Bloomberg BNA

BNA's
Health Law Reporter™

Meaningful Use Electronic Health Record Incentive Payment Audits: Are You Ready?

By Michael A. Dowell

In 2009, Congress created the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program as part of the American Recovery and Reinvestment Act (ARRA).[1] The Medicaid and Medicare EHR Incentive Program provides funds to eligible Medicaid and Medicare providers to purchase EHR systems and to state Medicaid agencies to administer and make incentive payments to eligible Medicaid providers. The EHR incentive payments are expected to promote the adoption and ''meaningful use'' of EHR systems which will in turn improve patient outcomes and the effectiveness of the health care system. As of the end of July, more than 3,880 hospitals and more than 267,220 eligible professionals have registered for Medicare and/or Medicaid meaningful use incentive payments related to the adoption of electronic health records.[2]

To receive either the Medicare or Medicaid incentive payments, a provider must be a meaningful user of EHR. ''Meaningful use'' requires: (1) use of EHR in a meaningful manner; (2) connection of this EHR in a manner that provides for the electronic exchange of health information to improve the quality of care; and (3) in using this technology, the provider submits to the Centers for Medicare & Medicaid Services (CMS) information on clinical quality measures (CQMs) and such other measures selected by CMS. Providers must complete an attestation form when initially enrolling in the EHR incentive program to verify they meet program eligibility requirements and must re-enroll annually over the duration of the incentive payment program.[3].

An April 2012 General Accounting Office (GAO) audit report on CMS's approach to auditing providers under the Health Information Technology for Economic and Clinical Health (HITECH) Act, part of ARRA, recommended further meaningful use audit diligence.[4] The GAO indicated that it will be auditing the auditors (CMS) to assure the integrity of the EHR incentive program's expenditures. The report indicates that the most active audit content will be to verify that providers actually own the certified software they attested to having.[5]

If you are a health care provider who has completed an attestation form for EHR incentive payment for either Medicare or Medicaid EHR incentive programs, it is important that you prepare your organization for recent meaningful use audits implemented by CMS and the HHS Office of the Inspector General (OIG). Citing its statutory authority under ARRA, CMS has began to audit the attestation materials for providers who have received payments under the EHR incentive program. If, based on an audit, a provider is found to not be eligible for an EHR incentive payment, the payment will be recouped.

CMS Meaningful Use Audits on Medicare and Dually Eligible (Medicare and Medicaid) Providers

The Attestation. Medicare eligible professionals, eligible hospitals, and critical access hospitals must attest to meeting various program requirements including meaningful use through the CMS registration and attestation system. CMS has provided a user-friendly web app, *the Meaningful Use Calculator* for determining

[1] ARRA §§ 101 and 4201, amending Titles XVIII and XIX of the Social Security Act.

[2] Centers for Medicare and Medicaid Services (CMS), July 2012 Monthly Report.

Michael A. Dowell is a partner in the Los Angeles office of Hinshaw & Culbertson LLP and is a health care law attorney who counsels health systems, hospitals, physician organizations and other health care entities on regulatory compliance, transactional and operational issues.

[3] Medicare and Medicaid Electronic Health Records Incentive Program, from CMS website: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/

[4] ''GAO Recommends Further Meaningful Use Audit Diligence,'' http://gao.gov/assets/600/590538.pdf.

[5] Id.

 ISSN 1064-2137

whether an eligible professional (EP) or hospital has demonstrated meaningful use successfully. After the user has specified that a provider is either an EP or hospital, he/she is prompted to answer more than a dozen questions, which include supplying numerators and denominators for applicable questions. The tool approximates the actual process that providers will undergo during an actual attestation.

During the attestation process, providers fill in numerators and denominators for the meaningful use objectives and CQMs, indicate if they qualify for exclusions to specific objectives, and legally attest that they have successfully demonstrated meaningful use. Some EHR systems will provide reports of the numerators, denominators, and other information. Many EHR systems may require upgrades, modifications, or add-ons such as reporting applications. After data are manually entered, providers will qualify for a Medicare EHR incentive payment upon completion of a successful online submission through the CMS registration and attestation system. Any provider attesting to receive an EHR incentive payment for either the Medicare EHR incentive program or the Medicaid EHR incentive program potentially may be subject to an audit. CMS leads the auditing efforts for Medicare providers and each state Medicaid agency is responsible for auditing its Medicaid EHR incentive program.

Risks of Noncompliance. One deficiency in meeting a required meaningful use measure will result in a finding of noncompliance, and CMS will move to recoup the entire EHR incentive payment. By attesting, the hospital or EP is submitting a claim for payment from the government. As such, any misrepresentations, material omissions, false claims, statements, or documents are subject to prosecution under federal or state criminal laws and potentially civil penalties. Under Medicare, providers who do not meet meaningful use requirements are subject to penalties, including, but not limited to, withholds from claims payment amounts. If a provider receives full payment and then is found to not be a meaningful user, this potentially could trigger False Claim Act (FCA) violations and penalties.

The federal False Claims Act imposes liability on any person submitting a claim to the federal government that he or she *knows*, or *should know*, is false. No proof of specific intent to fraud is required and ''knowledge'' includes (1) actual knowledge of the information; (2) deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard for the truth or falsity of the information. State laws also may result in civil or criminal penalties for false claims. Failure in an audit of meaningful use attestation may result in a recoupment of the incentive payments at a minimum, but for Medicare also may trigger FCA penalties. For almost any health care organization, failure to comply with meaningful use requirements has the potential to be a significant financial burden, public relations disaster, and drain on human resources. In light of the above, health care organizations should take the time to seek out resources, answers, and support so that they have a well-documented compliance file that supports each and every attestation point on the CMS site, and be able to demonstrate that appropriate systems are in place to maintain meaningful use of EHR.

The CMS Audits. CMS has began to audit providers, requesting documentation supporting providers' claims that they have met the meaningful use requirements. Any eligible professional or hospital can be chosen for an audit. Some may be selected based on specific information or risk factors, but they also may be random selections, according to CMS.[6] Through these audits, CMS is seeking four types of information:

1. A copy of the provider's certification from the Office of the National Coordinator for the technology used to meet the incentive program's requirements, as proof that the provider has a certified EHR system;
2. Documentation to support the method (observation services or all emergency department visits) used to report emergency department admissions;
3. Supporting documentation for the completion of the attestation regarding the core set mandatory objectives and measures; and
4. Supporting documentation for the completion of the attestation regarding the menu set voluntary objectives and measures.

Appeals Process. If a provider believes that the audit decision is in error, it can appeal that decision through an administrative appeals process. The Office of Clinical Standards and Quality (OCSQ), an office within CMS, provides a two-level appeal process comprised of an informal review and a request for reconsideration. Generally, providers can file an eligibility appeal, a meaningful use appeal, or an incentive payment appeal, although incentive payment appeals for hospitals are referred to the Provider Reimbursement Review Board. All of these types of appeals must be filed quickly. All relevant issues must be raised in the initial appeal. Deadlines for filing an appeal are:

- Eligibility appeals must be filed no later than 30 days after the two-month period following the end of the payment year.
- Meaningful use attestation/audit appeals must be filed no later than 30 days from the date of the demand; and
- Incentive payment appeals must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any federal determination that the incentive payment amount was incorrect.

State Meaningful Use Audits on Medicaid Providers

States and their contractors will perform audits on Medicaid providers. Medicaid providers attest to information regarding their eligibility by submitting information to the states. The states may conduct some prepayment verification of eligibility and reporting requirements. In a recent OIG study, 13 states reported that they plan to verify at least half of the applicable eligibility requirements prior to making EHR incentive pay-

[6] Medicare and Medicaid Electronic Health Records Incentive Programs, Registration & Attestation, from CMS website: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/RegistrationandAttestation.html.

  HLR ISSN 1064-2137

ments.[7] To verify eligibility requirements, states plan to compare self-reported eligibility information to other data sources. Almost all states reported plans to partially verify practitioners' Medicaid patient volume percentages, and all 13 states plan to use the CHPL database to verify that practitioners and hospitals have certified EHR technology.[8]

Most states plan to use Medicare hospital cost reports to verify hospital eligibility requirements, and nine states indicated that they will use Medicare hospital cost reports to help them completely verify hospitals' reported Medicaid patient volume percentages. Eight states reported that they plan to use Medicare hospital cost reports to verify prior to payment that hospitals have an average length of stay of 25 days or fewer .[9] States may later audit a sample of providers to ensure they met eligibility and reporting requirements. If states determine during an audit that Medicaid providers failed to meet eligibility or reporting requirements, their incentive payments may be recouped.

OIG 2013 Work Plan Meaningful Use Audits

The OIG work plan for 2013 indicates that the OIG will undertake a review of ARRA which will include probes into the EHR incentive payment program.

> We will review Medicare incentive payments to eligible health care professionals and hospitals for adopting EHR and CMS safeguards to prevent erroneous incentive payments.[10]

In its 2013 work plan, the OIG states that it will look at incentive payments CMS made beginning in 2011 to identify payments to providers that should not have received incentive payments—those that did not meet the meaningful use criteria. Further, for the Medicaid program, the OIG will review whether the Medicaid financial incentives to ''providers to purchase, implement, and operate EHR technology were claimed in accordance with Medicaid requirements.''[11] The OIG also will assess CMS's plans to oversee incentive payments for the duration of the EHR incentive program and actions taken to remedy erroneous incentive payments, according to the OIG work plan.[12]

How Do I Prepare for a Meaningful Use Audit?

The achievement of meaningful use, proper documentation, and successful attestation is a complex matter. CMS will use some type of risk factor approach to decide whom to audit. CMS has not disclosed the risk factors that it considers; however, some of the criteria could include whether the provider submitted optional documentation with the attestation, whether the provider previously has been audited, and/or those providers who have reported EHR data breaches to the OIG.[13]

Providers will have two weeks to comply with a CMS meaningful use audit. While prior audits have not been comprehensive or detailed, and did not involve site visits, it is important that each health care organization checks its records and is prepared to respond to a meaningful use audit.

Attestations. It is critical, that, before attestation, the hospital or eligible professional reasonably have the knowledge to attest that it was a meaningful user during the applicable EHR reporting period and that all data (1)are accurate and complete to the best of his or her knowledge; (2) includes information on all patients to whom the measure applies; and (3) for CQMs, that the numerators and denominators were generated as output from certified EHR technology. The hospital or EP must ensure that all measure thresholds were appropriately met, all patients to whom a measure applied were included in the denominator (or properly excluded), and interpretations of any ''grey areas'' are clearly documented.[14]

Check and re-check your calculations before data are entered in the attestation module. Initiate a review of any already submitted attestations to make sure they are accurate, truthful, and backed up by documentation. Seek guidance from health care law counsel if your review finds problems. If the attestation or submitted information was incorrect, contact the CMS EHR Information Center and begin the process of amending the information that you previously have submitted, even if was for a 2011 attestation. If you did not meet the requirements for EHR incentives, you will need to return the incentive payments. Better to take corrective action now than to have your health care organization embroiled in an audit process with an uncertain outcome.

Documentation. Each health care organization should obtain and maintain EHR system licensing and certification documentation, and documentation for each core or menu set item. You should save all electronic and/or paper documentation which support your original attestation, payment calculation documentations, and CQMs, if applicable. Specific information to consider including in your documentation of meaningful use attestation includes:

General Documentation

- The reasons for claiming an exemption from any meaningful use measure that does not apply to your health care organization or practice.
- Report logic.
- Validation workbooks.
- Print screens.

[7] Office of Inspector General, ''Early Review of States' Planned Medicaid Electronic Health Record Incentive Program Oversight,'' OEI-05-10-0080 (July 15, 2011), https://oig.hhs.gov/oei/reports/oei-05-10-00080.asp.

[8] The CHPL database contains a list of EHR products that have been certified according to regulations promulgated by the Office of the National Coordinator for HIT.

[9] Note 5, supra.

[10] Office of Inspector General Work Plan Fiscal Year 2013: https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf.

[11] Id.

[12] Id.

[13] Jim Hook, ''The Meaningful Use Audit—Coming to a Location Near You Soon,'' May 12, 2012, http://www.foxgrp.com/blog/meaningful-use-audit-coming-soon/.

[14] Krystyna Monticello, ''Legal and Practical Implications of Meaningful Use Attestation,'' May 15, 2012, http://www.legalhie.com/meaningful-use/legal-and-practical-implications-of-meaningful-use-attestation/.

- Evidence of your data exchange test—whether the test was successful or not.
- The actual patient list you generated (if you selected this menu measure).

EHR Licensing Documentation

- License agreement for each eligible provider
- Proof that the license was paid for and in place before and throughout the attestation period
- Proof that the EHR was certified during the attestation period
- Proof that required EHR functionality was utilized throughout the attestation period

Documentation for Each Objective and Clinical Quality Measure

- CMS definitions with reference to specific section of the code, including:
  - o Objective,
  - o Measure,
  - o Numerator and denominator,
  - o Specifically defined terms, and
  - o Exclusions.
- Your interpretation of the objective and any related rationale.
- Criteria for exclusions.
- Data sources and how you calculated the measure (include alternate calculations).
- What certified technology was used.
- Individuals responsible for this measurement.
  - o Oversight
  - o Implementation
  - o Calculation documentation
  - o Maintenance documentation
- References to your related policies and procedures including those that support the core and menu set items.
- Method for training and communication.
- Other pieces of information that influenced your interpretation (e.g., CMS FAQ)
- Your EHR's Automated Measure Calculation report—showing the numerators and denominators for each of the meaningful use measures that are numerically based
- Clinical quality measures report—clinical quality measures must be reported ''exactly as generated as output from the certified EHR technology.''
- Clinical decision support rule—perhaps a dated screen shot to show that a CDS rule was implemented for the reporting period
- Documentation of the security risk analysis you conducted—what you did, deficiencies you identified, corrective actions you took
- Your test of the ability to submit immunization data and/or syndromic surveillance data—either proof that you conducted the test or documentation that the registry/public health agency cannot electronically accept the data (if you claim that exclusion)

All relevant documentation supporting your attestation should be retained for at least six years, and all documents supporting payment calculations should be retained according to your business's current documentation retention processes.[15] We recommend that hospitals and eligible providers include ''self-audits'' of meaningful use attestations as part of their compliance program to ensure that they will be able to produce documentation to support the meaningful use attestation statements at the time of a future audit.

HIPAA Security Risk Analysis. There are concerns that the majority of eligible professionals who have attested and received incentives have not completed Core Measure #15, ''Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.''[16] Eligible professionals must conduct or review a security risk analysis of certified EHR technology and implement updates as necessary at least once prior to the end of the EHR reporting period and attest to that conduct or review. The testing could occur prior to the beginning of the first EHR reporting period. However, a new review would have to occur for each subsequent reporting period. A security update would be required if any security deficiencies were identified during the risk analysis. A security update could be updated software for certified EHR technology to be implemented as soon as available, changes in workflow processes or storage methods, or any other necessary corrective action that needs to take place in order to eliminate the security deficiency or deficiencies identified in the risk analysis.

Health care organizations should ensure that they have a written copy of their privacy and security risk analysis compliance with the HIPAA security guidelines, any corrective action plan prepared as part of this analysis, and documentation that corrective action items have been completed. If a health care organization already has attested to meaningful use but has not conducted a risk analysis, it should conduct a risk analysis as soon as it can.

Privacy and Confidentiality. If you are audited, be mindful to protect patient confidentiality and de-identify patient information, per HIPAA and state law requirements. Although the audits are supposedly confidential, you should proceed cautiously and provide only the ''minimum necessary information requested.''

Audit Response. Each health care organization should designate a meaningful use audit response team and draft an audit response plan. Qualified health care legal counsel should review and comment on the audit re-

[15] See, e.g., Brad Adams, ''Preparing for Meaningful Use Attestations and Audits,'' Oct. 31, 2012 (http://www.tnhfma.org/newsletter/preparing-for-meaningful-use-attestations-and-audits.html).

[16] See, Jim Tate, ''Meaningful Use Attestation Process and EHR Incentives,'' Dec. 13, 2011 (http://www.hitechanswers.net/meaningful-use-attestation-process-and-ehr-incentive-audits/).

   ISSN 1064-2137

sponse plan and should be prepared to assist if the health care organization is audited.