



33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 252-946-3546
Fax: 252-940-1130
E-mail:
himssEHRA@himss.org

AllMeds, Inc.
Allscripts Healthcare Solutions
Amazing Charts
Aprima Medical Software, Inc.
athenahealth, Inc.
Cerner Corporation
CoCentrix
CompuGroup
CPSI
CureMD Corporation
Digital MD Systems
eClinicalWorks
Emdeon
e-MDs
Epic
GE Healthcare IT
Greenway Medical
Technologies
Healthcare Management
Systems, Inc.
Healthland
Lake Superior Software (LSS)
Data Systems
MacPractice, Inc.
McKesson Corporation
MED3000
MEDHOST
MEDITECH
NexTech Systems, Inc.
NextGen Healthcare
Practice Fusion
Pulse Systems Incorporated
QuadraMed Corporation
SammyEHR
Sevocity, Division of
Conceptual MindWorks Inc.
Siemens
SRS Software, LLC
STI Computer Services
Suncoast Solutions
Välant Medical Solutions, Inc.
Vitera Healthcare Solutions
Workflow.com LLC
Xpress Technologies

January 14, 2013

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: MacKenzie Robertson
Patriots Plaza III, 355 E Street, SW., Washington, DC 20201

[Filed Electronically]

Re: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of
Electronic Health Records (EHRs)

Dear Ms. Robertson:

On behalf of the members of the EHR Association, we are pleased to submit our comments on the HIT Policy Committee Stage 3 Request for Comment. We also congratulate the Secretary and the entire Department of Health and Human Services on the success of this important program in clearly accelerating the adoption of health IT through Stages 1 and 2, part of the broader effort to transform and improve healthcare delivery for all Americans.

The attached responses were developed through the collaborative effort of the 40 EHR Association member companies, working through the efforts of workgroups that focus on public policy, meaningful use, standards and interoperability, patient safety, quality measurement, privacy and security, and clinician experience. Over the past several weeks, we have worked to ensure a comprehensive review and consideration of the Request for Comments and to develop balanced recommendations that serve all health IT stakeholders. We appreciate the Policy Committee's responsiveness to the experiences of Stage 1 and attention to what we are all beginning to learn from Stage 2. While we encourage you to focus on our detailed comments, a few key points warrant highlighting in this cover letter.

Overall Approach Proposed

In summary, and in contrast to the approach in this Request for Comments, the EHRA strongly recommends that Stage 3 focus primarily on encouraging and assisting providers to take advantage of the substantial capabilities established in Stage 1 and especially Stage 2, rather than adding new meaningful use requirements and product certification criteria. In particular, we believe that any meaningful use and functionality changes should focus primarily on interoperability and building on accelerated momentum and more extensive use of Stage 2 capabilities and clinical quality measurement.

We further believe that ONC and CMS should not start Stage 3 until at least three years after the start of Stage 2, focusing on the areas mentioned above.

Finally, we suggest that CMS and ONC should continue to invest in quality measure alignment, infrastructure and standards, and focus on building on the foundation begun in Stage 2 without adding a significant number of new quality measures. Please see the attached EHR Association document, *Meaningful Use: Stage 3 and Beyond*, for more on this approach.

Our proposed alternative approach is offered in recognition that the public and private sector shifts to accountable care and value-based payment are now creating a business case for providers to adopt and use EHRs and other health IT, and to identify needed functionality to meet their varied technology requirements. More broadly, such market-based demand will drive additional customer-requested functionality and EHR use patterns for those who have already adopted and demonstrated sophisticated use by attesting for Stages 1 and 2. The needs of such experienced and often sophisticated users will best be met by market innovation, while extensive and detailed standardized requirements dictated by the federal government are not only unnecessary but may actually interfere with the pace and direction of needed innovations.

Learnings from Stages 1 and 2

Our detailed comments are based on the central idea that we need to encourage and assist providers in maximizing the capabilities required in Stages 1 and 2, rather than introducing new meaningful use requirements, product certification criteria and clinical quality measures (CQMs). Our experiences inform this recommendation, both from the perspectives of our member companies, constrained by the needs to focus on Stage 1 and 2 requirements and unable to focus on pursuing elements of new and innovative technologies and EHR functionality, as well as from the perspectives of our customers – hospitals and physicians’ practices – who are working hard to keep up with incentive program requirements while maintaining high quality care standards for growing patient populations.

We strongly believe that Stage 2, along with Stage 1, and especially the 2014 Edition certified EHR capabilities, provide a very solid base for robust use of EHRs, including key interoperability building blocks such as standardized terminology, standards for clinical summaries and their packaging for transport, and data transport standards. As you will see in our detailed comments, we recommend that Stage 3 requirements build on earlier stages and our collective experiences to continue to move forward to achieve our shared objectives of broad adoption and meaningful use of EHRs and health IT.

Timing and the Scope of Meaningful Use Beyond Stage 3

As we have learned, Final Rules are just the “tip of the iceberg” and do not provide all of the information EHR developers and healthcare providers need for technology development and implementation guidance necessary. For Stage 2, all initial materials were not final until late December 2012 — almost four months after the Final Rules were published and *less than one year* before Stage 2 starts for hospitals.

As has been repeatedly conveyed to CMS, ONC, and the HIT Policy Committee, this timing is insufficient. Software developers and providers need at least 18 months with these materials to develop and implement major new EHR functionalities. We see no reason to assume that needed information will be available any sooner for Stage 3 or beyond, for which CMS expects full year reporting periods, and therefore urge that a realistic assessment of the timing of Stage 3 relative to release of the Final Rule and all associated materials be considered and inform planning for future stages and associated regulations. We urge that Stage 3 start no earlier than three years after the start of Stage 2, and strongly recommend that all required materials, such as the final quality measure specifications and certification test scripts be made available no later than 18 months before the start of Stage 3.

Beyond initial implementation of Stage 3, any subsequent revisions to meaningful use and certification should focus on maintenance changes needed to keep certification and meaningful use requirements current with standards changes and emerging technology and practice. This approach reflects the fact that the Medicare incentives will be completed, and that it will be feasible and appropriate to let normal interactions between providers and vendors drive future product development as EHRs and other health IT platforms evolve.

Quality Measures

CMS and ONC should continue to invest in quality measure alignment, infrastructure and standards. Building on the foundation begun in Stage 2, this process should incorporate the time needed for establishing the necessary standards, field testing, and collaboration among measure developers, providers and vendors during the measure development process to help validate this process. Given all of these considerations, we urge CMS to consider finalizing fewer measures for Stage 3, and to be more selective with the measures chosen. In addition, we urge the HITPC, ONC and CMS to consider the following recommendations:

- Electronic Clinical Quality Measures (eCQMs) should be developed de novo, and should undergo feasibility testing during the development process. Feasibility testing should include validating that required data elements can be efficiently and accurately gathered within the provider’s workflow, and that the necessary standards exist to support the measure data requirements.
- eCQMs should undergo a rigorous test process prior to inclusion in federal programs such as meaningful use. This should include both controlled testing of the measures and measure logic, along with field testing of the eMeasure specifications.
- Collaboration between the measure developers, providers, EHR vendors, and federal agency program staff should be part of the measure development, validation, and implementation process.

- Any new Stage 3 quality measures should focus on measures that have a high level of value for all stakeholders, and that are aligned across other federal program requirements.

Standards and Interoperability

Stage 2, along with Stage 1, and especially the 2014 Edition certified EHR capabilities, provides a very solid base for robust use of EHRs, including key interoperability building blocks such as standardized terminology, standards for clinical summaries and their packaging for transport, and data transport standards. We agree with the Policy Committee that interoperability should be an essential element of Stage 3 and indeed, we think that it should be the primary focus. We agree with the Policy Committee's stated interest in expanded focus on query-based exchange in Stage 3.

In our detailed comments, we have provided comments regarding specific interoperability approaches, including areas where standards may not be sufficiently mature for Stage 3 use. The EHR Association and its members are pleased to work with the HIT standards Committee and ONC, including its S&I Framework, and strongly support initiatives to develop, test, and deploy new standards through our participation with standard development organizations and profiling organizations, such as HL7 and IHE. We recommend using those proven organizations and processes where standard development or refinement is needed.

Patient Engagement

We are proponents of the value of increased patient engagement, as noted in our comments on Stage 2. We pose a number of questions related to the best approach to use of patient-generated information that we hope will focus a useful dialog to resolve a number of related issues.

Interoperability for Images

We support the accessibility of images through EHRs and the future expansion of interoperability to include image exchange. Images provide critical information that providers use to diagnose and manage diseases; access to needed images by providers and patients should enhance care and prevent potentially duplicative imaging tests. At the same time, we identify several specific questions that should be addressed to achieve maximum progress in this area.

Estimating Development Effort

We have used a "token" model to attempt to **roughly** quantify estimated development efforts for EHRs to meet proposed Stage 3 requirements. We do this in part in response to one of the Policy Committee's key stated criteria for Stage 3 inclusion – "Reflect reasonableness/feasibility of products or organizational capacity." We also highlight three of the other criteria which relate to our desired approach to Stage 3:

1. Promote advancement, especially "not already driven by market forces"
2. Be achievable – e.g. mature standards widely adopted or could be by 2016
3. Prefer to have standards available if not widely adopted

Overall, we found it somewhat challenging to apply this approach across the various technologies and platforms involved – e.g., portal developers are working on different platforms with different tools than EHR developers; interface developers work differently than those developers tasks with integrating

CQMs into EHRs. In addition to considering the overall scope of development work, it will be important to ensure that certain areas of EHR functionality are not unbalanced.

These estimates, in any case, are very preliminary. At this point, they represent an illustrative and rough approximation of what it might take for any one EHR developer to develop its EHR capabilities to be compliant with some of the proposed requirements.

We encourage the HITPC to use this information along with other inputs received to consider a balance of development requirements to strike a balance across functional areas, taking care not to overload any specific areas (e.g., CQMs) and to align the scope overall with expected regulatory and implementation timelines.

Conclusion

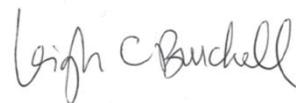
Given the breadth and depth of the meaningful use rules, the quality measurement criteria and associated certification requirements, providers and vendors are finding that meeting specific meaningful use requirements is squeezing out other customer-desired functionality changes and developer innovation, including areas related to usability and accountable care. Moreover, it will be a significant challenge to achieve large numbers of product upgrades between 2011, 2014 and 2016 certified EHR editions in a short period of time, a period that is likely to be highly compressed for Stage 3 if providers after their first year must report for a full year. Just based on providers who have received Medicare or Medicaid payments as of October 2012, at least 161,000 EPs and 3,238 hospitals will require upgrades between roughly April 2013 and November 2013. The numbers increase substantially when considering those who registered for the program through October.

On behalf of the EHR Association, we appreciate the effort that went into the development of this important next step in the meaningful use incentive program. We look forward to working with the Policy Committee, the HIT Standards Committee, ONC and CMS as the Stage 3 development process moves forward. And again, congratulate the Secretary and the entire Department of Health and Human Services on the success of this important program in clearly accelerating the adoption of health IT through Stages 1 and 2, part of the broader effort to transform and improve healthcare delivery for all Americans.

Sincerely,



Michele McGlynn
Chair, EHR Association
Siemens



Leigh Burchell
Vice Chair, EHR Association
Allscripts

HIMSS EHR Association Executive Committee



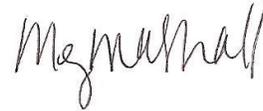
Jason Colquitt
Greenway Medical Technologies



Lauren Fifield
Practice Fusion, Inc.



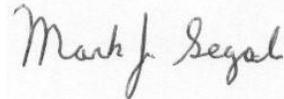
Charlie Jarvis
NextGen Healthcare



Meg Marshall
Cerner Corporation



Ginny Meadows



Mark Segal

About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himsssehra.org>.

In an effort to make our feedback more valuable for the HIT Policy Committee and ONC, we have attempted to provide greater specificity on how much effort would be required to develop in 2014 certified EHRs the new features proposed for Stage 3 and 2016 certification. The estimates are included below in the column labeled "Average EHR Association Development Estimate." Because estimates are slightly different for each EHR developer, we have presented development estimates here in "tokens." This gives a comparative sense of the expense of different projects. Based on the time available for Stage 3/2016 development (assuming the below schedule, which seems optimistic given past experience and also the need to learn from Stage 2 before final Stage 3 regulations), we do not think a scope of any greater than 100 tokens is appropriate.

We understand that the Policy Committee is working toward transmitting their final recommendations for Stage 3 to HHS in May 2013. We estimate therefore that there might be proposed rulemakings for Stage 3 and 2016 certification in late 2013 and final rulemakings for Stage 3 and 2016 certification in early-to-mid 2014. We have noted for consistency in our estimates the timeframes for other guidance/tools that will likely also be forthcoming after the final rules. Finally, we note that hospitals (EHs) would begin use of 2016 certified EHRs on October 1, 2015 and providers (EPs) on January 1, 2016, given the current schedule for Stage 3 to begin in FY/CY 2016. At that time, some EPs and EHs will be starting Stage 3 and others will use 2016 certified EHRs to continue to achieve Stages 1 or 2. In our comments below, when we have assessed the readiness of whether standards can be mature in time for implementation in Stage 3, we have evaluated whether the standard could be considered reasonably mature in early 2014. Standards not ready by that time should in general be deferred beyond the start of Stage 3.

Timeline estimates summary (based on the HITPC published schedule and past experience):

Estimated Date	Event
May 2013	HITPC transmits final MU3 recommendations to HHS
Nov 2013	Stage 3/2016 certification NPRMs
Summer 2014	Stage 3/2016 certification final rules
Fall 2014	Stage 3 quality measure specifications
End of 2014	2016 certification test procedure drafts and finals
October 2015	All MU EHs must use 2016 certified software
January 2016	All MU EPs must use 2016 certified software

Given a scope of 100 tokens, we recommend that the majority of the tokens be focused on projects furthering interoperability. We would recommend a token distribution as follows:

- 60 tokens – interoperability
- 30 tokens – quality measurement
- 10 tokens – other functional projects

We note that in Stages 1 and 2, quality measurement has generally required proportionately greater effort than interoperability. A limited number of well-defined quality measures for 2016 certification that build on the investment already put into 2014 certification should allow more effort to be invested in interoperability for 2016 certification, consistent with our proposed allocation of resources.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
Improving quality, safety, and reducing health disparities					
SG RP 10 1	<p>EP Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines</p> <p>EH Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines</p>	<p>Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order.</p> <p>(1) CPOE for medications includes DDI checking for “never” combinations as determined by an externally vetted list.</p> <p>Measure: More than 60% of medication, laboratory, and radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period</p>	<p>Seeking externally maintained list of DDIs with higher predictive value</p>	<p>(1) DDI checking – First, there is confusion about RxNorm and NDF-RT standards for DDIs. EHR developers would like more information about the standards for supplying the DDI list. We are concerned that, without such information being available, it is difficult to assess whether use of such a list in 2016 is viable. Based on past experience with implementing new standards relating to MU, we are significantly concerned that the timeline might not be viable.</p> <p>We are worried that requirement to consume “never DDIs” has a high risk of being further defined in ways that make it a very large development project, or where certification requires it to be implemented in a way not all EHRs would consider optimal.</p> <p>Based on other work in the industry, we assume that the “never DDI” list would be provided along with medication content from third parties and would not be a query that happens “on the fly” at the point of ordering. This overall approach as to whether this happens on the fly or if it is a periodic load would greatly affect the scope of the project. We don’t think it’s appropriate for HITPC/ONC to dictate EHR design by mandating one way or the other. We note that there are particular cases where checking on the fly is not appropriate, such as when providers are working without Internet access.</p> <p>From a standards perspective, there is concern that making DDI overly</p>	<p>Never DDI list – depends on how it is implemented. If incorporated into medication database content, 0-5 tokens. If not, 20-50 tokens, again depending on how implemented.</p> <p>Transmit lab orders electronically – 10 tokens to ensure current interfaces match standard.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>EP/EH Measure: More than 60 percent of medication, 30 percent of laboratory, and 30 percent of radiology orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p>	<p>are recorded using CPOE</p> <p>(1) Certification Criteria: EHR must be able to consume an externally supplied list of "never" DDIs, using RxNorm and NDF-RT standards along with a TBD DDI reactions value set.</p> <p>Certification Only for EPs</p> <ul style="list-style-type: none"> EHR must have the ability to transmit lab orders using the lab order and results Interface guidelines produced by the S&I Framework Initiative. 		<p>configurable increases the complexity of deployment.</p> <p>Overall, based on these considerations we do not recommend this item for inclusion into Stage 3 in the above timeline. In particular, there is insufficient indication that there is or will be clarity in -content standards (NDDF, RXNorm, etc) or technical standards (deployment, real-time use, API, etc.).</p> <p>(2) In the CMS Stage 2 Final Rule, the measure description for CPOE specified that CPOE must be used to create the "first record of the order". This language continues to create significant industry confusion about what was intended and measurement challenges (e.g., if something is previously recorded, how is that known by the EHR?). It seems that if the goal is to present clinical decision support to the CPOE user, it would be much simpler to broadly state that as the requirement, and remove this verbiage.</p>	
<p>SG RP 13 0</p>	<p>New</p>	<p>Objective: Use computerized provider order entry for referrals or transition of care orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create</p>		<p>Placing referrals orders is not as common in inpatient settings and workflow as it is in ambulatory settings. Thresholds and requirements should factor in the differences here between common ambulatory workflows and common hospital workflows.</p> <p>As with past orders-based objectives, tracking orders not entered in the EHR to constitute the denominator can be challenging.</p>	<p>0-5 tokens, assuming most EHRs already have this capability or close to it; that it is not specified in a way requiring EHR</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>the first record of the order. Measure: More than 20% of referrals/transition of care orders created by the EP or authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded.</p>		<p>We are assuming that this objective does not include or mandate electronic transmission or standard format for referral entry. We would have further concerns if that were envisioned.</p> <p>We are also concerned about broader incursion into referrals management functionality as not being core EHR functionality or appropriate for this program.</p>	<p>changes; and that electronic transmission and referrals management functionality is not required.</p>
<p>SG RP 10 3</p>	<p>EP/EH Objective: Generate and transmit permissible prescriptions electronically (eRx)</p> <p>Measure: More than 50% of all permissible prescriptions, or all prescriptions written by the EP and queried for a drug formulary and transmitted electronically using CEHRT.</p> <p>EH MENU Objective: Generate and transmit permissible discharge</p>	<p>EP Objective: Generate and transmit permissible prescriptions electronically (eRx) EP Measure: More than 50% of all permissible prescriptions written by the EP are compared to at least one drug formulary (reviewed for generic substitutions) transmitted electronically using Certified EHR Technology. EH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx) EH Measure: More than 30% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are</p>	<p>Advanced medication reconciliation to check for formulary compliance.</p> <p>Medication formulary checking:</p> <ul style="list-style-type: none"> • If Rx is formulary-compliant, transmit to pharmacy 	<p>NCPDP Script does not permit sending generic names when drugs are only available as brand names.</p> <p>EHR developers observe that generic comparison functionality is already available in the marketplace, and are concerned that this not be implemented for certification in ways that would require those already providing this functionality to change how it is already being used. For example, some EHRs use features provided by SureScripts for generic substitutions. ePrescribe certification (such as SureScripts) could be an efficient way to minimize further certification requirements.</p> <p>E-prescribing networks have been receiving complaints about lagging formulary updates.</p> <p>Querying of multiple formulary sources could introduce challenges to efficient prescription writing.</p> <p>It remains challenging for EHR developers to evaluate the Future Stage comments. There are open questions about what standards will be in</p>	<p>0 tokens if generic comparisons are required in a way that permits current EHR functionality to suffice.</p> <p>If new functionality is required, changes to medication ordering are often time-consuming so we estimate it would be a 30 token project.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>prescriptions electronically (eRx)</p> <p>EH MENU Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology</p>	<p>compared to at least one drug formulary and transmitted electronically using Certified EHR Technology</p> <p>How to include formulary checking into EHR and connection to formulary sources (e.g., PBMs)?</p>	<p>cy.</p> <ul style="list-style-type: none"> If Rx is not formulary compliant, prescriber presented with alternatives (if available through formulary database) or provided a structured prior-authorization form to complete 	<p>use at that time and whether further development is needed.</p> <p>We suggest that vocabulary be harmonized across medication-related standards (e-prescribing, immunizations, C-CDA) by January 2014 to ensure these standards share the same code sets for common fields to avoid unnecessary mapping and maintenance of multiple code sets.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>e before Rx transmitted. Capability for automatic approval of prior-auth should be available.</p>		
<p>SG RP 10 4</p>	<p>EP Objective: Record the following demographics</p> <ul style="list-style-type: none"> • Preferred language • Sex • Race • Ethnicity • Date of birth <p>EH Objective: Record the following demographics</p>	<p>Retire prior demographics objective because it is topped out (achieved 80% threshold).</p> <p>Certification criteria:</p> <ul style="list-style-type: none"> • (1) Occupation and industry codes • (2) Sexual orientation, gender identity (optional fields) • Disability status <ul style="list-style-type: none"> • Differentiate between patient reported & medically determined 		<p>We have comments about the new demographics proposed for certification. We worry that these are being proposed without a comprehensive understanding of what would be involved in adding the ability to capture these demographics. Adding support for these items will require significant EHR development, and should only be required if the burden is carefully weighed and determined to merit the cost relative to other features EHR developers could be working on:</p> <p>(1) Occupation and industry</p> <p>We note that the occupation and industry codes are currently part of the cancer registry reporting for 2014 certification. There are thousands of these codes. It is very challenging and EHR users have not expressed</p>	<p>Occupation and industry codes – If adding one field for occupation and one for industry, 5 tokens. If extensive data capture is required (e.g., primary or lifetime</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<ul style="list-style-type: none"> • Preferred language • Sex • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH <p>Measure: More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data.</p>	<ul style="list-style-type: none"> • Need to continue standards work <p>Do commenters agree with retiring the measure, or should we continue this objective?</p> <p>Continuing the measure would mean an additional number of objectives that providers will need to attest to.</p>		<p>interest in this type of complexity or in entering data of that granularity. We do not suggest adding this.</p> <p>(2) Sexual orientation and gender identity Tracking sexual orientation and gender identity could be a very large development project depending on how it is implemented. For example, it is possible that every place where sex is shown or used in the application would have to be reevaluated to determine if sex should continue to be shown, if gender identity should be shown, if both need to be shown, if one or both need to be used for every type of clinical decision support, and so forth.</p> <p>EHR developers who have investigated this have discovered that this is a complicated area of documentation. EHR users do not seem to be in agreement as to how best to approach this issue.</p> <p>We propose that use of this field by providers be optional and that the certification requirements simply focus on adding a new field, with no requirement to use this field in either certification or meaningful use or in other criteria referencing demographics (such as clinical decision support).</p> <p>(3) Disability status There are several issues regarding to privacy in relation to collecting information when it does not relate to care of the patient. There are not clear standards in this area and widely different definitions of what is considered a disability status.</p>	<p>occupation, history of occupation, tracking over time), 20 tokens.</p> <p>Sexual orientation and gender identity – If adding two fields, 5 tokens. However, we do not think this is what is requested and we estimate the requested integration of this information into the EHR is likely a 30-60 token project.</p> <p>Disability status – Difficult to estimate without standards. 10-30 tokens.</p>
SG	Consolidated in	Certification criteria only: EHR	Patient	We are very concerned by the first portion of this criterion. We do not	Cannot estimate

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
RP 10 5	<p>summary of care objective - Maintain an up-to-date problem list of current and active diagnoses</p>	<p>systems should provide functionality to help maintain up-to-date, accurate problem list</p> <p>Certification criteria only: Use of lab test results, medications, and vital signs (BP, ht, wt, BMI), to support clinicians' maintenance of up-to-date accurate problem lists. Systems provide decision support about additions, edits, and deletions for clinicians' review and action. For example, if diabetes is not on the problem list but hypoglycemic medications are on the medication list: the EHR system might ask the provider whether diabetes should be on the problem list. It would not automatically add anything to the problem list without professional action.</p> <p>The implementation of these criteria will assist in achieving the CDC's goal of using EHR technology features to identify patients meeting criteria for</p>	input to reconciliation of problems	<p>think it is sufficiently defined for effective or accurate public comment. It sounds appealing as a proposal, but there is no indication of how it would be implemented or required, and we suspect that if further detail were given, public comment might be much different.</p> <p>For this reason, we do not think it is a very good candidate for certification. Certification will tend to prescribe specifically how this is done and that might not be desirable even to stakeholders who support the broader direction.</p> <p>We question whether the second proposed criterion would really be the best way to further the goals of this program. If the goal of the program is appropriate diagnosis of diabetes and hypertension, we should write a clearer outcomes-oriented objective around that goal, rather than broader requirements about problem list functionality that might not be what is envisioned by users and would not actually further better care. The more specific the goal, the more likely that outcomes will be changed.</p> <p>We note that CDS requirements already support interventions based on lab test results, medications, and vital signs, so we are not sure what additional functionality is envisioned by this objective and are concerned that further requirements may become overly prescriptive to EHR design.</p> <p>For the future proposal, we were confused by what is proposed. Patients adding problems to the EHR? Patients reconciling problems added by clinicians?</p> <p>Certification is helpful in establishing a baseline of functionality for things</p>	<p>given unclear proposal.</p> <p>If taking advantage of existing CDS functionality that is part of 2014 certification, 0 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>hypertension who are not yet diagnosed and managed for the disorder.</p> <p>How to incorporate into certification criteria for pilot testing?</p> <p>The intent is that EHR vendors would provide functionality to help maintain functionality for active problem lists, not that they supply the actual knowledge for the rules.</p>		<p>like problem lists. But for more sophisticated tools, we are concerned that certification artificially imposes one solution to a problem that actually has several creative answers. We propose that the market will be more effective in driving creative, innovative solutions based on user feedback, and that certification might drive development in ways that are not desirable to all users.</p>	
<p>SG RP 10 6</p>	<p>Consolidated with summary of care - Maintain active medication list</p>	<p>Certification criteria only: EHR systems should provide functionality to help maintain up-to-date, accurate medication list</p> <p>Certification criteria only: Use of problems and lab test results to support clinicians' maintenance of up-to-date accurate medication lists. Systems provide decision support about additions, edits, and deletions for clinicians' review. For example, an</p>	<p>Certification criteria: Use other EHR data such as medications filled or dispensed, or free text searching for medications to support</p>	<p>We are very concerned by the first portion of this criterion which is very vague. We do not think it is sufficiently defined for effective public comment. It sounds appealing as a proposal, but there is no indication of how it would be implemented or required. We suspect that if further detail were given, public comment might be much different.</p> <p>For this reason, we do not think it is a very good candidate for certification. Certification will tend to prescribe specifically how this is done and that might not be desirable, even to stakeholders who support the broader direction.</p> <p>We are concerned that the second criterion is based on data assumptions that are not always true. For example, the EHR would not always know whether a particular medication was associated with a particular</p>	<p>Cannot estimate given unclear proposal.</p> <p>If taking advantage of existing CDS functionality that is part of 2014 certification, 0 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>antibiotic (not for acne) has been on the medication list for over say a month, the EHR system might ask the provider whether the medication is a chronic medication. The system will not make any changes without professional approval.</p> <p>How to incorporate into certification criteria for pilot testing?</p> <p>The intent is that EHR vendors would provide functionality to help maintain functionality for active medication lists, not that they supply the actual knowledge for the rules.</p>	<p>maintenance of up-to-date and accurate medication lists.</p>	<p>diagnosis as is assumed in the one example. Also, medication lists are maintained by multiple users so there is high likelihood that this type of decision support could be complex to implement without annoying clinicians. We worry that certification requirements in this area have a high risk of being overly prescriptive and impeding innovative design.</p> <p>We are concerned that the complexity of designing CDS on when to remove medications from the med list will require significant development that is not supported by EHR user requests.</p> <p>Also, we suggest that the existing requirement to perform medication reconciliation should address the identified issue of maintenance of medication lists, and that this certification requirement does not make sense.</p> <p>Certification is helpful in establishing a baseline of functionality for things like med lists. But for more sophisticated tools, we worry that certification artificially imposes one solution to a problem to which there are actually several creative answers. We propose that the market will more effectively drive creative, innovative answers based on user feedback, and that certification might drive development in ways that are not desirable to all users.</p>	
<p>SG RP 10 7</p>	<p>Consolidated with summary of care - Maintain active medication allergy list</p>	<p>Certification criteria only: EHR systems should provide functionality to code medication allergies and link to related drug family, and code related reaction.</p>	<p>Contraindications that could include adverse reactions</p>	<p>We note that the "intent" statement does not seem to be reflected any longer in the proposed certification criteria. We assume the language that was referenced was intentionally removed, and we support its removal. A requirement similar to what was proposed for problem lists and medication lists makes even less sense in relation to allergy lists.</p>	<p>Cannot estimate given unclear proposal.</p> <p>If taking advantage of</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>The intent is that EHR vendors would provide functionality to help maintain functionality for active medication allergy lists, not that they supply the actual knowledge for the rules.</p>	<p>and procedural intolerance.</p> <p>Certification criteria: Explore greater specificity for food-drug interactions</p>	<p>We are uncertain what exactly is proposed by the certification criterion that is not already part of certification and allergy coding today.</p> <p>Certification is helpful at establishing a baseline of functionality for things like allergy lists. But for more sophisticated tools, we worry that certification artificially imposes one solution to a problem for which there are several creative answers. We propose that the market will be more effective at driving creative, innovative answers based on user feedback, and that certification might drive development in ways that are not desirable to all users.</p>	<p>existing CDS functionality that is part of 2014 certification, 0 tokens.</p>
<p>SG RP 10 8</p>	<p>Objective: Record and chart changes in vital signs:</p> <ul style="list-style-type: none"> • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI <p>Measure: More than</p>	<p>Retire measure because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0018</p> <p>Do commenters agree with retiring the measure, or should we continue this objective?</p> <p>Continuing the measure would mean an additional number of objectives that providers will need to attest to.</p>		<p>It remains important to capture vitals for clinical decision support and for clinical quality measures, so it makes sense to continue to focus attention on capture by measuring. The tools are already available to take advantage of.</p>	<p>0 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data				
SG RP 10 9	<p>EP/EH Objective: Record smoking status for patients 13 years old or older</p> <p>Measure: More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency</p>	Retire measure because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0028		It remains important to capture smoking status for clinical decision support and for clinical quality measures, so it makes sense to continue to focus attention on capture by measuring. The tools are already available to take advantage of.	0 tokens.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data				
SG RP 11 2	<p>EH MENU Objective: Record whether a patient 65 years old or older has an advance directive</p> <p>EH MENU Measure: More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.</p>	<p>Ensure standards support in CDA by 2016</p> <p>EP MENU/EH Core Objective: Record whether a patient 65 years old or older has an advance directive</p> <p>EP MENU/EH Core Measure: More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.</p>		<p>We suggest that the standards to support the exchange of advance directive information reflect the fact that the relevant C-CDA document only needs to contain an indication of the presence of an advance directive, but is not required to embed the actual advance directive.</p> <p>We suspect that some specialists (for example, dermatologists) will be uncomfortable adding a new discussion about advance directives to all of their patient discussions. It is more suited to PCPs.</p>	0 tokens, assuming inclusion in CDA does not mandate additional documentation requirements. New data capture is likely 10 tokens.
SG RP	EP/EH Objective: Use clinical decision support	Objective: Use clinical decision support to improve performance	<i>Procedure /Surgery/la</i>	On the proposed certification criteria:	Tracking CDS triggers and

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
113	<p>to improve performance on high-priority health conditions</p> <p>Measure: 1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an EP, eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving</p>	<p>on high priority health conditions</p> <p>Measure: 1. Implement 15 clinical decision support interventions or guidance related to five or more clinical quality measures that are presented at a relevant point in patient care for the entire EHR reporting period. The 15 CDS interventions should include one or more interventions in each of the following areas, as applicable to the EP's specialty:</p> <ul style="list-style-type: none"> • Preventative care (including immunizations) • Chronic disease management (e.g., diabetes, hypertension, coronary artery disease) • Appropriateness of lab and radiology orders • Advanced medication-related decision support* (e.g., renal drug dosing) <p>2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting</p>	<p><i>b/radiology /test prior authorization v.A:</i> for those procedures/surgeries/lab/radiology /test with clear and objective prior authorization requirements and a structured data prior authorization form is available, clinician fill out the prior authorization form using structured data fields</p>	<ol style="list-style-type: none"> 1. We note that tracking CDS triggers and responses is appropriate for active interventions where it is clear when it is triggered and responses are obvious. But with more passive forms of clinical decision support, it is much harder to determine when such passive CDS is triggered or if it was responded to. 2. For appropriateness, CDS as proposed in bullet three, meaningful use should not require or imply the use of proprietary content. Competition among content providers would be important to control cost and encourage innovation. Look to the results of the ongoing CMS evaluation of imaging appropriateness guidelines. 3. We are uncertain what "preference-sensitive conditions" are and what type of decision support would be provided to patients. Is there a standard or common understanding of a "preference-sensitive condition"? We are uncertain if this type of CDS is viable in the proposed timeframe given our uncertainty about what it is. 4. If requiring structured SIG standards, it needs to support compounded drugs and tapers, which might require further standards work. It is unclear what standards are to be used for SIGs. 5. Regarding connections to central CDS repositories, we question how widely used this would be. Will the repositories be updated reliably going into the future? Will EHR users have regular Internet access allowing the use of web services for this type of connection? Our understanding is that standards are not likely to be mature in time for implementation in Stage 3. We are not certain that this is a priority for EHR users such that it should be a requirement for all EHRs for certification. We suggest that core CDS requirements are already met by certification and further CDS enhancements should be determined by market forces and innovation. We are concerned that the recommendation creates a major configuration issue. Experience 	<p>responses -- varies. 0-10 tokens for EHR developers who already include this functionality, assuming it is not defined in a very specific way requiring redevelopment. Potentially 50 tokens for those who do not include currently as it involves major new data structures. Estimate that at least half of EHR vendors include.</p> <p>If flagging of preference-sensitive conditions requires new EHR functionality, 20 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>healthcare efficiency.</p> <p>2. The EP, eligible hospital, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</p>	<p>period.</p> <p>Certification criteria only:</p> <ol style="list-style-type: none"> 1. Ability to track CDS triggers and how the provider responded ** 2. Ability to flag preference-sensitive conditions, and provide decision support materials for patients. 3. Capability to check for a maximum dose in addition to a weight based calculation. 4. Use of structured SIG standards 5. Ability for EHRs to consume CDS interventions from central repositories (e.g., rules for drug-drug interactions, rules for reporting diseases for public health departments, preference-sensitive care lists) <p>The goal of this objective is to create EHR capability to introduce efficiencies into process for providers. The EHR should have capacity to query (via web services) available databases to</p>	<p>and prior authorization can be granted electronically and in real-time by the payor.</p> <p><i>Procedure/Surgery/lab/radiology/test prior authorization v.B:</i> for those procedures/surgeries/lab/radiology/test, for which prior authorization is non-standardized and is highly individualized, a</p>	<p>to date with Arden Syntax indicates the many challenges to incorporate CDS rules. While there are substantial efforts in progress under the S&I Framework Health eDecisions (HeD) initiative, this initiative has not moved far enough along yet to address the challenging implementation questions and associated guidance to achieve reasonable maturity by January 2014 to mandate wide adoption. We suggest postponing #5 until a later stage.</p>	<p>Structured SIG – assuming EHRs already accommodate, 0 tokens.</p> <p>Consuming CDS from central repositories via web services, 40 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>identify "trigger events" conditions (e.g., case reporting criteria, drug-drug interactions, potentially relevant trials) based on patient's health condition, diagnoses, location, and other basic facts). The EHR should be able to identify these trigger events and then assist clinicians to act on that information.</p> <p>*Kuperman,GJ. (2007). Medication-related clinical decision support in computerized provider order entry systems: a review. <i>Journal of the American Medical Informatics Association: JAMIA</i>, 14(1):29-40.</p> <p>**this is used to improve the effectiveness of CDS interventions</p>	<p>standardize d form is created that collects from the clinician text fields answering an agreed upon set of medical necessity questions, standardize d form is sent electronically to insurer for review, insurer responds with Approval/D enial (with rationale if denied) using a standardize d format</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			text document back to clinician with either approval and/or denial with rationale.		
SG RP 11 4	<p>EP/EH Objective: Incorporate clinical lab-test results into Certified EHR Technology as structured data</p> <p>Measure: More than 55 percent of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23 during the EHR reporting period whose</p>	<p>Objective: Incorporate clinical lab-test results into EHR as structured data</p> <p>Measure: More than 80% of all clinical lab tests results ordered by the EP or by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data</p>		The Lab Results Interface IG is ambulatory focused. We suggest that considering this guide for EH EHRs is premature without first establishing an effort to address an expanded scope of both hospital-based lab to EH EHRs. Until then we support continued stratification of the certification criteria for EP EHRs vs. EH EHRs.	0 tokens, assuming no changes to measurement.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	results are either in a positive/negative affirmation or numerical format are incorporated in Certified EHR Technology as structured data				
SG RP 11 5	<p>EP CORE Objective: Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach</p> <p>EP CORE Measure: Generate at least one report listing patients of the EP, eligible hospital or CAH with a specific condition.</p>	<p>EP Objective: Generate lists of patients for multiple specific conditions and present near real-time (vs. retrospective reporting) patient-oriented dashboards to use for quality improvement, reduction of disparities, research, or outreach reports. Dashboards are incorporated into the EHR's clinical workflow for the care coordinator or the provider. It is actionable and not a retrospective report.</p>		<p>Although many EHRs likely include such features as competitive differentiators, we are concerned that this is a tricky area where over-prescriptive design in certification requirements will cause significant waste in development effort just to meet certification rather than focusing development on the needs of EHR users.</p> <p>For example, we consider the terms "near real time," "patient-oriented", "dashboards," and "incorporated into clinical workflow" all vague and unclear as to what they mean or would require from a development perspective. We are not certain there is consensus among the industry or commenters on this item in what they are envisioning. When one person envisions a "dashboard", he may picture something very different than another respondent. This discrepancy in how different industry stakeholders read the requirement is likely to cause issues.</p> <p>We are concerned that as this criterion is further defined, it is likely to include requirements that might be expensive to develop and not important to EHR users. We do not think this is a good area for regulation to drive. We strongly suggest that the market drive development of dashboarding tools rather than defining them via regulation in this program.</p>	<p>Difficult to estimate given vague specifications – 20 to 50 tokens, depending on how specified. Not recommended.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
				<p>Previous regulation has focused on the ability to generate lists, which has been an appropriate core EHR function. "Dashboards" likely has further connotations that cause great concern about over-prescriptive design.</p> <p>Some analytics and dashboarding tools are available as third party software packages, and we have concerns about requiring these packages to be part of the EHR incentive program.</p>	
SG RP 11 6	<p>EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder per patient preference.</p> <p>Measure: More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient</p>	<p>EP Objective: Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care</p> <p>EP Measure: More than 20% of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference</p> <p>Exclusion: Specialists may be excluded for prevention reminders (could be more condition specific).</p>		<p>Many healthcare providers send reminders from non-EHR systems (e.g., scheduling systems, reminders systems), so this workflow should be considered when writing EHR certification criteria.</p> <p>We are not certain that 20% of the patients of all EPs need a reminder for preventive or follow-up care every year. In particular, patients who might most require reminders might be those in a provider's panel who have not been seen in the last two years, though we appreciate the limitation from a measurement perspective. However, we caution that further investigation is necessary prior to raising the threshold to 20%. The threshold is further raised by including patients who have only had one office visit with the EP (rather than two in Stage 2), which is also of concern. Two visits would be more indicative of an ongoing relationship with the EP that would warrant sending preventive care reminders.</p> <p>Specialists in particular need to be considered for exclusions or threshold changes.</p> <p>We expect that the thresholds might be reasonable for certain providers and very challenging for other specialists. We encourage reference to</p>	<p>Assuming that the changes to the wording are errors and not intended to change the measure, 0 tokens.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	preference when available			Stage 1 and 2 experience, although that data may not necessarily provide a representative sample.	
SG RP 11 7	<p>EH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)</p> <p>Measure: More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using eMAR.</p>	<p>EH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)</p> <p>Measure: 1) More than 30% of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR. 2) Mismatches (situations in which a provider dispenses a medication and/or dosing that is not intended) are tracked for use in quality improvement.</p>		<p>We are not certain exactly what is intended by tracking mismatches, so it is difficult to evaluate feasibility. We assume the intention is that the EHR retain a log of when the medication that is documented using assistive technology does not match what was ordered for that patient, and that log is to be made available to quality administrators.</p> <p>There is also confusion on what is expected to be reported, as EHRs typically prevent dispensing and administration of inappropriate medication, assuming it is the attempt to dispense the med that is intended to be tracked here.</p>	<p>If it is the attempt to dispense that is supposed to be tracked, assuming EHRs already do this. it is 0 tokens.</p>
SG RP 11	<p>MENU Objective: Imaging results consisting of the image</p>	<p>CORE Objective: Imaging results consisting of the image itself and any explanation or</p>		<p>Adding ECGs is probably a material change from the current requirement, as the storage of those images might be different than radiation involved images. ECGs are stored in a variety of formats and</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
8	<p>itself and any explanation or other accompanying information are accessible through Certified EHR Technology.</p> <p>MENU Measure: More than 10 percent of all tests whose result is one or more images ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology.</p>	<p>other accompanying information are accessible through Certified EHR Technology.</p> <p>CORE Measure: More than 10 percent of all tests whose result is an image (including ECGs) ordered by the EP or by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology</p> <p>What barriers could be encountered in moving this to core?</p>		<p>are typically not considered diagnostic images. Moreover, having a single measure for both ECGs and images would dilute the effectiveness of the image access measure, due to the overwhelming number of ECGs relative to images. We suggest further clarification of the definition of different types of images to enable assessment of appropriate standards and/or approaches for access. Moreover, having a single measure for both ECGs and images would dilute the effectiveness of the image access measure, due to the overwhelming number of ECGs relative to images.</p> <p>We generally agree with moving this to core but it is still challenging to project barriers in 2016; this is too far out to predict. We encourage use of Stage 2 adoption data in determining feasibility for core in Stage 3. We encourage the HIT Standards Committee to consider multiple standards that could be used to facilitate image access.</p>	
SG RP 11 9	<p>MENU Objective: Record patient family health history as structured data</p>	<p>CORE Objective: Record high priority family history data</p> <p>CORE Measure: Record high priority family history in 40% of</p>		<p>Why is the Stage 3 objective "high priority family history data" different from the Stage 2 objective, "patient family health history as structured data"? We assume the different wording is intended to introduce a new element in Stage 3 but are unclear on what is being changed.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>MENU Measure: More than 20 percent of all unique patients seen by the EP or admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives</p>	<p>patients seen during reporting period</p> <p>Certification criteria: Make sure that every appropriate CDS intervention can take into account family history for outreach (need to move that functionality along as part of preventative outreach).</p>		<p>We do not see that any change is merited from the requirements being introduced in Stage 2 and think that the wording used should be consistent or the intention should be made clearer.</p> <p>We discourage use of vague terms like "high priority" that require further definition.</p> <p>We note that specialists indicate that recording family history is not always relevant to their practice.</p> <p>We are confused by the proposed certification criteria and suspect that it needs to be clarified with better wording and likely relocated to other criteria.</p> <p>If the intention is that certain kinds of clinical decision support interventions happen based on family history, we are not clear why that is proposed here and not in the CDS objective. We suggest including all triggers for CDS interventions in the CDS objective and removing confusing cross references from family history.</p> <p>Next, we are not sure how certification could ensure "every appropriate intervention" could take family history into account. EHR certification can assure a functional capability but does not control the CDS content within the EHR, which might come from a variety of sources. We oppose any certification requirements that would dictate how CDS content must be delivered. We also seek clarification regarding what is intended by "outreach" and how that would be reflected in certification criteria.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
				<p>Also, we are confused by the relation of CDS interventions and outreach. What is intended by this wording? It seems that the intention is that a provider could send reminders based on family history items, in which case we think that would be more appropriately included in the objective to send reminders.</p>	
<p>SG RP 12 0</p>	<p>EP/EH MENU Objective: Record electronic notes in patient records EP MENU Measure: Enter at least one electronic progress note created, edited and signed by an eligible professional for more than 30 percent of unique patient office visits. Notes must be text-searchable. Non-searchable scanned notes do not qualify but this does not mean that all of the content has to be character text. Drawings and other content can be included with text notes under this</p>	<p>Record electronic notes in patient records for more than 30% of office visits within four calendar days.</p>		<p>Is this intended to be menu or core? We are comfortable with this being made into a core objective.</p> <p>Changing the basis of this measure from unique patients to office visits would have the de facto effect of raising the threshold impact.</p> <p>We suggest not adding the Stage 3 requirement regarding four days as this may be too intrusive into clinical practice and not appropriate for all types of visits, especially with the shift to core. We suggest maintaining the threshold of Stage 2 (and measure population) and just moving the measure to core.</p> <p>Also, is this excluding EHs? We are confused since the only reference is to office visits in Stage 3.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>measure.</p> <p>EHMENU Measure: Enter at least one electronic progress note created, edited, and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period.</p> <p>Electronic progress notes must be text-searchable. Non-searchable, scanned notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be</p>				

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	included with text notes under this measure.				
SG RP 12 1	<p>EH MENU Objective: Provide structured electronic lab results to ambulatory providers</p> <p>EH MENU Measure: Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received</p>	<p>EH CORE Objective: Provide structured electronic lab results to eligible professionals.</p> <p>EH CORE Measure: Hospital labs send (directly or indirectly) structured electronic clinical lab results to the ordering provider for more than 80% of electronic lab orders received.</p>		<p>We have significant concerns about the certification requirements in 2014 for this objective, and worry that there will be challenges for both EHRs and lab systems to meet the certification requirements. Such challenging certification requirements are likely to make lab interfaces more expensive. If this is to be made a core objective, then efforts will be required to ensure that the certification requirements are reasonable and that the interfaces required can be developed efficiently.</p> <p>Preliminary experience in Stage 2 indicates that this is very difficult and will not be commonly chosen as a menu objective. We think it will be hard to make core or increase the threshold, and doing both does not seem feasible.</p>	
SG RP 12 2		<p>Objective: The EHR is able to assist with follow-up on test results</p> <p>Measure: 10% of test results, including those which were not completed are acknowledged within 3 days</p> <p>Certification Criteria:</p> <ul style="list-style-type: none"> • EHRs must have the ability to identify abnormal test results and to notify the ordering providers 		<p>The objective could be written more clearly, as the objective identifies an EHR capability, not an expectation of an EP or an EH. We suggest that the objective be rewritten to clarify the expectation of the EP or EH.</p> <p>Is this intended as an EP objective or an EH objective or both?</p> <p>The measure also seems confusing, and needs more definition. Within 3 days of what event? It might not be practical to expect the majority of your lab results (depending on specialty) to be returned quickly. This measure seems likely to force providers to frequently review results that are not yet completed. The measure seems to introduce inefficiency and</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>when results are available or not completed by a certain time.</p> <ul style="list-style-type: none"> • EHRs must record date/time test results are reviewed and by whom 		<p>waste time for busy clinicians.</p> <p>We are strongly concerned about the language, "EHRs must have the ability to identify abnormal test results." Does "identify" mean label or highlight in some fashion visible to the EHR user? Or does "identify" mean compare against a reference range and determine if abnormal? We suspect the latter is what is intended, since we believe EHRs already do the former and it would not need to be required in certification. However, the latter is extremely problematic as the abnormal status must come from the lab and does not come from the EHR. Including it in certification will greatly complicate the already complicated lab/EHR crossover in certification because here you would have EHR features (lab results review) and lab features (identification of abnormal results) in the same criterion. We think it is essential that the HITPC consult with lab and EHR experts and avoid prescriptive certification requirements that mix the two functionalities.</p> <p>The measure here, three days, seems to be both too vague and too specific. Why three days?</p> <p>What is meant by lab results that are not completed? Is that intended to mean results not received back from the lab in a certain period of time? Are we expected to know and configure a reasonable amount of time to wait for a lab result per type of lab?</p> <p>This is also premature without applicable standards.</p>	
Engage patients and families in their care					
SG	EP Objective: Provide	• EPs should make info	Building on	"Make info available within 24 hours" – We understand the philosophical	False precision

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
RP 20 4A	<p>patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP.</p> <p>EP Measure: 1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information. 2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized</p>	<p>available within 24 hours if generated during course of visit</p> <ul style="list-style-type: none"> For labs or other types of info not generated within course of visit, it is made available to pts within four business days of info becoming available to EPs Potential to increase both thresholds (% offer and % use) based on experience in Stage 2 <p>Note: Depending on experience in Stage 2, CMS may want to give credit to some providers (e.g. specialists) for view/download/transmit where the patient has requested that they prefer info to be sent to a location they specify (such as another provider portal or PHR), rather than only making available information on the provider's portal.</p>	<p>Automated Transmit:</p> <p>1a. Create the ability for providers to review patient-transmitted information and accept updates into EHR.</p> <p>1b. Related certification criteria: Standards needed for provider directories in order to facilitate more automated transmissions per patients' designations.</p>	<p>intent of making information generated during the visit available within 24 hours, but comment that this could be quite challenging to implement for automated measure calculation from a development perspective, depending on how it is specified. For example, in many ambulatory situations the start/finish of a visit might not be clearly documented in the EHR. So, it is not really possible to have a precise cutoff of 24 hours after the visit, nor is it completely possible to identify what information was generated during the course of the visit.</p> <p>We note that these kinds of very specific timings are examples of where we can all support the intention of the objective, but where the way it is specified can determine whether EHR developers have to invest significant time into new tracking and reporting (without a clear benefit to providers or patients), or whether it can be based on proxies that are already captured. In that vein, we urge flexibility in reporting and no further requirements for specific documentation of when a visit is ended.</p> <p>Similarly, while we agree with the intention that lab results be made available to patients within four business days of the result becoming available to the EP, we note that this is also an extremely complex area for reporting. For example, it seems clear that if a patient has 20 lab results in a year and 19 of them took two weeks to be provided to the patient after they were seen by the EP, and only one of them was provided to the patient in four days, this provider is not meeting the measure for that patient. However, if a patient has 20 lab results in a year and 19 of them are made available within two days and one of them takes five days to get out because the provider was on vacation, does that also mean this patient fails the measure?</p>	<p>around measuring 24 hour ranges of visits, 10 tokens.</p> <p>Automated transmit, 20 tokens.</p> <p>Image exchange, 40 tokens</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>representatives) view, download, or transmit to a third party their health information.</p> <p>EH Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission</p> <p>1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge</p> <p>2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department</p>	<p>MENU item: Automated Transmit*: (builds on "Automated Blue Button Project"): Provide 50% of patients the ability to designate to whom and when (i.e. pre-set automated & on-demand) a summary of care document is sent to patient-designated recipient** (for example, a one-time request to send information from specialist to primary care, or a standing request to always send an updated care summary when certain events arise, such as a change in medication or the completion of new tests or procedures).</p> <p>*Subject to the same conditions as view, download, transmit</p> <p>**Before issuing final recommendations in May 2013, HITPC will also review the result of Automated Blue Button pilots, in addition to considering public comments received.</p>		<p>We are also concerned by the language of the information being available within the course of the visit. Is this intended to measure information that is available but not within the EHR? This will not be possible to measure within the EHR.</p> <p>"Automated transmit" – We note that a key factor in determining how difficult this requirement is to implement in the EHR could be the trigger points the EHR is expected to accommodate. These "certain events" are not clearly specified. We suggest that the implementation of this functionality is likely to be far more complex than the example indicates. It is unlikely that you would want the EHR to automatically send a document upon changes in medication or the completion of a procedure. The recipient could potentially get spammed with documents each time the patient has a visit.</p> <p>We suggest that if such a requirement is introduced, it would be much simpler (and less likely to generate "noise") if simpler trigger points are selected, such as the completion of encounter documentation for an office visit or the discharge of a patient from the ED or inpatient department.</p> <p>We also question whether the applicable standards will be sufficiently mature for Stage 3 given the regulatory and implementation timetable. In addition, we urge consideration of the potential degradation of system performance if a large number of summaries are transmitted automatically.</p> <p>"Including images" – This is a desirable direction that is currently challenging and expensive. Recent and ongoing work on image sharing</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>(POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.</p>	<p>Explore the readiness of vendors and the pros and cons of including certification for the following in this objective:</p> <ul style="list-style-type: none"> • Images (actual images, not just reports) • Radiation dosing information from tests involving radiation exposure in a structured field so that patients can view the amount of radiation they have been exposed to <p>Add a MENU item to enable patients to view provider progress notes (re: Open Notes: Doctors and Patients Signing On. Ann Intern Med. 20 July 2010;153(2):121-125)</p> <p>What is the best way to ensure that individuals access their health information through the view/download/transmit capability are provided with transparency and education about the benefits and potential</p>		<p>standards continues, which is an important step toward this goal.</p> <p>Two of the challenges are:</p> <ol style="list-style-type: none"> 1. It incorporates non-EHR systems such as PACs or image viewers. 2. Medical-quality images are very large, so transmission or downloading of the images can have ramifications on bandwidth. <p>Despite these challenges, there is significant interest in working toward provider-to-provider image exchange and/or patient download and transmission of images. We agree that this is a frequently requested feature by EHR users. Therefore, the EHR Association would like to move forward with this requirement, given the following assumptions:</p> <ol style="list-style-type: none"> 1. The scope of what is otherwise required for Stage 3/2016 certification is such that sufficient attention can be given to this project. 2. Standards work is at a point in 2014-2015 (when development would have to happen) that development can proceed efficiently. 3. Certification is carefully constructed in a way that does not require PACS functions of the EHR or patient portal. 4. It may make sense to start with simpler images like x-rays. 5. It may make sense to focus on the ability to query to the images via a link/pointer included in the transmission. We note that a reference to a DICOM study can be included in the CCDA structure. 6. We also note that, as a practical matter, we need to consider performance issues if there are frequent downloads of large images from PACS as part of VDT. Burning of CDs for patient access is often done "after hours" because of performance reasons. 	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>risks of downloading health information, consistent with the HIT Policy Committee's recommendations of August 16, 2011? Is certification an appropriate vehicle for ensuring such transparency is part of CEHRT? If so, what would the certification requirement look like? If not, what are other mechanisms for ensuring transparency to consumers using the view/download/transmit capabilities?</p> <p>In its recent final rule, and in response to comments, ONC adopted Level A conformance as the standard for the accessibility web content in accordance with the Web Content Accessibility Guidelines (WCAG). ONC indicated per commenters suggestions that WCAG Level AA conformance would be considered for the next edition of certification criteria. Given that all EHR technologies certified to the view, download, transmit to</p>		<p>"Radiation dosing" – We note that for this information to be accurate (and meaningful to a patient), it will likely need to be populated by specialty procedural modules (e.g., radiology information systems, cardiology information systems, oncology information systems, etc.). Population of that information into the EHR/portal could mean expensive interfaces for providers. If the information is in the EHR, we don't see making it available in the portal as a large project, but we question whether it is worthwhile if the information is likely to be incomplete due to the expense of gathering the data reliably.</p> <p>It seems a bit secondary to include dosing in the EHR in relation to VDT. It might be more appropriate to consider dosing in the EHR more comprehensively (where all of the same concerns above also apply).</p> <p>"Transparency and education" – We think a certification requirement that a portal allow a provider to display information about risks to the patient is reasonable. We do not think certification should be prescriptive as to how this is done or what the information is, as different portals and different providers might want to approach such education differently.</p> <p>WCAG Level AA – In our estimates, if 30 tokens are required to assure a portal meets Level A requirements, it will take 10-20 tokens to go from meeting Level A requirements to meeting Level AA requirements for the same portal features. If portal features are expanded (for example, also including image exchange and automated transmit) and Level AA is expected, then Level AA compliance would be a 30 token project.</p> <p>Standards – We suggest that upon transmit, not all data of interest should be required to be included but that the recipient is enabled to</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>a 3rd party certification criterion will have met Level A, how difficult would it be for EHR technology to have to meet Level AA conformance?</p>		<p>query/link to additional information as needed, particularly when images are involved or further detail is needed. Transmitting large images in these documents will pose substantial infrastructure challenges, while providing links with associated viewers supports more practical solutions to access the relevant data.</p> <p>We suggest that the objectives should not prefer one transport method over another. Information exchange should be valid whether pushed to a patient or pulled by the patient.</p> <p>General point – There has been a lot of progress with VDT functionality in Stage 2, and we see lots of potential to move forward with the existing functionality in Stage 3 without adding new certification or meaningful use requirements. Additional requirements might jeopardize more thorough adoption of the functionality that we have already invested in.</p> <p>We think that as patients become engaged, patient requests and provider feedback will drive innovation additions to the patient portal. This market-driven approach might be better than prescriptively adding specific data elements to all portals via this program.</p>	
<p>SG RP 20 4B</p>	<p>New</p>	<p>MENU: Provide 10% of patients with the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care (e.g. patient experience,</p>		<p>While we definitely think that submission and use of patient-generated health information is an important area, we are concerned about including this in EHR certification. As evidenced by the examples given in the objective as described here, there are clearly a lot of ways in which this activity could happen. We are concerned that when further specified in certification, flexibility and innovation in this area will be impeded. Along with this concern about impeding innovation is the concern that (especially if specified in an overly prescriptive manner) this could</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>pre-visit information, patient created health goals, shared decision making, advance directives, etc.). This could be accomplished through semi-structured questionnaires, and EPs and EHRs would choose information that is most relevant for their patients and/or related to high priority health conditions they elect to focus on.</p> <p>Based upon feedback from HITSC this should be a MENU item in order to create the essential functionality in certified EHRs.</p> <p>Readiness of standards to include medical device data from the home? What information would providers consider most valuable to receive electronically from patients? What information do patients think is most important to share electronically with providers? How can the HITECH incentive program support allowing doctors and</p>		<p>become a very large project for EHR and patient portal developers. We urge that the development required for this project be weighed against other proposed projects and that requirements for 2016 and future certification stages be carefully considered.</p> <p>In our experience, many medical devices used at home employ proprietary standards for transmitting data to other systems. Lack of a common standard means that support for each device can be expensive to develop. It does not seem wise to invest a lot in proprietary, differing standards for each device across all EHRs. Instead, it seems better to settle on common standards and then incorporate the standard into EHRs.</p> <p>We note that there are two models of devices support for patients. One model is where a provider enables a device and gives/loans/sells it to the patient. Another model is where a patient might buy his own device and then needs to enable/connect it himself. These might vary significantly in the challenges of supporting them within the patient portal/EHR. We caution about making assumptions about which model would be used when considering the development difficulty or the expense of this as a requirement. For example, if providers are assuming that patients will be able to buy and connect their own devices and EHR developers are assuming that the device will be known to the provider before the patient connects it, there are challenges. However, we do not think it is appropriate to mandate one particular model, especially given the current lack of standards in this area. Mandating specific device models is likely to impede innovation.</p> <p>There are concerns about reconciling patient-generated information with</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>patients to mutually agree on patient generated data flows that meet their needs, and should the functionality to collect those data be part of EHR certification? Please provide published evidence or organizational experience to support suggestions.</p>		<p>provider-generated information if there is a conflict.</p> <p>The measurement being suggested is not clear. Is it 10% of an EP's patient panel, of those seen in the measurement period, patients with particular conditions, or some other qualifier?</p> <p>Because we see market forces already at work in this area, we suspect the market will continue to drive further portal/device integration in innovative ways, and do not suggest incorporating this into certification.</p> <p>If added, keep this item very non-prescriptive and take careful precautions to not constrain EHR functionality.</p>	
<p>SG RP 20 4D</p>	<p>New</p>	<p>Objective: Provide patients with the ability to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) through VDT in an obvious manner.</p>		<p>We find it very challenging to comment meaningfully on this proposal as it is very unclear what is envisioned. It would be easier for us to provide helpful and specific feedback if the proposal were more clear (or more intentionally vague).</p> <p>For example, we suggest that using the existing secure messaging features to send a message describing the error in the record should be sufficient. Or is something complex requiring patient discrete interaction with all portions of the record going to be required?</p> <p>Depending on further definition, we consider this a high risk of being a very large project and therefore a risk to other innovative projects.</p> <p>The 0-1 token response to this is to use existing secure messaging feature to suggest a change.</p>	<p>0-1 tokens – remove as a new requirement and use secure messaging for this purpose.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
				<p>We are confused by the lack of a measurement.</p> <p>Overall, we suggest removing this as an objective and a certification requirement because the goal can be accommodated by secure messaging.</p>	
SG RP 20 5	<p>EP Objective: Provide clinical summaries for patients for each office visit</p> <p>EP Measure: Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits.</p>	<p>The clinical summary should be pertinent to the office visit, not just an abstract from the medical record.</p> <p>What specific information should be included in the after visit summary to facilitate the goal of patients having concise and clear access to info about their most recent health and care, and understand what they can do next, as well as when to call the doctor if certain symptoms/events arise?</p>		<p>Without experience with Stage 2, this is premature. Stage 2 already specifies what information should be included in the clinical summary – it is not just an abstract from the medical record. The C-CDA supports eight types of summaries and Stage 2 already supports this functionality. It would be better to address any concerns that emerge in Stage 2 via ONC and CMS FAQs, but don't affect measurement/reporting.</p>	
SG RP 20 6	<p>EP/EH Objective: Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the</p>	<p>Additional language support: For the top 5 non-English languages spoken nationally, provide 80% of patient-specific education materials in at least one of those languages based on EP's or EH's local population,</p>		<p>This will be very challenging for providers. EHRs support is not particularly challenging. However, we anticipate several challenges with content:</p> <ol style="list-style-type: none"> 1. Content is not necessarily available and could be expensive. 2. How would you measure whether such content is available? 3. The top five languages are not relevant in all geographic areas. 	<p>10 tokens, if patient education vendor has support for patient education in the required languages. If this</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>patient</p> <p>EP CORE Measure: Patient specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period</p> <p>EH CORE Measure: More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient- specific education resources identified by Certified EHR Technology</p>	<p>where publically available.</p>		<p>4. Why five? We note that statistics on languages used throughout the country show a sharp drop off in numbers after English and Spanish.</p> <p>The proposed measurement is quite confusing. Do we give 80% of non-English speaking patients this? 80% of patient education materials to patients speaking a specific supported language? 80% of patient education materials in one of the non-English languages? Is this referring to preferred language in the demographic area or any language read/spoken by the patient?</p> <p>Tagalog is a top-five language right now; We have not found any patient education vendor with that content.</p> <p>80% where publically available is not measurable because availability cannot be determined. There could also be high costs to providers depending on the languages required.</p>	<p>requires translation or more complex search of patient education materials, then it a very complex and much larger project.</p>
<p>SG RP 20</p>	<p>EP Objective: Use secure electronic messaging to</p>	<p>Measure: More than 10% of patients use secure electronic messaging to communicate with</p>	<p>Create capacity for electronic</p>	<p>Wording – First, we’re confused by the change in wording in the measure. Is the measure in Stage 3 intended to be something different than the measure in Stage 2? We assume so because the wording is</p>	<p>There do not seem to be functionality</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
7	<p>communicate with patients on relevant health information</p> <p>EP Measure: A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period</p>	<p>EPs*</p> <p>*What would be an appropriate increase in threshold based upon evidence and experience?</p>	<p>episodes of care (telemetry devices, etc.) and to do e-referrals and e-consults</p>	<p>different, but it is unclear to us what the intended difference is.</p> <p>Threshold – 5% is already challenging, especially for a 90 day reporting period. We are not sure that patient demand for messaging supports such a high threshold. Much lower percentages of messaging likely indicate thorough adoption.</p> <p>One option would be to change the measurement. Doing this must carefully weigh the confusion introduced by changing measurements. However, if the new measurement were more appropriate, the confusion and effort might be warranted. Experience indicates that some patients will never message and some patients might frequently message. While having some patients quite engaged through messaging is a good indicator of adoption, it is not reflected in this threshold. It might be more appropriate to measure total messages received/unique patients seen during EHR reporting period.</p> <p>That new measure might mean that it is possible to exceed 100%, but we don't think that is likely. And even if 100% is exceeded, we think the total volume of messages received would be a good indicator of whether the functionality is being broadly encouraged and used.</p> <p>For physicians with healthy panels, measuring volume is better. Consider that healthy patients coming in just for preventive visits don't message. Patients whose encounters are time-limited, such as patients being seen for a broken leg, are not likely to message. It would be more important to have functionality available rather than specify messaging volumes.</p> <p>The EHR Association could survey mature portal users among our clients</p>	<p>changes, so 0 tokens.</p> <p>Measurement changes would require tokens for automated measure calculation.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
				<p>and give their current volume.</p> <p>Overall, we urge the Policy Committee, ONC, and CMS to make policy decisions on thresholds based on actual experience with Stage 2 and keep the measure language the same as in Stage 2.</p>	
SG RP 20 8	Not included separately (in reminder objective)	EP and EH Measure: Record communication preferences for 20% of patients, based on how (e.g., the medium) patients would like to receive information for certain purposes (including appointment reminders, reminders for follow up and preventive care, referrals, after visit summaries and test results).		<p>Our comments are based on the assumption that this item would be measured against the standard "unique patients" denominator.</p> <p>Most EHRs already accommodate one communication preference, but this requirement indicates more fields and clicks are necessary.</p> <p>When measuring, must all types be documented to satisfy the requirement? At least two types? Etc.</p>	<p>1 comm preference, 0 tokens</p> <p>Multiple comm preferences, ?? tokens</p>
SG RP 20 9	New	<p>Certification Rule Only:</p> <p>Capability for EHR to query research enrollment systems to identify available clinical trials. No use requirements until future stages.</p> <p>The goal of this objective is to facilitate identification of relevant clinical trials for an individual patient, subject to patient</p>		<p>There are general concerns about adding functionality that is rarely requested by users. Even if there is not an associated meaningful use objective/measure, there are costs to providers in terms of development resources being diverted from higher priority provider development preferences and also making EHR workflow more complex than necessary. With respect to this new proposed certification criterion, clients are not asking for this functionality.</p> <p>We are not aware of a centralized registry that is ready to accept these queries and give back the results. We are concerned that this will create a situation as we saw in public health where all the EHRs were certified</p>	Possibly large tokens for standards community

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		interest.		<p>to a standard that public health agencies could not reliably support. NIH has a clinical trials registry where most are captured but they are not able to parse information in this way right now.</p> <p>Real time evaluation is challenging. There can be performance challenges to do this.</p> <p>This approach seems to dictate that the EHR is always electronically connected, which is not always possible. For example, might be portable and not always connected, or might be used in areas without broadband.</p> <p>We suggest that ONC, CMS and NLM could facilitate this direction without requiring new functionality. InfoButton capabilities might be a useful tool. We are not familiar with existing standards/implementation guides that support this query capability, although HL7 V2 has basic building blocks to put a guide together. Absence of such guidance indicates it is too premature to pursue this objective.</p>	
Improve Care Coordination					
SG RP 30 2	EP/EH CORE Objective: The EP/EH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation.	EP / EH / CAH Objective: The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform reconciliation for: - medications - medication allergies - problems	Reconciliation of contraindications (any medical reason for not performing a particular therapy;	<p>The workflow impact on providers needs to be carefully considered. For example, consider a scenario where an EP is reconciling an allergy. One chart says "rash" as the reaction, another says "hives." They don't match exactly, but the EP might not want to prioritize figuring out whether the reaction is really rash or hives or both.</p> <p>Fundamentally we would like to see analysis of the use of Stage 2 functionality to reconcile allergies and problem lists prior to expanding any reconciliation requirements for meaningful use. We suggest that ONC</p>	PAM reconciliation is already in 2014 certification, so 0 tokens for that.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>EP/EH CORE Measure: The EP, eligible hospital or CAH performs medication reconciliation for more than 50% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)</p>	<p>EP / EH / CAH Measure: The EP, EH, or CAH performs reconciliation for medications for more than 50% of transitions of care, and it performs reconciliation for medication allergies, and problems for more than 10% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23). SC&C Recommendation: Standards work needs to be done to adapt and further develop existing standards to define the nature of reactions for allergies (i.e. severity).</p>	<p>any condition, clinical symptom, or circumstance indicating that the use of an otherwise advisable intervention in some particular line of treatment is improper, undesirable, or inappropriate)</p> <p>SC&C Recommendation: Standards work needs to be done to support</p>	<p>look to the IHE reconciliation profile.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			the valuing and coding of contraindications.		
SG RP 30 3	<p>EP/EH CORE Objective: The EP/EH/CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care provides summary care record for each transition of care or referral.</p> <p>CORE Measure: 1. The EP, eligible hospital, or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of</p>	<p>EP/ EH / CAH Objective: EP/EH/CAH who transitions their patient to another setting of care or refers their patient to another provider of care</p> <p>Provide a summary of care record for each site transition or referral when transition or referral occurs with available information</p> <p>Must include the following four for transitions of site of care, and the first for referrals (with the others as clinically relevant):</p> <ol style="list-style-type: none"> 1. Concise narrative in support of care transitions (free text that captures current care synopsis and expectations for transitions and / or referral) 2. Setting-specific goals 3. Instructions for care during transition and for 48 hours 		<p>What is DECAF?</p> <p>30% for electronic transitions might face same referral pattern influence of Stage 2.</p> <p>This capability is already supported in the C-CDA. If this change is made, keep it general and focus on the addition of narrative vs. specific content. Avoid measurement problems that will come from specific requirements that cannot be verified by the EHR. We question the expected timing of the new S&I data for inclusion in the C-CDA.</p> <p>From a standards perspective:</p> <ol style="list-style-type: none"> 1. (1)"Concise narrative in support of care transitions..." is confusing as it is not clear whether this is intended to be a separate supporting document to manage administrative aspects of the care transition, or whether this is merely a narrative of the reason for transition to be sufficiently expanded upon in the main transition document. 2. (2) "Setting-specific goals" and (3) "Instructions for care...." are confusing. What is really meant with these? We need more specifics to understand scope. Is the intent to be clinician-focused goals, patient-focused goals, either? 3. There is a sense that (4) "Care team members...." could be addressed 	Development implications seem small, but could require more implementation.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>transitions of care and referrals.</p> <p>2. The EP, eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either (a) electronically transmitted using CEHRT to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a NWHIN Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the nationwide health information network.</p>	<p>afterwards</p> <p>4. Care team members, including primary care provider and caregiver name, role and contact info (using DECAF)</p> <p>Measure: The EP, eligible hospital, or CAH that site transitions or refers their patient to another setting of care (including home) or provider of care provides a summary of care record for 65% of transitions of care and referrals (and at least 30% electronically).</p> <p>Certification Criteria: EHR is able to set aside a concise narrative section in the summary of care document that allows the provider to prioritize clinically relevant information such as reason for transition and/or referral.</p> <p>Certification Criteria: Inclusion of data sets being defined by S&I Longitudinal Coordination of Care WG, which and are expected to</p>		<p>through (1) as part of header information. Is that the idea, or is this meant to be something different? It is not clear whether in this case family members/caregivers are to be considered part of the care team or not.</p> <p>4. The Beacon Communities, working with EHR developers, have published a C83 to C-CDA glide path. The EHR/HIE Interoperability Workgroup and eHealth Exchange (just re-started very recently) are jointly working on a similar C32 to C-CDA glide path. These efforts should be consolidated.</p> <p>5. We suggest that the standards being developed/updated to support Longitudinal Coordination of Care (and other new/updated standards for next edition as well) go through, at a minimum, the equivalent of two IHE Connectathons (lighter weight than pilots. This would help identify and resolve specification and implementation issues, while ideally a number of actual implementations further demonstrate that the standards are implementable.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>3. An EP, eligible hospital or CAH must satisfy one of the two following criteria: (A) conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for EPs the measure at §495.6(j)(14)(ii) (B) and for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2); or (B) conducts one or more successful tests with the CMS</p>	<p>complete HL7 balloting for inclusion in the C-CDA by Summer 2013:</p> <ol style="list-style-type: none"> 1) Consultation Request (Referral to a consultant or the ED) 2) Transfer of Care (Permanent or long-term transfer to a different facility, different care team, or Home Health Agency) 			

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	designated test EHR during the EHR reporting period.				
SG RP 30 4	New		<p>EP/ EH / CAH Objective: EP/ EH/CAH who transitions their patient to another site of care or refers their patient to another provider of care</p> <p>For each transition of site of care, provide the care plan information , including the following</p>	<p>We support the S&I Framework initiative to further define the interoperability requirements and specific standards/implementation guidance in support of this future objective. Depending on its progress and maturity, further timing of this objective should be considered. We agree this would be some time after Stage 3.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>elements <u>as applicable</u>:</p> <ul style="list-style-type: none"> •Medical diagnoses and stages •Functional status, including ADLs •Relevant social and financial information (free text) •Relevant environmental factors impacting patient's health (free text) •Most likely course of illness or condition, in broad terms (free text) 		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<ul style="list-style-type: none"> •Cross-setting care team member list, including the primary contact from each active provider setting, including primary care, relevant specialists, and caregiver •The patient's long-term goal(s) for care, including time frame (not specific to setting) and 		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>initial steps toward meeting these goals</p> <ul style="list-style-type: none"> •Specific advance care plan (POLST) and the care setting in which it was executed <p>For each referral, provide a care plan if one exists</p> <p>Measure: The EP, eligible hospital, or CAH that transitions or refers their patient to</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>another site of care or provider of care provides the electronic care plan information for 10% of transitions of care to receiving provider and patient/care giver.</p> <p>Certification Criteria: Develop standards for a shared care plan, as being defined by S&I Longitudina</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>Coordination of Care WG. Some of the data elements in the shared care plan overlap content represented in the CDA. Adopt standards for the structured recording of other data elements, such as patient goals and related interventions.</p>		
SG RP 30	New	EP / EH / CAH Objective: EP/EH/CAH to whom a patient is referred acknowledges receipt of	Continue working to close the	We are not clear what is being proposed for tracking. We think what is being tracked is:	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
5		<p>external information and provides referral results to the requesting provider, thereby beginning to close the loop.</p> <p>Measure: For patients referred during an EHR reporting period, referral results generated from the EHR, 50% are returned to the requestor and 10% of those are returned electronically</p> <p>Certification Criteria: Include data set defined by S&I Longitudinal Coordination of Care WG and expected to complete HL7 balloting for inclusion in the C-CDA by Summer 2013: Shared Care Encounter Summary (Consultation Summary, Return from the ED to the referring facility, Office Visit)</p>	<p>loop with an acknowledgment of order receipt and tracking for completion.</p> <p>Certification criteria: Include standards for referral requests that require authorizations (or pre-certifications) for procedure, surgery, lab, radiology, test orders.</p>	<p>1. I received this referral in my EHR. 2. If the referral encounter happens, then that the result of the referral encounter is sent to referrer.</p> <p>We note that it will be challenging to measure this when the referral result is not a referral letter, e.g., if the referral result is just a test result.</p> <p>The requirement to return results electronically can still be challenging if the referrers don't have EHRs.</p> <p>We are concerned that while materials may begin to be available mid-2013, there is insufficient time to mature and solidify the guidance by the time this would need to be implemented to support widespread, mandated adoption. As this objective also requires acknowledgement of receipt, it introduces further complexities to manage that workflow properly between disparate systems. It is unclear that this workflow is well defined in terms of content, behavior, and responsibilities. Would this involve a simple "accept"-level acknowledgement by the system or application-level acknowledgement possibly involving a provider's express acknowledgement?</p> <p>Note that the 360x project may not be far along to enable a mature standard to be referenced.</p> <p>In sum, this proposed objective/measure is premature for Stage 3, although there is relevant work in progress as referenced. We think the indicated timing and activated maturity are too optimistic.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
SG RP 12 7	New	New	Ability to maintain an up-to-date interdisciplinary problem list inclusive of versioning in support of collaborative care		
SG RP 12 5	New	New	Medication reconciliation: create ability to accept data feed from PBM (Retrieve external medication fill history for medication adherence monitoring)		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			Vendors need an approach for identifying important signals such as: identify data that patient is not taking a drug, patient is taking two kinds of the same drug (including detection of abuse) or multiple drugs that overlap.		
SG RP 30 8	New	EH Objective: The EH/CAH will send electronic notification of a significant healthcare event in a timely manner to key members of the patient’s care team, such as the primary care provider,		The goal is desirable but there is some complexity to be ironed out around measurement. The definition of “significant events” is important, as is “key members of the team”. There are several ambiguous terms used that would make measurement difficult. It is unclear what is meant by “electronic	Token estimate depends on approach and the availability of standards. Would have both

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>referring provider or care coordinator, with the patient's consent if required.</p> <p>EH Measure: For 10% of patients with a significant healthcare event (arrival at an Emergency Department (ED), admission to a hospital, discharge from an ED or hospital, or death), EH/CAH will send an electronic notification to at least one key member of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required, within 2 hours of when the event occurs.</p>		<p>notification". Should there be a standard, or would it be better to be non-prescriptive? We suggest deferring the proposed objective but, if retained, we propose that the method should remain unspecified.</p> <p>As we focus on increased exchange, and hospitals are starting to send ED notifications and summary of care reports, we do not think that this additional requirement is warranted, especially where measurement is so problematic.</p> <p>Note that many of the events cited by this proposed measure occur when a care manager is involved. Moreover, ACOs are likely to implement such efforts, and it could be challenging to track care management (using non-EHR functionality) vs. meaningful use.</p> <p>Finally, what notifications would require patient consent? The need for consent could further complicate measurement.</p> <p>Overall, reporting will be problematic given the definition. There are also privacy issues. Fundamentally, there are too many contingencies for implementation and measurement for meaningful use. We believe that the market will drive this functionality and that the timing is too tight for Stage 3 certification and meaningful use.</p>	development and implementation impact.
Improve population and public health					
SG RP 40 1A	EP/EH Objective: Capability to submit electronic data to immunization registries or immunization	EP/ EH Objective: Capability to receive a patient's immunization history supplied by an immunization registry or immunization information	EP/EH Objective: Add submission of vaccine	We are concerned that using immunization data discretely within the chart for CDS would require reconciliation, as registries sometimes include duplicate documentation of the same immunization. If bidirectional interfaces for immunizations will be created and are expected to be discretely reflected in the EHR for clinical decision	Consuming discrete immunization data would be similar to clinical

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>information systems except where prohibited, and in accordance with applicable law and practice</p> <p>EP/EH Measure: Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period</p>	<p>system, and to enable healthcare professionals to use structured historical immunization events in the clinical workflow, except where prohibited, and in accordance with applicable law and practice.</p> <p>Measure: Documentation of timely and successful electronic receipt by the Certified EHR Technology of vaccine history (including null results) from an immunization registry or immunization information system for 30% of patients who received immunizations from the EP/EH during the entire EHR reporting period.</p> <p>Exclusion: EPs and EHs that administer no immunizations or jurisdictions where immunization registries/immunization information systems cannot provide electronic immunization histories.</p> <p>Certification criteria: EHR is</p>	<p>contraindication(s) and reason(s) for substance refusal to the current objective of successful ongoing immunization data submission to registry or immunization information systems.</p>	<p>support, then it will likely be necessary to reconcile immunizations. This could be a large project. It would be more reasonable to start with bidirectional interfaces that are not reconciled discretely. Information is still available to providers in this way.</p> <p>We suggest that this be a menu item, if added.</p> <p>The criterion should only indicate that the EHR is able to receive, and should not over-prescribe who initiates the request and how that happens.</p> <p>In the measure, it is unclear what "timely" receipt is. We suggest avoiding that complexity in measurement and instead focusing on a simpler measure of how many patients had immunizations and how many queries happened.</p> <p>We suggest a low threshold to start the implementations without causing problems with a high threshold.</p> <p>It would be good to know how many states will have the ability to do this in 2016. It may be appropriate to have this as a menu item for use where states are ready.</p> <p>CDC CVX/NDC work would need to align that work with these timeframes. Our recommendation:</p> <ol style="list-style-type: none"> 1. Evaluate final CDC guidelines. 2. Evaluate which states can implement. If >25 states can support, then we would want to move forward as menu. 3. Keep threshold low to allow some experimentation prior to expanded 	<p>information reconciliation for problems, meds, allergies. Would need to match to individual formularies for CDS to work.</p>

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		able to receive and present a standard set of structured, externally-generated, immunization history and capture the act and date of review within the EP/EH practice.		use. Overall, this objective and measure are very challenging and premature. There is too much state implementation variability. The CDC has an important role in clarifying state capabilities. There would also be a need to reconcile immunization information.	
SG RP 40 1B	New	<p>EP/EH Objective: Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations (including immunization events from immunization registries or immunization information systems) as applicable by local or state policy.</p> <p>Measure: Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization.</p>		<p>This is very premature.</p> <p>There is complexity to the measure that would need reduction and revision.</p> <p>It is not clear which standard is intended to be used to exchange these recommendations, or whether this refers to the CDC's immunization forecasting rules set. Depending on the complexity of the required EHR support (electronic receipt of a rule set, or manual set-up according to a common rule set), this objective may not be achievable during Stage 3. Electronic transmission would require further guidance if the Health eDecisions approach is to be used, or an alternative needs to be established. Neither will be attainable by the time this would need to be implemented for Stage 3.</p> <p>Reminders for immunizations are likely common practice. But standards for this, local variations, interoperability of such recommendations, more complicated catch up schedules, etc., add significant complexity. This requirement is very challenging to evaluate.</p> <p>What is meant by local variation? Is it supported by a flexible mechanism or are vendors expected to accommodate all local variations?</p>	Not enough information to evaluate, potentially large.

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>Exclusion: EPs and EHs that administer no immunizations.</p> <p>Certification criteria: EHR uses a standard (e.g., national, state and/or local) rule set, plus patient age, gender, and prior immunization history to recommend administration of immunizations; capture the act and date/time of recommendation review.</p>			
<p>SG RP 40 2A</p>	<p>EH Objective: Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice</p> <p>Measure: Successful ongoing submission of electronic reportable laboratory results from Certified EHR</p>	<p>EH Objective (unchanged): No change from current requirement for electronic lab reporting which generally is sent from the laboratory information system</p>		<p>We suggest that the implementation guide for electronic lab reporting to public health needs to further harmonized with the laboratory results interface for ambulatory providers to ensure full consistency when transmitting lab results for one or both purposes.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	Technology to public health agencies for the entire EHR reporting period.				
SG RP 40 2B	New	New	EP Objective: Capability to use externally accessed or received knowledge (e.g. reporting criteria) to determine when a case report should be reported and then submit the initial report to a public health agency, except	Standards for accessing knowledge are not mature, while standards for receiving knowledge are in progress (S&I Framework Health eDecisions). We support further efforts to complete and mature the necessary standards in support of this objective for consideration some time after Stage 3.	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>where prohibited, and in accordance with applicable law and practice.</p> <p>Measure: Attestation of submission of standardized initial case reports to public health agencies on 10% of all reportable disease or conditions during the entire EHR reporting period as</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>authorized, and in accordance with applicable state/local law and practice.</p> <p>Certification criteria: The EHR uses external data to prompt the end-user when criteria are met for case reporting. The date and time of prompt is available for audit. Standardize</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>d (e.g., consolidated CDA) case reports are submitted to the state/local jurisdiction and the data/time of submission is available for audit. Could similar standards be used as those for clinical trials (SGRP209)?</p>		
SG RP 40 3	<p>EP MENU Objective: Capability to submit electronic syndromic surveillance data to public health agencies,</p>	<p>No change from current requirements.</p>		<p>This seems appropriate given current state of this objective.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>except where prohibited, and in accordance with applicable law and practice</p> <p>EH Objective: Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice</p> <p>EP/EH Measure: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period</p>				
SG	EP only MENU	EH/EP Objective: Capability to		We question whether these registries really will all accept a standard	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
RP 40 4	<p>Objective: Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice.</p> <p>EP only MENU Measure: Successful ongoing submission of cancer case information from CEHRT to a public health central cancer registry for the entire EHR reporting period</p>	<p>electronically participate and send standardized (i.e. data elements and transport mechanisms), commonly formatted reports to a mandated jurisdictional registry (e.g., cancer, children with special needs, and/or early hearing detection and intervention) from Certified EHR to either local/state health departments, except where prohibited, and in accordance with applicable law and practice. This objective is in addition to prior requirements for submission to an immunization registry.</p> <p>Measure: Documentation of ongoing successful electronic transmission of standardized reports from the Certified EHR Technology to the jurisdictional registry. Attestation of submission for at least 10% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable State law and</p>		<p>format. We would like a list of registries that accept the standard formats.</p> <p>This requirement needs mature standards at the time the final rule is defined so that it can be implemented by 2016. We request clarification of what "build" means. We suggest that it can be any combination of automatic and/or clinician-composed reports, using standards, such as the cancer staging standard by AJCC (www.cancerstaging.org). Where standard vocabulary is appropriate, this should be clarified.</p> <p>Please confirm that the provider can choose which registry to submit to. Attestation is important for meaningful use given patient registry qualification requirements.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>practice.</p> <p>Certification criteria: EHR is able to build and then send a standardized report (e.g., standard message format) to an external mandated registry, maintain an audit of those reports, and track total number of reports sent.</p> <p>Exclusion: where local or state health departments have no mandated registries or are incapable of receiving these standardized reports</p>			
<p>SG RP 40 5</p>	<p>EP only MENU Objective: Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice.</p>	<p>EP Objective: Capability to electronically submit standardized reports to an additional registry beyond any prior meaningful use requirements (e.g., immunizations, cancer, early hearing detection and intervention, and/or children with special needs). Registry examples include hypertension, diabetes, body mass index,</p>		<p>Again, we question whether the recipients can take the standard report. We suggest that ONC encourages registries to align their implementation guides with the C-CDA document family. This will promote consistency of reporting across registries, easing implementation efforts for software developers, providers, and registries alike.</p> <p>Increasing the number of interfaces increases costs for providers, which must be balanced with the interest in collecting this data.</p> <p>We suggest combining 404 and 405, and choosing one for Stage 3 to move in that direction.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
	<p>EP only MENU Measure: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period</p>	<p>devices, and/or other diagnoses/conditions) from the Certified EHR to a jurisdictional, professional or other aggregating resources (e.g., HIE, ACO), except where prohibited, and in accordance with applicable law and practice.</p> <p>Measure: Documentation of successful ongoing electronic transmission of standardized (e.g., consolidated CDA) reports from the Certified EHR Technology to a jurisdictional, professional or other aggregating resource. Attestation of submission for at least 10% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable state/local law and practice.</p> <p>Certification criteria: EHR is able to build and send a standardized message report format to an external registry,</p>		<p>The first "e.g., in EP Objective" is confusing. For example, we are not sure about the origin of "early hearing detection and intervention, etc." being considered prior meaningful use requirements. They were not in Stage 2.</p> <p>We suggest that that while the EHR may be certified against a particular standard (transport and/or content), providers can count reporting using any format or method towards their measurement attainment for this objective and measure.</p> <p>We note that modular certification could be very important for this item. In addition, ONC and CMS should be clear that not all submitted data need come from CEHRT.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		maintain an audit of those reports, and track total number of reports sent.			
SG RP 40 7	New	<p>EH Objective: Capability to electronically send standardized Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) using a common format from the Certified EHR, except where prohibited, and in accordance with applicable law and practice.</p> <p>Measure: Documentation of successful electronic transmission of standardized healthcare acquired infection reports to the NHSN from the Certified EHR Technology. Total numeric count of HAI in the hospital and attestation of Certified EHR electronic submission of at least 10% of all reports during the entire EHR reporting period as authorized, and in accordance with applicable State law and</p>		<p>The common format currently in use requires a large number of data elements, including ones that likely have to be manually abstracted. We are not sure that encouraging abstraction is a good direction for the EHR program. We suggest that if included, this should definitely be a menu item, and should be considered optional in certification of a complete EHR.</p> <p>The current standard (HAI CDA in ballot) should be used. A clear definition of "successful electronic transmission" will be needed for measurement. For example, "sent" vs. "system acknowledgement" vs. "application acknowledgement" vs. "end-user confirmation of receipt". The transport mechanism chosen would need to support whatever is necessary for measurement.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>practice.</p> <p>Certification criteria: EHR is able to sending a standard HAI message to NHSN, maintain an audit and track total number of reports sent.</p>			
SG RP 40 8	New	New	<p>EH/EP Objective: Capability to electronically send adverse event reports (e.g., vaccines, devices, EHR, drugs or biologics) to the Federal Drug Administration (FDA) and/or</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>Centers for Disease Control and Prevention (CDC) from the Certified EHR, except where prohibited, and in accordance with applicable law and practice.</p> <p>Measure: Attestation of successful electronic transmission of standardized adverse event reports to the FDA/CDC</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			<p>from the Certified EHR Technology. Total numeric count (null is acceptable) of adverse event reports from the EH/EP submitted electronically during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.</p>		

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
			Certification criteria: EHR is able to build and send a standardized adverse event report message to FDA/CDC and maintain an audit of those reports sent to track number of reports sent (Common Format).		
Information Exchange					
IEWG 101	New	MENU objective: For patients transitioned without a care summary, an individual in the practice should query an outside entity. The intent of this		We support adding query functionality in Stage 3, with a continued focus on document access. These functions are generally consistent with applicable IHE profiles. We can see the advantages of these features in both peer-to-peer exchanges as well as with HIE intermediaries.	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>objective is to recognize providers who are proactively querying.</p> <p>Certification criteria: The EHR must be able to query another entity for outside records and respond to such queries. The outside entity may be another EHR system, a health information exchange, or an entity on the NwHIN Exchange, for example. This query may consist of three transactions:</p> <ul style="list-style-type: none"> a) Patient query based on demographics and other available identifiers, as well as the requestor and purpose of request. b) Query for a document list based for an identified patient c) Request a specific set of documents from the returned document list <p>When receiving inbound patient query, the EHR must be able to:</p>		<p>We note that there is no measure proposed for this objective. We strongly support addition of query functionality in EHRs and the ability of providers to use query functionality. We urge choosing final measures that can be readily captured by the EHR and that reflect the availability of needed infrastructure, while also providing an impetus for such system capabilities to be available.</p> <p>Some suggestions of areas that will need particular attention for implementation:</p> <ol style="list-style-type: none"> 1. Protecting patient privacy. Of particular concern is not confirming association of an individual with a particular covered entity prior to patient authorization. Attention should be given to how this association happens in non-electronic workflows to ensure that electronic workflows do not introduce new risks. 2. Non-prescriptive requirements will need to be in place for establishing a trusted query. 3. Additional work on patient authorization and consent standards will be needed, and the timeline for this work will need to be expedited if this is to be included in Stage 3. 4. Generally, existing IHE profiles (XCA, XDS-b, XCPD, PIX, BPPC) can support the query requirements. 5. It might make more sense to break this requirement into two separate certification criteria, one for sending queries and one for responding to queries. If a provider wishes to have separate systems to perform the functions, having separate criteria could be important. The rationale is that a provider might want to have his EHR perform a query for a patient who is here for an office visit, but that the provider's EHR might not be available 24/7 to be queried, and that 	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>a) Tell the querying system whether patient authorization is required to retrieve the patient's records and where to obtain the authorization language*. (E.g. if authorization is already on file at the record-holding institution it may not be required).</p> <p>b) At the direction of the record-holding institution, respond with a list of the patient's releasable documents based on patient's authorization</p> <p>c) At the direction of the record-holding institution, release specific documents with patient's authorization</p> <p>The EHR initiating the query must be able to query an outside entity* for the authorization language to be presented to and signed by the patient or her proxy in order to retrieve the patient's records. Upon the</p>		<p>the provider might accomplish making his charts available through another means such as sending records to an HIE to make those records accessible for query.</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		<p>patient signing the form, the EHR must be able to send, based on the preference of the record-holding institution, either:</p> <ol style="list-style-type: none"> 1. a copy of the signed form to the entity requesting it 2. an electronic notification attesting to the collection of the patient's signature <p><i>*Note:</i> The authorization text may come from the record-holding EHR system, or, at the direction of the patient or the record-holding EHR, could be located in a directory separate from the record-holding EHR system, and so a query for authorization language would need to be directable to the correct endpoint.</p>			
IE WG 10 2	New	Certification criteria: The EHR must be able to query a Provider Directory external to the EHR to obtain entity-level addressing information (e.g. push or pull		<p>Is this already incorporated in the HISP functionality in Direct applicability statement?</p> <p>We are concerned with establishing this as a distinct Stage 3 requirement for EHRs. While there are standards, there are issues around implementation: who will host, what are the costs, what is the</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		addresses).		<p>relative value? Furthermore, the maturity level is not high enough to begin widespread mandated implementation. Actual implementations are necessary to further establish the necessary implementation guidance.</p> <p>We note that under the S&I Framework, attempts were made to find simpler approaches, e.g., web mark-up. That work gained some traction, but ultimately lost momentum. For example, embedding addresses in web pages would circumvent ownership, governance, and inclusion/exclusion management issues. These issues need to be resolved.</p> <p>We suggest this topic be reinvigorated within the S&I Framework before this can be considered for inclusion, which would be after Stage 3.</p>	
IE WG 10 3	New	<p>Certification criteria: Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the</p>		<p>In general, we do not support expanding beyond new Stage 2 functionality and urge the Policy Committee, ONC, and CMS to evaluate the usage/effectiveness of the 2014 certification requirement.</p> <p>Keep this objective aligned generally with the C-CDA requirement for other objectives and the common meaningful use data set. If one or two new data elements are to be added for other Stage 3 objectives, add those, but do not expand this data set beyond what is otherwise in the C-CDA and the current requirement.</p> <p>We suggest that this objective uses the same content as for transition of care/summary of care documents, and allow for individual encounters to be transmitted as individual documents. This addresses the ability of the receiving system to manage data consistently as if it was a transition of</p>	

ID #	Stage 2 Final Rule	Stage 3 Recommendations	Proposed for Future Stage	EHR ASSOCIATION	Average EHR ASSOCIATION Development Estimate
		specified standard(s): (i) <i>Encounter diagnoses</i> . The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3); (ii) <i>Immunizations</i> . The standard specified in § 170.207(e)(2); (iii) Cognitive status; (iv) Functional status; and (v) <i>Ambulatory setting only</i> . The reason for referral; and referring or transitioning provider's name and office contact information. (vi) <i>Inpatient setting only</i> . Discharge instructions.		care. Thus, for one patient the summary could be multiple documents or just one. This objective would benefit from an S&I Framework initiative to better define use cases, alternative methods, value proposition, etc., for potential changes after Stage 3.	

Meaningful Use

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

First, we note that providers meet all core objectives and a set of the menu objectives, not all criteria, so the first sentence is not strictly accurate. Nonetheless, it is true, and sometimes problematic, that providers must fully exceed the measures for all of their applicable core and menu items. On balance, we think that some level of flexibility is worth exploring if it can be done in a way that does not complicate compliance or reporting.

If we understand the that intention of the question is whether it would be better to provide flexibility in the model, requiring the provider to score at least 10 points for a particular goal; and then for the same goal (e.g., VDT), different thresholds could achieve different points (say 10% earns one point and 20% earns two points), we

are supportive of this approach. The provider could choose which objectives to focus on high achievement of a threshold vs. which objectives might be deferred or achieved at a lower level. We suggest that there might be a required number of points per priority area to keep balance in achievement of different goals.

Overall, we believe that flexibility such as the example described above would be appealing to hospitals and eligible professionals in allowing them to focus on areas where they think they can make the most difference for their patients. We note that there would likely be increased complexity in understanding what is required, since that would vary based on a particular goal. Broadly, we defer to providers and hospitals as to whether this is appropriate flexibility for the program. As EHR developers, we note that if adding flexibility to the program creates new requirements for automated measure calculation (i.e., something other than numerator/denominator capture and display), the cost of such reporting changes would have to be considered among all of the other development expenditures proposed above. We suggest that if flexibility is added, it be done in a way that does not require changes to automated measure calculation.

We suggest that it would be important for the CMS web portal or other tools to be able to help providers understand how to achieve more flexible goals.

Another option for providing flexibility would be to give each provider/hospital a "pass" for one or a particular number of objectives that they are exempted from reporting, on top of the existing exclusions and menu choices.

Another idea is to expand greatly the menu set and narrow the core set, giving more choices to providers on where to focus their efforts.

2. What is the best balance between ease of clinical documentation and the ease of practice management efficiency?

We are not sure we understand the question. We do not see a general conflict between ease of clinical documentation and practice management efficiency. The common goal in both cases should be accurate documentation achieved in ways that take optimal advantage of health IT capabilities. Overall, providers are best positioned to answer this question.

3. To improve the safety of EHRs, should there be a meaningful use requirement for providers to conduct a health IT safety risk assessment? Are there models or standards that we should look to for guidance?

We believe that responsibility for patient safety related to health IT is a shared responsibility among providers, health IT vendors, patients, and other stakeholders. At the same time, in the absence of clear standards and experience, we are concerned about the potential burden of a required safety risk assessment as part of meaningful use, especially for smaller ambulatory practices. We do note that this is an area where there are likely differences in the capabilities and appropriateness between EEs and EPs. For example, Joint Commission is working in this area for hospitals, but we are not aware of current work of a similar nature that would be applicable to individual physician practices. Further guidance in this area could be helpful. Overall, we think that this would be a premature requirement as there are not existing standards and the burden could be quite substantial for many providers.

4. Some federal and state health information privacy and confidentiality laws, including but not limited to 42 CFR Part 2 (for substance abuse), establish detailed requirements for obtaining patient consent for sharing certain sensitive health information, including restricting the recipient's further disclosure of such information.
 - How can EHRs and HIEs manage information that requires patient consent to disclose so that populations receiving care covered by these laws are not excluded from health information exchange?
 - How can meaningful use help improve the capacity of EHR infrastructure to record consent, limit the disclosure of this information to those providers and organizations specified on a consent form, manage consent expiration and consent revocation, and communicate the limitations on use and restrictions on re-disclosure to receiving providers?
 - Are there existing standards, such as those identified by the Data Segmentation for Privacy Initiative Implementation Guide, that are mature enough to facilitate the exchange of this type of consent information in today's EHRs and HIEs?

Our experience has been that requirements and expectations for patient consent differ entity-by-entity and across health IT vendors. Often, the current state is an "all or nothing" approach—either the entire patient record is shared or nothing is shared. More granular consent requirements are addressed through contract and policy, not through technology. The existing approaches, such as the Data Segmentation for Privacy Initiative, are too granular and unproven to adopt in a single step. Rather, what is needed is a series of interim steps from the current state to the ideal state. As such, we recommend that segmentation should first cover user-initiated pushes, while allowing time for standards to evolve for segmentation for automated query. User-initiated pushes can occur from providers that have obtained patient consent, or from the patient themselves through VDT features. In addition, we recommend that confidentiality flags should first be tracked at a clinical document level. Then, over time, the standards can become more granular to place confidentiality flags on individual clinical items.

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

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

We agree with the assertion that the boundaries of an EHR are not clearly followed as requirements are defined by either policymakers or the market to go beyond the scope of what the market would consider an EHR. Also, to date the focus has primarily been on inter-provider/organization interoperability requirements. We agree that it would be beneficial in support of further enhancing intra-provider/organization interoperability to build a library of standard implementation guides for most common use cases.

To date, substantial interoperability has been achieved within organizations, but many implementations have been purpose-built for a specific combination of systems for a specific provider/organization. Mostly, base standards were used that are characterized by substantial flexibility thus yielding widely varying interpretations for similar use cases. We suggest that implementation guides with clear conformance statements should be established. We do not believe that the standards referenced above (e.g., C-CDA, Direct, Exchange) are suitable for most of those use cases. Intra-organization interoperability requires substantial workflow management support that C-CDA, Direct, or Exchange do not require. But expansion of the Laboratory Results Interface, upcoming Laboratory Orders Interface, and eDOS implementation guides would be examples of guides that can provide a starting point for establishing an intra-provider/organization interoperability library.

6. What can be included in EHR technology to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based. This capability will need to support measures that occur in all stages of MU (e.g. there are yes/no measures in stage 1 that still need to be supported). Are there objectives and measures that should be prioritized to assist providers in showing that the capability was enabled during the reporting period?

It is generally reasonable to expect an EHR to report evidence of events that happen in the EHR. It is far more challenging to report on actions that happen partially within and partially outside of an EHR. Even when reporting on events that happen within the EHR, depending on how they are tracked within the EHR, retroactive reporting might or might not be possible. We suggest that further discussion of this topic between ONC, CMS, and EHR vendors is appropriate. If such a discussion is held, EHR vendors can bring possible options for additional tracking to the discussion for consideration.

Overall, as stated in our comments on the Stage 2 NPRM and as reflected in the Stage 2 Final Rule, tracking yes/no events can be surprisingly challenging in many cases, for example, when specific CDS "interventions" were in use or not, as we move beyond a narrow focus on CDS "rules." In other cases, an EHR may have as the default function a capability such as drug-drug interaction checking, with limited ability to disable this function. In addition, ongoing submission to public health agencies might be difficult to track given unclear definitions of what level of ongoing submission is sufficient. Creating an elaborate tracking capability of such a capability would likely not be warranted. As part of our proposed discussion with ONC and CMS, we suggest that consideration be given to the kinds of documentation, outside of the EHR, that could be sufficient and optimal for many yes/no items.

Privacy and Security

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

We do not believe that multi-factor authentication should be a requirement placed on the EHR as part of certification for Stage 3. This is not a core competency for EHRs; instead, EHRs leverage surround technology (that may be already in place at the practice or hospital). As pointed out by the HITPC, this is an evolving area, and we recommend waiting until the industry has greater adoption and more experience with these technologies. The approach taken should be flexible enough to allow providers to adopt best-in-breed technology.

Current two-factor technologies can introduce substantial burden and increased cost, especially among smaller providers. Two-factor technologies have inconvenience and time costs that impact provider workflow. This has to be balanced against other requirements, such as emergency access. In addition, it is not clear how two-factor technologies impact access through mobile devices.

Moreover, virtualization and mobile technologies can blur the lines of what is considered "remote". As such, we also think it would be helpful to clearly define use cases for remote access, as well as the risks that are mitigated through the use of two-factor technologies. For example, is connecting using a mobile device at a hospital different from a physician working at home using the same mobile device via VPN? Finally, we would like to point out that two-factor technologies are not required under HIPAA, so we believe that covered entities should have the freedom to use this technology (or not) to meet their compliance obligations and reduce security risks based on their unique use cases.

2. How would ONC test the HITPC's recommendation in certification criteria?

As discussed in our prior comments, we recommend that this criterion not be included in Stage 3. If it is included in future stages, we ask that it is reconciled with other regulations that require multi-factor authentication, such as the DEA Electronic Prescription of Controlled Substances regulations. In addition, vendors and providers need flexibility to innovate and implement new types of authentication factors as they emerge. Since EHR vendors will likely incorporate existing technology from third party vendors, we recommend attestation be used for how the EHR integrates with the two-factor technology.

3. Should ONC permit certification of an EHR as stand-alone and/or an EHR along with a third party authentication service provider?

As we state above, this approach will likely be the appropriate one in many cases, as two-factor technologies are not core EHR competencies. We suggest handling third party dependencies the same way that database and operating system dependencies are handled in certification today.

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

We agree that employee training and other administrative controls from the HIPAA Security Rule are important, but do not believe that these need to be added to meaningful use attestation. They are already HIPAA obligations and, as a matter of principle, meaningful use should not attempt to duplicate existing regulatory requirements.

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

It is not possible to assess feasibility without knowing the prescribed standard and we are still waiting on the final Accounting of Disclosures Rule.

6. Is it appropriate to require attestation by meaningful users that such logs are created and maintained for a specific period of time?

The proposed Accounting of Disclosures Rule had guidance around audit log retention requirements. We recommend waiting for that Rule to become final before introducing additional retention requirements.

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

We agree that it is desirable to have a standard audit log format to allow cross-enterprise security incident analysis. However, we are not aware of a mature standard that is ready to be adopted.

8. Are there any specifications for audit log file formats that are currently in widespread use to support such applications?

We are not aware of such specifications that are in widespread use.



Meaningful Use: Stage 3 and Beyond

Summary Proposal

- In contrast to the approach outlined in the HIT Policy Committee's recent Request for Comments, Stage 3 should focus primarily on encouraging and assisting providers to take advantage of the substantial capabilities established in Stage 1 and especially Stage 2, rather than adding new meaningful use requirements and product certification criteria.
- ONC and CMS should not start Stage 3 until at least three years after the start of Stage 2.
- Any meaningful use and functionality changes should focus on interoperability, with a focus on building on accelerating momentum and deepening use of Stage 2 capabilities and measures.
- CMS and ONC should continue to invest in quality measure alignment, infrastructure and standards.

Background

The earliest meaningful users are now entering their third reporting year, and as an industry we have nearly four years of experience with the enabling legislation, regulations and program. Given everything learned to date, as we look to Stage 3 of meaningful use and beyond, it is time to take a new look at the current "staged" approach to meaningful use, focusing on the need to ensure sustainability in the face of a rapidly evolving healthcare system.

The EHR incentive program, established in 2009 through the HITECH Act, has generally been successful in meeting its intended purpose. Since passage of the Act, EHR adoption and incentive payments for demonstrated meaningful use of certified EHRs has climbed, with our nation approaching or perhaps having passed a clear tipping point in the use of EHRs and other health IT to support healthcare delivery.

As of October 2012, over 325,000 eligible professionals (EPs) and just over 4,000 eligible hospitals (EHs) had registered for the Medicare or Medicaid incentive programs. Just over \$4.4 billion has been paid for Medicare meaningful use and about \$3.8 billion for Medicaid health IT incentives, of which \$3.5 billion was for "adopt, implement, upgrade" (AIU) and about \$300 million for meaningful use.¹ Medicare Advantage payments were about \$189 million; with 88,138 Medicare EPs,

¹ <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>



67,500 Medicaid EPs, 11,117 Medicare Advantage EPs and 3,238 hospitals having been paid for meaningful use or AIU.

Overall, EHR adoption and use continues to grow, whether as reflected in meaningful use data or, more generally, with 71.85% of physicians having adopted EHRs as of 2012 according to the NCHS, up from 57% in 2011.² In addition, according to a recent report issued by the Commonwealth Foundation, 69% of primary care physicians used EHRs in 2012, up by 50% from 46% in 2009.³ The incentive program has almost certainly accelerated this growth in adoption of interoperable EHRs and other health IT.

Moreover, much of this accelerated adoption is almost certainly focused on EHRs that have robust functionality and are intended to meet meaningful use certification criteria. An ONC analysis of the NCHS data shows high and increasing levels of implementation of most of the key dimensions of meaningful use.⁴ It is also important to emphasize that incentive dollars only flow to the extent that providers actually meet legislative and regulatory goals regarding adoption (and upgrade or implementation for Medicaid), and meaningful use for both Medicare and Medicaid.

Given this progress, and what we have learned after four years, it is a prudent time to take another look at how the program will progress after its first two stages, considering several key points.

First, the program and path established by the Congress regarding Medicare and Medicaid incentive payments should remain in place. Widespread adoption and truly meaningful use of interoperable EHRs is an essential foundation for needed delivery system reforms, which have bipartisan support. In thinking about this program, it is important to recognize that the window in which these incentive payments are available is drawing to a close, as planned, especially for the Medicare incentives that will affect most eligible professionals. The last year for which an eligible professional can start meaningful use and gain any Medicare incentives is 2014 (2015 for hospitals), the first year of Stage 2 of the program, and all Medicare incentive payments end with 2016 (the likely first year of Stage 3).

Second, CMS and ONC have significant flexibility in how to implement the HITECH mandate to increase the rigor of meaningful use over time. The specific structure of

² Hsiao CJ, Hing E. Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001-2012. NCHS data brief, no 111. Hyattsville, MD: National Center for Health Statistics. 2012.

³ S. Thomson, R. Osborn, D. Squires, and M. Jun, International Profiles of Health Care Systems, 2012, The Commonwealth Fund, November 2012

⁴ King J, Patel V, Furukawa MF. Physician Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2009-2012. ONC Data Brief, no. 7. Washington, DC: Office of the National Coordinator for Health Information Technology. December 2012.

stages, stage content, number of stages, and duration per stage are not specified in HITECH and can be adjusted to best advance program goals. Certainly, many stakeholders have raised concerns that the pace and complexity under current regulations, and especially as suggested by the HIT Policy Committee for Stage 3, could hinder ultimate program success and thus risk not fully achieving the goals defined by HITECH.

Third, we have learned much from actual experience with Stage 1 and now initial Stage 2 processes, as well as the major changes in the healthcare environment over the past four years, notably the push toward health IT-enabled accountable, value-based, and integrated care. These latter drivers create outcomes-based demand for HIT solutions, including those that address evidence-based medicine, interoperability and exchange, care coordination, patient engagement, population health, and quality measurement and reporting.

Learnings from Stages 1 and 2

- Stage 2, along with Stage 1, and especially the 2014 Edition certified EHR capabilities, provides a very solid base for robust use of EHRs, including key interoperability building blocks such as standardized terminology, standards for clinical summaries and their packaging for transport, and data transport standards.
- Release of Final Rules just starts provision of the full set of information that EHR developers and healthcare providers need for technology development and implementation. For Stage 2, all initial materials were not final until late December 2012 — almost four months after the Final Rules were published and *less than one year* before Stage 2 can start for hospitals. *This timing is insufficient.*

As was repeatedly conveyed to CMS, ONC, and the HIT Policy Committee, software developers and providers need at least 18 months with these materials to develop and implement major new EHR functionalities. The much shorter timing that has emerged for Stage 2 is only *potentially workable* for Stage 2 (with real risks as we have stated), given the very positive CMS decision to require that providers after their first year of meaningful use need use only a *single quarter reporting period* in 2014 and not the full year. We see no reason to assume that needed information will be available any sooner after Final Rules for Stage 3 or beyond, for which CMS expects full year reporting periods, and *therefore urge that a realistic assessment of the timing of Stage 3 materials*

should drive timeline planning for future stages and associated regulations.

- Given the breadth and depth of the meaningful use rules, the quality measurement requirements, and associated certification requirements, providers and vendors are finding that meeting specific meaningful use requirements is squeezing out other customer-desired functionality changes and developer innovation, including areas related to usability and accountable care. Moreover, it will be a significant challenge to achieve large numbers of product upgrades between 2011, 2014 and 2016 certified EHR editions in a short period of time, a period that is likely to be highly compressed for Stage 3 if providers after their first year must report for a full year. Just based on providers who have received Medicare or Medicaid payments as of October 2012, at least 161,000 EPs and 3,238 hospitals will require upgrades between roughly April 2013 and November 2013. The numbers increase substantially when considering those who registered for the program through October.
- Healthcare continues to face “perfect storms” of major environmental and regulatory changes, such as meaningful use, ICD-10, accountable care, payment reform, payment cuts, implementation of the Affordable Care Act, and others. These drivers are all stretching provider and vendor capabilities. In addition, potential pressures for greater oversight and regulation of health IT development, including application of quality management systems and user centered design, will place even greater pressures around software development, further making the two-year cycle untenable.
- Both the HIT Policy and Standards Committees are increasingly dictating specific functionality and technical requirements for EHRs, as opposed to identifying needed capabilities. This approach limits opportunities for innovation at a time of major delivery system change.
- For most providers, after Stage 2, the Medicare financial incentives needed to support acquisition and implementation of product upgrades will be gone. Payment adjustments, while providing incentives, do not supply the resources for provider investment in additional health IT capabilities, including training and workflow shifts to support moves to the next stage of the program.
- The public and private sector shifts to accountable care and value-based payment are now creating a business case for providers to adopt and use EHRs and other health IT, and to identify needed functionality to meet their varied

technology requirements. More broadly, such market-based demand will drive specific added functionality and EHR use patterns for those who have already adopted and demonstrated sophisticated use by attesting for Stages 1 and 2. The needs of such experienced and often sophisticated users will best be met by market innovation, while extensive and detailed standardized requirements dictated by the federal government are not only unnecessary but may actually interfere with the pace and direction of needed innovations.

Detailed Proposals

1. *Stage 3 should 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.* The Stage 3 Request for Comment by the HIT Policy Committee poses over 60 questions, highlighting the complexity of the proposed approach to Stage 3, which also has substantially more challenging requirements. Adding such complexity will lessen the chances for success of the meaningful use program.
2. *ONC and CMS should, given recent experience with Stage 2, reconsider and extend the timeline for initiating Stage 3.* We suggest that two years after the start of Stage 2, as has been proposed, will likely not allow sufficient time for the required regulations, post-regulatory guidance, and EHR development and implementation. We suggest that CMS and ONC not implement Stage 3 requirements until meaningful use attestation percentages exceed an appropriate, pre-determined threshold.
3. *Meaningful use and functionality changes for Stage 3 should focus on interoperability as a priority area* that enables evidence-based practice, care coordination, patient engagement, and public health reporting, with a focus on building on accelerating momentum and deepening use of (and expanding on only as absolutely needed) capabilities and measures added in Stage 2, such as those related to interoperability, patient access to information, and care coordination.
4. *CMS and ONC should continue to invest in quality measure alignment, infrastructure and standards.* Building on the foundation begun in Stage 2, this process should incorporate the time needed for establishing the necessary standards, field testing, and collaboration among measure

developers, providers and vendors during the measure development process to help validate this process. *Given all of these considerations, we urge CMS to consider finalizing fewer measures for Stage 3, and to be more selective with the measures chosen.*

5. *Beyond initial implementation of Stage 3, any subsequent revisions to meaningful use and certification should focus on maintenance changes needed to keep certification and meaningful use requirements current with standards changes and emerging technology and practice.* This approach reflects the fact that the Medicare incentives will be completed, and that it will be feasible and appropriate to let normal interactions between providers and vendors drive future product development as EHRs and other health IT platforms evolve.
6. CMS and ONC should consider staggering implementation of new certification requirements to align with when related functionality is needed for meaningful use.