Getting the Low Down: Meaningful Use and Managing Associated Risks

By Bethany Page with contributions from Cliff Baker & Peter Cizik

Executive Summary

The Federal Healthcare Meaningful Use (MU) incentive program is focused around leveraging technology and information for improvements in the delivery of quality care and gaining efficiencies in operations. As such, MU impacts every aspect of a provider's operations. The time frames are also aggressive and many organizations will find themselves rushing to comply with the deadlines to qualify for financial incentives and avoid penalties.

These dynamics have propelled MU compliance to the top of the list of risk exposures for organizations over the next several years. While many organizations are establishing project teams to address the technology and operational requirements, few have established programs to effectively manage the compliance aspects and mitigate the risks associated with MU.

This article outlines an overall approach for leaders in compliance and audit to establish a program for managing the compliance and related documentation requirements of MU. This structured approach is necessary to manage the complexities and associated risks of MU compliance and avoid false or noncompliance situations that may have a significant financial impact to an organization.

Meaningful Use refers to a federal incentive program that encourages physicians and hospitals to adopt Electronic Health Records (EHRs). It was passed as part of the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009. Qualifying organizations must first implement an EHR system that has been certified through an accredited Meaningful Use certification authority, and then prove they are "Meaningful Users" of the technology by successfully fulfilling an array of objectives.

Meaningful Use provides significant benefits to an organization for implementing an EHR, but there are related costs and challenges to fulfilling compliance expectations. In this regard, while many providers have heard of Meaningful Use, they are hesitant because they may not understand the process requirements and potential rewards.

Organizations need to be prepared when going through Meaningful Use and apply appropriate risk management processes to avoid potential regulatory scrutiny. Risk managers need to have a basic understanding of the measures and establish a framework to ensure the proper controls are in place to manage the attestation process. Executive governance and oversight, leveraging vendor expertise for reporting, and clear documentation trails will ensure your risk of noncompliance is mitigated.

Why do it?

Meaningful Use requirements are intended to reduce health disparities and improve the quality, safety and efficiency of patient care. Implementing Meaningful Use objectives benefits an organization just as much as the patient. By effectively using an EHR under the Meaningful Use objectives, providers can better understand a patient's medical history and improve care coordination. The more thorough and accurate information there is available, the better the patient care. Overall, this leads to higher quality, fewer mistakes and better outcomes.

At a national level, this will ultimately help contain the rising cost of healthcare by eliminating the need to repeat tests and reduce readmissions into hospitals. Other benefits include allowing more patient and family engagement in their own healthcare by providing easier access and knowledge.

Privacy and security protections for Personal Health Information have taken on an elevated importance with the increased use of EHRs, so one of the required Meaningful Use measures includes specific security protections for any Personal Health Information stored in an EHR.

Under the Medicare and Medicaid EHR Incentive Programs associated with Meaningful Use, Eligible Professionals (or EPs), Eligible Hospitals (or EHs) and Critical Access Hospitals (or CAHs) have the opportunity to receive monetary payments after implementing a certified EHR technology.

Implementing Meaningful Use objectives benefits an organization just as much as the patient.

Eligible professionals who care for a minimum percentage of Medicare patients and who satisfy Meaningful Use requirements are eligible to receive incentives of up to $44,000. So, a ten-member physician practice group that uses a certified EHR and meets the Meaningful Use requirements by 2012

Exhibit 1. Medicare EHR incentive payments for an Eligible Professional

Calendar Year	First Calendar Year in which an Eligible Professional Receives an Incentive Payment					
	2011	2012	2013	2014	2015- Subsequent Years	Not Reporting Meaningful Use Penalty
2011	$18,000	----	----	----	----	
2012	12,000	$18,000	----	----	----	
2013	8,000	12,000	$15,000	----	----	
2014	4,000	8,000	12,000	$12,000	----	
2015	2,000	4,000	8,000	8,000	$0	-1% Medicare
2016	----	2,000	4,000	4,000	0	-2% Medicare
Total	$ 44,000	$44,000	$39,000	$4,000	$0	

Exhibit 2. Medicaid EHR incentive payment schedule for an Eligible Professional

Calendar Year	First Calendar Year in which an Eligible Professional Receives an Incentive Payment					
	2011	2012	2013	2014	2015	2016
2011	$21,250	----	----	----	----	----
2012	8,500	$21,250	----	----	----	----
2013	8,500	8,500	$21,250	----	----	----
2014	8,500	8,500	8,500	$21,250	----	----
2015	8,500	8,500	8,500	8,500	$21,250	----
2016	8,500	8,500	8,500	8,500	8,500	$21,250
2017	----	8,500	8,500	8,500	8,500	8,500
2018	----	----	8,500	8,500	8,500	8,500
2019	----	----	----	8,500	8,500	8,500
2020	----	----	----	----	8,500	8,500
2021	----	----	----	----	----	8,500
Total	$63,750	$63,750	$63,750	$63,750	$63,750	$63,750

would qualify for up to $440,000 total in incentive payments.

Providers that meet the Medicaid requirements can receive up to $63,750 per Eligible Professional. For Eligible Hospitals, incentives can be as large as $11 million. Eligible hospitals may receive incentives from both Medicare and Medicaid, but Eligible Professionals may not and must select one program to receive incentives. Both Medicaid Eligible Professionals and Eligible Hospitals can only select one state from which to receive their incentives each year.

The 15 states that opened their Medicaid incentive program beginning in January 2011 have had incentive payments of over $83 million[1] distributed across their Eligible Professionals and Eligible Hospitals in only four months.

Keep in mind, Meaningful Use is a long-term approach to healthcare reform and not a short list of money-making tasks. Medicare Eligible Professionals who do not successfully demonstrate Meaningful Use by 2015 onward will have a payment adjustment to their Medicare reimbursement.

The payment reduction will start at 1% and increase each year the Eligible Professional is noncompliant, to a maximum of 5%. As National Coordinator Farzard Mostashari, MD puts it, "It's not, 'you jump through these hoops and you get money.' It's about achieving higher quality, safer, more efficient, more coordinated care."

This is obvious when you find out there are an additional two stages a provider is required to fulfill after they attest to Stage 1. Eligible professionals and Eligible Hospitals must select an attestation year of their choice, which in turn affects the amount of incentive dollars they will receive initially and over time.

Medicare Eligible Professionals must begin participation by 2012 to get the

[1] www.cms.gov/FFSProvPartProg/EmailArchive/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=descending&itemID=CMS1248485&intNumPerPage=10

maximum incentive payment, and 2014 is the last year to begin participation. The program may be governed to work as an incentive program, but requirements are mandatory to fulfill by 2015 and penalties do exist for not meeting the requirements in time.

Understanding Meaningful Use requirements and criteria

There are three objective categories to serve as a guide on what needs to be in place for hospitals and clinicians to achieve Meaningful Use. These are defined as 1) Core, 2) Menu Set and 3) Clinical Quality Measures.

- Hospitals must complete 14 Core objectives, five out of ten Menu Set objectives and 15 Clinical Quality Measures.
- Eligible professionals must complete 15 Core objectives, five objectives out of ten from Menu Set, and six total Clinical Quality Measures (three Core or alternate Core, and three out of 38 from Menu Set).
- Once a provider feels they have satisfied all Meaningful Use objectives, they are ready to "attest" that they are Meaningful Users.

To attest, hospitals must use the CMS' web-based registration and attestation system to fill in Meaningful Use objectives and Clinical Quality Measures. A large part of this process requires a continuous 90-day reporting period of these measures.

The government initially planned to track EHR measures electronically for reporting by 2012; however, this effort has been postponed until further notice and organizations should continue to follow current reporting procedures, manually typing in daily EHR results.

Stage 2 and 3 reporting was supposed to be tracked automatically as well, but since the government is not ready for electronic reporting, requirements are now unknown for these two stages. This has left many organizations hesitant to initiate Stage 1 attestation due to the uncertainty around the future two stages.

> A large, award-winning health system revealed that they had been prepared to attest for Stage 1 and start the reporting process, but decided to hold off for now. The Chief Information Security Officer explained, saying, "We are able and ready to submit for the reporting period to begin [i.e., file for notice], but we won't, because as soon as we do our clock starts ticking on Stage 2. Stage 2 is completely unknown—why would we sign up to be a guinea pig to that? As soon as it's known, we'll file for notice and begin reporting officially."

A large part of this process requires a continuous 90-day reporting period of these measures.

The last thing the government wants to do is discourage providers from following through with Meaningful Use by setting unreasonable expectations. CMS is expected to issue the Final Rule on Stage 2 by mid-2012. Organizational efforts and federal expectations seem to be in alignment so far for Meaningful Use, Stage 1.

Up until the second week of August 2011, a total of 2,383 Eligible Professionals attested under the Medicare Meaningful Use program and only 137 were unsuccessful— that is a less than 6% failure rate.

For hospitals, all 100 early adopters attested successfully.[2] At the end of July 2011, CMS announced that 77,000 providers had registered for the EHR Meaningful Use Incentive Program and by the end of August 2011, 90,000 Eligible Professionals had registered, making a 30% jump in just one month.

Managing Meaningful Use attestation

There are nine Menu Set and Core items that allow you to attest by simply stating "yes" or "no"; however, you should still be prepared to support your "yes" with evidence. Other measures are more complicated to attest to, and require calculating information gathered from the organization's EHR. For these measures, you must provide a numerator, denominator and resulting percent. When going through the attestation process, organizations should adhere to the following key tasks:

- *Quality Measures:* Select measures, identify owners, perform baseline measurements, implement performance improvement, track progress against measures
- *Core Measures:* Determine problem areas, remediate issues, perform baseline measurements, track sign-off readiness
- *Gather Evidence:* Select evidence that will be tracked and maintained, identify secure storage mechanisms, catalog the evidence
- *Perform Attestation:* Review attestation readiness with key stakeholders, obtain signoff on attestation readiness, attest via CMS website

Governance

The attestation process also requires appropriate governance, as it touches on every part of the hospital. For example, the information technology department will oversee tracking the related Core Measures, while the clinical department will be responsible for selecting and gathering information over the clinical Core Measures.

CMS is expected to issue the Final Rule on Stage 2 by mid-2012.

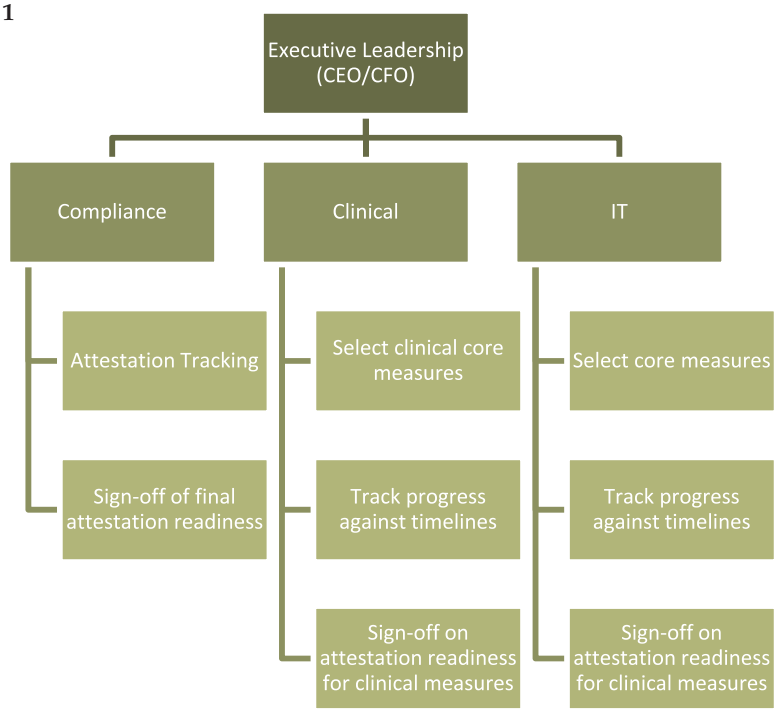
Both departments will need to coordinate with each other to track their progress against timelines to ensure they are compliant and ready to attest. The compliance department should oversee the entire attestation planning and tracking process, and officially sign off on "final attestation readiness" when appropriate. A diagram of the key stake holders and their related responsibilities is reflected in Figure 1.

Challenges are real

Often providers are challenged the most with satisfying care coordination measures. In fact, the most commonly deferred Menu Set objectives were medication reconciliation and summary of care at transitions. For Core criteria, organizations are finding it challenging

[2] Robert Tagalicod. Director, Office E-Health Standards Services (OESS). *Meaningful Use Analysis*, Webinar. August 3, 2011. www.slideshare.net/brianahier/meaningful-use-analysis

Figure 1



to satisfy the requirement for providing patients with an electronic copy of their medical records if requested. CMS's Meaningful Use attestation calculator[3] is a helpful resource that an organization should utilize before attestation.

Having more than one EHR can also tack on additional work when it comes time to attest. If an organization has multiple EHRs, they will need a method to aggregate each EHR's numerator, denominator and the resulting percent. This is why it is important to have a good relationship with your EHR vendor. As so many Meaningful Use-experienced chief executive officers have stressed before, a good partnership with your EHR vendor facilitates a more efficient planning process to get Meaningful Use underway.

Reducing the risk of noncompliance

There's a strong perception among many providers, large and small, that "the EHR will do it." As audit and compliance professionals, you know that you cannot just assume—make sure you can prove it. And you should document that it was proved. Also, don't just rely on the information technology team to figure it out. Make sure the clinicians who are using the system and benefiting from the incentive payments are trained to understand the measures and validate that their internal workflows will actually collect the data such that the calculated Meaningful Use measurements accurately portray what is being done in practice.

Again, you can add value and credibility to the end product by helping design validation testing scenarios prior to implementation and helping assess personnel training material.

While working with the various Regional Extension Centers across the country tasked with helping providers get to Meaningful Use, we were surprised by the number of (typically smaller) organizations that were still not HIPAA compliant. Since this is one of the core measures, it's critical that this objective be satisfied before attesting. As such, auditors should confirm the organization is compliant with HIPAA.

To prevent the risk of noncompliance, a provider will need to have processes established with supporting documentation for each objective being measured. The processes should be maintained with appropriate governance and tested to ensure accuracy. Reports should also be generated to establish accountability with the produced results.

As evidence, all supporting documents should be securely maintained in storage and tracked, following a multi-year plan. This also creates a great source of documentation for audit trail purposes. Quite naturally this is right up the alley of internal auditors who should hold everyone's feet to the fire.

CMS audits

Speaking of audits, future CMS audits are in store. CMS will perform audits on Medicare and dually eligible providers. States will perform audits on Medicaid providers. No announcement has been made on when to expect these audits, but the government does plan to validate that documentation supports the accuracy of attestation and incentive payments.

Providers and hospitals should retain *all relevant* electronic and paper documentation supporting attestation for six years post-attestation. This includes yes/no responses to measures (e.g., clinical decisions support rule, generating lists of patients by specific conditions), as well as what's being used to support your Clinical Quality Measures and record the EHR numerator and denominator.

Hospitals should also maintain documentation to support their payment calculations. Here auditors need to weigh in to be sure the documentation exists and that there is a procedure in place to secure the documentation. Be sure the organization understands this and has assigned responsibility for it.

You can add value and credibility to the end product by helping design validation testing scenarios

On the CMS Attestation website, whoever is attesting to the organization's Meaningful Use is required to attest to the "completeness and accuracy" of all information. Simply stating that your EHR is certified, so it must be complete and accurate, may not be good enough when responding to an auditor.

Again, as an auditor or compliance professional you need to be sure your organization can prove or otherwise demonstrate "completeness and accuracy." If you weigh the possibilities, going through with attestation now is probably a lot easier than getting audited by CMS and providing mounds of detailed documentation up to six years down the road.

[3] Meaningful Use Attestation Calculator: www.cms.gov/apps/ehr/

Common challenges

Complex reporting requirements	• Each facility must attest individually • Each physician must attest individually by NPI (ambulatory) • Multi-year process
EHR reporting limitations	• Initially some data consolidation will be needed • Consolidation of data for hospitals with several EHRs • EHR vendors required to be able to send data electronically by 2012
Governance	• Set up appropriate governance with key stakeholders • Program management office to monitor and track all activities related to attestation readiness
Evidence	• Requirements to maintain Meaningful Use records • Evidence required for potential CMS audits • Types of evidence needed: reports from attestation period, risk assessments, policies and procedures

Build an evidence checklist

Organizations should implement an *Evidence Checklist* to ensure certain documents are retained. The following five key evidence areas provide specific examples of what an organization should be gathering and maintaining on record. Auditors should assist their organizations in determining the specific items that need to be on the list. Additionally, key individuals should be identified as being responsible for the listed items.

1. Link to archived reports from certified EHR demonstrating Meaningful Use compliance (i.e., core measure compliance) over 90-day reporting period
2. Link to archived other documentation demonstrating compliance (i.e., communication with patient about electronic health record)
3. Information security risk assessment and associated corrective action plan
4. Readiness sign-off by key stakeholders
5. Copy of attestation reports

You need to be sure your organization can prove or otherwise demonstrate "completeness and accuracy."

Have a detailed project plan

You have to really dig in and identify where all the requirements would come from, what metrics are needed, and what the calculation is (i.e., the numerator is known, but what's the denominator and how do you get it?). You need to be asking what systems, metrics, and event triggers contribute to the numerator part of the EHR calculation and if all the systems even have that.

Quick overview and other key lessons learned

It is here that internal auditors can add value to the organization in several ways. As auditors you should challenge the organization on the following points.

- *Be an Informed Buyer:* Vendors are using scare tactics to try to sell things to hospitals they don't need to buy in order to achieve compliance.
- *Team Up:* Organizations are establishing Meaningful Use Core Objective teams and assigning a program manager to oversee the entire attestation process.
- *Privacy and Security, Double Protection:* There is a required security risk assessment that organizations must go through within the required Core objectives. Consider including Meaningful Use documentation as part of the review for attestation.
- *Document… Everything!:* Especially for future CMS audit purposes. You need to explain what all the Core measure stuff means and what the deliverable is for attestation. When the Core measure report comes out, you need to be hitting the recommended CMS percentile

Core Objectives

Criteria: Eligible Hospitals must complete 14 objectives and Eligible Professionals must complete 15 objectives.

Health Outcomes Policy Priority	Stage 1 Objective	Stage 1 Measure
Improving quality, safety, efficiency, and reducing health disparities	Use CPOE for medication orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local, and professional guidelines	More than 30% of unique patients with at least one medication in their medication list seen by the EP or admitted to the eligible hospital or CAH have at least one medication entered using CPOE
	Implement drug-drug and drug-allergy interaction checks	The EP/eligible hospital/CAH has enabled this functionality for the entire EHR reporting period
	EP only:	More than 40% of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology
	Record demographics: preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 50% of all unique patients seen by the EP or admitted to the eligible hospital or CAH have demographics as recorded structured data
	Maintain up-to-date problem list of current and active diagnoses	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one entry or an indication that no problems are known for the patient recorded as structured data
	Maintain active medication list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one entry (or an indication that the patient is not currently prescribed any medication) recorded as structured data
	Maintain active medication allergy list	More than 80% of all unique patients seen by the EP or admitted to the eligible hospital or CAH have at least one entry (or an indication that the patient has no known medication allergies) recorded as structured data
	Record and chart vital signs: height, weight, blood pressure, calculate and display BMI, plot and display growth charts for children 2-20 years, including BMI	For more than 50% of all unique patients age 2 and over seen by the EP or admitted to the eligible hospital or CAH, height, weight, and blood pressure are recorded as structured data
	Record smoking status for patients 13	More than 50% of all unique patients 13 years or older seen by the EP or admitted
	Implement one clinical decision support rule and the ability to track compliance with the rule	Implement one clinical decision support rule
	Report clinical quality measures to CMS or the States	For 2011, provide aggregate numerator, denominator, and exclusions through attestation. For 2012, electronically submit clinical quality measures.
Engage patients and their families in their healthcare	Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies, discharge summary, procedures), upon request	More than 50% of all unique patients of the EP, eligible hospital or CAH who request an electronic copy of their health information are provided it within 3 business days
	Hospitals Only: Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	More than 50% of all patients who are discharged from an eligible hospital or CAH who request an electronic copy of their discharge instructions are provided it.
	EPs Only: Provide clinical summaries for each office visit	Clinical summaries provided to patients for more than 50% of all office visits within 3 business days
Improve care coordination	Capability to exchange key clinical information (ex: problem list, medication list, medication allergies, diagnostic test results), among providers of care and patient authorized entities electronically	Performed at least one test of the certified EHR technology's capacity to electronically exchange key clinical information
Ensure adequate privacy and security protections for personal health information	Protect electronic health information created or maintained by certified EHR technology through the implementation or appropriate technical capabilities	Conduct or review a security risk analysis per 45 CFR164.308(a)(1) and implement updates as necessary and correct identified security deficiencies as part of the EP's, eligible hospital's or CAH's risk management process.

http://www.cms.gov/EHRIncentivePrograms/

and that's not always easy—there's a lot of time to be spent on process improvement and communication.

Conclusion

Many providers may find Meaningful Use compliance a daunting, complicated and high-risk compliance effort. Active and early participation by compliance and audit leaders is essential to manage the overall compliance obligations and mitigate the risks associated with MU.

Clinical, IT, finance and operational leaders will address the day-to-day tasks associated with meeting MU criteria, but Compliance and Audit must take accountability for ensuring that all organizational assertions are accurate, documentation support is appropriately captured and stored, and their organizations are well positioned to meet the requirements of this landmark compliance effort for the industry. **NP**

Menu set objectives *Criteria: Hospitals and Eligible Professionals may defer 5*	
1.	Drug-formulary checks
2.	Record advanced directives for patients 65 years or older
3.	Incorporate clinical lab test results as structured data
4.	Generate lists of patients by specific conditions
5.	Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate
6.	Medication reconciliation
7.	Summary of care record for each transition of care/referrals
8.	Capability to submit electronic data to immunization registries/systems*
9.	Capability to submit electronic submission of reportable lab results to health agencies*
10.	Capability to provide electronic syndromic surveillance data to public health agencies*

* At least one public health objective must be selected

Electronic specifications for reporting

Clinical quality care measures *Criteria: Hospitals must report on ALL 15*	
1.	Emergency Department throughput – Admitted patients median time from ED arrival to ED departure for admitted patients
2.	Emergency Department Throughput – Admitted patients – admission decision time to ED departure time for admitted patients
3.	Ischemic stroke – Discharge on anti-thrombotics
4.	Ischemic stroke – Anticoagulation for A-fib/flutter
5.	Ischemic stroke – Thrombolytic therapy for patients arriving within 2 hours of symptom onset
6.	Ischemic or hemorrhagic stroke – Antithrombotic therapy by day 2
7.	Ischemic stroke – Discharge on statins
8.	Ischemic or hemorrhagic stroke – Stroke education
9.	Ischemic or hemorrhagic stroke – Rehabilitation assessment
10.	VTE prophylaxis within 24 hours of arrival
11.	Intensive Care Unit VTE prophylaxis
12.	Anticoagulation overlap therapy
13.	Platelet monitoring on unfractionated heparin
14.	VE discharge instructions
15.	Incidence of potentially preventable VTE

Eligible Professionals must report on six total Clinical Quality Measures, three required Core Clinical Quality Measures (or alternate core), and three additional Clinical Quality Measures from a set of 38. Refer to CMS's website for a complete view of measure specifications.

www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp

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