Community Health Center Association of Connecticut
Meaningful Use: Audit Preparedness And Other Challenges
February 12, 2015

Joan W. Feldman, Esq.
William J. Roberts, Esq.

Forward Thinking Healthcare Solutions
It’s What We Do
Medicaid Meaningful Use ("MU")

EHR Incentive Program

• The Medicaid Electronic Health Record (EHR) Incentive Program provides incentive payments to physicians and other designated health care providers (referred to as “eligible professionals” or “eligible providers” and “EPs” for short) that successfully demonstrate MU use of EHRs.

• The program’s objectives are:
  ❖ To improve the quality, safety, and efficiency of care while reducing disparities;
  ❖ To engage patients and families in their care;
  ❖ To promote public and population health;
  ❖ To improve care coordination; and
  ❖ To promote the privacy and security of EHRs.
Medicaid EHR
MU Incentive Program

• The Medicaid EHR Incentive Program consists of 3 stages of demonstrable MU and each stage has its own set of objectives:
  ❖ Stage 1: Data capturing and sharing;
  ❖ Stage 2: Advanced clinical processes; and
  ❖ Stage 3: Improved Outcomes.

• During each stage, EPs must meet certain “core” objectives and may select from a list of “menu” objectives to demonstrate that they are “meaningfully using” their certified EHR.

• At the end of each reporting period for each stage, EPs must “attest” to satisfying that stage’s MU requirements.
Medicaid EHR
MU Incentive Program

• Because FQHCs and look-alikes cannot participate directly in the MU program, many opt to participate through their employed EPs.
  ✤ The health center typically manages MU participation, selects the objectives to meet and provides resources to the EPs, such as hardware and software, audit support and technical support.
  ✤ The EPs then assign MU payments received to the health center.
Medicaid MU: Stage 1

• As of 2014, EPs must meet a total of 18 objectives:
  ❖ 13 required core objectives; and
  ❖ 5 menu objectives from a list of 9.
• An EP may seek an exclusion from meeting one or more of the objectives.
  ❖ When changes to the EHR Incentive Program for 2014 were first announced, CMS stated that if an EP needed to take an exclusion on a menu objective, the EP would need to meet all 9 menu objectives. CMS has since changed the guidelines and now allows for one or more valid exclusions without the requirement to meet all 9 objectives.
  ❖ An exclusion may be granted when, for example, an EP sees too few patients, does not see the type of patient addressed by a measure.
  ❖ Exclusions are not available for all measures.
Medicaid MU Stage 1: Core Objectives

- Computerized provider order entry (CPOE)
- Drug-drug and drug-allergy checks
- Maintain an up-to-date problem list of current and active diagnoses
- E-Prescribing (eRx)
- 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
- Implement clinical decision support
- Provide patients with the ability to view, download, or transmit their health information online
- Provide clinical summaries for patients for each office visit
- Protect electronic health information
Medicaid MU Stage 1: Menu Objectives

- Must submit 5 measures from the 9 menu measures: (must do one of the first two)
  - Submit electronic data to immunization registries
  - Submit electronic surveillance data to public health agencies
  - Drug formulary checks
  - Incorporate clinical lab-test results
  - Generate lists of patients by specific conditions
  - Send reminders to patients for preventive/follow-up care
  - Patient-specific education resources
  - Medication reconciliation
  - Summary of care record for transitions of care
Medicaid MU Stage 1: Clinical Quality Measures (CQM)

• Clinical quality measures do not have thresholds that you have to meet - you simply have to report data on them.
• You don’t have to do any calculations for the clinical quality measures. Your certified EHR will produce a report with clinical quality measure data, and you must enter that data exactly as your certified EHR produced it.
• As of 2014, EPs must report 9 of the 64 CQMs.
Medicaid MU: Stage 2

• There are 23 MU objectives for EPs, 20 of which must be met to qualify for the incentives (17 core objectives, 3 menu objectives).

• Stage 2 new objectives to address:
  - Clinical lab-test results
  - Generating patient lists
  - Identifying patients for preventive/follow-up care
  - Identifying patient-specific education resources
  - Medication reconciliation
  - Summary of care records
  - Immunization registries
  - Secure electronic messaging
Medicaid MU Stage 2: Core Objectives

• Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders
• Generate and transmit permissible prescriptions electronically (eRx)
• Record demographic information
• Record and chart changes in vital signs
• Record smoking status for patients 13 years old or older
• Use clinical decision support to improve performance on high-priority health conditions
• Provide patients the ability to view online, download and transmit their health information
• Provide clinical summaries for patients for each office visit
• Protect electronic health information created or maintained by Certified EHR Technology
Medicaid MU Stage 2: Core Objectives

- Incorporate clinical lab-test results into Certified EHR Technology
- Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach
- Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care
- Use certified EHR technology to identify patient-specific education resources
- Perform medication reconciliation
- Provide summary of care record for each transition of care or referral
- Submit electronic data to immunization registries
- Use secure electronic messaging to communicate with patients on relevant health information
Medicaid Stage 2: Menu Measures

- EPs must submit 3 of the 6 MU Measures:
  - Submit electronic syndromic surveillance data to public health agencies
  - Record electronic notes in patient records
  - Provide imaging results accessible through CEHRT
  - Record patient family health history
  - Report cancer cases to a public health central cancer registry
  - Report specific cases to a specialized registry
Medicaid MU Stage 2: CQMs

• Beginning in 2014, eligible professionals must select and report on 9 of a possible list of 64 approved CQMs for the EHR Incentive Programs.

• There is also a new requirement in 2014 that the quality measures selected must cover at least 3 of the 6 available National Quality Strategy (NQS) domains, which represent the Department of Health and Human Services’ NQS priorities for health care quality improvement. The 6 domains are:
  - Patient and Family Engagement
  - Patient Safety
  - Care Coordination
  - Population and Public Health
  - Efficient Use of Health Care Resources
  - Clinical Processes/Effectiveness
Security Analysis

• Privacy and security are some of the highest risks to the successful and optimal use of an EHR.
• Development of an integrated compliance model focused on the identification and prioritization of compliance-related risks including clinical documentation completeness, proper ordering, and privacy and security of PHI.
• Risks include privacy breach, damages, class action, and identity theft.
• Controls include implementing security standards, security training, organizational policies and procedures; retention strategy, data leakage prevention, enhance BAA, limits on use of sensitive data.
Security Audit Tips

- Conducting a SRA to meet the standards of HIPAA is included in the MU requirements of the EHR Incentive Program.
- MU does not impose new or expanded requirements, nor does it require specific use of every security standard that is included in the EHR technology.
- HIPAA requires that you conduct an accurate and thorough analysis of the potential risks and vulnerabilities to the confidentiality, integrity and availability of ePHI. Once the risk analysis is done, you must take additional “reasonable and appropriate” steps to reduce risk to reasonable and appropriate levels.
Security Audit Tips

• Perform the full SRA as you adopt EHR. Each year or when changes to your practice or electronic systems occur, review and update the prior analysis for changes in risks. Reviews are required for each EHR reporting period. Do you send risk assessment?

• Have proof that a thorough security risk assessment of the certified EHR technology and its environment was performed prior to the end of the reporting period. (Report should include the procedures used and the findings).

• Simply installing a Certified EHR does not satisfy the SRA MU requirements.

• EHR vendors not responsible for SRA, rather it is the sole responsibility of the EP/health center.

• SRA must extend beyond the EHR and include all electronic devices that store, capture or modify PHI.

• All risk mitigation does not have to be completed prior to attesting, but rather must follow the timeline for risk mitigation.
Security Analysis

• NIST is the standard for federal agencies, but it represents good business practices for securing ePHI.
• Security updates implemented before end of reporting period.
• Keep all copies of all policies and procedures that support the SRA.
• It is not completely clear that security risk findings won’t be reported to OCR.
The Attestation Process

- EPs utilize CMS' web-based Medicaid EHR Incentive Program Registration and Attestation System.

- Who may attest?
  - The EP; or
  - Individuals registering or attesting on behalf of an EP must have an Identity and Access Management System web user account and be associated to the EP’s NPI.

- An EP may attest only after he or she has completed his or her EHR reporting period.
The Attestation Process

• In the Registration and Attestation System:
  ❖ EPs complete the necessary information for each applicable MU objective and CQM;
  ❖ Indicate if they qualify for exclusions to specific objectives; and
  ❖ Legally attest that they have successfully demonstrated MU.
Attestation Requirements

• Attestation is the process by which an EP indicates to CMS that it agrees with several statements regarding its MU:
  ❖ The clinical measure information submitted was generated by certified EHR technology. Certified EHR technology meets or exceeds the standards adopted by the Office of the National Coordinator for Health Information Technology;
  ❖ The information is accurate (to the knowledge and belief of the EP); and
  ❖ The information is complete (includes information on all patients to whom the measure applies).
Attestation Requirements

• CMS considers data to be accurate to the extent that it is identical to the output generated from certified EHR technology:
  ❖ MU does not require data validation;
  ❖ EPs are not liable for unknown software errors. However, because not all certified EHR systems can generate data and reports for each measure, EPs may provide data or generate reports from a separate, uncertified system on measures other than CQM; and
  ❖ When non-certified systems are used to generate data or reports, the EP must have documentation and records to support the attestation.
Amending/Correction Attestations

- Once an EP has submitted his or her attestation and has either been scheduled for payment or had a payment issued, the EP will not have the ability to amend the information submitted.
- If an error is discovered after attestation, the EP must determine if corrections would enable them to continue to demonstrate MU:
  - If not, it is the EP’s responsibility to return the incentive payment;
  - MU incentive payments are ‘all or nothing’. If one component of the attestation is not met or if one measure is not met due to the amended/corrected data, all of the money must be returned; and
  - Failure to return incentive payments after amended/corrected data indicate that the attestation requirements were not met may result in False Claims Act liability (the knowing retention of an overpayment or a “reverse false claim”).
Potential Liability for Violating Attestation Rules

- Knowingly submitting inaccurate data, or knowingly attesting to meeting MU measures which were not in fact satisfied, may result in:
  - Recoupment of incentive funds paid;
  - False Claims Act liability;
  - Reputational damage; and/or
  - Future target for more audits.

- Health Management Associates (Oct. 2013):
  - Hospital chain refunded $31 million for 11 hospitals after an internal audit discovered that certain measures were not satisfied.

- Shelby Regional Medical Center (Feb. 2014):
  - Hospital CFO attested to meeting the MU measures despite knowing that certified technology was not used to meet certain measures. CFO could face up to 5 years in federal prison if convicted.
CMS Approach: Pay Now, Look Later

- To date, CMS has paid out more than $25.7 billion in incentive payments to eligible hospitals and professionals participating in the MU program.
  - 60,561 eligible professionals had attested to MU
  - 3,696 eligible hospitals had attested to MU
- Post-payment audits began in 2012, pre-payment audits began in 2013.
- Over 25% of EPs audited fail the audit and are required to return incentive payments received.
Post-Payment Audit

- Figliozzi and Company is performing the audits on behalf of CMS.
- If you are selected for an audit, you will electronically receive a letter from the auditor with the CMS and EHR logos sent to the e-mail address provided during registration.
- EPs have two weeks to gather information – must send information by secure web portal or mail and remove PHI.
- The initial review takes place at the auditor’s location.
- Auditor may ask for additional information and/or perform an onsite visit which may include a demonstration of the EHR.
- Once the audit is concluded, the provider will receive an Audit Determination Letter informing the EP of whether he/she was successful in establishing MU of the EHR.
What Might Trigger an Audit

CMS does not intend to make the risk profile public, but some clues have been given:

• Measure values with several standard deviations from the norm - each objective with numeric values will go through regression analysis to identify outliers.
• Measure improvement trends that seem too quick relative to when the provider adopted an EHR.
• Measure data anomalies (such as different denominators being the same or different when the opposite is the norm).
• Criteria comparison: verify that measures using the same denominator are applied consistently.
• Use secondary sources to validate the attestation data
• EPs receiving large payments.
MU Audit Documentation

• Providers should make sure they retain all relevant supporting documentation used in their attestations:
  ❖ “I hereby agree to keep such records as are necessary to demonstrate that I met all Medicare/Medicaid EHR Incentive Program requirements and to furnish those records to the Medicaid State Agency, Department of Health and Human Services, or contractor acting on their behalf.”

• Appoint a specific individual to coordinate the MU attestation process and maintain supporting documentation.

• Providers should save any electronic or paper documentation that supports attestation and save documentation that supports the values entered in the Attestation Module for CQM.

• Providers should also maintain documentation that supports their payment calculations. CMS recommends that documentation be retained for at least 6 years post-attestation - we recommend 10 years.
MU Audit Documentation

• Starting point for most reviews:
  - The numerators and denominators for the core/menu measures;
  - The time period the report covers; and
  - Evidence to support that it was generated for that EP.

• Because some EHR systems are unable to generate reports that limit the calculation of measures to a prior time period, CMS suggests that providers download and/or print a copy of the report used at the time of the attestation for their records.
MU Audit Documentation

- For each MU objective with a percentage-based measure, certified EHR technology must include the capability to electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage for these measures. However, with the exception of CQMs, MU measures do not specify that this capability must be used to calculate the numerators and denominators.

Note: Even though there is not a requirement that numerators and denominators for the core and menu measure percentage-based reports be generated out of CEHRT, the auditors are asking for this additional rigor (FAQ 3063). Take screenshots whenever you can.

- Providers should also retain a report from the certified EHR system to validate all clinical quality measures data entered during attestation since all CQMs must be reported directly from the certified EHR system.
Screenshots/Documentation for ‘Yes’ Attestation

• Screenshots:
  - Clinical decision support;
  - Drug-drug, drug-allergy interaction proof that the functionality is available, enabled, and active during the entire reporting period;
  - Electronic Exchange of Clinical Information with other provider-screenshots from the EHR;
  - Drug formulary - functionality is available, enabled, and active in the system during the entire reporting period;
  - Immunization registry; and
  - Syndromic surveillance.

• Be aware of vendor permission to copy their logo.

• Remove PHI from screenshots.

• Exclusions - report from the certified EHR system that shows a zero denominator or qualifies for the exclusion.
Audit Preparation

• Assume you will be audited.
• Centralize, backup, print and save all documentation.
• Have proof of your certified EHR for the entire reporting period (e.g., letter from vendor, screenshots of system).
• Prepare an audit response team.
• Monitor your MU registration email account.
• Conduct a mock audit to develop a prepared response in a timely manner and correct any issues before the audit. Are you keeping all source documentation; can you find documentation; are the relevant audit participants identified; is the person who will be in charge of the audit identified?
• Make sure that upgrades in EHR don’t affect the certification status.
Audit Tips

- Dates on the reports match the reporting period dates during the attestation.
- Numerators and denominators from the reports match the numbers that were entered during the attestation.
- If you provide a summary report, that the dates on the reports match the reporting period dates during the attestation.
- That the numerators and denominators from the reports match the numbers that were entered during the attestation.
- If you provide a summary report from your EHR system as support for your numerator and denominator, make sure that you can identify the report as coming from the EHR. Logo, step by step screenshots.
- Use PDF to prove a report was not modified post attestation.
- Don’t send more than what is requested to auditors.
- Don’t contest the validity of what the auditors are requesting.
- Don’t expect CMS and Office of National Coordinator for HIT to intervene in the audit process.
Appeal

- Must be submitted within 30 days of the demand.
- Must have submitted all requested documentation.
- New data only.
- Where to file:

Penalties for EP Failing to Satisfy MU Objectives

- If a provider is eligible to participate in the Medicare EHR Incentive Program, they must demonstrate meaningful use in either the Medicare EHR Incentive Program or in the Medicaid EHR Incentive Program, to avoid a payment adjustment.
  - Medicaid providers who are only eligible to participate in the Medicaid EHR Incentive Program are not subject to these payment adjustments.
  - This payment adjustment will be applied to the Medicare physician fee schedule (PFS) amount for covered professional services furnished by the eligible professional during the year (including the fee schedule amount for purposes of determining a payment based on the fee schedule amount). Eligible professionals receive the payment adjustment amount that is tied to the year that they did not demonstrate meaningful use.
  - Payment adjustments begin January 1, 2015 and can be as high as 5%.
Hardship Exemption

• CMS may grant an EP a hardship exemption from the penalty payment rate reductions in three instances:
  ❖ Infrastructure (i.e. vendor connectivity);
  ❖ New provider; or
  ❖ Unforeseen circumstances (inability to obtain updated certified software or natural disasters).

• Exemption lasts for one year and an EP must reapply annually, if desired.
Joan W. Feldman, Partner

Joan W. Feldman is Chair of the Health Law Practice Group. She has devoted her legal career to representing health care providers in connection with health care, business, regulatory and administrative law matters. She regularly advises her clients on corporate governance, best practices, corporate and business issues and combinations, mergers, acquisitions, affiliations, joint ventures, physician/hospital strategic alliances; state and federal regulatory issues, including Medicaid and Medicaid reimbursement, fraud, abuse, and Stark and Anti-kickback issues; corporate compliance, governmental audits and investigations (e.g., state and federal recovery audit contractors); privacy and HIPAA issues, state and federal investigations relating to privacy breaches; information technology and software licensing; medical staff and credentialing matters; medical ethics and end-of-life issues; quality of care regulatory matters, developing quality improvement and assessment programs; and clinical research matters, including regulatory compliance and medical ethics. Joan is a frequent speaker, educator and prolific writer on a variety of subjects of interest to health care providers, including compliance, medical ethics, regulatory and reimbursement matters and health care reform, including accountable care organizations, medical homes and other innovative strategies focused on cost containment and quality improvement.
William J. Roberts, Associate

Bill Roberts is an associate in the Health Law Practice Group and a member of the Life Sciences and Medical Products Client Team. Bill has experience representing hospitals, health care providers, federally qualified health centers and behavioral health care facilities on a broad range of business and regulatory issues. Bill regularly advises clients on corporate and regulatory compliance, medical staff matters, fraud and abuse, telemedicine, licensure, social media, government and internal investigations and risk management issues. As a member of the Life Science and Medical Products client team, Bill represents medical device companies, pharmaceutical companies, clinical laboratories, tissue banks and organ procurement agencies. Bill advises clients on contracting matters, employment and independent contractor agreements, accreditation, product reimbursement (including Federal Supply Schedule, Medicaid, and other public payers) and regulatory compliance, including FDA, marketing, and data security requirements. In both the health care and life science contexts, Bill works extensively with clients on the development and implementation of compliance programs and responding to compliance incidents. Bill is often asked to conduct employee trainings, review and prepare compliance policies and procedures, and represent clients during privacy breaches and government inquiries.
Questions?