think social media and crowd sourced input. The input may not always be relevant, but it's useful.
- I am not sure what channels you are using but I would imagine it is mostly federal channels like CMS or have contracted consultants to provide reports. Most provider associations are working on their own quality measure programs. Perhaps asking them directly to provide an aggregated report based on person centric electronic longitudinal care coordination.

Discussion:

It is very challenging for health IT professionals outside of Washington to participate in providing feedback. We should go out into the community and not expect the community will come to us.

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
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?

SUMMARY OF PUBLIC COMMENT:

- **Support consumer reported data**- most of the commentors support consumer reported data being used for quality measurement. Many provided examples, such as PROMIS10, CAHPS, functional status and PHQ-9. Many also suggested incorporation of biometric data from consumer devices, such as glucose meters, scales, pedometers and home blood pressure cuffs. A few recommended patient entry of data on past history including immunization and cancer screening status.
- **Do not support consumer reported data for MU3**- a few commenters expressed concerns that the data standards and EHRs are not yet ready for consumer reported data. They suggested further work be done on meta data standards, provider review/accept tools and software- both EHR and PHR, before consumer generated data become routine in quality measurement.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

- There does seem to be value in capturing patient-entered data; however, the first element to enable such data collection at all was just balloted in HL7. It is too early to attempt to include mandatory capture of patient-entered data.
- Early attempts to collect such data might be best accomplished through a PHR portal or an exchange service such as Bluebutton. The easiest data to capture from patients might be medication reconciliation and adverse events.
- It is critical to estimate the additional cost and burden of capturing this data and difficult to know what the extent patients would enter data into the record.
- More research is needed on patient-entered data.

Comments:

- Only consumer-reported data should be used for exceptions or exclusions unless they can be derived from existing clinical data. Such a requirement would greatly enhance provider purchase and use of patient facing applications. Those with such applications will have data on exceptions (or exclusions) that those without such applications will not have the data. To be sure of compliance, the provenance of the exception (or exclusion) data element is essential (i.e., that it cam from the patient).
- Additionally, consumer-reported outcomes from known validated functional status and risk assessment instruments would enhance both the measures and also the frequency of interactions between patients and providers to more closely achieve the shared decision making of interest to the HITPC.
- To be sure information is coming from the patient / consumer, provenance at the data level will be needed, not merely at the CDA header level.
- If patient-reported data is to be incorporated (efficiently, effectively, and safely) into high-value care processes (and thence into CQMs), the performance characteristics (e.g., sensitivity and specificity) of the data will need to be known. Evidence shows that patients can report their height as accurately as nurses can measure it (at least in standard care). Validation studies of the accuracy of other patient-reported data are needed, e.g., symptoms of diseases (such as self-reported PND), known adverse effects of drugs such as metformin and ACEIs. Validate instruments will be needed to enable patients to input preferences, goals, etc
- If patients had a PHR or the Blue Button had a send capability the consumer could send CQM data such as OTC Medications for Medication Reconciliation, falls, side effects. At the beginning it should be simple items

QMWG07, continued

Discussion:

- If patients had a bluebutton or PHR it would be much easier to capture OTC meds and adverse events.
- The standards work on consumer-reported data is very early. The patient authored note was just balloted in HL7. It is too early to consider using patient reported data in CQM. Currently only the ability to label a note as patient-authored is possible—there is no way to capture the actual content of that data.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- Summary statement: This question asked for public comment on creating measures that combine clinical and patient-generated data for quality measurement. The majority of comments discussed the use of patient-generated data within the EHR. Responses were fairly balanced between pros and cons.
- Key Points
  - Clear recommendation against using generated and physician generated data in quality measures 5 responders
  - Clear recommendation to combine or join patient and physician data: 5 responders.
  - Caution toward patient-generated information in the electronic record: 10
  - Support for patient-generated information in the electronic record:8

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

More information needs to be collected to determine what patient-directed data currently exists. Testimony should be provided to the workgroups. This data should be stratified from the other information in the medical record and labeled by source if integrated into the record overall. This would likely require the creation of new attributes.

Comments:

- This question should be answered by invited testimony to fully understand how it can be answered.
- Patient-collected data on the patient's experience of care is extremely important. I am not familiar with what published data may exist in the question, but I strongly suspect that patients would prefer that their health care providers only see their feedback anonymously, which might preclude viewing such data mixed with EHR data at the individual patient level. However, it is likely that important insights could be derived from aggregate analysis of patient-collected data on patients' experience of care with EHR data on the same patients.
- This data must be stratified: Some will be as accurate and directly actionable as clinician-input data. Some will be informative, but only indirectly actionable (usually after clinician interpretation). Without validation of patient-generated information (i.e., the instruments used to collect them), its integration would be potentially dangerous. Even after it is validated, such data (like all data) would need to be visibly (to clinicians) marked as patient-generated.
- I do not think the public is aware of the capability of shared decision making. The data should indicate whether it came from the patient or the care provider.

Discussion:

- Public is not even aware generally about shared decision making and PHR.

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
QMWG09	Please provide comment on how the HITPC should proceed with our focus on clinical outcomes. Should the HITPC focus its efforts on building point-of-care process measures or value-centered outcome measures?

SUMMARY OF PUBLIC COMMENT:

	Both Supported	Value-Based Outcome	Process Only	HITPC Should Not Build Measures	Different Question Answered	N/A
Count	20	16	3	3	5	5

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENTS:

- There was broad dissent on this topic. While some workgroup members felt that both types of measures had utility, some thought that processes of care should have higher focus to align with the goal of patient-centered care.
- Others felt that quality measures in their current form sometimes measure for the sake of measurement without ensuring any improvement in health outcomes. This factor depends somewhat on the size of the population in question.
- Several people noted physicians are hesitant to be measured on outcomes because they feel many factors in outcomes are outside their control. It was also noted the current framework for measures is better prepared to accommodate outcome measures because the logic needed for process measures is not ready for deployment.

Comments:

- Point of care process measures require significantly complex logic and structured data that are not a part of routine practice (nor should they be). Outcomes determined by discrete, structured results ((lab, exam findings) or results of validated instruments are a much better fit to enhance practice workflow and results. Process measures tend to lead to 'checking the box' and not real outcomes.
- I think our current environment and adoption of standards does not well support meaningful standardized longitudinal eMeasures. They are better suited to POC measures that are aligned with CDS functions. That is not to say that longitudinal analysis is impractical or unimportant, just the opposite. It's that specific MU CQMs for this are difficult and should be done via a different, less restrictive, process that can better adapt to the variances across the patient populations in paly.
- Outcome measures are often unpopular with physicians for the understandable reason that they hold physicians accountable for factors not within their control. It is likely best to favor process measures, perhaps with an option for EPs and EHs to elect some outcome measures. EPs and EHs who feel they are in a position to be accountable for patients' overall health status (along the lines of the "ACO" concept) might be more comfortable with outcome measures.
- This is really a question of the population size required for a measure to be valid. Outcome measures require populations that are two or more orders of magnitude larger than process measures. (Mant. 1995. BMJ 311:9; 766.) So, for an individual EP or a small hospital, process measures may be the only measures that are valid. Of course, the process measures need to be validated (and perhaps re-validated) as being correlated with outcomes.
- Both but as an evolution not a revolution. If you consider person centric electronic longitudinal care as the ultimate goal point of care would have to be included.

QMWG09, continued

Discussion:

- If you consider patient-centered care as the ultimate goal, then processes of care have to be considered.
- Yes, they should focus their efforts on both. If one had to prioritize them, outcome measures should probably be primary.
- Distinguishing between population and individual measures should be considered in the context of the population size. A relatively large sample is needed to determine the overall effect. Outcome measures could be inadequate at a lower threshold.
- This is a very touchy issue among physicians who don't want to be held responsible for events outside their control but there are events such as ACOs that might appreciate the opportunity to be measured on outcome. It might be politik to require outcome measures initially but they likely still have value. It is unclear whether these outcomes are public information or not.

ID#	Questions
QMWG10	Is this a false or unnecessary dichotomy? Should we instead consider a third approach, to promote process-outcome measure "suites", combinations of end outcome measures that are potentially associated with process measures? For example, Stage 2 eCQM set will include three HIV measures. The outcome of viral load suppression is accompanied by two related process measures for an HIV medical visit and for Pneumocystis Pneumonia prophylaxis.

SUMMARY OF PUBLIC COMMENT:

	Supports Suite	Provides Suite Example	Research for Suite	Outcome Only	Process Only	Does NOT Support Suite	Other Comment	Different Question Answered	N/A
Count	20	7	2	4	1	1	12	6	1

For HITPC Consideration/General Suggestions

- Outcomes should be the focus. Providers need freedom to choose processes that will allow them to achieve
- It is critically important that pediatrics be included in the development of such suites
- Include specialist expertise to ensure relevance of measures clinically and for patient perspective
- Quality improvement should shift from quality measurement to registry reporting

eCQM Suite will be Challenging

- Suites may require the same denominator for each measure.
- Complexity can hinder reporting

"Suites" are an opportunity for Research

- Use measure suites to evaluate strength of relationship to outcome. With time, refine the process measures used in the suites.
- Preventive health measure suite. To capture - screening, counseling, referral, and follow up

QMWG10, continued

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENTS:
The discussion about process outcomes is sometimes confused by the definition of outcomes and the validity of the measurement in question. However, there was unanimous agreement that suites of measures are superior to individual measures. New evidence shows that measure suites more accurately estimate quality of care.

Comments:

- Some process-measure outcome "suites" make sense such as the HIV measures noted. It is important to understand key process indicators to which successful or challenging outcome results can be attributed. However, the more processes that are considered raise the specter of increasing exceptions and/or exclusions. The more processes can be 'hard and fast' (i.e., no allowed exclusions or exceptions) the better.
- I agree that packaging such measures together makes sense if longitudinal outcome measures remain central to the approach. At least then the outcome measure can be defined using data used in the POC measures so some consistency can be maintained.
- No, I do not think this is a false dichotomy.
- HIV medical visit is not evidence-based and should be dropped. PCP prophylaxis is evidence-based and should be kept. The language here remains tortured; it often seems that "outcome" is used for "validated process measure." Viral-load suppression is not a result that a patient can experience as an outcome, while time to development of AIDS or one of the complications of AIDS is. Viral-load suppression is a validated process measure.
- Suites are the only way QM can be meaningful when the patient is under chronic care with co-morbidities.

Discussion:

- Viral load is not an outcome. Patients don't experience viral load suppression. This discussion is always limited
- A series of papers on bundling and suites of equality measures and quality of care indicates that suites are the most appropriate way to approach these measures.

Agree.

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
QMWG11	Please comment on challenges and ambiguities in retooling legacy paper abstracted and claims based eCQMs.

SUMMARY OF PUBLIC COMMENT:

- **Summary statement: There is general consensus that retooling paper-based quality measures is challenging and often results in unintended consequences. Based on struggles to date 19 commenters prefer de novo eCQM development over retooling of existing paper-based measures. 1 commenters prefers retooling and 2 commenters prefer a system that includes both retooling and de novo development. Specific challenges noted include:**
  - Patient-provider attribution
  - Claims based exceptions & exclusion not routinely documented in current workflows
  - Claims based visit definitions limit the longitudinal benefits of EHR data
  - Lack of consistent data field inclusion/exclusion criteria
  - Need for dual data entry
  - Mismatched reimbursement models drive data collection for payment vs. quality improvement
  - Unknown or unknowable denominator or numerator components

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Generally it was thought to be ideal to develop new measures for electronic purposes; however, most were wary of disregarding a large body of research to be better aligned with measures. Much testimony has been presented to the HITPC and other venues about the issues with retooled measures.

1. Measures intended from reporting as claim information at the time of a patient visit to the physician (PQRS) inherently identify the attributable physician as a part of the process of reporting. Retooled for EHR queries causes patients to be identified for whom the physician may have had one acute care episodic visit but for whom care is provided by another physician in the practice. Also, by reporting at the time of the visit the physician assures that the patient was seen that year. A query of all patients with a specific diagnosis may pull patients who left the practice or died yet the records are not inactivated (hence incorrect denominators).
2. The claims-based reporting method allowed for definition of exceptions or exclusions at the time the claim code was entered. Seeking similar information in the clinical record implies that such information is part of routine documentation (which it is not and it should not be).
3. The claims-based approach can identify each visit as a single entity. An approach to query an EHR for all visits requires more complex logic construction to determine around which visit a specific action occurred (e.g., treatment within 3 days of a pharyngitis episode – which episode of pharyngitis for which treatment regimen).

On the inpatient measures, a team of trained record abstractors combed through charts to determine if criteria are present. Without such abstractors, data requirements either need to be relaxed or extensive additional documentation must be required.

QMWG11, continued

Comments:
Much testimony has been presented to the HITPC and other venues about the issues with retooled measures. The issues are many but a few include:

1. Measures intended form reporting as claim information at the time of a patient visit to the physician (PQRS) inherently identify the attributable physician as a part of the process of reporting. Retooled for EHR queries causes patients to be identified for whom the physician may have had one acute care episodic visit but for whom care is provided by another physician in the practice. Also, by reporting at the time of the visit the physician assures that the patient was seen that year. A query of all patients with a specific diagnosis may pull patients who left the practice or died yet the records are not inactivated (hence incorrect denominators).
2. The claims-based reporting method allowed for definition of exceptions or exclusions at the time the claim code was entered. Seeking similar information in the clinical record implies that such information is part of routine documentation (which it is not and it should not be).
3. The claims-based approach can identify each visit as a single entity. An approach to query an EHR for all visits requires more complex logic construction to determine around which visit a specific action occurred (e.g., treatment within 3 days of a pharyngitis episode – which episode of pharyngitis for which treatment regimen).

- On the inpatient measures, a team of trained record abstractors combed through charts to determine if criteria are present. Without such abstractors, data requirements either need to be relaxed or extensive additional documentation must be required.
- I strongly feel that an analysis based on eMeasure data cannot be compared (except for a research discussion) to any analysis based on abstraction methods for paper measures. While there are good measures on paper that should be the basis for eMeasures, the process of "retooling" changes the measure. Of note, some important measures should never be eMeasures and should always be abstraction-based.
- De Novo and looking at QM from a fresh point of view is better than automating existing paper QM workflows

ID #	Questions
QMWG12	Is this a shift away from retooling legacy paper-based CQMs in exchange for designing CQMs de novo a reasonable course of action?

SUMMARY OF PUBLIC COMMENT:
A shift from retooling of existing paper-based CQMs to de novo development is supported by the commenters (41 comments: 58.5% yes, 14.6% no, 7.3% both, 14.6% NA). Removing the comments that either provided only guidance or did not comment results in 68.5 % support for de novo CQM measure development. Many comments included deep insight into this issues of measure development.

- Boston Medical Center – "In contrast to legacy paper measures we have found that the de novo measures, if well designed, are easier to complete."
- HIMSS continues to call attention to the increased burden on the provider to collect data for both manually abstracted measures and eMeasures, and we continue to urge the HIT Policy Committee to reduce this burden.
- Kaiser Permanente - There are too few de novo measures designed and intended for EHR-based measurement to provide an informed comment.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Generally it was thought that the program should shift away from retooling paper measures and move towards intentional electronic measures.

QMWG12, continued

Comments:

- It is the only feasible course of action.
- it's a necessary and good process that is a consequence of moving to HIT. Again, abstraction-based analysis should still be maintained for certain measures – human assessment of gestalt process.
- It seems quite reasonable to me. The yardstick should be what quality measures are supported by high-quality evidence, will address high-impact processes (low NNT), and as alluded to above, be addressed with EHR data without excessive data-entry burden.
- If the course includes using the content of legacy CQMs (when evidence-based) and using it as the basis for a new CQM designed from the ground up. "De novo" could be read as excluding this re-use of content.
- Yes

ID#	Questions
QMWG13	Please comment on the provider/payer/patient experience with using retooled measures as opposed to experience with de novo measures designed and intended for EHR-based measurement.

SUMMARY OF PUBLIC COMMENT:

- In general comments reflect a poor experience with retooled measures and a relative lack of experience with measures developed de novo. Providers have experienced increased burden, attribution problems, significant clinical issues/errors, inefficient workflow modifications, uncertain reporting results, confusion and lack of value add (patients and providers) with retooled measures. According to commenters it is not possible to access patient experience with either retooled or de novo measure because there is currently a relative lack of patient-centric CQMs. However if provider assessments are accurate regarding clinical issues/errors one would ascertain a negative experience for patients with retooled measures. The comment pool did not contain sufficient input from the payer space to comment regarding experience.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
More investigation is needed to determine the provider/payer/patient experience with de novo measures because few if any of these measures exist.

Comments:

- There are almost no measures developed de novo so this question cannot be answered.
- I am not aware that this dimension of CQMs is as influential as posited (although the construction of measures that use all the developments noted remains appropriate).

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
QMWG14	Please comment on aligning CQMs with MU Objectives. Would eCQM-MU Objective alignment be clinically valuable to providers or might this be a redundant exercise in shifting resources?

SUMMARY OF PUBLIC COMMENT:

- The vast majority of commenters encourage HITPC to push for a single set of national measurement standards for reporting across various quality programs as well as standardized measure definition, calculation and logic. However, there is concern that alignment maybe redundant if reporting remains separate. A number of commenters encourage HITPC to develop a process whereby organizations could submit new measures for consideration. Finally, new measures were proposed, focusing on perinatal health, medication management, care transitions and long term care.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Ideally objectives would fade away as they were incorporated into the measures but it is reasonable to continue to have some objectives at this time. Alignment should not simply create duplicate measures but is a laudable goal.

Comments:

- If MU measures are limited to attestation then CQMs are the only way to determine if the attested functions are actually used. To manage these issues as CQMs implies a certification requirement for EHRs to provide utilization statistics for the functions indicated in the measures. Otherwise, the elements would not be feasible.
- as long as multiple programs require similar but un-aligned data, an undue burden exists. Either align the data expectations or remove the dispartities.

Discussion:

- This is consistent with the retiring of objectives discussed above.
- It would be most valuable if the alignment didn't create new duplication of measures.

ID #	Questions
QMWG15	Which measures and objectives, in particular, have the greatest potential to maximize meaningful alignment? Please recommend eCQM/Objective alignment opportunities.

SUMMARY OF PUBLIC COMMENT:

- Commenters provided examples of existing measures and data elements which should be considered for alignment. Commenters encourage ONC to also consider alignment of reporting requirements not only across quality programs but also for payor requirements. There are several suggests for new measures as well as methods of developing new measures.
- Key Points
  - Align around feasible componenents of existing measures and priorities:
    - vital signs; weight assessment; counseling; medication reconciliation & safety;
    - transitions of care; and CMS eMeasure 26/NQF 0338 with EH core objectives 6 and 10.
  - Suggest measures include those focused on congestive heart failure, medication management, population health, and long term care
  - Methods for development: invite testimony from organizations that are aligning measures; accept submission from across the healthcare industry, not just professional organizations; standardize submission process; fund pilot tests to determine feasibility and cost benefit; and involve measure developers in the process.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Hypertension, BMI, cardiovascular measures could incorporate this alignment. Patient data could be incorporated. Problematic data elements should be removed and corrected first.

Comments:
To truly address meaningfulness measures should address expected certified technology to show the EHR is appropriately used. Such a measure should apply to any condition, practice or domain.

Discussion:

- It is critical to align the data elements within the measures. There are 3 ways to collect data such as tobacco within the quality measures.
- Within different care settings,
- SNOMED changes 15 measurements to 20 measurements regarding pressure ulcers.
- There are also multiple ways to collect data regarding falls. It is a huge burden on providers

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
QMWG16	Which, if any, high priority domains should receive prioritized attention in Stage 3? What measure concepts, addressing these domains, should be considered for development? What EHR capabilities should be leveraged to realize these concepts?

SUMMARY **OF PUBLIC COMMENT:**

- **The comments roughly were divided between those that identified NQS domains that should received additional attention in Stage 3, those that name clinical areas that should receive attention in Stage 3 and those that either explicitly rejected the NQS domains and/or suggested that clinicians should decide for themselves and their patient populations what their priorities are.**
    - Care Coordination (6)
    - Safety(5)
    - Care Effectiveness/Complex Management (6)
    - Patient Engagement /Shared Decision Making (7)
    - Population and Public Health (5)
    - Care Efficiency (2)
    - Allow Practitioners to choose priority (5) (VA, Siemens, etc)*not an anticipated response
- FACA efforts should focus on creating infrastructure for health conditions identified as high priority by payers.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Transitions of care should be a greater focus. More outcomes measures might improve care quickly. Recommend more research.

Comments:

- Priority domains should include the measures that use expected certified technology to show the EHR is appropriately used. Such a measure should apply to any condition, practice or domain. Prioritization of clinical domains is a policy issue.
- The high priority domains are skilled nursing facilities (SNF) and home care agencies. A large percentage of discharges from eligible hospitals go to either a SNF or home care agency. In the future assisted living facilities will have to be added. Transitions of care and harmonized eQMs should be incorporated as they are being developed by the S&I Framework

Discussion:

- Transitions of care should be a major area and are being developed by the S&I framework.

ID#	Questions
QMWG17	Are there EHR based exemplar measures that exist, or that are being conceptualized or developed, that address these domains and theses concepts? What scientific evidence, if any, supports these concepts and exemplars?

SUMMARY OF PUBLIC COMMENT:

- Summary statement: Wide variety of responses, those that pointed to measures or groups of exemplar measures are below:
  - Consider Centers of Excellence Measures (CHA)
  - AMA PCPI Maternity Health Measures (ACOG)
  - Support for clinical Society involvement (Greenway)
  - "Increased Flexibility" (AMA)
  - Communicate with non-physician providers
- There really was not consensus but there was consistent comments from EHR vendors suggesting that HHS defer to specialty societies.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
There are MU2 measures that look at transitions of care. Future developments in transitions of care should include two way transmission of data, two way communication and role assignments as well as expansion of the participating members of the care team.

Comments:

- It is important to exercise caution in considering EHR-based exemplar measures. Measures that use clinical data obtained from EHRs at individual organizations are most often managed using data warehouses or external analytical tools to evaluate the measure components. They may be highly specialized to local terminology and processes and they may not translate well to national, interoperable queries.
- There are currently eQM dictated by the MDS and OASIS CMS systems that could be worked on with MU eQMs. An example is falls.

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
QMWG18	Please comment on the desirability and feasibility of such an innovation track as a voluntary, optional component of the MU CQM requirement.

SUMMARY OF PUBLIC COMMENT:

- There was strong support for an some form of a flexible innovation track to be added

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Alternative measure sources are generally thought of as a desirable, ideal state. New measure developers could move into this space without further difficulty and without using the traditional measure development profess.

Comments:

- Seems good. Need to define reasonable expectations for the documentation of these home-grown items to help set the bar for “good work”. This would require clear guidance and tools.
- While it might be useful to encourage care-delivery organizations and others to submit CQMs that they regard as being evidence-based for review by some appropriate agency (which would require funding), enabling the use of such measures as satisfying MU would predictably introduce low-quality quality measures into the system. Among other things, such a course would disregard the challenges of noted in QMWG11 above.
- This would be very valuable because it is from people treating patients and using practical workflows. The key is to ensure that the QMs are not silos. The clinical LTPAC stakeholders have to be involved both in the ultimate design of the QM and in providing input.

Discussion:

- If we have these streams of quality measures the evidence would be as great in the long run as starting with high-impact, high evidence
- We need a quality measure for quality measures?
- There are too many people developing quality measures. There should be a leader to hold the entire process together. A reasonable set should be focused on outcomes.
- #24—the limit should be what is reasonable to measure to improve clinical outcomes and reduce fraud but without adding cost and duplication/waste
- Certain care settings have needs that are specific and deserve to have special measures as long as they don’t conflict with the existing measures.

ID#	Questions
QMWG19	The QMWG has considered two approaches to institution-initiated eCQMs. A conservative approach might allow "Certified CQM Development Organizations", such as professional societies and IDNs to design, develop, release and report proprietary CQMs for MU. An alternate approach might open the process to any EP/EH but constrain allowable eCQMs with certain design standards. There are advantages and disadvantages to both. Please submit comments on either, both or unique approaches.

SUMMARY OF PUBLIC COMMENT:
This question asks if only large experienced "Certified" organizations should be allowed to build innovation measures or should the process be open to any EP/EH. Also, responses to 19, 20, and 21 tended to overlap. Answers roughly are split between those that recommend centralized (e.g. NQF) validation of an innovation track or decentralized/local validation with a constrained development environment

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Generally there was support for local development of CQMs; however, there were a number of caveats and potential problems discussed by the CQWG. The measure development process being developed by the MU program should be leveraged to be available for local developers. Quality assurance processes available for MU should be made available, particularly help with data element selection and logic creation. An improved Measure Authoring Tool will be a requirement for opening measure development to others.

Some sort of training or certification for new measure developers was suggested but others thought it was important not to add too many barriers to those interested in doing measure development. New measure developers should be encouraged in specialty areas and new care settings.

Comments:
Institution-initiated eCQMS have the benefit of addressing issues important to the quality of care and business direction of the institution. However, such measures are generally developed based on individual organizational EHR capabilities which may be more extensive and/or customized with respect to MU expectations and 'model' vendor products. Such measures are also often analyzed and evaluated in local data warehouses using data initially entered into the EHR during routine care processes but not necessarily using even advanced EHR functions. An example is a VHA measure of days within threshold for INR for patients receiving antithrombotic therapy. While the INR results are available in the EHR as are height, weight and other required data, the analysis requires evaluation outside the scope of an EHR.

Similarly, measures developed by specialty organizations can be managed in registries because data are submitted either manually, by abstractors or directly from feeds from EHRs. The analysis, however, is performed in the registry warehouse and not the EHR.

Measure development requires knowledge of available data, but also knowledge of how to apply evidence in a manner that addresses reliability and importance and validity of the result such that it is reproducible. CQM development organizations may be more reasonable, but clear criteria for development, testing and subsequent endorsement in a much more rapid, agile fashion is needed. Organizations such a National Quality Forum have some of the infrastructure and the broad based membership that is required for endorsement, but the processes for eCQMs requires a new process for robust, rapid endorsement and evaluation to support the MU process. Measure development in its current state is too expensive to survive without specific funding.

A new process may be more advantageous: A community of practice that establishes clearly defined rules and allows participation of all interested parties that agree to follow those rules is needed. The measures and data element feasibility should be managed similar to the National Library of Medicine Value Set Authority Center – i.e., feasible data elements should be maintained and made available from a central source or truth with links to the NLM VSAC. And a valid measure library that uses such feasible elements should also be made available. The community of practice can support creation of new measures from feasible elements and, when approved by the Measure Authority Center entered into the available database for use.

- I'd set the bar a bit lower than a "certified" organization since the work of determining how to certify (openly) is the work necessary to let anyone play. We want to encourage this everywhere and we'll learn from it. But it should be a decent set of criteria drawn from what we've learned from NQF.
- Both are calculated to produce sub-optimized measures.
- LTPAC providers and vendors have to be involved in order to achieve person centric electronic longitudinal care. Transitional dQMs have to be developed. All existing QMs have to be taken into consideration so there is not a duplication of administrative efforts which would take away from direct care.

ID#	Questions
QMWG20	What information should be submitted with a locally developed CQM to help CMS and other healthcare providers assess the innovative measure? For example, should the submission form include a brief description of: 1) importance/rationale of the measure domain; 2)evidence basis for the specific measure; 3) feasibility, and 4) usefulness of the measure?

SUMMARY OF PUBLIC COMMENT:

- Comments roughly answered in three ways: recommending full NQF endorsement (4 commenters), some process managed by HHS that was similar too but not as extensive as NQF endorsement (11), a submission of basic measurement information (12)

COMMENTS:

SUMMARY COMMENT:
These are reasonable criteria for investigation and evaluation. The proposed logic framework and data elements are also relevant, and metadata and the location/source for capture should be included.

Comments:

- All of the options listed in the question are needed and all are part of exiting endorsement criteria. However, these metadata about the measure do not guarantee feasibility of data capture and usage. Therefore, each measures should provide evidence that each data element is shown to be feasible. Since that process would be overwhelming for most measure developers, a central process for determining data feasibility should be made available to all measure developers who can then only use data elements proven to be =feasible. Note that the value set is only one part of a data element. Its context of use is also important as is its source (i.e., provenance of the data element. The feasibility evaluation must include all metadata required about a data element to determine if it is truly available in existing systems.
- Also use of standard terminology value sets and alignment with the common clinical model noted above.
    - QALY gain in the population if the measure were effectively achieved. How would these measures get into EHRs—assuming that HIT developers could not reasonably be required to accommodate them?
- all of those listed plus if there exists an similar QM from CMS or other organizations.

ID#	Questions
QMWG21	What constraints should be in place? Should individual providers have an option to choose and/or design their own measures outside of the established CQM EHR Incentive Program set? Should these "practice-level" measures be required to conform to the Quality Data Model data elements and/or entered into the Measure Authoring Tool or conform to a simplified HQMF XML?

SUMMARY OF PUBLIC COMMENT:

- The comments to this question primarily split into two groups: those that recommend standards be created to conform to a consistent e-measures data model and those that suggested innovation or usability will be limited by imposing such constraints.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
There are a number of QDM elements, concepts that are not easily captured, and other HQMF inconsistencies that need to be addressed before measure authorship should be opened to anyone.

Comments:
The Quality Data Model requires ongoing maintenance to be useful. Measures that adhere to QDM definitions should be able to be evaluated for feasibility. Many of the MU 2 measures use the QDM inappropriately leading to confusion and inconsistency. Software such as the Measure Authoring Tool cannot assure appropriate use of the QDM on which it is based. A measure and data element feasibility process is required before measures are entered into any authoring tool.

An example of a feasibility concern is the use of Problem Lists to determine conditions. Problem Lists are not routinely managed to update activity or resolution of problems, they are inherently inaccurate sources of information. Diagnoses from claims have other issues and are primarily useful when tied to an encounter to at least suggest continued activity. Unless Problem Lists can be continuously updated and used routinely to manage EHR activities, active conditions may be better determined using a set of criteria (similar to a Risk Assessment which is a component of QDM) to determine the likelihood of a diagnosis before including a patient in a denominator.

The HQMF is in its early stages. The complexity of many measures cannot be expressed in HQMF partly due to the complexity of the HL7 Reference Information Model on which it is based. A simplified logic that is consistent with Clinical Decision Support requirements is needed. Until HQMF can be made more stable and capable, and interim standard is needed, based on a standard data model (such as the QDM) from which EHR vendors and users can compile queries based on how data are managed in their own products. Even the simplified HQMF XML is insufficient since it maintains the complexity of the RIM.

Allowing providers to design their own measures will lead to a chaotic situation contrary to the intent of the MU program. The intent is to improve patient outcomes through use of the EHR. This goal can be evaluated more effectively by selecting appropriate measures and defining them consistently.

- Let them do a process outside the defined set but establish criteria that must be met (as above). Explain that not many are expected to do this and there is no guarantee it will continue, it's a test.
- This appropriate questions point out how expensive to govern such a system would be. Would they be required to pay NLM for developing or validating and curating the needed value sets?
- Providers should always be allowed to design their own QM to match their practice. With this said, there should be a reasonable set of eQMs based on person centric electronic longitudinal care that all stake holder agree to measure so the system is held together using eQMs as a cohesive factor.

ID#	Questions
QMWG22	What precautions might be necessary to mitigate fraud, waste and abuse and to avoid submission of trivial new measures that are unlikely to advance the field ?

SUMMARY OF PUBLIC COMMENT:

- The recommendations varied broadly but coalesced around using the submission process to ensure measures were useful and impactful.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
A review process needs to be established for measures and criteria should be developed for submission. It is prudent to have a preliminary process to track the status and concepts of measures to avoid multiple, misaligned measures in the same domain being worked on at the same time.

Comments:

- A central measure authority is required to determine the importance, feasibility, reliability and validity of all measures used in government programs. The process to perform analysis of measures must address the iterative nature of measure development and address data element feasibility. It must also be agile and provide feedback on a regular basis with 30-60 day turn-around times for decisions.
- By making the criteria for submission reasonable and scholarly. Then see what comes. Time limit the process…
- There are too many QM input organizations and regulations. There is no single leader. There needs to be one recognized leader that all providers respect and obtain agreement. An example of such an organization is HL7. Also eQMs should not be designed for penalty management but for clinical outcomes.

ID#	Questions
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)?

SUMMARY OF PUBLIC COMMENT:
There is strong support for a measure-level toolkit to support consistent implementation. Commenters described both a federal convening organization and/or a web-portal with open-source tools. Many comments described features of the learning health system. The comments overlapped in describing the above and don't lend themselves to a useful quantitative account. Several commenters noted that every measure should have intent, HQMF xml, workflows, and test-patients that are exhaustive of logic permutations. No commenter dissented or disagreed with the need for a more robust toolkit. Multiple commenters noted the inadequate current state of tools to support implementation.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
See prior answers in this section. Value set standardization and standardized test patient data.

QMWG23, continued

Comments:

- Value set standardization is essential and the NLM VSAC provides an excellent mechanism to manage the value sets. Moving forward, data elements need to be evaluated for feasibility based on all of the expected metadata about the elements, not only the value sets. Such a process also needs a sponsor which should be a public-private partnership with federal input.
- Providing test patient data in standard format (perhaps CDA) for entry into the user's EHR is a good step. Vendors should be required to provide functionality so that users can import such test cases and report on their output.
- Provide test data in an open way and let submitters modify this and require systems that choose this approach to also submit all needed value sets (they should be drawn from VSAC and meet criteria for acceptance, and to submit test cases adopted from the standard set.
- This appropriate questions point out how expensive to govern such a system would be.
- Work together with a leading organization to ensure continuity of eQMs across the spectrum of care and that there are no duplications or slight changes to fit special organizations. It is the patient that has to be the focus not the provider.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- Comments urge HITPC to ensure that current measures are being collected effectively, are useful to EPs/EHs, and are positively impacting patient care and outcomes. Further, comments stress a strong need for alignment and standardization of measures across federal programs as well as payor organizations. New measures should be weighed for their impact on patient outcomes balanced by their burden on EP/EH. Commenters suggested taking a population management approach to measure development. Several commenters urged the HITPC to defer to MAT or, at a minimum, develop a standardized approach to development which would actively engage a broad stakeholder group. Commenters caution HITPC in regard to over burdening EP/EH with new measures, as this may shift focus from using quality data meaningfully to a focus on simply attaining reporting goals. Finally, commenters urge the HITPC to support policies which would rapidly advance technology capabilities for seamless and less burdensome reporting.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

The type of provider, care setting, effort required for reporting measures, and clinical area should dictate the number of measures in part. The total cost and effort of implementation should be strongly considered, along with the workflow implications. There is no clear evidence to support what might be an appropriate limit. Different menus of options might be the most reasonable.

Comments:

- If measures were simpler queries that could address existing data based on semantic interoperability the number of measures would be less problematic. However, the nature of implementations expected even with MU 3 will not provide sufficient sematic interoperability.
- There is no clear evidence to support what might be an acceptable number.
- This should not be part of application certification.
- The limit should be what is reasonable to achieve the objective of measuring an individuals quality of care and quality of life to improve clinical outcomes. They should be designed that also prevent fraud, etc. but do not require high administrative costs and do not duplicate other required QMs

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
QMWG25	Please comment on the value and feasibility of the eCQM and EHR features listed below: - Ability to accept downloaded specifications for new measures with little tailoring or new coding - Minimal manual data collection or manipulation - Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc) - Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions) - Ability to build multi-source data records, including claims, patient reported data - Ability to implement machine-readable HQMF that minimizes manual vendor coding - Ability to drill-down on reported measures for QI analyses

SUMMARY OF PUBLIC COMMENT:

- On the whole, commenters overwhelmingly supported all technology features described in this QM. Comments regarding each element are summarized below. Commenters expressed a number of concerns including: a lack of standards; vendors' ability and time requirement to develop required capabilities; prematurely being prescriptive with data and capability use; accommodating specialty practice settings; and expense. A few commenters note vendors and organizations with experience in these capabilities including Elsevier, population management platform vendors, and Pharmacy e-HIT Collaborative
- Ability to accept downloaded specifications for new measures: Commenters express some doubt that measure will be sufficiently detailed that they will not require manipulation. Thus they encourage a great degree of testing.
- Minimal manual data collection/manipulation: There is great interest in this capability however, commenters point out that data should be captured during the normal course of workflow and that automated abstraction needs to be thoroughly tested in order to gain provider confidence.
- Aggregate measure data across units: Commenters remind HITPC that not all care units have the same level of technical functionality. Security and confidentiality remain a concern.
- Ability to build cross-setting measures: comments remind HITPC that interoperability standards will be need to achieve this capability. Further, they suggest learning for ACOs and HIEs for best practices as well as considering data warehouse and analytic products as part capability development.
- Ability to build multi-source data records: Commenters see this ability as an opportunity to conserve resources by avoiding duplicate data entry. The capability will require patient identification methods, significant standardization of patient-entered data and may warrant analysis of claims data external to EHRs.
- Ability to implement HQMF:HQMF is still under development and not yet a turnkey solution
- Ability to drill down: In order to take advantage of drill-down capability, commenters note a need to shift from current retrospective practices; assured confidentiality ; dashboard functionality and the ability to provide detail patient level data;

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

All of these features are valuable; however not all are feasible.

Measures that cross organizational boundaries are not currently very feasible.

QMWG25, continued

If the focus was person-centric then they could be feasible but certainly the business model has to be made for these features.

In regards to the specific feature feasibility:

- Ability to accept downloaded specifications for new measures with little tailoring or new coding –early in the standards process
- Minimal manual data collection or manipulation - This is important but significantly restricts what can be done in an eMeasure. If we can accept the restriction - good
- Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc) - important and somewhat valuable but not critical
- Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions) - yes critical but not possible at this time
- Ability to build multi-source data records, including claims, patient reported data- less important on "types" (claims data may be in the same system as clinician data) but yes important on system integration (patients enter data one place, various clinicians each in different systems, etc.)—not widely feasible
- Ability to implement machine-readable HQMF that minimizes manual vendor coding- important but not critical.—already in development in limited settings
- Ability to drill-down on reported measures for QI analyses- not very practical yet.

Action needs to be taken to move towards the implementation of these abilities rapidly.

Comments:

1. Until HQMF can be enhanced beyond the simplified version now being balloted tailoring will be required. A simplified XML based on a standard data model (such as the QDM used appropriately can provide a template to which vendors can come closer to providing download ability.
2. Data for measures for MU 3 should only be selected from feasible elements based on context and source desired (data feasibility) to avoid the need for manipulation
3. Many measures are better address by business units as described rather than individual physicians or other practitioners.
4. Incorporating cross-setting records by definition is outside the individual EHR. Such measures are appropriate for HIEs or regional, or organizational data warehouses
5. Patient-reported data should be incorporated (with clear provenance as to source) within EHRs. To include claims and EHR-data requires analysis external to the EHR itself.
6. Same answer as the first bullet
7. Drill-down requires sufficient metadata that requires local analysis
   - Ability to accept downloaded specifications for new measures with little tailoring or new coding – valuable but a bit early in the standards process
   - Minimal manual data collection or manipulation - This is important but significantly restricts what can be done in an eMeasure. If we can accept the restriction - good
   - Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc) - important but not critical
   - Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions) - yes critical
   - Ability to build multi-source data records, including claims, patient reported data- less important on "types" (claims data may be in the same system as clinician data) but yes important on system integration (patients enter data one place, various clinicians each in different systems, etc.)
   - Ability to implement machine-readable HQMF that minimizes manual vendor coding- important but not critical.
   - Ability to drill-down on reported measures for QI analyses- not as practical yet.
     - High-value care-delivery organizations will have to calculate hundreds to thousands of measures (most of them validated process measures, by the way). The operative question is "How well do national measures reflect the evidence base for providing effective, efficient, satisfying care?" If they reflect it well, national measures could be useful in helping care-delivery organizations identify measures that might be useful to them—the more such measures developed and validated, the better. If they do not reflect it well, the more measures developed, the worse the burden.
     - Valuable and Feasible - Ability to accept downloaded specifications for new measures with little tailoring or new coding
     - Valuable and Feasible - Minimal manual data collection or manipulation
     - Valuable but not Feasible - Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc)
     - Valuable but not Widely Feasible - Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions)

QMWG25, continued

- Valuable but not Widely Feasible - Ability to build multi-source data records, including claims, patient reported data
- Valuable and Feasible - Ability to implement machine-readable HQMF that minimizes manual vendor coding
- Valuable and Feasible - Ability to drill-down on reported measures for QI analyses

If the focus is person centric the information can be aggregated to achieve what you have listed

ID#	Questions
QMWG26	What other features, if any, should be considered? Please make suggestions.

SUMMARY OF PUBLIC COMMENT:

- Several commenters request the ability to query information in real time, consider additional population health capabilities, and focus on workflow and cross healthcare team collaborationneeds. Commenters remind HITPC that there remains a need for well defined standards as much functionality is critically dependent on interoperability. Further HITPC is reminded that the medical record is the legal record of care; therefore managing aggregated data from across disparate systems may be outside of an EHR's intended us. Comments suggest solutions for providing aggregation capability outside of the EHR. Finally, commenters encourage HITPC to set aggressive goals to force the healthcare industry to innovate.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Clinical decision support and presentation layers customized to user were mentioned but more discussion is needed.

All of the above would be useful. In addition, it would be very useful for EHRs to easily drive real time point-of-care clinical decision support functionality based on the electronic specification of a CQM, perhaps with some expansion of the HQMF to address any additional data requirements that would obtain.

Usability tested presentation layers for aggregation and drill-down by patient, business unit, payer.

ID#	Questions
QMWG27	What is the role of muliti-source data exchange in achieving these features?

SUMMARY OF PUBLIC COMMENT:

- Commenters agree that multi-source data exchange is essential to many of the features described in QMWG 24-26. Commenters request clear standards and suggest that prescriptive EHRs specifications may be necessary. Further, comments suggest that data aggregation, warehousing and analytic processes belong outside of EHRs in data warehouses or Accountable Care Organizations. Finally Commenters remind ONC and CMS that Clinical EHRs do not have any current practical reason to generate or receive such transactions (e.g., administrative, claims or other clinical data) thus quality data warehouses or analytic products might be better suited for exchange.

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:

Data exchange is necessary to achieve the full vision of many of these features, but it is unclear how to achieve it. Strong encouragement for action on multi-source data exchange should be ongoing and immediate.

Comments:

- Critical, if patients are to have reliable, efficient, convenient care. Not very feasible

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
QMWG28	Please comment on the value and feasibility of the CQM Population Management Platforms. Is there an evidence basis for clinical population management platform use? Is there a business case? Is this an area that could benefit from HITPC policy guidance or will the market mature and evolve without input?

SUMMARY OF PUBLIC COMMENT:

- There is broad consensus that a business case exists for population management platforms. The majority of commenters, especially the providers, feel there is a role for increased standards and possibly certification for population health platforms or features. A few commenters, especially software companies and some organizations, worry that the market and standards are too immature for certification at this time. They propose a combination of guidance, incentives and grants with continued work on data and interoperability standards rather than certification.
- Key Points:
    - Accountable Care- there is strong consensus that new payment models such as accountable care, are driving the market for population management tools.
    - Demonstrated evidence and value- a number of commenters provided specific evidence of value, especially in chronic disease management, managed care and public health

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
Further discussion is needed on this very broad topic.

It seems potentially valuable; however it is unclear how feasible these platforms are currently.

Comments:

- There is a business case for CQM Population Management for ACOs and for PCMH.
- I see all these as goals that are important but can only be built upon successful implementation of the initial MU goals. Seems reasonable to say this is where we want to be able to go if we get things consistent and work out the kinks, but not a MU3 goal.
- The business case is based on increasing demands for reportable quality and on the inevitability of lower overall reimbursements. As 30 indicates, there is a corridor of options between HITPC policy guidance and no input.

Population platforms can result from person centric eQM aggregation. There is a business case if decision makers can place a financial value on prevention and how to reward prevention. Is there a clinical value? Yes, as catching a adverse trend early is a value

ID#	Questions
QMWG29	What information or features might be present in a basic clinical CQM population management view (population score, denominator members, patient-level data element drill down, provider comparison, risk adjustment, ad-hoc queries, etc)?

SUMMARY OF PUBLIC COMMENT:
There is broad consensus on a number of data elements and features are core to population management tools. The features include provider attribution, benchmarking, population stratification, roll up and drill down. The consensus for core information focuses on risk scores, quality scores, care gaps, diagnosis and procedure status. More advance features include ability to modify cohorts, ad hoc query, stratification and ability to act (e.g. order) from population management tools

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
It may not be necessary to require these features, as they are necessary for organizational and administrative functions. More discussion and research is needed to comment on the specific features.

Comments:

- All of the elements listed are needed for organizational management. Defining such elements as requirements seems too prescriptive for regulation. Publication of best practices for population management may be valuable but the measures should be at the ACO or PCMH level.
- This is too new and fluid for feature specification to be effective and efficient.

ID#	Questions
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?

SUMMARY OF PUBLIC COMMENT:

- There is broad consensus for HITPC and ONC to continue to develop guidance, open source prototypes, demonstrations and challenge grants for population health. There is strong support for creation and enforcement of standards. There is mixed opinion about a role for regulation- some organizations such as Pharmacy e-HIT encouraging a role for regulation while others such as the Alliance of Specialty Medicine encourage a non-regulatory approach
- Key Points
    - Continue work on standards, challenge grants, open source prototypes
    - Consider separation of EHRs transaction system from analytic tools
    - Incorporate clinical decision support integration

SUMMARY OF HITSC COMMENTS:

SUMMARY COMMENT:
It is probably not desirable to be overly prescriptive—both industry, public health entities, and clinical stakeholders should be engaged in the process to overcome technical challenges. It should include robust collaboration and communication between stakeholders and could utilize some of the incentives mentioned.

QMWG30, continued

Comments:

- Guidance and publication of best practices and a forum for sharing such practices will be beneficial but may be available elsewhere through the private sector. As noted in the answer to QMWG25 any more would be too prescriptive.

We recommend encouraging innovation in pilot or demonstration projects. It is noted that EHR Vendors are willing to provide labor, but not labor and lost revenue due to standards that are not set in stone

II. 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
PSTT01	How can the HITPC's recommendation be reconciled with the National Strategy for Trusted Identities in Cyberspace (NSTIC) approach to identification which strongly encourages the re-use of third party credentials?

SUMMARY OF PUBLIC COMMENT:

- 41 comments received
- Many comments state that strong identity proofing and multi-factor authentication should be required for MU3 and that the NSTIC Model can be adopted in healthcare
  - Existing standards such as NIST SP 800-63, CIO Council Guidance, FEMA, and OMB, and DEA standards are suggested for consideration
- Some comments do not believe that multi-factor authentication should be required for MU3 citing that:
  - The deadline to implement is unrealistic
  - The requirement would introduce burden and increased costs, especially on small providers
  - Multi-factor authentication is not a core competency of EHRs

SUMMARY OF HITSC COMMENTS:

We see no conflict here; the HITPC's recommendation and the NSTIC approach are complimentary. However, we would note that a provider's decision whether to accept NSTIC is a policy decision. For Stage 3, EHR certification can require EHRs to support 2-factor authentication and permit one of the factors to be a third-party solution, in anticipation of NSTIC credentials becoming available. Then later, when the NSTIC program is fully implemented, NSTIC could be added as a standard for the third-party authentication.

We doubt that a fully operational NSTIC approach will be ready in time for meaningful use stage 3.

We also note that NSTIC offers benefits for authenticating both consumers and providers, and we may see consumers presenting NSTIC credentials before NSTIC has been broadly adopted by providers. Thus, we would recommend ONC avoid forcing the two uses of NSTIC (authenticating of providers and consumers) to progress in tandem

[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
PSTT02	How would ONC test the HITPC's recommendation in certification criteria?

SUMMARY OF PUBLIC COMMENT:

- 26 comments received
- Comments suggest possible approaches including:
  - Developing a checklist to verify the system set-up, while also requiring appropriate documentation
  - Requiring vendors to attest to having an architecture that supports third-party authentication and demonstrate examples
  - Checking for use of a federation language standard
  - Developing a model audit protocol for the community to use to self-test
  - Developing an iterative and phased testing program covers the population of organizations
- Existing standards and guidance that could be the basis of test procedures include:
  - DEA Interim Final Rule (IFR)
  - NIST 800-63
  - FIPS 201
  - HSPD-12
  - NSTIC/Identity Ecosystem Accreditation Standards

One comment suggests that the domain is not mature enough for certification

SUMMARY OF HITSC COMMENTS:

The EHR certification program must be able to accept NSTIC certification as normative and "conformant" once it is available.
We encourage the ONC to support rapid cycles of development of the NSTIC approach by providing the NSTIC program with a reasonable set of prioritized use cases for consumer & providers.

ID#	Questions
PSTT03	Should ONC permit certification of an EHR as stand-alone and/or an EHR along with a third party authentication service provider?

SUMMARY OF PUBLIC COMMENT:

- 30 comments received
- Many comments support both models
- Several comments suggest the EHR and third-party authentication service be certified independently of each other
- Logistic suggestions for the two models include:
  - Third-party dependencies could be handled the same way that database and operating system dependencies are handled in sectors such as the Payment Card Industry
  - In lieu of requiring certification ONC could implement NSTIC
  - Certification could be carried out to an ONC recognized healthcare trust framework by an NSTIC Accreditation Authority
  - Use external labs capable of and experienced in testing identity and authentication technologies in accordance with FIPS 201 for third party authentication providers

PSTT03, continued

SUMMARY OF HITSC COMMENTS:

Either should be allowed, so long as standards are followed. We recommend that EHR technology be configurable to enable an organization to require different levels of authentication and identity proofing (IDP) based on their role within the organization. For example, physicians, mid-level providers, and possibly clinical staff with full access and write/edit capabilities should have IDP to at least NIST Level 3, while non-clinical staff without write/edit capabilities might more appropriately have IDP to NIST Level 2. NIST is working on SP 800-63-2 which should allow hospitals to provide Level 3 IDP through the medical staff office (which completes a very extensive identity proofing on each physician). However, a contingency should be included in case SP 800-63-2 is not promulgated or does not include this: IDP for physicans and mid-level-provider to appropriate level for 2-factor authentication would match the DEA requirements in their Interim Final Rule for ECPS (not a strict "NIST Level 3"). NIST criteria would be preferable if available.

More generally, as the Privacy and Security Workgroup has recommended previously with respect to EHR modules, MU Stage 3 needs to do a better job of certifying products that use third-party software. Not just in the case of authentication. Interoperability Standards are critical to this. For example with third-party authentication services one must leverage an interoperability specification such as PKI, LDAP, Kerberos, SAML, or oAuth. These standards are important, but as standards they are broad and support many variations in implementation. Thus these standards are not sufficient, and implementation profiles are necessary. For example certificates for the use of Direct are currently being profiled by organizations such as DirectTrust. The resulting profile is important to some use-cases. In this case the DirectTrust profile helps assure that the resulting certificate carries sufficient policy backing. Another example is the profiling of SAML assertions found in the MU2 Transport (c). This profiling of SAML assures that the identity carry with it sufficient attributes about the individual and also statements about the context of the transaction (purpose Of Use).

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
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.

SUMMARY OF PUBLIC COMMENT:

- 46 comments received
- Workforce security training:
  - Comments for - cite the importance of the workforce in keeping health information secure
  - Comments against - cite attestation is either burdensome or duplicative of the HIPAA Security Rule
- Safeguard and training areas to emphasize include:
  - Access controls
  - Audits
  - Data integrity
  - Encryption
  - Identity management
  - Implementation of backup and recovery plans
  - Policies and procedures related to prevention of local PHI storage
  - Malware on all workstations accessing EHRs and EHR modules
  - Social media, bring your own device (BYOD), and mobile devices
  - Local data storage security controls
- Some comments say more HIPAA Security Rule guidance and education is needed for providers

SUMMARY OF HITSC COMMENTS:

We do not think any single HIPAA Security Rule standard or implementation specification should be called as a MU measure requiring attestation. The required administrative, physical, and technical protections should continue to be accomplished through the HIPAA process (risk assessment, reasonable and appropriate implementation, etc).

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
PSTT05	Is it feasible to certify the compliance of EHRs based on the prescribed standard?

SUMMARY OF PUBLIC COMMENT:

- 30 comments received
- Majority of comments state prescribed standard is feasible
- Many comments focus on whether or not there should be a standard
  - Many comments suggest there should not be a standard yet
  - Some comments suggest MU standards premature until final Accounting of Disclosures Rule issued
  - Some comments say question implies combining audit log and accounting of disclosures requirements
    - Audit logs require more information than necessary for an accounting of disclosures

SUMMARY OF HITSC COMMENTS:

Privacy & Security WG: Yes, ASTM E-2147-01 is a functional specification that can be translated into certification criteria and test scripts. Section 7 contains an enumerated list of data elements that must be included in an audit log, and Section 8 contains an enumerated list of data elements that must be included in a disclosure log. However, it is important to note that ASTM E-2147-01 defines “disclosure” to include the access, release, or transfer of health information to any “internal or external user or entity.” HIPAA defines “disclosure” as “the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.” So Section 8 should be interpreted relative to an accounting of disclosures between organizations and not within organizations.

ID#	Questions
PSTT06	Is it appropriate to require attestation by meaningful users that such logs are created and maintained for a specific period of time?

SUMMARY OF PUBLIC COMMENT:

- 37 comments received
- Comments suggest waiting until the Accounting of Disclosures Rule requirements are finalized before addressing attestation
- Comments supporting attestation also suggest other audit log requirements
  - Be able to certify a separate audit log system
  - Rely on NIST/Federal or State regulation
  - Incorporate into risk assessment
  - Credential users
  - Base on standards that give guidance for content
  - Specify period of time
  - Identify a minimum data set
- Other comments suggest attestation to all requirements in the HIPAA Privacy and Security Rules
- Majority of comments are neutral toward attestation requirements, citing a need to:
  - Wait for final Accounting of Disclosures Rule
  - Complete additional feasibility studies/research
  - Leverage audit log requirements in other industries
  - Defer to providers and hospitals for feedback
- Some comments do not support attestation requirements, citing:
  - Administrative burden
  - Need to also require demonstrating function
  - No improvement to security
  - Audit log is functionality of EHR, not a provider attestation requirement

SUMMARY OF HITSC COMMENTS:

We do not think any single HIPAA Security Rule standard or implementation specification should be called as a MU measure requiring attestation. The required administrative, physical, and technical protections should continue to be accomplished through the HIPAA process (risk assessment, reasonable and appropriate implementation, etc).

ID#	Questions
PSTT07	Is there a requirement for a standard format for the log files of EHRs to support analysis of access to health information access multiple EHRs or other clinical systems in a healthcare enterprise?

SUMMARY OF PUBLIC COMMENT:

- 32 comments received
- Many comments state that there is no adequate standard format requirement
- Most comments support a need for standard format requirement
- Some comments are neutral toward standard format requirement, suggesting that:
  - Government should dictate what but not how
  - Variability on details captured presents a challenge to creating a standard
  - Use of SIEM standard
- Some comments disagree with need for standard format requirement
  - Requirement elements can be mandated and should define a minimum data set
  - Burden on health care organizations and vendors
- Some comments state there is no need for MU based standards related to Accounting of Disclosures Rule

SUMMARY OF HITSC COMMENTS:

We believe it is most important for regulations to 1) focus on requiring the ability of EHR technologies to capture and maintain the necessary information to support analysis of security-relevant events that occur within an organization; and 2) define a minimum set of data elements through a standard (which is already provided by ASTM-E-2147). We also believe It would be valuable to have the data mapped to a common format to support, in larger organizations, internal interoperability across systems.

ID#	Questions
PSTT08	Are there any specifications for audit log file formats that are currently in widespread use to support such applications?

SUMMARY OF PUBLIC COMMENT:

- 37 comments received
- Some comments mention specifications that could be considered for audit log purposes, such as:
  - IHE ATNA Specification
  - HL7
  - DICOM
  - ASTM E E-2147-01
  - World Wide Web Consortium (W3C)
  - SYSLOG
  - UNIX-based operating systems
- Some comments state there are no existing standards or no existing standards in widespread use
- Other comments oppose new MU requirements based on proposed rule

SUMMARY OF HITSC COMMENTS:

ASTM E2147-01 (Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems) specifies the data elements that need to be included in audit log, and is an EHR standard, as of Stage 2.

Standards that specify data format include IETF RFC 3881 (Security Audit & Access Accountability), DICOM (Supplement 95), and IHE's Audit Trail and Node Authentication (ATNA, ISO 12052) profile which recommends RFC 3881 as a schema. However, none of these are in widespread use, and RFC 3881 is informative (not normative).

We believe it is important to distinguish, as we have done in the previous comment, between the minimum set of data elements and the format in which those elements are captured and maintained.