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Meaningful Use Risks - Internal Audit Assessment and Response

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Introduction

The level of strategy, information technology, and process change currently occurring for healthcare providers is unprecedented. One of the most significant initiatives relates to financial incentives available under the American Recovery and Reinvestment Act of 2009 (ARRA). Under ARRA, eligible professionals (EPs), eligible hospitals (EHs) and critical access hospitals (CAHs) can receive financial incentives as they adopt, implement, and upgrade Electronic Health Records (EHR) technology. These provisions of ARRA are referred to as the Health Information Technology for Economic and Clinical Health (HITECH) Act. Providers must use EHR in a manner that meets the criteria for Meaningful Use (MU), as outlined by The Centers for Medicare & Medicaid Services (CMS), to receive the financial incentives. CMS has proposed a three-stage approach *(Capture/Share Data, Advanced Care Processes with Decision Support, and Improved Outcomes)* for the adoption of EHR and related technology solutions.

The key risks that Meaningful Use poses to the typical provider include:

- Unused and underutilized functionality of EHR systems to facilitate improved patient care and outcomes
- Unrealized benefits of EHR to improve clinical workflows
- Loss of significant financial incentives related to timely adoption
- Extended reduced reimbursement
- Unprepared for an attestation or CMS audit

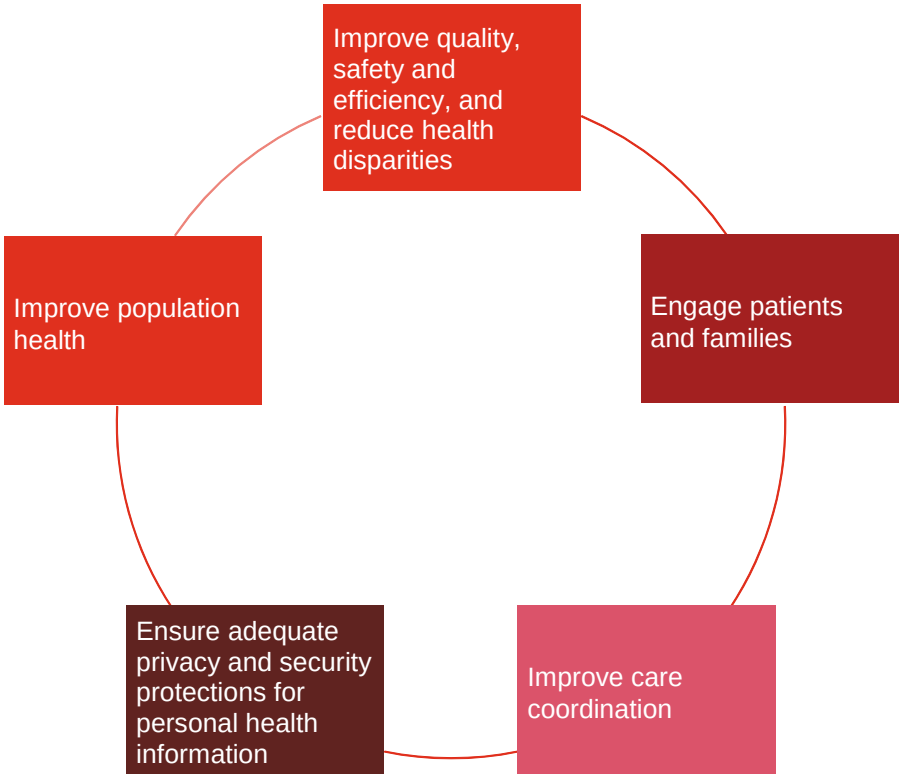
Nearly all healthcare providers have implemented, are implementing, or are planning to implement EHRs in the very near term with the objective to meet MU criteria. The goals for MU of EHRs are profoundly significant and strategic to not only providers, but the overall objectives of health reform.

The Internal Audit function has a unique opportunity to play a significant role in assisting their organization's successful transition to this new era of healthcare technology. Meaningful Use roles for Internal Audit could include the following:

- Act as a risks/controls sounding board and provide the steering committee a project assurance role with periodic reports and recommendations.
- Act as an "independent assessor" of the entire MU criteria, either by the department or through co-sourcing.
- Evaluate specific risk areas for MU audits and perform detailed risk reviews.

Whatever responsibilities Internal Audit ultimately assumes, this function can play a leading role in helping organizational management know it has successfully achieved and can demonstrate MU compliance.

The following diagram depicts the Federal Government's Health Information Technology (HIT) Policy Committee recommendations for the development and adoption of a nationwide health information infrastructure and the goals of MU.



Internal Audit departments typically align internal audits, risk assessments, and reviews with the strategic risks of the organization. However, the linkage between enterprise risks and audits is not always apparent. It is evident that, without MU coverage, there are clear short and long-term quantitative risks related to the incentive payments, as well as the reimbursement impact from CMS and potential penalties.

Internal Audit's ability to assess and assist in addressing the MU risks in the organization will be an integral part of the overall enterprise risk management strategy, linked directly to the organizational IT strategy. This whitepaper will summarize the goals of MU, and explore a potential roadmap for Internal Audit departments in addressing MU risk. Internal Audit's specific role can vary, and even the smaller departments should consider the risks presented.

The level of Internal Audit effort will vary, depending on the assessed risk associated with the organization, and specifically, the comfort level of the individual who is formally attesting to MU. Generally, all departments involved in an organization’s EHR deployment will gain an understanding of the organization's current state and MU strategy, performing some form of risk assessment as part of the overall process.

How the organization responds to those identified risks in terms of providing MU project assurance, will be a critical part of the organization's risk management strategy. Related to that, the level of on-going monitoring processes as the organization progresses throughout the three stages of MU compliance in support of management's attestation will help define the Internal Audit approach. The Internal Audit approach will also be

impacted by technology maturity, executive sponsorship/ leadership, and the magnitude of incentive payments/ penalties at stake.

Note that the primary focus of this white paper is related to the eligible hospital Medicare incentive payment program requirements for Meaningful Use. The Medicaid program regulations are less stringent for the first year of Stage 1, but there are specific requirements for Stages 2 and 3 that Internal Audit should be knowledgeable of, as well as any unique individual State requirements.

In addition, although the primary focus of this document is related to the requirements for eligible hospitals, Internal Audit should also understand the regulations for eligible professionals, as the impact of incentive payment for these individuals could be significant. Internal Audit, as part of their discussions with senior management, should consider how to monitor the elements of Meaningful Use for eligible professionals, and compliance monitoring thereon, as part of the overall risk assessment process.

Key Components and Goals for Meaningful Use

HIT Policy Committee's five priorities and care goals

CMS' criteria for MU were adopted from recommendations of the HIT Policy Committee, grouping the objectives under Care Goals, which are in turn grouped under health outcomes policy procedures. The HIT Policy Committee's five priorities and care goals related to those priorities are as follows:

1. Improve the quality, safety and efficiency of healthcare delivery, while reducing disparity

- Provide access to comprehensive patient electronic health information for the patient's healthcare team
- Use evidence-based order sets and Computerized Physician Order Entry (CPOE)
- Apply clinical decision support at the point of care
- Generate lists of patients who need care and reach out to those patients (reminders, instructions)
- Report information to patient registries for quality improvement and public reporting

2. Engage patients and families

- Provide the patients and their families with timely access to electronic health information, knowledge and tools to make informed decisions and to manage their own health

3. Improve care coordination

- Exchange key clinical information among the providers of care and entities authorized by the patient electronically

4. Improve population and public health

- The patient's healthcare team utilizes electronic data to communicate public health data to the appropriate agencies

5. Ensure privacy and security protections for PHI

- Protect electronic health data through appropriate policies, procedures, and certified EHR technology and compliance with applicable law
- Provide transparency of sharing electronic health data to the patient

HITECH ARRA Meaningful Use Stage 1 Core and menu set objectives

MU objectives include both a core set and a menu set of objectives that are specific to every eligible professional and hospital. The core objectives for EHs and EPs related to the Care Goals, from which the measures are developed, are the basis of the testing described in Step 3 of the Internal Audit approach noted below. A listing of the eligible hospital and eligible professional objectives, as well as a description of Stage 2 and Stage 3 proposed metrics for each measure, is provided in Appendix A.

Core objectives enable organizations to build a strong foundation with fundamental EHR functionality, upon which the future can be advanced. Menu objectives enable healthcare organizations latitude to select their own path toward full EHR implementation and MU.

For eligible professionals, there are a total of 25 MU objectives. To qualify for payment, 20 of these 25 objectives must be met, including:

- 15 required core objectives
- 5 menu set objectives that may be chosen from a list of 10

For eligible hospitals and critical access hospitals (CAHs), there are a total of 24 MU objectives. To qualify for payment, 19 of these 24 objectives must be met, including:

- 14 required core objectives
- 5 menu set objectives that may be chosen from a list of 10

Stage 1 Meaningful Use Attestation

In order to attest, successfully demonstrate meaningful use, and receive an incentive payment under the Medicare EHR Incentive Program, eligible hospitals must indicate that they agree with several attestation statements. The attestation is performed utilizing the CMS online Attestation System. Once the eligible hospital has successfully completed the attestation, they qualify for the payments.

The providers must agree that the information submitted:

- is accurate to the knowledge and belief of the hospital or the person submitting on behalf of the hospital;
- is accurate and complete for numerators, denominators, exclusions, and measures applicable to the hospital;
- includes information on all patients to whom the measure applies; and
- for clinical quality measures (CQMs), was generated as output from an identified certified EHR technology.

By agreeing to the above statements, the hospital is attesting to providing all of the information necessary from certified EHR technology, uncertified EHR technology, and/or paper-based records in order to render complete and accurate information for all meaningful use core and menu set measures except CQMs.

CMS considers information to be accurate and complete for CQMs to the extent that it is identical to the output that was generated from certified EHR technology. In other words, the hospital is only attesting that what was put in the attestation module is identical to the output generated by its certified EHR technology. Therefore, the numerator, denominator, and exclusion information for CQMs must be reported directly from information generated by certified EHR technology.

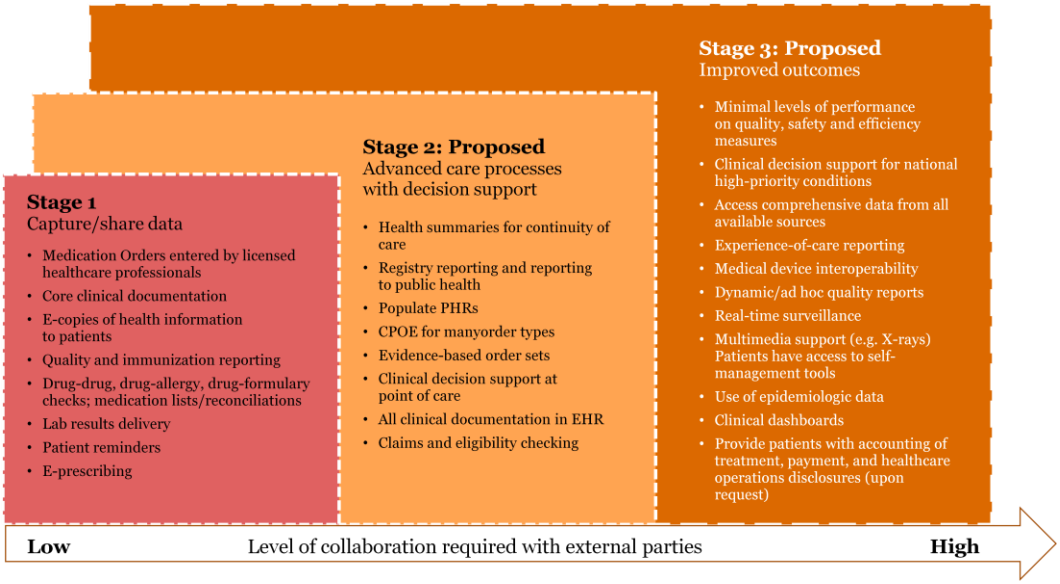
CMS, through Meaningful Use, does not require any data validation. Eligible hospitals are not required to provide any additional information beyond what is generated from certified EHR technology in order to satisfy the requirement for submitting CQM information, even if the reported values include zeros. If a hospital has concerns about the accuracy of its output, the hospital can still attest but should work with its vendor and/or the Office of the National Coordinator for Health Information Technology to improve the accuracy of the individual product and/or the level of accuracy guaranteed by certification.

CMS recommends that hospitals print out or save an electronic copy of the CQM report used at attestation from their certified EHR. The eligible hospital should retain this copy for its records so that the hospital can show its numbers in the event of an audit. Upon audit by CMS, this documentation will be used to validate that the hospital accurately attested and submitted CQMs.

The attestation could be performed by any appropriate officer of the organization, and could be, but is not limited to, the Chief Financial Officer, Corporate Compliance Officer, Chief Medical Officer or Chief Information Officer.

Staged approach to Meaningful Use

The following is a summary of the proposed three-stage approach for EHR adoption, and related technology solutions:



Timing of incentive payments for Meaningful Use

The Medicare incentive payments for hospitals are being calculated based on the product of:

- An initial amount: Base amount of $2 million plus a factor that is based on the number of discharges for each eligible hospital.
- The Medicare share: Based on estimated Medicare fee-for-service and managed care inpatient bed days, divided by estimated total inpatient bed-days, and modified by charges for charity care.
- A transition factor: Phases down incentive payments over the four-year period.

Stage 1 incentive payments are made approximately four to eight weeks after eligible professionals and hospitals meet program requirements and successfully attest.

Medicare payments will cease after five years, while Medicaid payments will be processed through 2021. Medicare payment adjustments will begin in 2015. Eligible hospitals that are not meaningful users will face penalties that will be reductions to market basket updates (upward adjustments to providers' price indices): 25% in 2015, 50% in 2016, and 75% thereafter (allowances may be made for hardship exceptions).

For Medicaid payments, the States will pay up to 85% of allowable costs for EHR by Medicaid eligible hospitals, which must have at least 10% Medicaid volume to be eligible for the payments.

Under the proposed rules for Meaningful Use Stage 2, the staged approach for the Medicare payments is summarized as follows:

	Payment Year										
First Payment Year[1]	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	Stage 1	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD	TBD
2012		Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD	TBD
2013			Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD
2014				Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD
2015					Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD
2016						Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3
2017							Stage 1	Stage 1	Stage 2	Stage 2	Stage 3

Understand and Assess the Organizational Meaningful Use Governance Structure

Internal Audit Approach

This section provides a four-step process in planning and developing a MU risk assessment, and in turn, a MU Internal Audit and compliance monitoring plan for all stages of Meaningful Use. These steps may be more or less complex depending upon the level of planning and risk assessment that may have already been completed by the organization. Internal Audit can provide value in a number of ways related to MU compliance, including but not limited to the following:

- Act as a risks/controls sounding board and provide the steering committee a project assurance role with periodic reports and recommendations.
- Provide formal project assurance on an on-going basis as they progress throughout the three stages of MU compliance.
- Act as an "independent assessor" of the entire or specific MU criteria, either by the department or through co-sourcing.
- Help their organizations in providing an adequate level of assurance they have met the appropriate criteria as they approach the attestation stage during the first payment year.
- Assist management as they prepare for potential CMS audits by ensuring that proper documentation is available to support their attestation.

It is important to note that, with MU compliance being assessed annually, if a provider meets the Medicare meaningful use criteria in one payment year but not in a later year, it will not qualify for incentive payments for that later year. Consequently, on-going monitoring will be critical to the provider and does present an opportunity for Internal Audit to help their organization.

Step 1: Assess the Organization's Current State and Planning

Internal Audit should begin by obtaining a thorough understanding of the MU regulation, the organization's strategic goals and objectives regarding ARRA HITECH, the organization's MU governance structure, and the organization's MU project plan and key milestone dates and deliverables. After identifying each unique EP and EH group, Internal Audit should conduct meetings with each group to identify key internal stakeholders, and define and develop:

- Short and long-term goals and objectives in applying for Meaningful Use Incentive payments
- The extent of the timing of the Internal Audit risk assessment process that will be conducted, as well as the nature of the analysis and associated procedures that will be performed as part of this process
- Technologies, and services supporting the certified EHR platform
- Appropriate status reporting and other communication protocols

An additional tool that could significantly help Internal Audit and the MU team would be an agreed-upon timeline that would overlay the organization's MU high-level timeline with key aspects of the Internal Audit assistance, from planning through reporting and monitoring. Senior management and governance could then contribute to the determination of:

- The appropriate level of Internal Audit assistance necessary at each stage of attestation and the type and timing of reports
- The timing of the project
- When the results of the findings would be reported
- When the remediation plan will be completed
- How long the monitoring process should be conducted
- Who within the organization will be attesting to MU compliance
- What will be utilized by the attestor(s) to provide assurance that the organization has met the appropriate criteria

Step 2: Develop and Conduct a Robust Risk Assessment

This phase could be part of the ongoing enterprise-wide risk assessment for internal audit planning, or be a separate risk assessment specific to MU. Collaboration with the relevant stakeholders will allow for a more integrated, combined approach to providing assurance related to the management of key risks of MU compliance, including the clinical impact, information technology strategy, process workflow and change management. Timing is also critical to MU attestation.

Surveys should be distributed to relevant stakeholders identified during planning, including:

- Information Technical Staff implementing the EHRs
- Information Security Staff
- Physician Practices / Departments
- Internal Audit
- Compliance and Privacy Departments

A sample of inquiries with senior management in these areas would include:

- Who has been assigned ultimate responsibility for MU compliance in your organization?
- What is the governance model that has been developed to promote MU compliance?
- Is there a resource-loaded project plan that defines and addresses key milestones, measures, and deliverables?
- Is there a MU Program/Project Manager with requisite experience and skill-sets to successfully manage this initiative?
- Is there a MU initiative dashboard for monitoring status?
- Have the greatest barriers to achieving MU compliance been identified?
- If the organization will use a variety of information systems for MU compliance, what is the integration plan?
- Have the vendor systems been certified to meet MU compliance?
- Has a security risk assessment been conducted, and if so, what were the results?

The survey should be tailored to the organization's specific operating and technology environment. The following chart can be used as a guide for identifying key stakeholders:

Surveyed Body	Information Security / Technical Staff	Physician Practices / Departments	Audit	Compliance
Risk Families	• Information Security Policies • Identity Management • Emergency Access • Passwords • Secure Transmissions and Management of Unstructured Data • Breach and Incident Reponses • Laptop / Mobile Devices • Wireless LANs • Encryption and decryption • Malware / Anti-Virus • Audit Logging • Configuration Management • Network Security • Asset Inventory • Vulnerability and Patch Management • Physical Security • Disposal • Change Management Business Continuity / Disaster Recovery Planning	• Roles & Responsibilities • Security Policies (Practice Specific) • Security Delegation • Security Administration Processes • Passwords • Sharing Access • Emergency Access • Sanction Policy • Access Monitoring • 3rd Parties • Training • Physical Security	• Information Security Audits (Internal) • Information Security Audits (External) • Credentials	• Risk Management Function • Risk Assessments • Risk Identification • Risk Sources • Risk Assessment Frequency • Risk Quantification / Qualification • Risk Integration

Internal Audit should follow-up the survey with a reasonable number of in-depth interviews with staff and executive leadership, share survey results and develop a deeper understanding of the responses to each question. With this understanding, Internal Audit can finalize and document an understanding of risks, vulnerabilities, and controls placed into operation to manage those risks for review, acceptance and approval.

Another approach Internal Audit may consider is utilizing a risk assessment framework, similar to the following diagram that depicts key areas that must be considered as part of the organization's transformation to MU. These areas should be heat-mapped, as a result of the relative risk within the organization as determined by the MU Internal Audit team, and based on discussions with senior management. Descriptions of these areas are highlighted below.

Workflow and Change Management

Standardization and reducing non value-added variation should be pursued across organizational units using the same EHR. To optimize the use of an EHR, best practice clinical workflows need to be understood, and current practices redesigned, to first and foremost enhance patient care, while also ensuring proper alignment with the regulatory environment requirements.

Technology Solution Development

Technology-enabled solutions will need to be developed for general optimization needs, as well as ongoing external reporting/sharing requirements.

Reporting Solution Development

To support ongoing operational metrics monitoring as well as MU metrics, reports must be developed and continually refined to adjust to regulatory changes.

Privacy and Security

Privacy and security are some of the highest risks to the successful and optimal use of an EHR. The HITECH Act has specific privacy and security regulations, including a specific Core Objective within the MU Stage 1 framework.

Compliance Monitoring

Development of an integrated compliance model is necessary to focus on the identification and prioritization of compliance-related risks including, but not limited to, clinical documentation completeness, proper ordering, and privacy and security of patient information.

Communication and Education

For effective clinician and end-user adoption, formal training, education, and awareness activities need to occur to reinforce changes needed to provide high-quality patient care and to maintain regulatory compliance.

Governance and Project Management

Project success is measured against the on-time delivery of anticipated benefits within project capital and operating dollar budgets, effective engagement of stakeholders and organizational acceptance. Processes should be in place to accomplish these objectives.

The following is an example Objective, Risk and Control table for the privacy and security key risk area described above:

Objective	Risk	Control
• Optimize safety and security of patient information • Compliance with regulatory agency requirements	• Privacy breach for lack/failure of safeguards • Damages and class actions result • Data threats include identity theft, denial of care, or inappropriate access, use or disclosure of records	• Implement security standards (HIPAA, HITRUST) to ensure maximum compliance • Security training for all users including refresher training • Organizational policies and procedures to govern EHR use • Retention strategy • Data leakage prevention • Enhanced Business Associate Agreements • Limits on use or requirements to protect sensitive data

Assessing the Significant Identified Risks

An important part of the risk assessment process is determining the significance of the risks identified. The Internal Audit team should consider a number of factors, including:

- The linkage to strategic priorities within IT and impact on long-term strategies.
- The potential impact CMS audits could have on the incentive program payments and prospective reimbursement from Medicare (see CMS Audit section).
- Patient Care risks due to misunderstood, unused, or underutilized EHR functionality by physicians, nurses, and other care givers.
- Risks to senior management and governance, based on their responsibility for the attestation of MU compliance.

Development of a Risk Assessment Template

As a key deliverable of a MU risk assessment, Internal Audit should use a framework and develop a template that would allow the team to assign the appropriate risk rating, as determined during the risk assessment process. These ratings would be linked to each of the core objectives, and testing in these areas could be developed accordingly. See the example Risk Assessment Dashboard below, that indicates examples of risk ratings, heat-mapped from low (green) to high (red).

Eligible Hospital objectives	Risk Rating
Core Objectives	
Computerized physician order entry (CPOE)	
Drug—drug and drug-allergy interaction checks	
Maintain up-to-date problem list of current and active diagnoses	
Maintain active medication list	
Maintain active medication allergy list	
Record demographics	
Record and chart changes in vital signs	
Record smoking status for patients 13 years or older	
Report hospital clinical quality measures to CMS or States	
Implement one clinical decision support rule	
Provide patients with an electronic copy of their health information, upon request	
Provide patients with an electronic copy of their discharge instructions at time of discharge, upon request	
Capability to exchange key clinical information among providers of care and entities electronically	

Eligible Hospital objectives	Risk Rating
Protect electronic health information	
Menu Objectives	
Drug—formulary checks	
Record advanced directives for patients 65 years or older	
Incorporate clinical lab test results as structured data	
Generate lists of patients by specific conditions	
Use certified EHR technology to identify patient-specific education resources and provide to patient, if appropriate	
Medication reconciliation	
Summary of care record for each transition of care/ referrals	
Capability to submit electronic data to immunization registries/systems	
Capability to provide electronic submission of reportable lab results to public health agencies	
Capability to provide electronic syndromic surveillance data to public health agencies	

Step 3: Develop and Execute a MU Internal Audit and Compliance Monitoring Plan

Based on the results of the risk assessment, the next step would be to assist management in their development of a MU compliance monitoring plan and related test plan. The scope will depend on the size of your organization, the MU strategic initiatives, key risks and controls established to mitigate risk. Management and Internal Audit should decide which areas will be tested.

As the final level of testing is developed, based on the results of the risk assessment, and in coordination with the steps mentioned above, Internal Audit should:

- Understand the core and menu set objectives, the numerators and denominators for each core criteria, and existing knowledge of the environment to scope the work and prepare test plans.
- Execute test plans/Internal Audit program to validate compliance with core and menu set objectives.
- Team and collaborate with business owners/compliance to share knowledge.
- Use dashboard reporting by core and menu set objectives to track status and compliance.
- Provide recommendations for remediation in areas of non-compliance, where applicable.

Based upon the MU related role (s) in their organization, Internal Audit must consider the cross-functional nature of the skill sets require to conduct MU audits, including expertise from clinical, IT, privacy and other areas.

See Appendix B for a suggested test plan approach for a selected core objective. An example of a roadmap for Strategy, Technology and Systems, Workflow and Process and Reporting Tools is depicted below.

Proposed initiatives	Immediate Next Steps			Short-term			Long-term	
	Next 6 Months			6– 12 Months			12 + months	
Strategy								
Align strategy and approach with Hospital CIS installation and options for integration of data								
Evaluate the necessity of/prioritize other IT initiatives to manage resource and funding allocation								
Technology and Systems								
Evaluate capabilities to exchange/share data with external entities including public health								
Complete analysis and design in alignment with MU								
Conduct HITECH & MU privacy/security assessment								
Integrate Inpatient CIS with Hospital CIS								
Workflow and Processes								
Develop approach for enterprise reporting processes and tools for operational, and regulatory/MU metrics								
Establish project management & compliance monitoring function for CIS and ARRA Meaningful Use								
Reporting Tools								
Align enterprise governance and PMO for CIS implementation and ARRA HITECH MU compliance								

In addition, an evaluation of policies and procedures that address the significant processes related to EHR and MU should be conducted. Specifically, each organization should perform a gap analysis to determine where policies/procedures are lacking, and if any of these standards contradict documented workflow processes regarding MU.

Organizations that have transitioned to, or are in the process of transitioning to EHR, will need to have documented the information that comprises:

- the health record for business and legal purposes
- the various sources and location of the information
- the media in which the information are to be maintained and stored
- the record retention standardized numbering process, methods or retrieval, monitoring, and programmatic review

Mapping existing policies and procedures to MU and quality controls measures will solidify that MU is based on operations, as well as technology. Associating policies and procedures, interpretations and workflow processes together are a stronger defense position to demonstrate compliance with MU guidelines.

Step 4: Reporting

Internal Audit should report on the results in the manner agreed-upon by all stakeholders, and assess the qualitative and quantitative factors of each risk or vulnerability that has been identified. Reporting can be addressed to senior management and governance, as deemed appropriate.

Internal Audit must consider not only reporting on overall project status at various points in time, but also identifying and real-time reporting and escalation on elements of the plan that could jeopardize projected deadlines and important goals.

Senior management is responsible for accepting and approving all conclusions related to the prioritization of findings reported, including an action plan for remediation. Internal Audit should develop an appropriate follow-up process with management to ensure the remediation plan has been completed timely and appropriately.

On-going Monitoring

It is important to note that if a provider meets the Medicare MU criteria in one payment year but not in a later year, it will not qualify for incentive payments for that later year. On-going monitoring is critical to the provider and presents an opportunity for Internal Audit to add value for continued involvement.

On-going monitoring of the organization's MU compliance after the initial attestation includes various elements of the assessment, testing and reporting indicated above. This approach should be determined by management, Internal Audit and governance, based on the results of the initial compliance testing efforts.

Subject to the frequency of testing, whether this is performed quarterly or semi-annually, reporting to the appropriate governance structure on the results of Internal Audit activities is critical. Depending on the structure of Internal Audit, results could be reported to the audit committee, a board quality committee and/or a MU steering committee. Adherence to the timeline mentioned in Step 2 is a critical element to on-going monitoring.

CMS Audits

EPs and EHs attesting to MU for either the Medicare or the Medicaid incentive programs are subject to audit. CMS will likely begin their MU Incentive Program audits in 2012. Hospitals attesting to receive incentive payments should retain all relevant supporting documentation used in the completion of the attestation module responses for six years, whether in paper or electronic formats, as well as the documentation to support their CQMs. Hospitals should also maintain documentation to support their payment calculations.

Upon audit, the documentation will be used to validate that the hospital accurately attested and submitted CQMs, as well as to verify that the incentive payment was accurate. Documentation to support payment calculations (such as cost report data) will continue to follow the current CMS documentation retention processes.

There are numerous pre-payment edit checks built into the EHR Incentive Programs' systems to detect inaccuracies in eligibility, reporting and payment. If, based on an audit, a provider is found to not be eligible for an EHR incentive payment, the payment will be recouped.

A false attestation may also be the basis for liability under the federal False Claims Act or similar state laws. Audits could be rigorous, especially if CMS decides that contractors should perform the audits and be compensated based on a percentage of unsupported incentive payments, similar to the Recovery Audit Contractor program.

Conclusion

As healthcare providers prepare for the multi-billion-dollar federal EHR Meaningful Use initiative, Internal Audit can play a significant role in helping keep their organization on pace to achieve their goals and remain in compliance. The three-stage implementation approach can guide Internal Audit in its effort to track expectations and contribute to the enterprise efforts towards meeting defined objectives.

MU is a journey, not a destination. The organization may consider developing a long-term strategic plan for how Internal Audit can continue to add value along the way. Internal Audit should be positioned to be an integral partner in helping the organization to assess, achieve and maintain MU compliance.

Do not be watching from the sidelines. Internal Audit's effective participation in their organization's MU process is important in helping achieve a positive outcome. The MU effort will have far-reaching, long-term consequences for the success of the organization.

Portions of this white paper have been developed using the following websites:

http://www.cms.gov/
http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1108_scherb.html
http://www.healthdatamanagement.com/news/electronic-health-records-meaningful-use-43439-1.html

Appendix A

Detail of the Core and Menu Set Objectives for Eligible Hospitals and Professionals

A full list of core and menu set objectives, as well as a description of proposed Stage 2 and Stage 3 proposed metrics for each measure, is as follows:

Number	Measure	Provider Population	S1 Meaningful Use Objective - Final Rule July 2010	Stage 2 - Final Rule TBD	Stage 3 - Final Rule TBD
1	Core	Hospitals and EPs	Computerized Physician Order Entry **30%** of unique inpatients and ED patients	Increase threshold to **60%** and add lab and radiology orders	Proposed threshold is **80%**
2	Core	Hospitals and EPs	Enable drug-drug and drug-allergy checks	Enable evidenced based drug-drug and drug-allergy checks	May add drug-lab contraindi-cations
3	Core	EPs only	**40%** of permissible prescriptions electronically (eRx)	Raise threshold to **60%** of orders (outpatient and hospital discharge)	Proposed threshold is **90%**
4	Core	Hospitals and EPs	Maintain an up-to-date problem list of current and active diagnoses for at least **80%** of unique inpatients and ED patients	**80%** of problem lists are up to date	**80%** of problem lists are up to date
5	Core	Hospitals and EPs	Maintain active medication list for at least **80%** of unique inpatients and ED patients	**80%** of medication lists are up to date	**80%** of medication lists are up to date
6	Core	Hospitals and EPs	Maintain active medication allergy list for at least **80%** of inpatients and ED patients	**80%** of med allergy lists are up to date	**80%** of med allergy lists are up to date
7	Core	Hospitals and EPs	Record Demographics (preferred language, gender, race, and ethnicity, date of birth, data and cause of death in the event of mortality) for at least **50%** of unique inpatients and ED patients	Raise threshold to **80%** (produce stratified quality reports)	Increase threshold to **90%**
8	Core	Hospitals and EPs	Record and chart changes in vital signs (height, weight, blood pressure, calculate and display BMI, plot and display growth charts for children 2-20 years old, including BMI) for at least **50%** of inpatients and ED patients	Increase threshold to **80%**	Increase threshold to **80%**
9	Core	Hospitals and EPs	Record smoking status for **50%** of unique inpatients and ED patients 13 years old or older	Increase threshold to **80%**	Increase threshold to **90%**
10	Core	Hospitals and EPs	Report hospital or ambulatory clinical quality measures to CMS or the States	This is being handled by Quality Measures Workgroup	
11	Core	Hospitals and EPs	Implement 1 clinical decision support rule related to high priority hospital conditions	Stages 2 and 3 propose to use clinical decision support to improve performance on high-priority hospital conditions, and to add various certification requirements.	
12	Core	Hospitals and EPs	Provide patients with an electronic copy of their health information upon request within 3 business days for at least **50%** of patients requests	Provide at least **50%** of patients with an electronic copy of their health information upon request	Increase threshold to **90%**

Number	Measure	Provider Population	S1 Meaningful Use Objective - Final Rule July 2010	Stage 2 - Final Rule TBD	Stage 3 - Final Rule TBD
13	Core	Hospitals only	Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request for at least **50%** of discharged patients making the request	Increase threshold to **80%**	**%** Increase threshold to **90%**
14	Core	EPs only	Provide clinical summaries to patients for each office visit	Allow patients to view or download within 24 hours of encounter	Data is to be in structured form
15	Core	Hospitals and EPs	Capability to exchange key clinical information among providers of care and patient authorized entities electronically. Accomplished by performing test of exchange	Connect to at least 3 external providers in "primary referral network or to establish bi-directional connection to at least 1 information exchange	Connect to at least 30% of providers in "primary referral network, or connect to establish bi-directional connection to at least 1 information exchange
16	Core	Hospitals and EPs	Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities		Additional privacy and security objectives are under consideration by Privacy and Security team
1	Menu	Hospitals and EPs	Implement drug-formulary check	Move to core measures	80% of orders are checked against relevant formularies
2	Menu	Hospitals only	Record Advance Directives for patients 65 years or older for **50**% of unique inpatients	Move to core measures - **50%**	Increase the threshold to **90%**
3	Menu	Hospitals and EPs	Incorporate **40**% of clinical lab test results into EHR as structured data	Move to core measures - **40**%	Increase threshold to **90%**, and reconcile with structure lab orders, when available
4	Menu	Hospitals and EPs	Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach	Move to core measures	Use the lists to manage patients for high-priority health conditions
5	Menu	EPs only	Send reminders to patients per patient preference for preventive/ follow up care	Move to core measures	**20%** of patients who prefer to receive reminders electronically receive preventive or follow-up reminders
6	Menu	EPs only	Provide patients with timely electronic access to their health information (including lab results, problem lists, medication lists, medication allergies) within 4 business days of the information being available to the EP	Patient has the ability to view and download (on demand) relevant information, with data available in readable form	Data to be available in structured form
7	Menu	Hospitals and EPs	Identify and provide patient specific education resources for **10%** of unique inpatients and ED patients	Continue Stage 1	Raise threshold to 20% and to offer the resources online in the common primary languages

Number	Measure	Provider Population	S1 Meaningful Use Objective - Final Rule July 2010	Stage 2 - Final Rule TBD	Stage 3 - Final Rule TBD
8	Menu	Hospitals and EPs	Perform medication reconciliation at relevant encounters and transition of care for 50% of the provider's inpatients and ED patients that had transitions of care	Increase threshold to **80%**	Increase threshold to **90%**
9	Menu	Hospitals and EPs	Provide summary care record for relevant transitions of care and referrals for **50**% of the provider's inpatients that had transitions of care and referrals	Move to core measures	Increase threshold to **80%**
10	Menu	Hospitals and EPs	Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Mandatory and for some immunizations to be submitted on an ongoing basis to IIS	Immunizations to be submitted to IIS and providers must review their IIS records via their EHR
11	Menu	Hospitals only	Capability to provide electronic submission of reportable lab results (as required by state and local law) to public health agencies and actual submission where it can be received	Move to core measures	Mandatory test and to submit reportable lab results and reportable conditions if accepted and as required by law
12	Menu	Hospitals and EPs	Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice	Move to core measures	Mandatory test and submit if accepted

Appendix B

Example Test Plan: Stage 1 Meaningful Use

The following is an example test plan for a sample core objective, with the test steps reflected on the following page:

Objective	Measure	Attestation Requirements	Test Steps
CPOE for Medication Orders Use computerized provider order entry (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 percent of all unique patients with at least one medication in their medication list seen by the EP have at least one medication order entered using CPOE.	DENOMINATOR: Number of unique patients with at least one medication in their medication list seen by the EP during the EHR reporting period. NUMERATOR: The number of patients in the denominator that have at least one medication order entered using CPOE. EXCLUSION: EPs who write fewer than 100 prescriptions during the EHR reporting period would be excluded from this requirement. EPs must enter the number of prescriptions written during the EHR reporting period in the Exclusion box to attest to exclusion from this requirement. The resulting percentage (Numerator ÷ Denominator) must be more than 30 percent in order for an EP to meet this measure.	(see following page)

Compliance Assessment – Example Test Plan for CPOE, continued

Test Steps

Perform walkthrough procedures to understand the process for using CPOE for medication orders.

- Conduct a walkthrough meeting with management to gain an understanding of the types of medication orders, how CPOE is used to enter medication orders, where the data is stored within the EHR and how it is secured, the parameter(s)/data source(s) used to generate the report depicting compliance with this measure, and observe the generation of this report.
- Validate that the CPOE occurs when the order first becomes part of the patient's medical record and before any action can be taken on the order.
- Understand whether any EPs wrote fewer than 100 prescriptions during the EHR reporting period, as they are excluded from this requirement.

Validate compliance with this measure.

- Validate the completeness of the information on the report from the EHR system depicting compliance with this measure.
- Validate the accuracy of the information on the report from the EHR system depicting compliance with this measure.
- Recalculate the percentage calculation on the report from the EHR system depicting compliance with this measure to test its accuracy and validate that it meets or exceeds the criteria defined in the measure.
- Validate that only licensed healthcare professionals per state, local and professional guidelines can enter medication orders into the medical record.

Appendix C

Acronyms

ACO

Accountable care organization

An organization charged with the coordination of care among hospitals, physicians, and other healthcare providers. These providers agree to be accountable for the quality, cost, and overall care of patients. They share efficiencies and information in an attempt to provide more cost-effective, high-quality care.

ARRA

American Recovery and Reinvestment Act of 2009

The $787 billion act passed in 2009 to help stimulate the economy. This act is also referred to as "the stimulus package."

CPOE

Computerized physician order entry

Electronic entry of medical practitioner instructions for the treatment of patients.

CIS

Clinical Information System

Information systems used to collect, integrate, and distribute data to the appropriate areas of responsibility, as a component of the overall hospital information system.

CQM

Clinical Quality Measures

Measures of processes, experience and/or outcomes of patient care, observations or treatment that relate to one or more of the Institute of Medicine six domains of healthcare quality. These have been adopted by the Medicare EHR incentive program.

EDI

Electronic data interchange

Electronic communication of business transactions, such as healthcare claims, billing, and payment in a standard format. Under HIPAA, transactions and code set standards govern the electronic exchange of health-related administrative information.

EHR/EMR

Electronic health record/electronic medical record

A digital record that contains information about a patient's medical history, allergies, lab results, radiology images, etc. and is capable of being shared across different healthcare settings by being embedded in network-connected, enterprise-wide information systems.

HHS

Health and Human Services

The US government's principal agency for protecting the health of all Americans and providing essential human services.

HIM

Health Information Management

Maintenance and care of health records by traditional and electronic means.

HIPAA

Health Insurance Portability and Accountability Act of 1996

HIPAA established national standards for electronic healthcare transactions and encouraged a move away from paper medical records. HIPAA standards provide for the security of electronic protected health information and the confidentiality of personally identifiable health information.

HIT

Health Information Technology

The comprehensive management of health information and its secure exchange among consumers, providers, government, quality entities, and insurers.

PHR

Personal Health Record

Software that allows patients to accumulate and have access to their own health information.

PMO

Project Management Office

Often there is an IT PMO that oversees a hospital Meaningful Use program.

RAC

Recovery Audit Contractor program

A state and federal government program intended to ferret out waste, fraud, and abuse by identifying improper Medicare payments that were not detected through existing error detection and prevention program efforts. With increasing pressure to control healthcare costs, the RAC program is not only likely to remain a permanent part of the Medicare landscape but is expanding to other federal healthcare programs, such as Medicaid, and may even be adopted by private insurers.

About the Project Teams

PwC Whitepaper Project Team

David Merriam, CPA	Partner
Gary Moss, CPA	Managing Director
Anwesha Dutta	Manager

AHIA Whitepaper Project Team

Mark Eddy, CPA	HCA Healthcare
Michael Fabrizius, CPA	Carolinas Healthcare System
Linda McKee, CPA	Sentara Healthcare
Glen Mueller, CPA (Chair)	Scripps Health
Mark Ruppert, CPA	Cedars-Sinai Health System
Debi Weatherford, CPA	Piedmont Healthcare

Additional Contributors

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About AHIA

Founded in 1981, the Association of Internal Auditors (**AHIA**) is a network of experienced healthcare internal auditing professionals who come together to share tools, knowledge and insight on how to assess and evaluate risk within a complex and dynamic healthcare environment. **AHIA** is an advocate for the profession, continuing to elevate and champion the strategic importance of healthcare internal auditors with executive management and the Board. If you have a stake in healthcare governance, risk management and internal controls, **AHIA** is your one-stop resource. Explore our website (www.ahia.org) for more information. If not a member, please join our network.

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PwC's Health Industries Risk Assurance practice provides internal audit, compliance and risk solutions for healthcare providers. For more information contact PwC's National Healthcare Provider Assurance leader, Tim Weld, at timothy.r.weld@us.pwc.com or PwC's Meaningful Use Advisory Program leader, Anwesha Dutta at anwesha.dutta@us.pwc.com.