

January 14, 2013

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

Dear Mostashari:

On behalf of the American College of Physicians, I am writing to share our views on Stage 3 of Meaningful Use. ACP is the largest physician specialty society and second-largest physician membership organization in the United States. ACP represents 133,000 internal medicine physicians and medical student members. Internists specialize in primary and comprehensive care of adolescents and adults.

ACP applauds the HIT Policy Committee and its Meaningful Use Work Group for their diligence and hard work in developing recommendations for the Meaningful Use portion of the EHR Incentive Program. Please consider this letter and the attached document containing our section-by-section comments as you weigh your final recommendations to ONC and CMS.

Summary of Perceived Strengths:

- 1. Inclusion of functional measures as CORE that reflect fundamentally important actions (e.g., CPOE for laboratory and radiology orders)
- 2. CEHRT certification criteria that require more robust clinical decision support (e.g., maximum dose, weight-based dosing, structured SIG standards, suggesting Problem List additions based on results, findings or medications ordered/prescribed)
- 3. Requirement that text-searchable electronic notes are available in a timelier manner.
- 4. The core requirement that EHs provide structured lab results to EPs
- 5. The expectation that results received in the EHR are reviewed/acknowledged in a timely manner
- 6. Signaling the importance of CEHRT support for patient submission of online health questionnaires and other information that can be incorporated into the EHR and contribute data (e.g., HPI; Past/Family/Social Hx, ROS, weights, BP readings, glucose readings) to clinical encounters and decision support
- 7. Providing patients with tools to contribute to accurate and up-to-date lists (problems, medications, allergies) online, specify preferences (e.g., language, communication methods).
- 8. Certification criteria that facilitate identification of clinical trials appropriate for a given patient, or patients who may be appropriate candidates for enrollment in a specific trial.
- 9. Expectation of timely EH/CAH notification of significant events (e.g., ED arrival) to a patient's PCP, referring provider or care coordinator
- 10. Certification criteria support for querying a Provider Directory external to the EHR for entity-level addressing information (if accurate and complete)

Summary of Concerns:

1. The Stage 3 proposal continues to be a large and growing collection of functional measures rather than what we expected would be a shift toward measuring and demonstrating improvements in patient health outcomes.

- 2. We are deeply concerned that EPs and EHs will perceive the time, energy, cost and effort required to understand and comply with the proposed Stage 3 measures to be so arduous and difficult to meet that they will be unwilling to strive to achieve them. We believe this problem will be amplified by what they will interpret as a focus on accountability for increased documentation rather than improved outcomes.
- 3. As ACP noted in its response to the Stage 2 NPRM, a number of the proposed Stage 3 measures require significant increases in documentation requirements, require new and potentially complex workflows, are likely to be difficult for many EPs to understand, or depend on technologies that are not yet widely deployed and demonstrated to be usable. For examples, please see SGRP303, SGRP304 and IEWG101.
- 4. Some of the new functional measures over-prescribe how EPs and their staff are to perform and document highly specified tasks without clear evidence of how doing so constitutes meaningful use of health IT vis-à-vis improving patient care quality or satisfaction.
- 5. The functional measures require EPs to perform the same actions for nearly all patients, too often without clear evidence of the value of the action or recognition that different patients have unique needs, goals and desires which also vary based on the setting in which the care is provided.
- 6. Extending the same approach from Stages 1 and 2 to Stage 3 of Meaningful Use perpetuates the idea that the promulgation of requirements (that are too often underdeveloped or overspecified) will lead to meaningful use of health IT.
- 7. EHR certification criteria and the requirement to implement the newly certified features/functions into practice are still too often in lock step rather than separated in time.

General Recommendations (please see comments below and the attachments for specific recommendations on each measure and the supplemental questions):

- 1. We believe that Stage 3 is the time to greatly reduce the number of functional measures and focus instead on achieving threshold results on EP/EH-selectable, CEHRT reportable, electronic clinical quality measures (eCQMs).
- 2. Stage 3 should specify only essential elements to be included in communication between EPs and EHs and then otherwise leave it up to EPs and hospital-based professionals to use their clinical judgment to determine what should be sent and received.
- 3. HITPC needs to avoid oversimplifying clinical processes and over-specifying required metrics. This is particularly important for care coordination, transitions, and other activities involving communications among healthcare professionals.
- 4. Rather than impose measures that prescribe specific practice activities, EPs and their staffs should be encouraged to experiment with approaches that they believe are most appropriate for their patients, their specialty, and their practice setting. The effectiveness of the actions taken should be visible in the quality measures reported that depend on meaningful use of CEHRT.
- 5. Where functional measures need to persist, we would like to see them focus more on encouraging physicians and other health professionals to record, review, manage, and share information that more fully achieves the original goals and objectives of the problem-oriented medical record as described by Dr. Lawrence Weed.

Comments:

The Medical Informatics Committee of the American College of Physicians is concerned that the Stage3 proposal continues to be a large and growing collection of functional measures rather than shifting to what we expected would be a focus on measuring improvements in patient health outcomes. Instead, the proposed Stage 3 measures appear nearly identical in structure to those in previous stages. There are no measures related specifically to outcomes. We see a host of new functional measures that prescribe how EPs and practices are to perform and document highly specified tasks without rationale or evidence that completion of such time-consuming tasks actually constitute meaningful use of health IT (which by Stage 3 should mean improving outcomes), or clearly improves quality of care or patient satisfaction.

Further, many of the prescribed practices do not appear to consider the logistics or practicalities of the day-to-day practice of medicine. As a consequence, we believe the requirements are likely to result in new, inefficient workflows and activities that shift physician focus away from the intended goal of IT-enabled patient-centered care and toward habits in which our eyes and attention are taken away from our patients and instead focus too much on the data we need to get into the computer system for purposes that conflict with our sense of what is truly needed for quality, safety, and value. While the excessive attention to structured data entry was tolerable in the early Stages of MU when EPs were learning to use Certified Electronic Health Record Technology (CEHRT), by Stage 3 this should not be the case.

The functional measures require EPs to perform the same actions for nearly all patients, too often without clear evidence of the value of the action or recognition that different patients have unique needs, goals and desires which also vary based on the setting in which the care is provided. The measures also inadequately recognize, and often discourage, the creativity, intuition and innovation that physicians and other healthcare professional possess and would like to use to provide better care for their patients. HITPC seems to accept the argument made by health IT vendors that over-regulation will stifle innovation. Healthcare professionals feel entitled to the same level of deference but too often tell us they feel constrained in their ability to determine how best to use their EHR systems to improve quality and value.

While the impact of innovations in health IT can be hard to measure, the impacts of such innovations in practices can be measured by properly designed clinical quality measures (CQMs) and expectations that EPs and EHs demonstrate incremental improvements in the measures that matter to them. Rather than requiring that patients and practices must communicate in certain ways, Meaningful Use should stimulate patients and practices to experiment and determine what works best using the features/functions of the chosen CEHRT in the service of their patient population. Data collected through patient satisfaction measures and outcomes-focused CQMs will give ONC and CMS useful data to suggest what works best for specific patients in specific settings, while providing flexibility for EPs to use CEHRT in a way that is most effective and efficient for their patients and practice.

This same approach should also be applied to care coordination, transitions, and other activities involving communications among healthcare professionals. Requiring all doctors and other healthcare professionals to send and receive long and growing lists of data elements that may not be clinically relevant for a particular situation has already proven to be counter-productive and may possibly introduce safety concerns due to the obfuscation caused by long documents and notes in which the key information is difficult to parse from required documentation that does not add value. Much has been made in the news about bloated notes and extraneous information obscuring more important and clinical assessments and plans that have become buried in what are supposed to be distilled summaries of care. The expansive slate of requirements specified by the draft measures for these lists will contribute to this problem. Instead, Stage 3 should specify only essential elements to be included and then otherwise leave it up to EPs and hospital-based professionals to use their clinical judgment to determine what should be sent and received.

We believe that Stage 3 is the time to greatly reduce the number of functional measures and focus instead on achieving threshold results on EP/EH-selectable, CEHRT reportable, electronic clinical quality measures (eCQMs).

- All measures that involve reporting on the collection of structured data elements should become unnecessary if these and other data elements must already be collected consistently and accurately to be able to report on performance against quality measures for all patients in the care of the EP/EH.
- Rather than impose measures that prescribe specific activities within the practice, practices should be encouraged to experiment with approaches that they believe are most appropriate for their patients, their specialty, and their practice setting. The effectiveness of the actions taken should be visible in the quality measures reported.

Focus: Measure refinement vs. thresholds and expansions – We encourage ONC and CMS to review the concepts advanced by Dr. Lawrence Weed in his discussions of problem-oriented medical records going back as far as the late 1960s (http://www.visualdx.com/about/larry-weed-1971-grand-rounds-at-emory-video). In this view, the patient's chart is not simply a collection of scribbled notes to partially capture events for future recall or current billing, but rather a "guidance system" and "thesis" that more closely represents a patient-centered research notebook of careful observations, results, interpretations, conclusions and reflections about future directions.

Therefore, where functional measures need to persist, we would like to see them focus more on encouraging physicians and other health professionals to record, review, manage, and share information that more fully achieves Dr. Weed's original goals and objectives. One example would be to advance the original meaningful use objective of ensuring an accurate and up-to-date Problem List rather than retiring or consolidating the Problem List as a measure and assuming that this issue has been solved with the minimal requirements specified in Stage 1. Some of this is alluded to in the Stage 3 proposed measure in which a comparison could be made of findings indicating a high likelihood of a certain condition (e.g., hyponatremia, diabetes mellitus, hypertension) against a Problem List, allowing for the development of a measure that could rate Problem List quality (accuracy, completeness).

Another example would be requiring a threshold amount of structured association of problems with medication, laboratory and imaging orders, so it is clear what tests and treatments are associated with which problem(s), and allowing for decision support regarding medical necessity and appropriateness of tests or treatments, such as incorporating evidence and recommendations from the ACP's High Value Care initiative (http://www.acponline.org/clinical_information/resources/high_value_care/) and the American Board of Internal Medicine Foundation's "Choosing Wisely" campaign (http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx) to help decrease the uses of tests and treatments that do not add value. Creating measures that add structure and clinical decision support to problem assessments and plans would further encourage thoughtful documentation as well as the assemblage, review and comparison with prior assessments within efficient workflows.

Specific concerns and suggestions:

- **Do not introduce new functions without appropriate testing.** Measures should be thoroughly tested in a simulator environment for effectiveness, health IT safety, usefulness, usability and user acceptance (provider and patient) before they are required to be used by EPs and EHs. Untested proposed functions may create unintended consequences, including patient safety risks. Functions must have a history of safe and effective use in actual practice settings before clinicians are required to use them to avoid penalties. The recent report by Walker et al. (Health IT Hazard Manager Beta-Test: Final Report; AHRQ Publication No. 12-0058-EF) underscores the importance of assessing health IT safety, identifying IT hazards and mitigating them.
- Choose additional EHR provider note documentation requirements wisely and reduce existing requirements that do not add value. The patient's office visit notes and hospital progress notes are becoming choked with information included principally to support coding and billing requirements and to document evidence of Meaningful Use rather than their intended purpose to serve as a concise summary of the relevant information needed to illuminate the path to comprehensive yet relevant problem identification, assessment, planning, effective action (quality and value) and education. The succinct one to two page office note or hospital progress note has "e-volved" to become many pages of documentation that too easily obscures the most clinically useful data that informs best current and future care.
- Require usability testing with a specific focus on reducing data collection burdens. CEHRT needs to support more efficient and less burdensome data capture and sharing through improved usability, enabling data entry by patients and families, and data capture from devices at any relevant point in time, including outside the face-to-face care encounter.

- Do not add functional requirements that have not been adequately defined. While we understand that Meaningful Use is intended as a floor rather than optimal use, we would like to see Stage 3 Meaningful Use measures encourage best use through achievement of high performance against quality (including value) measures. While Meaningful Use includes important elements that facilitate the goals of the HITECH Act to capture and share data, promote improved clinical processes and enable better outcomes, continuing to add to a long list of functional requirements that have not been sufficiently defined, refined or harmonized (up-to-date Problem List, medication reconciliation, summary of care record) and that utilize technologies that are nascent or not widely available risks unintended negative consequences, including unusable and possibly dangerous systems or workflows.
- Understand the implications of intensively focusing vendor programming capacity on Meaningful Use requirements. The race by vendors to implement under-specified and untested functionality to meet deadlines for Meaningful Use certification is expensive and time-consuming for all stakeholders, and could introduce potential disruptions of care delivery. Vendors are prioritizing the delivering systems that conform to the letter of the requirements as they understand them without the time necessary to integrate the functionalities into desirable workflows or to test to ensure that quality, safety or usability problems are not introduced. Too often, vendors end up meeting the "letter of the law" by bolting on a functionality that has low usability, is wasteful, or misses an opportunity to actually improve quality or value.
- Consider the direct and indirect cost implications to EPs when adding new Meaningful Use requirements. Whereas the EHR incentive program was never designed to cover all of the costs of EHR purchase/implementation, the willingness to expend additional financial and personnel resources to achieve the increasing strenuous requirements of Stages 2 and 3 will likely diminish as the program moves from decreasing incentives to the penalty phase, particularly in a healthcare system that still does rewards volume over value and where the incentive is based on functional measure not directly tied to quality measures that EPs and EHs are less likely to be motivated to achieve than CQMs that they are passionate about improving. While we expect that most physicians will use EHR technology effectively in their practices, we are concerned that too many will choose to accept the penalty and accept fewer Medicare patients rather than spend resources to achieve measures that they do not perceive add commensurate value, or simply cost more to implement than their practices can afford to spend. Stage 3 measures must be considered in this light.

In prior comments, ACP has strongly urged ONC and CMS to separate in time the certification of EHRs from the requirement to implement new features/functions into practice. We reassert the comment we made in our letter for the Stage 2 NPRM, in which we wrote:

The approach throughout Meaningful Use to-date has been for CMS to call for EPs to perform new functions at the same time as ONC is requiring EHR system vendors to add the new functionality to their systems. This commonly results in unanticipated negative consequences where the functionality is incompletely or poorly implemented, with usability challenges that make it difficult for EPs to incorporate the new functionality into existing workflows, or that forces modification of existing workflows to ones that are less efficient.

We believe a much more sensible approach would be for ONC-Authorized Certification Bodies (ONC-ACBs) to certify functions as in place and usable for each certified EHR technology at least 2 years ahead of CMS incorporating them into "core" measures for Meaningful Use.

Another problem caused by the current staging process is that vendors are placed in a position of having to implement functions in advance of fully balloted and tested standards. Just as demonstration of Meaningful Use must wait for mature functionality, mature functionality requires the availability of tested standards.

We ask that these earlier comments also be considered as the HITPC finalizes its recommendations regarding Stage 3 measures.

ACP is also very supportive of the comments offered by HIMSS Electronic Health Record Association (EHRA). In particular, ACP supports the following EHRA recommendations:

- Focus primarily on encouraging and assisting providers to take advantage of the substantial capabilities established in Stages 1 and especially Stage 2, rather than adding many new meaningful use requirements and product certification criteria;
- Given recent experience with Stage 2, reconsider and extend the timeline for initiating Stage 3;
- Meaningful use and functionality changes for Stage 3 should focus on interoperability as a priority area;
- Invest in quality measure alignment, infrastructure and standards.

The Medical Informatics Committee of the American College of Physicians respectfully submits this letter and the attached comments in the hope that it will assist ONC in the finalizing the Stage 3 Meaningful Use measures and its important work of improving healthcare in the United States through the appropriate use of health information technologies.

Sincerely,

Michael H. Zaroukian, MD, PhD, FACP, FHIMSS

Chair, Medical Informatics Committee

American College of Physicians

Milm H Zaronhomin

Comments of the American College of Physicians regarding specific items in the HITPC Request for Comments for proposed Stage 3 Meaningful Use measures – January 14, 2013

SGRP 101: Use computerized provider order entry (CPOE)

Should be, "...per state, local, OR professional guidelines..."

Is licensure a requirement? Would change to, "...any healthcare professional who can enter orders..."

What is acceptable as an externally vetted list?

Identifying abnormal test results for imaging studies will be a major challenge. Although there are some imaging results for which a classification scheme has been identified that can be structured and equated with abnormal vs. normal (e.g., BI-RADS scores for mammograms, T scores for bone mineral density), the textual nature of most impressions in imaging studies does not easily equate to a designation of "normal" vs. "abnormal."

The challenge with systems in this regard is the fact that for many tests, there is considerable time flexibility in when it is medically acceptable to do the tests (e.g., any time between now and the next visit), yet the provider is required to put in an "expected" date, which not only may trigger an overdue message when it is not back in time but it may cause the lab to refuse the patient if he/she appears too early for the test, or to automatically cancel it if overdue and not performed. We currently have a +/- 2 week window on labs that causes significant patient and provider disruption and only occasionally is for an actual time-sensitive result (e.g., INR), so it would be nice to limit this to "for tests the provider considers time-sensitive."

We welcome the use of an externally verified (and standardized) list of "never" medication combinations. A significant barrier to use of drug-drug alerting technology is the large number of "false-positive" alerts due to poorly formulated interaction lists provided by external vendors. A thoughtful review of this problem is detailed here:

http://prescribersletter.therapeuticresearch.com/ce/cecourse.aspx?pc=12-216&AspxAutoDetectCookieSupport=1

SGRP 130: Use CPOE for referrals/transition of care orders

Should be, "...per state, local, OR professional guidelines..." Would change to, "...any healthcare professional who can enter orders..."

Creating/recording these orders in EHR is reasonable. We want to confirm that TRANSMITTING them electronically is not required until such time as it is clear that all EPs who are meaningful users have systems capable of sending and receiving to each other directly or via a ubiquitously available and affordable HIE or transport protocol.

Unclear what a referral of care order would look like in practice and how this brings value. Unclear why an EP would need to enter these – is this not an administrative task? We do not believe it is necessary for a discharging physician to enter an "order" to transfer care back to the patient's PCP.

SGRP 103: Generate and transmit permissible prescriptions electronically (eRx)

Should be "if available"

This doesn't seem to indicate that the EP must use formulary recommendation. How will this be tracked? Is color-coding provided in the EHR to reflect on formulary (green)/off formulary (red) adequate to meet this requirement.

Formulary quality is variable and may not be helpful. Also, the data may be out of date.

Further clarification of what will qualify as medication reconciliation going forward is also important. In one popular EHR, a simple button indicating Med Rec was completed (essentially attestation) is used, while in another, every single medication must have an active decision (resume, continue, discontinue, prescribe). While this may seem better, implemented as a forcing function can force some users (surgeons) into discontinuing an important chronic med the patient is noncompliant with rather than having a mechanism to alert the prescribing physician of noncompliance so the issue can be handled.

We applaud the goal of providing much more information up front to providers regarding formulary coverage, including front-loading the "prior authorization" process into the ordering process as proposed for a future stage. It is not clear how this will apply to patients without prescription insurance, or whose prescription insurance formulary data is not available – these should not be counted against providers.

Generic substitution is irrelevant in states where such substitution is required.

SGRP 104: Record the following demographics...

Are there data to support the contention that this has been "topped out" and that this will remain high if retired?

We assume the HITPC means retiring the measure rather than retiring the objective per se, as it remains important to the goals of the incentive program. The HITPC must ensure that these data will be effectively used by appropriate quality measures, clinical decision support, information exchanges, or other measures to ensure that the objective is met in a clinically relevant way. Many data elements must be collected because they are part of the care summary or are required for other purposes such as to trigger CDS and to report quality measures. Since the data must be recorded for other purposes, we agree that a measure that simply indicates collection is unnecessary. More meaningful measures that actually use the collected data are required.

Retiring measures that EPs are doing well in runs the risk of sending the message that this measure no longer matters, so ONC/CMS must clearly communicate to EPs that recording of such information is still required to support CQMs, CDS, and exchange of summaries. Even then, if one can meet a stage 3 measure that assumes collection of data on a retired measure even though it has not actually been collected, the objective will not have been met.

Some patients are reluctant to give gender orientation, especially to staff. A sexual history would be more relevant (sex with men, women, both).

SGRP 105: Maintain an up-to-date problem list

In Stage 2, the Stage 1 measure for Problem Lists was essentially "retired" (by incorporating into another measure without explicitly measuring compliance with the original measure, rather than made more robust according to the MU objective of accurate and up-to-date. This is a lost opportunity to improve quality through robust capture of information that matters with problem-informed clinical decision support (Diabetes and Hypertension and Hyperlipidemia and Chronic Kidney Disease, etc.).

As we stated in our August 22 letter:

We resonate with many of the concepts advanced by Dr. Lawrence Weed in his discussions of problem-oriented medical records going back as far as the late 1960s. In this view, the patient's

chart is not simply a collection of scribbled notes to partially capture events for future recall or current billing, but rather a "guidance system" and "thesis" that more closely represents a patient-centered research notebook of careful observations, results, interpretations, conclusions and reflections about future directions.

We would like to see the Meaningful Use measures focus more on encouraging physicians and other health professionals to record, review, manage, and share information that more fully supports the above-described goals. One example would be to advance the objective of ensuring an accurate and up-to-date problem list rather than dropping the problem list as a measure and assuming that this issue has been addressed with the minimal requirements specified in Stage 1.

Another example would be requiring structured association of major, chronic problems with medication, laboratory and imaging orders, so it is clear what tests and treatments are associated with which problem(s). Creating measures that add structure and clinical decision support to problem assessments and plans would further encourage thoughtful documentation as well as the assemblage, review and comparison with prior assessments within efficient workflows. It would also help limit unnecessary tests and treatments through decision support informed by associating a problem with a test or treatment.

This fails to acknowledge the complexity and risk involved in algorithmically determining a problem from other data. Often, more than one criterion must be met to consider adding a problem. For example metformin is used for polycystic ovarian disease, not just DM. Will the EP get a pop-up for all patients on metformin? Seizure meds are used for pain. This scheme needs to be refined and tested before being implemented. As we have stated previously in our Meaningful Use comments, MU measures should not be implemented in advance of either common, accepted, and evidence-based practices in healthcare delivery, or the routine use of technical functions that support the practices.

We can't leave this up to each vendor to decide. Does the committee envision this would be done through alerts? If so, would the alert automatically populate the problem list if the user agrees with the alert? If not, there will be extra work for the user. If this will not be done through alerts, then the committee is asking for an entirely new capability – one that would imply using a a knowledge base, or inference engine, etc.

SGRP 106: Maintain active medication list

Alert fatigue is a problem and any CDS alerts related to medications need to be "smart" about asking too many questions or these alerts will be ignored. Ideally, the EHR will ask on the front end for an "end date" on a prescription or use the duration of the prescription initiated (i.e., an antibiotic for 10 days without refills) to automatically move the Rx to another category for the EP to review when next accessing the patient's chart to be sure that the medication has indeed been discontinued. Similarly, if a medication is initiated, it should be associated with a specific problem or diagnosis by the EP so that the CDS can track it properly. Some EHRs can be configured to do this and it is very helpful to keep med lists from being cluttered with meds intended for temporary use that have not been removed from the med list. Others prevent the user from specifying an end date in the future, requiring the provider to detect and correct the inevitable error in the future medication list.

Current technology gathers data from Surescripts but does not include the retired military pharmacies, \$4 meds and prescriptions obtained abroad. Until the list is more complete, asking doctors to rely on searching meds will probably cause additional errors.

Who would create the rules?

Regarding searching text reports, why not make that a general capability?

SGRP 107: Maintain active medication allergy list

The signal-to-noise ratio on allergies/intolerances is too low, while we are missing medication side effects/intolerances as a cause of morbidity and increased health care costs. We would like to see a nonintrusive CDS that can take a symptom (e.g., nausea, dizziness, headache) and look at the patient's active med list, then provide information on the percent of patients taking the medication who report the symptom. This would go a huge way toward helping physicians recognize and respond to medication intolerance, as well as giving them a way to answer the real question behind intolerance "is this something the patient should never take again, can take again with precautions or other meds to mitigate side effects, etc.)

Who would create the rules?

SGRP 108: Record and chart changes in vital signs

Are there data to support the contention that this has been "topped out" and that this will remain high if retired?

We assume the HITPC means retiring the measure rather than retiring the objective per se, as it remains important to the goals of the incentive program. The HITPC must ensure that these data will be effectively used by appropriate quality measures, clinical decision support, information exchanges, or other measures to ensure that the objective is met in a clinically relevant way. Many data elements must be collected because they are part of the care summary or are required for other purposes such as to trigger CDS and to report quality measures. Since the data must be recorded for other purposes, we agree that a measure that simply indicates collection is unnecessary. More meaningful measures that actually use the collected data are required.

Retiring measures that EPs are doing well in runs the risk of sending the message that this measure no longer matters, so ONC/CMS must clearly communicate to EPs that recording of such information is still required to support CQMs, CDS, and exchange of summaries. Even then, if one can meet a stage 3 measure that assumes collection of data on a retired measure even though it has not actually been collected, the objective will not have been met.

SGRP 109: Record smoking status for patients 13 years old or older

Are there data to support the contention that this has been "topped out" and that this will remain high if retired?

We assume the HITPC means retiring the measure rather than retiring the objective per se, as it remains important to the goals of the incentive program. The HITPC must ensure that these data will be effectively used by appropriate quality measures, clinical decision support, information exchanges, or other measures to ensure that the objective is met in a clinically relevant way. Many data elements must be collected because they are part of the care summary or are required for other purposes such as to trigger CDS and to report quality measures. Since the data must be recorded for other purposes, we agree that a measure that simply indicates collection is unnecessary. More meaningful measures that actually use the collected data are required.

Retiring measures that EPs are doing well in runs the risk of sending the message that this measure no longer matters, so ONC/CMS must clearly communicate to EPs that recording of such information is still required to support CQMs, CDS, and exchange of summaries. Even then, if one can meet a stage 3 measure that assumes collection of data on a retired measure even though it has not actually been collected, the objective will not have been met.

SGRP 112: Record whether a patient 65 years old or older has an advance directive

We request clarification on any specific required wording regarding advance directive status that must be recorded as structured data.

SGRP 113: Use CDS to improve performance on high-priority health conditions

What is the basis for requiring 15 CDS interventions as opposed to fewer? Are there now or will there be 15 effective, clinically important CDS measures for each specialty?

Are there 15 CDS interventions for every specialty that can be used as indicated?

Scattering these interventions across categories seems arbitrary and unnecessarily complex.

Ability to consume CDS from central repository is unrealistic in the Stage 3 timeframe. How does the committee plan to identify the elusive solution to the "curly-braces" problem (the fact that all CDS interventions must be customized by hand to work within any system) that prevents the exchange of interventions between systems?

Prior authorization entry should auto-complete as many fields as possible, including searching for and including data that support the prior authorization (e.g., approval of ARB requiring pre-authorization by including evidence that ACEi had been tried previously but discontinued due to cough). This should be a certification requirement.

To achieve enough efficiency that the CDS is actually acted upon, emphasis needs to be given to making sure all CDS is actionable and that it has the capacity of setting rules to default appropriate action (e.g., automatically sets up batch orders for all of the recommended CDS interventions that can be reviewed in a single place and approved with one click).

It should be a requirement that CDS for potential Drug-Drug and other interactions fires during the first step in the addition of an order or prescription for a new medication, not just at the point of signing all orders. At least one popular EHR has a best practice approach for bringing up an obvious but nonintrusive alert for Drug-drug/Disease/Food/Alcohol/Pregnancy interactions (a large red STOP sign to the left of the med which if you hover over it shows the nature of the potential interaction), so you can see even before you finish the order details or add another med what the problem is and then choose an alternative or cancel. Other EMRs only show potential DDIs at the end of entering all orders, which is then too disconnected from the medication the provider ordered with no easy way to change without going back several steps.

There must be an authoritative process where CDS interventions are tested for efficacy and safety before they are published and distributed.

SGRP 114: Incorporate clinical lab-test results into CEHRT as structured data

80% is unreasonable until such time as all laboratory service providers are required to provide results by a consistent standard that CEHRT is also required to support, and that interfaces using this standard have been demonstrated to be functional.

What if the laboratory tests were not ordered by the EP but by a covering colleague?

Standards are needed for flags, comments, and notes.

SGRP 115: Generate lists of patients by specific conditions...

"Real-time" needs to be defined very carefully. 1 day? 1 hour? 1 minute from data entry?

Data for these purposes will always be a "retrospective" report – everything contained in an EHR is retrospective – so these terms must be well-defined.

How frequently are EPs "supposed" to manage/review "real-time" lists?

The verbiage suggests that retrospective reports are not actionable – which is incorrect.

It must be made clear that none of this activity is expected to occur during the face-to-face encounter. Otherwise, this would be highly disruptive.

We require further clarification on the term "actionable" - e.g., if an EP can get a list of patients with Diabetes, she'd like with a single click to be able to do things like: 1) order HgbA1c levels on every patient who is due for one; 2) send patient disease summaries to some or all of them directly into the patient portal; 3) send a message with a link to those identified as not yet having had a flu shot that would allow them to self-schedule a flu shot in her clinic or document where and when they had it done if already done, or to decline if they have decided not to get one despite advice.

This seems to be an application separate from the EHR that accesses the EHR database or an extract of that database. Perhaps the requirements in this category should be about the ability to access the data – this could then support multiple uses.

SGRP 116: Use clinically relevant information to identify patients who should receive reminders

Throughout all of the MU measures, the term "office visit" should be replaced with "encounter" wherever possible. The healthcare system is trying to move away from considering the office visit to be the center of healthcare delivery, yet the HITPC and ONC continue to try to put us back in that box.

See the flu shot example above (SGRP 115) that provides an example of how this could/should work.

Not all specialists should be excluded. There are appropriate prevention interventions for conditions that are typically treated by specialists.

This seems to be an application separate from the EHR that accesses the EHR database or an extract of that database. Perhaps the requirements in this category should be about the ability to access the data – this could then support multiple uses.

SGRP 118: Imaging results consisting of the image itself...

Do the images need to be of sufficient quality to act upon (diagnostically actionable)? If so, what are the implications for network speed, monitor resolution, and medicolegal issues? How quickly do they need to be accessible?

On what basis was the decision to move this from menu to core other than the progression to another stage? Are there any data to support the fact that this is something that practices have been able to do as a menu item?

Are there any data to support the effective use of images by generalists? If not, why is this measure being pushed? This will be an unreimbursed cost to practices for which no evidence of improved efficacy has been presented. The main benefit accrues to those specialists who today insist on going directly into a PACS client rather than using a lower resolution viewer and require a diagnostic quality resolution monitor. Please limit this as a menu item for them.

Additional concerns are:

- 1) The added cost, and
- 2) The interfaces/links to external systems. This will be technically challenging and costly, representing a particularly onerous burden for small office users.

Having a report should be CORE, having it be structured where possible (e.g., mammogram BI-RADS score, DEXA T-scores) should be core, but the image itself should remain MENU, except for EKGs, which could be pdf files that could be scanned and attached.

This seems to be an application separate from the EHR that accesses the EHR database or an extract of that database. Perhaps the requirements in this category should be about the ability to access the data – this could then support multiple uses.

SGRP 119: Record patient family health history as structured data

What is a "high priority" family history? A coded list of "high priority" elements must be provided with the measure. Collecting random, unrelated elements of family history clutters the record and increases the likelihood of missing the relevant items. Many patients do not have any accurate information about the health history of family members. The EP must be given latitude not to insert information of suspect quality into the record.

If it is 40% per year does that mean 80% within 2 years? Family history doesn't change. Is there credit for new patient Family History and then subsequent query about any changes rather than taking Family History once again just for the purposes of this measure?

How must they be recorded as structured data to count (ICD 10)? Does the EP need to enter only one high priority family history item? What if the EP includes some but not all items? Does the EP need to specify when no high priority family history items exist?

Also, one would need to know and keep a list of high priority items (which would also risk EPs ignoring the others) and then be able to report on those but filter out the others.

We would rather see a requirement for structured data entry for one or more first-degree relatives as specified in Stage 2 rather than a requirement for defining and coding/reporting only for high priority conditions.

SGRP 120: Record electronic notes in patient records

This should be "encounters" not just visits; 4 calendar days is much too long – should be second business day following the visit.

Clarify whether this proposed measure is meant for menu or core, EH and/or EP.

SGRP 122: The EHR is able to assist with follow-up on test results

Is this measure meant for EP, EH, or both?

Acknowledged by whom? We assume this means reviewed/acknowledged by the EP or other licensed healthcare professional. We also seek clarification on the phrase "those which were not completed" – does this mean reviewing/acknowledging results reported as "canceled" since they also likely need some form of follow-up?

However, if the goal is to make sure that abnormal test results are acknowledged, it would make most sense to focus on abnormal results, rather than all results. There is larger debate as to whether one should have to "touch" results that are entirely normal (some systems only route results that are abnormal to the EP), but less on whether abnormal results should be promptly acknowledged. If the focus is solely on abnormal results, then the performance threshold could be higher (e.g., 20%). While we understand the notion behind including tests that are not completed (e.g., cancelled), we would not encourage that these be counted until we have a robust mechanism and requirement that the service provider (e.g., lab) indicates the reason for the cancellation and what follow-up it is taking vs. that needed by the ordering provider (many are the lab canceling and then reordering due to specimen issues that are corrected on the spot and the patient redrawn or retested.)

SGRP 204A: Provide patients the ability to view online, download, and transmit (VDT)...

The movement of so much complex patient information beyond the security of the healthcare system presents enormous risks and challenges. Patients are not equipped to effectively use and manage these complex and sensitive data. EPs are not experts on the management and security of data beyond their walls. The burden of providing transparency and education to patients must not be placed on EPs. They are not equipped to provide such services. In fact, many of the patient engagement processes advocated in this document should not be the sole responsibility of EPs. There are many other actors throughout our society who are in a far better position to provide services to patients, yet the sole focus of patient advocacy remains the EP. EPs should not be required to take on the responsibility of educating patients/families about the management and security of IIHI beyond their practice through these new access points.

The specification of multiple, single-purpose access functions is putting the cart before the horse. Requirements for specific functions will result in a plethora of add-ons that will be un-maintainable with system upgrades. Instead, there should be general specifications for external access to data (including images) that can then support all sorts of applications.

The movement of individually identifiable health information outside of the HIPAA-regulated arena is regulated by the HIPAA Privacy Rule, specifically by 45 C.F.R. § 164.508. This portion of the rule specifies that detailed data be included in a formal patient request to have data sent to a non-covered third-party. The HITPC is obligated to educate all EPs regarding their legal obligations and risks regarding sending patient data.

We suggest one business day rather than 24 hours.

It is important that all data related to a visit or encounter be kept together so that they can be managed by a single process.

Consider extending the view/download/transmit issue by giving full credit if the specialist can record the portal the patient is subscribed to and then push results to the EP for populating the patient's preferred portal

SGRP 204B: Provide 10% of patients with the ability to submit patient-generated health information...

Focus in on functional status, patient experience or pain. Focus on issues that apply to many patients for whom collecting this information would be helpful to EPs/EHs and is likely to improve care.

This JAIMA article offers a reasonable set of patient-supplied data that would be most likely to be useful. [Estabrooks, P. et. al. Harmonized patient-reported data elements in the electronic health record: supporting meaningful use by primary care action on health behaviors and key psychosocial factors. J Am Med Inform Assoc. 2012;19;575-582. Doi:10.1136/amiajnl-2011-000576.]

We would not support device integration or a requirement to communicate with an external PHR. We support data collection instigated by the EP using any of a broad range of online tools to collect patient-entered data.

How can this be implemented practically unless it is a data entry feature that patients use to add data to an EHR? EHRs are capable of exporting structured data but not good at importing them.

SGRP 204D: Provide patients with the ability to request an amendment to their record online

This is not appropriate for VDT. VDT, as currently defined and implemented, is a one-way process. There is no provision for bidirectional communication of for proper management of any data flowing in the wrong direction. There needs to be a separate pathway which currently does not exist, other than through secure messaging.

What does "in an obvious manner" mean?

One concern is the clarity/structure of the request for corrections/changes. A long, unorganized textual request for change as free text will be challenging and error-prone, whereas a structured way of pointing to a medication that the patient no longer takes and having a structured request to remove it from the med list that can be approved and acted on with a single click in EMR would be a satisfier and help office efficiency when the patient is later roomed. The same could be said for adding a medication, resolving a problem/diagnosis, modifying family history information, etc.

Patients may not agree with statements in their records for reasons other than the factual validity of the statements. Patients may not agree that they are addicted to a substance or that they have physical or psychological limitations. This objective would therefore require additional functionality to provide EPs the ability to comment on a patient request for amending a record – especially when there is disagreement about the patient request. The practicality of such an exchange of request/documentation of comments needs to be evaluated in the context of work flow, medicolegal risks, and the resources required in a busy practice.

How can this be implemented practically unless it is a data entry feature that patients use to add data to an EHR? EHRs are capable of exporting structured data but not good at importing them.

SGRP 205: Provide clinical summaries for patients for each office visit

This is an area sorely in need of improvement, as today's clinical visit summary is far too often a 4-10 page bloated collection of information that too often hides the most important information needed for the summary in a sea of other information that is required to be included for MU but is not different or central to the things the patient needs to attend to or be aware of between visits or at transitions.

Patients may want an abstract of the medical record.

A summary of the visit might not encompass the important elements of care for a condition that spans several visits over several months/years.

We need to preserve flexibility to enhance value to patients by not over-specifying this.

Information should emphasize what actions the patients should take/follow up, not just be a data dump.

The required minimum subset should be limited to: Problems addressed at the visit, abnormal test results requiring follow-up, plan (diagnostic tests, therapies, referrals, and follow-up), goals, and patient instructions.

SGRP 206: Use CEHRT to identify patient-specific education resources...

This proposed measure makes unsupportable assumptions about the distribution of different primary languages spoken across the US. Requiring 80% of the education materials in one of the top 5 languages may be extraneous work for these practices. Further, the converse is true. An area of the country may have a population of which >50% speak a language not in the top 5 non-English languages. They would not be served well either. A better objective would be to provide materials in all languages identified as the primary language for 10% or more of the EP's patient population if such materials are available publicly.

The existing education measure also has other unintended consequences. For those EHR systems that are less intelligent than others but meet the letter of the MU rule (e.g., giving the patient drug information that the patient will be getting from the pharmacy just to count something in the numerator), the high-performing EP will find the right patient-specific education resource in a more manual manner (but still using EMR tools), yet this doesn't count as meaningful use and is thus discouraged. Until/unless ONC/CMS require specific functionalities in this regard (all problem list items must link to patient-specific education resources; all lab results to patient information on the test and how to interpret results), this will fail to live up to its potential.

If suitable materials are not available publicly at no charge, is the committee expecting practices to accept the burden of additional costs to meet this measure?

Not all available information sources are maintained and updated as often as needed. EPs cannot be held responsible if their vendor supplies out-of-date information.

SGRP 207: Use secure electronic messaging to communicate with patients...

Why is this specified to communicate with EPs? Why not with the practice team or just practice? There could be more value for patients exchanging secure emails with nurses, medical assistants, and administrative staff than with the EP. With respect to an increase in threshold, what was the experience in MU Stage 2?

This should include all patient-initiated messages, whether as originating messages or in response to a message sent by the office/EP.

This requirement that a threshold percentage of patients must use this technology is inconsistent with the principle of patient preference (see below).

SGRP 208: Record communication preferences for 20% of patients...

This could get very complex with patients requesting different media for different types of communication. This should be focused: What does the patient want the practice to use as the predominant form of communication? Record that...and that should be the end of this objective. This also needs to incorporate the answer of "I don't care which method you use."

There must not be an expectation that every practice will be able to accommodate every possible patient preference.

SGRP 209: Capability for EHR to query research enrollment systems...

This depends on registries to provide a standard API to support such inquiries.

This presumes that all of the information in the EHR is completely accurate and up-to-date - and that those fields line up with each and every database that includes research protocols. This seems like a huge task that would be better accomplished by making querying of such databases easier for EPs and patients.

If this measure goes forward, there should also be a requirement that there are no links to trials in which the provider is paid a case finding fee or any other compensation. There may be other ethical concerns with a patient's provider making recommendations regarding research participation.

The literature clearly demonstrates that selection of research subjects is complex, and all EPs may not be up to the task. Rather than giving practices the ability to query for studies, it would be more useful to give study organizers the ability to query for patients. [Hurdle, J., et.al. Identifying clinical/translational research cohorts: ascertainment via querying an integrated multisource database. J Am Med Inform Assoc 2013;20:164-171.doi:10.1136/amiajnl-2012-001050.]

SGRP 302: The EP...who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform reconciliation...

This seems premature – we need to establish workable standards for representing all these things – so far, we do medications somewhat well and maybe problem lists; these others are all terra incognita.

Define reconciliation of "problems" – that is less specific than medications/allergies. If the patient has a long "problem list" of active, inactive, chronic/acute, relevant/irrelevant to current situation – do we want EPs/EHs held responsible for reconciling all of this? Do we expect EPs to reconcile problems that are placed on the list, and are managed by other providers?

Recent reports from EPs make it clear that, in documents received post-discharge, hospital problem lists have not been generated, new problems have not been added, nor have resolved problems deleted. Enacting this measure will require a lot of change to work flows in the ambulatory practice.

We continue to lobby for rewording such as, "transitions of care or believes an encounter is relevant..." to harmonize the measure with the objective. Currently the measure does not accommodate those who actually want to do reconciliation at every visit but instead have to designate which encounters meet the criteria of a Transition of Care.

Also, one needs to be careful to parse out Med Rec from Problem Rec from Allergy Rec from "Other Orders Rec" as there are providers and the vendor severely entangled in the required workflow, the need to re-reconcile if someone adds a new med after Med Rec has been completed in order to allow discharge After Visit Summaries, etc.

Med rec also suffers from the following common quandary of the subspecialist. The patient reports she isn't taking this important chronic medication prescribed by her internist that is part of a quality measure (think ACEi therapy in diabetics or heart failure patients) and the orthopedist is seeing her for knee pain...does he have to remove the medication in order to meet the med rec requirements of his EMR for MU? Does his EMR support his noting that the patient isn't taking the med and messaging the prescriber to decide whether to reinforce use, modify Rx or prescribe something else? We have seen important errors in patient care (pulmonary edema in patients stopping furosemide, discontinuation of insulin or ACEi therapy in diabetics, and later discovering by PCPs that the specialist (actually his/her MA who queried the patient) removed the chronic medication you prescribed without informing you. When you ask the patient, they have no recollection of telling them that they were not taking the medication - waste and hazard without value.

EPs have a hard time envisioning how to implement reconciliation of contraindications in a reliable way. This suggests that this activity is not ready to implement yet alone to measure compliance. Also, we still lack clear agreement on the differences between allergies and intolerances.

SGRP 303: Provide a summary of care record for each site transition or referral when...

This is over-specified. The measure should be predominantly in support of providing a concise narrative in support of the transition in care – that will return the highest value for the effort (synopsis). The EHR should automatically populate the summary with the treating physician/clinician and consulting physicians who provided care during the relevant episode of care preceding the transition.

Too much information or highly specified requirements will result in clinically important information being overlooked.

This requires a combination of EHR features/functionalities along with new workflows and habits that may not be part of current integrated workflows. In particular:

- 1. Concise narrative in support of care transitions (free text that captures current care synopsis and expectations for transitions and / or referral) Seems like integration of a structured data field containing the assessment and plan for the problem for which a transition is indicated (e.g., referral for diabetic nephropathy), should suffice and not require extra documentation. Also need a clearer definition of "synopsis"
- 2. Setting-specific goals This needs clarification...which setting?
- 3. *Instructions for care during transition and for 48 hours afterwards* this is only sometimes relevant enough to specifically call out and instead is incorporated into A&P.
- 4. Care team members, including primary care provider and caregiver name, role and contact info (using DECAF). listing care team members is a great idea, particularly when accountability for quality becomes shared, but it is labor intensive and quickly becomes out of date if not maintained.

The requirements to send data where there is no previous history of the exchange of these data, is inappropriate and over-reaching. In all cases the measures must be limited to activities that have already demonstrated real measureable value in the care process. The MU initiative has been subverted in order push new untried processes unrelated to health IT. Not every great idea is a great idea. Advocates for new ideas must be required to provide evidence of value before the HITPC considers them.

The requirement to send a certain percentage of these electronically will depend upon the availability of a functional HIE with which the EHR can interface. The measure is also dependent on the ability of the receiving setting to receive the summary electronically. In many areas of the country, most nursing homes and home care agencies will remain incapable of receiving summaries electronically for a long time.

SGRP 304: For each transition of site of care, provide the care plan information, including...

This would be a huge amount of work and the free text nature of much of it makes it less useful for trending over time and between sites of care. We are not ready to code most of this.

The fact that HITPC is asking what data might be useful is a clear indication of the immaturity of this activity.

We understand the threshold is only 10% of the time but if an EP refers a 60 year-old with chest pain and underlying diabetes as well as stage III chronic kidney disease to a cardiologist, this information must be completed? Free text appears to be required for some elements neither necessary nor beneficial. Must this be done by the physician or can it be done by a team member? This is a large burden on a practice.

The elements of this list are not all collected by EPs in the hospital setting. Therefore, the transition of care plan needs to be compiled from documentation sources other than the EP when the patient goes from hospital to ambulatory care facility.

Of this long list, the most important and reasonable expectations for this list are:

- •Medical diagnoses and stages
- •Relevant social and financial information (not necessarily free text)
- •Most likely course of illness or condition, in broad terms (not necessarily free text)
- •Cross-setting care team member list
- The existence of the advance care plan (not the specifics).

The others are also important but are more challenging to provide – especially from the ambulatory environment to the inpatient environment.

Most of these elements are not justifiable in every clinical situation. The primary determinant of what appears in any clinical communication must always the judgment of the sender.

SGRP 305: EP/EH/CAH to whom a patient is referred acknowledges receipt of external information and provides referral results to the requesting provider

What does "acknowledgment" mean? Received? Reviewed? Signed? If exchanged electronically, isn't the absence of a bounce back acceptable for "received"? For "reviewed" isn't the provision of a consultation note back to the referring provider sufficient to prove that the consultant reviewed and used the data sent? Why is the committee trying to force additional confirmations when the product of the work should be sufficient proof? Certification criteria should include a function that provides an automatic "successful delivery" or receipt for electronic information sent in advance of a referral visit. Perhaps the reverse – when a consultant sends a note electronically, the successful receipt of that note by the referring EP is automatically generated. Beyond that this is imposing requirements that are beyond meaningful use.

Would skip the 50% returned and just focus on electronic transmission of clinical information at 10%.

If this is just an automated acknowledgement then the threshold seems less important.

How would any system enable a situation in which the specialist declines the patient?

SGRP 127: Ability to maintain an up-to-date interdisciplinary problem list...

We are concerned that this requirement is premature and could have unintended consequences on the quality of care. The problem list is already includes information from so many different stakeholders that it is losing its original value as an important reference for clinicians in caring for patients. Add to this the expectation that "all problems be reconciled" and that each EP will have a different perspective on this, and this could result in a situation in which no one has assessed the DM and HTN in 3 years because the cerumen impaction, difficulty in walking, nutritional status and other items have pushed it out of sight.

At least three different groups are now at work on new attempts to address this objective. Nothing should be considered by HITPC until a consensus approach is achieved (if that is even possible) and demonstrated in the real world to have value. Any future requirement for an interdisciplinary problem list must be accompanied by a requirement that it be filtered for views of different stakeholders and a process to require reconciliation only of those problems specific to one's role (e.g., physicians vs. nurses vs. physical therapists, etc).

SGRP 125: Medication reconciliation: create ability to accept data feed from PBM

EPs need relief from the requirement to get patient written permission prior to accessing medication fill histories. Many work in practices that don't collect this specific information and it is keeping them from being able to see fill histories.

In our surveys of actual users of EHR systems, we consistently see terrible usability scores for the reconciliation process as implemented in most EHR systems. While these sorts of functions may sound attractive and helpful, they will be nothing but trouble if they fail to work as the advocates describe. There should be no MU requirement until the functions have proven themselves in practice.

It is beyond the appropriate scope of the EHR system to monitor the national e-prescribing system to identify risks of the types described. Recent evidence suggests that many sources of this information, such as PBMs, are not yet capable of delivering accurate and complete information.

Currently a PBM does not allow EPs to send a message that they have stopped a medication or changed the dose. For example a patient is on Toprol 50 mg and at the current visit, the EP increases the dose to 100 mg. He has no way to electronically notify the pharmacy that the 50 mg dose was stopped. Often the patient is on "automatic refills" and the pharmacy refills the old 50 mg dose. Likewise this can happen if the EP discontinued the medication altogether.

SGRP 308: 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...

Laudable goal, but...Would consider changing the time interval to no greater than 6 hours to allow more information to be collected for anything other than a death (which should be immediate notification) although in some cases, 6 hours may not be enough – so some flexibility is warranted. As written, this could result in EPs being notified upon arrival at the ED of an "event" when relevant clinical data is unknown – and then another notification later. Clinician judgment should prevail so that the EP is notified when sufficient information is available – or when more information is needed – to avoid unnecessary calls/notification which could detract from time providing patient care.

How is the "electronic notification" sent? Text message? Email? Automated voice mail?

If this measure were to go forward, it must specify that the PCP must be notified of all these events along with the provider most directly involved with each particular event.

SGRP 401A: Capability to receive a patient's immunization history supplied by an immunization registry or immunization information system...

The measure, as written, doesn't make sense. As written, if the EP/EH did not provide any immunizations during the entire reporting period, then this would not apply since it reads, "...for 30% of patients who received immunizations from the EP/EH during the entire reporting period." It should be modified so that EP/EH able to receive immunization information for 30% of patients seen during the reporting period.

At this time, no implementable data standard exists for these transactions.

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

Contraindication or refusal is crucial for this measure since these would justify failure to immunize a patient for a particular vaccine and such patients qualify for inclusion in the numerator.

SGRP 401B: Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations...

This doesn't make sense. The only reason an EP would need the recommendation is if he/she did not plan to provide the immunization. A better measure would be: When the EP is presented with a recommendation (CDS) to provide an immunization, 20% of the patients for whom such a recommendation is made receive the vaccine or an indication regarding why the vaccine was not given is recorded in the clinical record.

There are significant local/state variations that need to be considered. The ability of national authorities to set definitive requirements in this space is severely limited.

At this time, no implementable data standard exists for these transactions.

Members have reported their experience with receiving recommendation information from our state immunization registry (Alert IIS, Oregon). There are significant limitations in this effort that makes these recommendations problematic. The recommendations from the state really work only for children who have a complete history in the state. Nearly all the recommendations for adult booster immunizations are inaccurate due to not having their primary series information in the state registry. There needs to be a method of ensuring the correct recommendations get to providers that includes assumptions about primary series and inclusion of information not in the state system.

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

A recent systematic review identified barriers to the use of such immunization interventions. [Pareira, J. et.al. Barriers to the use of reminder/recall interventions for immunizations: a systematic review. BMC Medical Informatics and Decision Making 2012, 12:145. Doi:10.1186/1472-6947-12-145]

SGRP 402A: Capability to submit electronic reportable laboratory results to public health agencies

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

SGRP 402B: Capability to use externally accessed or received knowledge (e.g. reporting criteria) to determine when a case report should be reported

Why is this tied to "externally accessed or received knowledge" as opposed to just simply recognition of a reportable case, receipt of laboratory test, etc.? EHRs should facilitate easy fact aggregation and reporting to appropriate state/regional authorities – BUT the EHR needs to have that information for each state/region.

Vendors will have to customize by state/region/county.

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

SGRP 403: Capability to submit electronic syndromic surveillance data to public health agencies

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

NY EPs are still waiting for the NYCDOHMH to be able to receive these data electronically.

Is this still a Menu item?

SGRP 404: Capability to electronically participate and send standardized...commonly formatted reports to a mandated jurisdictional registry

Will there be CDS to identify the mandated reporting for specific patients? Otherwise, how will the denominator be calculated?

At this time, no implementable data standard exists that covers all of these transactions.

State variations will make this complex and costly to implement.

SGRP 405: Capability to electronically submit standardized reports to an additional registry beyond any prior meaningful use requirements

Add "Exclusion: where local or state health departments have no mandated registries or are incapable of participating fully."

There cannot be thresholds for this measure. The local regulatory agencies can determine appropriate participation depending on the public health imperatives to report.

SGRP 408: Capability to electronically send adverse event reports

Menu or core?

The threshold for this measure appears to be zero. Is that correct?

Is the FDA and/or CDC prepared to receive such reports?

These should follow the AHRQ common formats.

At this time, no implementable data standard exists that covers these transactions.

What terminology will be specified for this report? Will EHRs be expected to translate SNOMED to MEDRA? This would be an unnecessary burden for systems to maintain, and another unreimbursable cost to EPs. Whenever a terminology not already required in the EHR is required for external reporting, the burden of conversion must be placed exclusively on to the receiver of the report. This should be a standard expectation for all external reporting to all third-parties.

IEWG 101: For patients transitioned without a care summary, an individual in the practice should query an outside entity.

This is unnecessary - and poorly worded regardless. The certification requirement is appropriate but the MU measure is unnecessary. If the EHR is able to provide the connectivity and query, then EPs and EHs will use it. It is in the best interest of the clinicians and patients to access these data when available. Make the functionality available and it will be used.

Not every criterion for certification needs to be paired with a measure of actual use.

Given our limited success to-date, and the less-than-stable state of exchange organizations, it seems unlikely that half of the EPs in this country will have even rudimentary query access to relevant records by Stage 3.

We have no agreed-upon method to identify patients across settings and systems. The HIT PC must establish a single patient identification method, or a very small set of such methods as a prerequisite to specifying the use of measures that require such unambiguous identification.

There is so much more work needed on usability and more basic functionality that this should not yet be on anyone's to-do list.

IEWG 103: Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to...

The proper superset of all data required for all MU measures should come over as the absolute minimum data set. This must be structured data where available and text in a readable format where text is the original storage format.

This is another item that relates to a non-EHR application that can access the EHR database or an extract. However, the export is easy compared to import – we would have to tackle this problem one domain at a time. Right now, we can't even import lab results very easily (except as text blobs). Of course, the ability to import could be a selling point for an EHR, but requiring it seems unnecessary.

MU 01: Meet all criteria?

There are likely valid practice criteria that will make specific MU requirements unachievable. An example in MU 1 is practices that use a public health immunization registry as their method of recording and tracking immunizations. For those practices reporting to an immunization registry is unnecessary. New 2016 criteria should be reviewed with a panel of experts from primary care and key specialties to establish criteria for "opting of" of each potential MU requirement. I.e., a set of well-defined and auditable criteria can be used as "exceptions" for each MU requirement.

Flexibility will be especially crucial with the new functionality proposed in Stage 3 and beyond. Many EHRs will have trouble meeting the requirements in elegant ways, if at all. Providers who are now locked into using these EHRs should not be penalized for the product's inability to meet the requirements. There should be the ability to select "5 of 7" (or whatever) and graded incentives, rather than all or none.

CMS could go one step further in stratifying measures (i.e., beyond core/menu). Some measures are foundational. For example, without capturing certain structured information other more complex features of EHRs will not function (i.e., CDS, drug-drug interactions). EPs/EHs should attain the specified thresholds for all FOUNDATIONAL measures. Then, introduce some flexibility on the CORE measures so that EPs/EHs need to achieve at least 80% of the thresholds specified, and similarly 80% of the measures specified for MENU. Year over year improvements (while maintaining the FOUNDATIONAL elements) would then be an expectation for CORE and MENU.

MU 02: Best balance - ease of clinical documentation and practice management efficiency

This is a confusing question as these two components of practice are directly related. We do not see how these are either/or. In fact, making the former easier will improve the latter. The question is how to make the functionality of the capture data better without making the capture more difficult and thereby working.

Practice efficiency depends on clinicians and clinical team members being able to document efficiently, accurately – and clinical documentation should support communication among and between everyone involved in a patient's care. Any inefficiency introduced as a result of poorly designed EHR systems directly or indirectly affect patient care. Time wasted on poorly designed systems is time not spent on patient care. Practices distracted by poorly designed workflow, sluggish reporting, etc. spend energy and staff resources on activities that do not lead to better care.

Allowing EPs the ability to delegate tasks and documentation as appropriate is an important way of increasing the productivity and effectiveness of the practice.

MU03: Health IT safety risk assessment.

We are not aware of any tools to facilitate this and uncertain that providers are qualified to perform such an assessment.

Vendors, testing entities, measure authors, etc. should bear responsibility for ensuring that any functionality introduced to EHRs are tested prior to implementation in practice, and then tested again by the vendor once the implementation is complete. This basic assurance could be complemented with aggressive reporting of health IT-related safety issues in practice. This reporting should be seamless, embedded into EHR products, and aggregated/studied by entities authorized to receive, analyze and report on findings – yet protected from medicolegal discovery. The airline industry model could serve as a template to design a health care version of such a reporting process.

Evaluation similar to the Leapfrog Group evaluation of hospital EHRs for safety is potentially reasonable. I.e., a series of patients with existing criteria are loaded into the systems as test patients and a specific script is followed to report the result. Vendors should provide a standard mechanism to load such test patients with discrete data (presumably from a structured CDA document) and to create a report of findings (also in a structured CDA document, perhaps similar to a QRDA Category 3). Providers should thus be able to quickly upload the test cases and send the reports (and view the reports themselves). The testing must be performed at the local implementation to address any modifications that have occurred to the 'model' EHR.

MU 04: Privacy and patient consent

As the committee makes clear with the phrasing of this question, granular consent appears harder and harder to accomplish the deeper you dig into the granularity and expand the complexity of the workflows. Early attempts to manage granular consent have also shown that patients routinely change their minds.

As we overload our systems in an attempt to manage granular consent, we are unlikely to ever be happy with the result. A better approach is to focus on identification and punishment of inappropriate use of patient data across the healthcare system.

We need to redraft HIPAA to clearly define what consent is required, what is opt in and what is opt out.

MU 05: Fostering innovation to share information...

We are reaching the saturation point for many of the EHR systems and the practices that implement them, particularly around clinical content, calculations, and decision support. MU should support standardized interfacing of this type of decision support to leverage investments across institutions.

The EHR is an overloaded term, and EHR systems are already overloaded with functions, such as quality reporting, that could be much better managed through special purpose software. The CCDA does not include all of the data that must be communicated to external apps, and the Direct/Exchange protocols were not designed for this purpose. A better model for managing patient data is the one used by large academic medical centers for years. A clinical data repository (CDR) is available to all clinical applications, including the one we call an EHR system. In smaller healthcare settings, the certified EHR system would be responsible for managing the CDR.

Anything that helps EPs and EHs compare structured data from one CEHRT system and its supporting technologies to those from another system and then decide whether and how to combine, replace, etc. would be helpful if not too challenging to create or implement.

Given the complexity of the standard, and the need for large amounts of technical code to wrap relatively small bits of clinical data, CCDA is potentially excess overhead. Yet it is insufficient to manage usable, structured information from innovative apps that can be used to evaluation and track patient performance over time. Specifically, the CCDA identifies the author of the CCDA as a summary document assuming that all data within the document originated with the author. As data are received from appropriate sources (devices, apps, patient generated information, etc.) the source (or provenance) of the data element is important to enable clear understanding and appropriate use of the information. Rather than requiring certification of each device or app, maintenance of the provenance of data can be required for EHRs as part of MU 2016 (source, not necessarily all systems through which it traversed). Such information (metadata) will help providers decide how to combine, replace, or just use the data and enhance its meaning.

These incentives can be related to practice management goals that are at the level of the practice, not the level of the application. How they meet the goals is up to them. MU should facilitate this by requiring EHRs to provide access to data (direct to database or to an extract).

This export is feasible. Import is not going to be feasible in the short-term – EHRs' data models are too convoluted to be able to write directly into them in any meaningful way.

MU 06: Giving providers evidence that a capability was in use during the EHR reporting period...

EHRs have auditing functions to determine the use of individual components during testing and evaluation of the system. Such functions of EHR component / function utilization should be a standard output of EHR utilization for 3 purposes:

- 1. For the local provider to understand what is being used and more effectively enhance the value of the product
- 2. For the vendor to understand what is used because it works and what is not used (either because of lack of understanding or because it doesn't work as intended) this process can enhance feedback to improve product function and usability.
- 3. For reporting to MU 2016

A standard log file of relevant transactions should be possible.

There could be a simple dashboard presentation of which functions/features are "on" and for what period of time they were "on" and when, if any, changes were made to the status of the capability (e.g., suspended, upgraded, deleted).

National Quality Forum published an expert panel report in 2010 "Health Information Technology Assessment Framework" that can shed some light on the issues.

QMWG 01: Opportunity costs...

Collection of data to support eCQMs should be solely based on expected routine data collected as a consequence of established/common workflows for the condition being measured. No additional work should be required of EPs/EHs.

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.

Certified EHR systems should also provide an easy-to-use mechanism for EPs to implement and track additional CQMs of their choosing. The certified functionality must not be limited to hardwired measures specified by the government o other outside organizations.

QMWG 02: High priority measures

Measures of things that impact care (orders for appropriate tests and therapies) should take priority over documentation for monitoring or reuse.

Measures of EHR usage should be a direct output of the EHR. See response to **MU06.** 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 came from the patient).

Cross-cutting measures that are sufficiently common that even small improvements in performance would have an effect on the population that can be measured (quality, cost, experience).

QMWG 03: Innovations or technological capabilities for measure development...

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.

QMWG 04: Should there be core CQMs for high priority health conditions?

We urge the HITPC to recommend the elimination of all MU Core/Menu objectives in favor of a slate of eCQMs that, if an EP/EH were able to report would be sufficient evidence of adequate use of the EHR system to, collect data effectively, process it, communicate/share, etc. This focus on quality measures, coupled with robust and omnipresent educational resources identifying the prerequisite activities/actions needed to report effectively, would be more relevant to patients, families and clinicians than MU measures.

The focus should be on mechanisms for setting priorities, not on particular conditions. Otherwise, systems will be built to address specific diseases and then need to be re-tooled for each disease.

If there are core CQMs, they should be 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 and 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).

QMWG 05: Capturing input from a wide variety of providers, patients...

Generate question lists like this one, and send the request for comment to various organizations, which in turn, distribute the questions to their constituents. The response would then be summarized by those organizations prior to submission to HITPC and QMWG. More thoughtful responses would be generated by smaller lists of questions and longer time periods provided for responses.

QMWG 06: Additional channels

A forum for data element feasibility is essential. 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.

QMWG 07: How consumer-reported data can be incorporated into CQMs

Collection of patient experience measures, functional measures, activation...could complement CQMs. The collection process should be funded and managed by processes external to practices and providers.

Patients can contribute free-text documents like any other external document. For structured data we would need to use a data entry form that writes to the EHR.

Consumer-reported data could 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 came 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.

OMWG 08: How patient-directed data is informing shared decision making

Allergy history may be the data that have the most impact. Data should not be separate – all data should be integrated, with data source made clear for all.

QMWG 09: Focus on POC Process Measures or Value-Centered Clinical Outcomes

Process measures will remain important. Outcome measures – if appropriately specified –should be the focus of Meaningful Use. If the focus is on outcomes, vendors will build outcome-specific systems. In the short term, the capability to adequately report results on both process and outcome measures could serve as evidence of effective (meaningful) use of health IT with the emphasis on moving in Stage 3 towards outcome measures as previously stated. Since these would be clinically relevant measures, EPs/EHs and patients/consumers would likely welcome the focus on these as opposed to measures that focus on structure and check boxes to satisfy MU objectives. It would also move away from attestation as EPs/EHs would report on these measures effectively – or not.

Many 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.

QMWG 10: Is this a false or unnecessary dichotomy?

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 process measures that are considered, the more potential exceptions and/or exclusions. The more process measures that can be 'hard and fast,' (i.e., no allowed exclusions or exceptions) the better.

QMWG 11: Retooling legacy eCQMs.

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.

QMWG 12: Is shifting away from retooling legacy paper-based CQMs a reasonable course of action?

It is the only feasible course of action.

QMWG 13: Experience with using retooled measures

There are almost no measures developed de novo so this question cannot be answered.

QMWG 14: Aligning CQMs with MU objectives...

CQMs should be the emphasis of MU as stated previously. We believe that Stage 3 is the time to greatly reduce the number of functional measures and focus instead on achieving threshold results on EP/EH-selectable, CEHRT reportable, electronic clinical quality measures (eCQMs). If MU measures are limited to attestation then CQMs are the only way to determine if the attested functions are actually used.

QMWG 16: Which measures in particular have the greatest potential to maximize meaningful alignment?

Specialty societies are formulating lists of data that should be captured. These items should be aligned with NIH-specified Common Data Elements to assure that the right things are captured for quality care and that they are reusable for research. A growing focus of specialty societies is high value care. MU should incorporate evidence and recommendations from efforts such as the ACP's High Value Care initiative

(http://www.acponline.org/clinical_information/resources/high_value_care/) and the American Board of Internal Medicine Foundation's "Choosing Wisely" campaign (http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx)"?

QMWG 19: EHR based exemplar measures?

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 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.

QMWG 20: What information should be submitted with a locally developed CQM?

All of the options listed in the question are needed and all are part of exiting endorsement criteria. Rationale is critical (e.g., how a CQM relates to actual improved outcome) and goal (target compliance with measure, not necessarily achievement of ultimate outcome).

However, these metadata about the measure do not guarantee feasibility of data capture and usage. Therefore, each measure 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.

QMWG 21: What constraints should be in place?

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.

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.

QMWG 22: What precautions might be necessary to mitigate fraud, waste and abuse...

Trusted measure authorities are 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. They must also be agile and provide feedback on a regular basis with 30-60 day turn-around times for decisions.

Specialty societies and boards might present good models for the types of organizations that could perform this work, much as is cone with Maintenance of Certification measures today.

QMWG 23: How can federal agencies better support consistent implementation of measures for vendors and local practices...

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.

QMWG 24: Is there a limit to the number of measures EPs and EHs calculate and report?

The volume of measures is a significant issue for EPs and presumably EHs. In particular, as the number of measures increases, the work load increases, the influence of work flows expands, and given the continued all-or-none scoring to get the EHR incentive payment means that there are more chance to fail and miss the opportunity for financial support for all of this additional work. Therefore, we recommend focusing in on foundational measures and putting more emphasis on CQMs as indicators of meaningful use of health IT functions.

The issue with CQMs is not a problem of volume. The key problems with current CQM reporting include poorly designed measures, measures that require complex data collection unrelated to direct patient care, use of inappropriate coding systems, and requiring reporting of measures that are inappropriate to the patient population.

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.

Systems should be designed to handle all these measures in a generic way, so that they can provide the counts as needed.

QMWG 25: Value and feasibility of the eCQM and EHR features listed below...

The listed abilities suggest a path forward for quality measurement that should lead us to a better understanding of the actions and activities that matter most in improving health and health care. There are at least two clear obstacles to achieving his vision. First, no matter how hard measure developers work to create measure that rely on structured data that is collected routinely during clinical processes, the exclusion criteria continue to require exceptional data collection efforts that subvert the care process.

Also, while everyone agrees that patient-focused measures that follow the patient across settings and processes hold tremendous promise, we have no agreed-upon method to identify patients across settings and systems. The HIT PC must establish a single patient identification method, or a very small set of such methods as a prerequisite to specifying the use of measures that require such unambiguous identification.

- 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

QMWG 27: What is the role of multi-source data exchange in achieving these features?

Incorporating cross-setting records by definition is outside the individual EHR. Such measures are appropriate for HIEs or regional or organizational data warehouses

QMWG 28: Value and feasibility of CQM Population Management Platforms.

There is a business case for CQM Population Management for ACOs and for PCMH.

QMWG 29: What information or features might be present in a basic CQM population management view?

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.

QMWG 30: Technological challenges to widespread release and adoption.

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.

Detection of quality measures should be analogous to event detection carried out by alerting and reminder systems – a general application with specific rules implemented within it. In fact, maybe alerting systems can be used for this purpose.

PSST 04: Security Risk Issues

The key to any such activity is the availability of truly useful education materials on the security rule to guide practices to the desired performance. Small practices lack the expertise needed to design and deliver such programs and therefore, must typically rely on outside sources of such content. We are concerned that this objective could result in practices having to pay for consultants to come in and deliver programs which would add considerable expense to maintaining compliance..

PSTT 07: Requirement for a standard format for log files of EHRs...

A standard for logging all events would be very useful for capturing compliance at the level of specific events (such as clinicians' recording of data or responding to alerts) that can then be pooled for reporting.

PSTT 08: Specifications for audit log file formats in current widespread use...

Ask the informaticians who build their own systems - they all do this. Some commonality will emerge.