

PRACTICE RESOURCE

Meaningful Use Audits: Preparation is the Best Representation

Steven J. Fox and Cynthia A. Haines

What is the issue? Eligible Professionals have received large incentive payments for use of electronic health record systems and will continue receiving relatively smaller payments if they qualify under the Centers for Medicare and Medicaid (CMS) Electronic Health Records Incentive Program. These awards, coupled with the complexity of the meaningful use requirements, increase the likelihood of CMS meaningful use audits.

What is at stake? Failing a meaningful use audit means recoupment or repayment of the full meaningful use incentive payment. For Eligible Professionals who have relied on the incentive payments to enhance their electronic health record systems, having to return these payments could be devastating. An adverse audit determination could also result in greater government scrutiny and increased liability for false claims.

What should attorneys do? Attorneys should assist Eligible Professional clients in assessing and documenting compliance of the meaningful use standards prior to an attestation of meaningful use submission to CMS. In the event of a meaningful use audit request, attorneys can assist in responding and appealing any adverse audit determination.

CITATION: Steven J. Fox and Cynthia A. Haines, *Meaningful Use Audits: Preparation is the Best Representation*, J. HEALTH & LIFE SCI. L., Oct. 2016, at 89. © 2016 American Health Lawyers Association, www.healthlawyers.org/journal. All rights reserved.

Author biographies appear on the next page.



Steven J. Fox is a Principal at Post & Schell. He is in the firm's Business Law & Litigation Department, Chair of the firm's Information Technology Practice Group, and Co-Chair of the firm's Data Protection/Breach Practice Group. His practice focuses on legal issues regarding information technology, data privacy, and health care information technology. Contact him via email at sjfox@postschell.com.

Cynthia A. Haines is a Principal at Post & Schell, where she is in the firm's Health Care Practice Group. She counsels and represents clients on state and federal health law and related regulatory and compliance issues. Contact her via email at chaines@postschell.com.

Fox and Haines: Meaningful Use Audits

CONTENTS

Introduction	92
Update on the EHR Incentive Program for EPs	93
Practical Advice for EPs Facing Meaningful Use Audits.....	97
Communication with the auditors	98
EHR Incentive Program publications	100
Procedures for meaningful use audits	101
Supporting Documentation	102
Supporting documentation of certification and source document	102
Documentation of reporting on meaningful use measures	104
Security risk analysis	106
Documentation of exclusions, transmissions, and attestations	107
Medicaid considerations	110
OIG audits	110
Incentives and Penalties	111
Appeals of Regulatory Standards and Methods for Meaningful Use.....	112
Conclusion	115

Introduction

This Practice Resource provides practical advice for attorneys to share with Eligible Professionals (EPs) and offers detailed recommended practices for gathering, creating, and reproducing supporting documentation that will be invaluable in the event of an audit and/or an appeal. The advice included in this Practice Resource also applies to many other types of audits.

On February 17, 2009, the American Recovery and Reinvestment Act (ARRA)¹ was enacted. Title XIII of ARRA, the Health Information Technology for Economic and Clinical Health Act (HITECH),² allocated \$19.2 billion toward the development of health care information technology. The primary goal of HITECH was to encourage the health care industry to take critical steps toward a nationwide, interoperable, private, and secure electronic health record system. The Act was intended to define “meaningful use” of electronic health records, encourage and support the attainment of meaningful use through incentives and grant programs, foster continued health information technology (HIT) innovation, and increase public trust in health care provider information systems by ensuring privacy and security.

Congress specifically authorized submission of information as to meaningful use through attestation that health care professionals meet certain standards.³ The Centers for Medicare and Medicaid (CMS) Electronic Health Records (EHR) Incentive Program requires eligible professionals, eligible hospitals, and critical access hospitals to own and implement a Certified EHR; register with Medicare, Medicaid, or both; demonstrate meaningful use; and attest to certain information.⁴ To

1 American Recovery and Reinvestment Act, Pub. L. No. 111-5, 123 Stat. 115, 516 (Feb. 19, 2009).

2 Codified at 42 U.S.C. § 300jj *et seq.*

3 42 U.S.C. §§ 300jj-31 to 300jj-38.

4 *EHR/HITECH*, CMS.gov, www.cms.gov/Outreach-and-Education/Look-Up-Topics/EHR-and-HITECH/EHR-HITECH-page.html (last visited July 15, 2016).

monitor the program, CMS has developed an audit strategy to ameliorate and address the risk of fraud, abuse, and misspending.⁵ As plainly stated on the [CMS Registration and Attestation website](#), any provider that receives an EHR incentive payment for either the Medicare or Medicaid EHR Incentive Program may be subject to an audit.

This Practice Resource focuses on the CMS EHR Incentive Program but is limited to the challenges faced by EPs,⁶ who are defined as physicians (primarily doctors of medicine and doctors of osteopathy), nurse practitioners, certified nurse-midwives, dentists, and physician assistants who furnish services in a Federally Qualified Health Center or Rural Health Clinic led by a physician assistant.⁷ According to CMS, credentialed medical assistants are also considered EPs for purposes of entering orders through an Electronic Medical Record (EMR), thereby expanding the scope of the program for many physicians' offices.⁸

Update on the EHR Incentive Program for EPs

Since its inception, meaningful use has received industry, vendor, patient, and government criticism for what are sometimes characterized as onerous criteria.⁹ In October 2015, CMS released a final rule that

-
- 5 Medicare & Medicaid Programs; Electronic Health Record Incentive Program, 47 C.F.R. pts. 412, 413, 422 et al., available at www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf.
 - 6 Although the focus of this Practice Resource is on the experience of EPs, much of the advice and practical tips are equally applicable to Eligible Hospitals and Critical Access Hospitals.
 - 7 *Who is Eligible to Receive EHR Incentive Program Payments?*, HRSA, www.hrsa.gov/healthit/toolbox/oralhealthittoolbox/meaningfuluse/eligible.html (last visited July 15, 2016).
 - 8 CMS, STAGE 2 ELIGIBLE PROFESSIONAL MEANINGFUL USE CORE MEASURES, MEASURE 1 OF 17 (Oct. 2012), available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_1_CPOE_MedicationOrders.pdf.
 - 9 Mark Hagland, *Breaking News: CMS and ONC Finalize Regulation on Stage 2 MU Reporting – Without Flexibility*, HEALTHCARE INFORMATICS (Aug. 29, 2014), www.healthcare-informatics.com/article/breaking-news-cms-and-onc-finalize-regulation-stage-2-mu-reporting-without-flexibility.

specifies the criteria that must be met to participate in the CMS EHR Incentive Programs, and with the final rule, the criticism continued.¹⁰

Comments and complaints about the reporting period prompted CMS to reduce the reporting period from 365 to 90 days.¹¹ CMS ultimately determined that the EHR reporting period for a payment adjustment year for EPs who had not successfully demonstrated meaningful use in a prior year (new participants) was any continuous 90-day period during calendar year 2015. This reduced reporting period reduced the scope of the CMS meaningful use audits, which are ongoing and conducted in rolling waves throughout the year.¹²

-
- 10 Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rules with Comment Period, 80 Fed. Reg. 62761 (Oct. 16, 2015), *available at* www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications; Letter from Thomas P. Nickels, Executive Vice President, Am. Hosp. Ass'n to Andrew M. Slavitt, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., Re: CMS-3310 & 3311-FC, Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017, Final Rule with Comment Period, Oct. 15, 2015 (Dec. 11, 2015), *available at* www.aha.org/advocacy-issues/letter/2015/151211-cl-stage3.pdf; Letter from Peter Basch, Chair, Medical Informatics Committee, Am. Coll. of Physicians to Andrew M. Slavitt, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 through 2017 [CMS-3310-FC and CMS-3311-FC] (Dec. 15, 2015), *available at* www.acponline.org/acp_policy/letters/acp_mu_stage_3_comments_2015.pdf.
 - 11 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program; Proposed Rule, 81 Fed. Reg. 45603 (Jul. 14, 2016), *available at* www.federalregister.gov/articles/2016/07/14/2016-16098/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment.
 - 12 Updates on the EHR Program generally are outlined in a tipsheet provided by CMS at CMS, EHR INCENTIVE PROGRAMS FOR ELIGIBLE PROFESSIONALS: WHAT YOU NEED TO KNOW FOR 2015 TIPSHEET, *available at* www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage3_EP.pdf; CMS, EHR INCENTIVE PROGRAMS FOR ELIGIBLE PROFESSIONALS: WHAT YOU NEED TO KNOW FOR 2016 TIPSHEET, *available at* www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_EPWhatYouNeedtoKnowfor2016.pdf.

New and returning participants who successfully demonstrate meaningful use during this period and satisfy all other program requirements will avoid negative payment adjustments in 2016 and 2017 if they successfully attested by February 29, 2016.¹³ In 2016, all EPs interested in the EHR Incentive Program attested to objectives and measures using EHR technology certified to the 2014 Edition, the 2015 Edition, if available, or a combination of the two.¹⁴ Generally, an EP must attest to providing all of the information necessary to render complete and accurate information for ten objectives and nine clinical quality measures (CQMs).¹⁵ Specifically, the EPs must agree that the information submitted (i) is accurate to the knowledge and belief of the EP or the person submitting on the EP's behalf; (ii) is accurate and complete for numerators, denominators, exclusions, and measures applicable to the EP; (iii) includes information on all patients to whom the measure applies; and (iv) for CQMs, was generated as output from an identified "certified EHR technology."

For 2015–2017, the EHR Incentive Programs include a consolidated public health objective, measures, and alternate exclusions for EPs.¹⁶ The objective's three measures included Immunization Registry Reporting, Syndromic Surveillance Reporting, and Specialized Registry Reporting. Importantly, there are public health exclusions and a requirement to demonstrate "active engagement"¹⁷ for reporting.

CMS audits began in January 2011 and are conducted by Figlioizzi and Company¹⁸ or other in-house or contracted CMS auditors, but Figlioizzi

13 *Id.*

14 *Id.*

15 *2016 Program Requirements*, CMS.gov, www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2016ProgramRequirements.html (last visited July 15, 2016).

16 CMS, EHR INCENTIVE PROGRAMS IN 2015 THROUGH 2017 PUBLIC HEALTH REPORTING FOR ELIGIBLE PROFESSIONALS IN 2016, *available at* www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_EPPublicHealthReporting.pdf.

17 *Id.*

18 Figlioizzi & Company: Certified Public Accountants, www.figlioizzi.com/ (last visited July 15, 2016).

and Company conducts the majority of the audits as a result of a three-year “time and materials” contract with CMS. The value of this contract is not to exceed \$3.13 million.¹⁹

Pursuant to a federal Freedom of Information Act (FOIA) request, CMS released informative data that reveals the volume of CMS Meaningful Use Audits conducted as of September 16, 2014.²⁰ The audit data only indicates who failed an audit, not who had that failure reversed by appeal or ultimately recouped incentives. The data reflects both Medicare and Medicare/Medicaid audits and is based on unique audits, not the number of providers. The FOIA request uncovered that as of September 16, 2014:

- 10,000 unique audits on EPs were conducted on 265,075 attestations,
- 4,601 audits have been completed,
- 24% of EPs selected for audit failed to meet meaningful use standards, and
- 98.9% of failing EPs did not meet appropriate measures and objectives.²¹

CMS did not release information on the reasons for audit failures. The 2014 FOIA response specified that overall incentives returned to CMS following post-payment audits totaled nearly \$33,000,000 as of September 16, 2014. CMS data indicates that the average returned incentive payment by an EP was \$16,862.81.²² This is significant, especially if the EP relied on the award to invest in its EHR system.

19 Recovery HITECH – EHR Meaningful Use Incentive Payment Program Audits and Compliance for Medicare, and Medicare Advantage Eligible Professionals (EPs) and all Eligible Hospitals (EHs), FEDBIZOPPS.GOV, www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=ad626006530c34ae815dbc9828578422&_cview=0 (last visited July 15, 2016).

20 Steve Spearman, *Meaningful Use Audit Outcomes: Data Released by CMS*, HEALTHIT ANSWERS (Feb. 16, 2015), www.rcmanswers.net/meaningful-use-audit-outcomes-data-released-cms/.

21 *Id.*

22 *Id.*

EPs need to be mindful that the meaningful use program is in flux. In April 2016, CMS released a proposed rule implementing the Medicare Access and CHIP Reauthorization Act (MACRA) as it pertains to the use of electronic health records and indicated that the new program will vary considerably from the requirements set forth for EPs in the meaningful use program. The proposed rule was published in the May 9, 2016 Federal Register and creates a “Quality Payment Program” to replace old reporting programs, including meaningful use.²³ The new program includes both the Merit Based Incentive Payment System (MIPS) and advanced alternative payment models.

Under MIPS, CMS has indicated that EPs will be measured on quality, resource use, clinical practice improvements, and meaningful use of certified EHR technology. CMS claims that in the new approach, EPs will be allowed to select the measures that reflect how they use EHR technology and what suits their practices.²⁴ As currently drafted, MACRA requires the rule implementing MIPS be published by November 1, 2016 with an effective date of January 1, 2017.²⁵ Although the program is in flux, much of the practical advice in this Practice Resource may be applicable to audits under this new Quality Payment Program.

Practical Advice for EPs Facing Meaningful Use Audits

Medicare and Medicaid EHR Incentive Program audits may focus on any number of issues or concerns. Every EP’s practice is different. Every

23 Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, 81 Fed. Reg. 28161 (proposed May 9, 2016) (to be codified at 42 C.F.R. pts. 414, 495), *available at* www.federalregister.gov/articles/2016/05/09/2016-10032/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm.

24 *Id.*, Marla Durben Hirsch, CMS Unveils MACRA Proposal; ‘Advancing Care Information’ to Replace MU for Medicare EPs, FIERCEHEALTHCARE (Apr. 27, 2016, 6:07 PM), www.fierceemr.com/story/cms-unveils-macra-proposal-advancing-care-information-replace-mu-medicare-e/2016-04-27.

25 *Id.*

auditor may have individualized requests and expectations. Following are practical tips for attorneys to apply when assisting EPs documenting meaningful use. The advice will prepare EPs to be in the best possible position should it be necessary to defend a submission or appeal a determination.

Communication with the auditors

An audit can take place in many ways: a pre-payment or a post-payment audit, or a desk audit or on-site audit. During an on-site audit, auditors may require a demonstration of the Certified EHR. An audit can also occur anytime in the six-year period following the attestation; therefore, a provider that has attested under the Medicare or Medicaid EHR Incentive Program should keep all audit documentation—including the actual attestation submitted—for at least six years.

Most meaningful use audits begin as “desk audits,” which is a limited scope examination of documentation and records conducted off-site from the EP’s place of business (usually via written correspondence, phone calls, and emails). These audits can be triggered either pre-payment or post-payment and include random audits, as well as audits that target suspicious or anomalous data or involve issues that have been brought to CMS’s attention via complaint. Given all of the variables, EPs should prepare as though an audit could occur at any time. Three types of audits related to the CMS EHR Incentive Program are possible:

1. Medicare audit focusing on documentation of meeting the meaningful use measures.
2. Medicaid audit focusing on documentation of eligibility and volume requirement for Medicaid payments, as well as the meaningful use measures.
3. Office of Inspector General’s (OIG) audit of a state’s Medicaid EHR program where the focus is to ensure that states are correctly validating the EP’s requirements. Although they are not

the target of this type of audit, EPs are expected to cooperate fully with the OIG.²⁶

As with any interaction with the government, communication is key. EPs must be responsive to the auditors. If an EP cannot meet a deadline, it is important to let the auditors know as soon as possible. If the EP has questions about the information being requested, the EP (or counsel) should ask the auditors for clarification.

EPs need to implement system requirements to track time/date of evidence creation, sign-off, and identity of the person recording the evidence; use a storage tool to support complex conditional processes and workflows; protect the evidence from alteration; store all evidence documents for six years post attestation; and allow for fast and easy retrieval of documentation, if audited.

For verification purposes, EPs should be prepared to share captured dated screenshots that document a software function that the auditor wants to verify (e.g., a test exchange of patient data with another clinician). It may be helpful to reach out to the auditor to describe the transaction memorialized in the screen shot. After an initial review of the submitted documents, the auditor may request additional information and even visit an EP's office to see a demonstration of the EHR system.²⁷ Having already developed a rapport can only facilitate a smoother and more productive visit.

During the entire meaningful use audit process, EPs also must remember to protect patient confidentiality and de-identify patient information per the requirements set forth in the Health Insurance Portability and Accountability Act (HIPAA), so as to avoid careless communication that could trigger an audit by the Office of Civil Rights.

26 OIG's audits of a state's Medicaid EHR Program are beyond the scope of this Practice Resource.

27 Marisa Torrieri, *Five Meaningful Use Audit Preparation Tips*, PHYSICIANS PRACTICE (Apr. 12, 2013), www.physicianspractice.com/blog/five-meaningful-use-audit-preparation-tips.

EPs should be advised that the initial list of requested documentation provided by the audit letter may not be all-inclusive and that auditors may request additional information to complete the audit. Initially, however, an EP should provide only the information requested in the audit letter and ask questions about the audit if unsure how to respond.

EHR Incentive Program publications

Given the widespread use of EHRs, CMS wants to see a return on its investment and will therefore pursue audits vigorously to confirm that meaningful use dollars were paid to Certified EHR users. Nonetheless, CMS guidance allows some flexibility in demonstrating meaningful use. The guidance is extensive (and free) and EPs and their attorneys should review it carefully.²⁸

CMS has many helpful publications that describe the EHR Incentive Program, the audit process, and the type of information that must be provided.²⁹ These publications also cite where there is a difference of opinion about what the standard requires or the nature of any assumptions. To advise EPs regarding documentation that should be saved prior to attesting, it is imperative that attorneys become familiar with CMS's resources concerning the [2016 requirements](#), which are available on the CMS website at the following links:

- [Eligible Professionals: What You Need to Know for 2016](#)
- [Health Information Exchange Fact Sheet](#)
- [Broadband Access Exclusions Tipsheet](#)
- [Security Risk Analysis Tipsheet](#)
- [Patient Electronic Access Tipsheet](#)

²⁸ *Id.*

²⁹ *Electronic Health Records (EHR) Incentive Programs*, CMS.gov, www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/index.html (last visited July 15, 2016) [hereinafter *EHR Incentive Programs*].

- Eligible Professionals: Public Health Reporting in 2016
- Guide for Eligible Professionals Practicing in Multiple Locations

Generally, information may be submitted electronically or by mail and must be supplied by the deadline stated in the audit letter. Initial reviews of submitted information are treated as desk reviews, but additional information may be requested. Site reviews may be conducted as well. After an audit is completed, the EP will receive a determination letter from the auditor stating whether the EP was successful in meeting meaningful use requirements for the reporting year. Unlike other types of audits, failure to meet any requirement means the entire incentive payment must be returned.

Procedures for meaningful use audits

In order to attest, successfully demonstrate meaningful use, and receive an incentive payment under the Medicare EHR Incentive Program, EPs must indicate that they agree with several attestation statements. The attestation is submitted using the CMS online [attestation portal](#). CMS's [Attestation Worksheet for Modified Stage 2 of the Medicare EHR Incentive Program in 2016](#) specifically guides EPs through the attestation process. Once the EP has successfully completed the attestation, the EP qualifies for payment.

As mentioned [above](#), Figliozi and Company is the contractor performing audits under the Medicare EHR Incentive Program while individual states arrange for audits under the Medicaid EHR Incentive Program. On behalf of CMS, Figliozi and Company will audit EPs eligible under both the Medicare and Medicaid EHR Incentive Programs.³⁰

30 A sample audit letter for eligible professionals can be found at the following link: Letter from Peter Figliozi, Figliozi & Co., to Dr. John Smith, FAAFP (Feb. 25, 2013), *available at* www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/SampleAuditLetter.pdf.

An EP may have as little as two weeks to respond to an audit request. Although responses can be uploaded, responses and requests for extensions are directed to Figliozi and Company. Documentation and information used for attestation (and any other helpful documents) should be maintained in an audit file that is secure and readily accessible to avoid confusion and unnecessary delay should an EP receive an audit request. Information for Medicare EHR Incentive Program audits can be provided by mail or by uploading to a secure portal provided by auditors.³¹ The quicker and more succinctly an EP is able to respond, the quicker the government can close out the audit.

Supporting Documentation

Documentation is critical in meaningful use audits. The information provided in the EP's source document, real-time attestation documentation, and documentation of a full-scale risk assessment of an EP's Certified EHR can be components of an effective audit response.

Supporting documentation of certification and source document

When it comes to many types of government audits, if it isn't documented, it didn't happen. Meaningful use audits are not any different. The initial documentation that will be requested in all audits is the source document(s) that the EP used when completing the attestation. The source document should provide a summary of the data that supports the information entered during attestation—ideally, a report that is readily available from the certified EHR system.

EPs should ensure that the version of the EHR being used is a certified product by comparing it against the Office of the National Coordinator

31 *EHR Incentive Programs.*

(ONC) Certified Health IT product list.³² The source document, which is usually a report from the Certified EHR, should include the following information: (i) numerators and denominators for all percentage-based measures; (ii) time period covered by the report; and (iii) evidence to support that the report was generated for a specific EP. Each page of the source document should specifically identify the provider and include the Certified EHR logo, version number, and date on each page. EPs should carefully review the reports generated by the Certified EHR and contact the Certified EHR vendor if anything is unclear or confusing.

EPs should work in consultation with the Certified EHR vendor to determine what documentation is appropriate to collect and maintain for auditors, but should not rely solely on the vendor. When negotiating the terms of a license agreement or purchase order, confidentiality provisions that prohibit sharing that document with government auditors should always be avoided. In the alternative, the EP must request another document from the vendor that evidences the relationship. EPs can request that vendors provide license summaries or similar documentation, for example. In any event, it is imperative to review any documentation from the Certified EHR vendor prior to sharing with auditors to maintain confidentiality and ensure relevance and accuracy.

Prior to implementing an upgrade of a Certified EHR, EPs should consider the Medicare and Medicaid EHR Incentive Program requirements (e.g., HIPAA) and determine if implementation of the upgrade may inadvertently cause a usage gap during a reporting period. CMS has stated that an EHR certified for other CMS programs may not necessarily be certified for the Medicare and Medicaid EHR Incentive Programs,

32 *Comprehensive List of Certified Health Information Technology*, CERTIFIED HEALTH IT PRODUCT LIST: THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., <https://chpl.healthit.gov/#/search> (last visited July 15, 2016); *Certified EHR Technology*, CMS.gov, www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html (last visited July 15, 2016).

which can be confusing.³³ Only EHRs certified for the Medicare and Medicaid EHR Incentive Program through ONC satisfy the requirement that an EP is using a “Certified EHR.”³⁴

Documentation of reporting on meaningful use measures

Being able to produce real-time attestation documentation (screen shots) is a distinct advantage in defending meaningful use representations to CMS. If the Certified EHR cannot generate reports for prior time periods, reports must be generated and maintained in a reproducible format. Screen shots must originate from the Certified EHR and must be from the reporting period. With some foresight, EPs can take screen shots before the end of the reporting period and maintain them in case of an audit. Screen shots should show date, provider, name of the Certified EHR vendor, and the version number.

If screen shots were not obtained during the reporting period, the EP will need to work with the Certified EHR vendor to determine how to obtain documentation showing that the applicable measures were met during the reporting period. EPs could include internal logs and any information demonstrating when a particular functionality was turned on or off, for example. Some Certified EHR vendors implement contractual restrictions on providing screen shots to auditors. Review the relevant license agreements, purchase orders, etc. to determine whether this is the case. Attorneys who negotiate EHR contracts should try to avoid contractual restrictions of this nature.

Attorneys should encourage EP clients to maintain a report to validate the clinical quality measures reported from the Certified EHR. CMS considers CQM information accurate and complete to the extent that it is identical to the output generated from certified EHR tech-

33 AN INTRODUCTION TO THE MEDICARE EHR INCENTIVE PROGRAM FOR ELIGIBLE PROFESSIONALS, CMS, available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/beginners_guide.pdf.

34 *Id.*

nology. In other words, the EP is only attesting that the information entered in the attestation model 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 does not require any data validation for the Meaningful Use Program. In other words, EPs are not required to provide additional information beyond what is generated from the certified EHR technology itself to satisfy the requirement for submitting CQM information, even if the reported values include zeros. If an EP has concerns about the accuracy of its output, the EP 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.³⁵

CMS may, however, request that providers selected for post-payment audits submit documentation, such as patient rosters, EHR screenshots, and reports generated by the EHR system to support data the providers reported to CMS during attestation. To protect patient confidentiality and privacy, EPs must redact patient-specific information before providing such information to auditors. Certain auditors (especially those auditing under the Medicaid EHR Incentive Program) may request patient-specific information. These requests should be analyzed carefully, and only the minimum data necessary for the auditors' purposes should be disclosed.

Data elements will be scrutinized. For example, not all percentage-based measures use the same denominator, so attesting with the same denominator in all percentage-based measures may raise questions that lead to an audit. Remind EPs that attesting to identical percentages for each percentage-based measure can also be problematic. If all EPs in a

35 *Registration & Attestation*, CMS.gov, www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/RegistrationandAttestation.html (last visited July 15, 2016).

practice attest with the same percentages, this may result in an audit. EPs should scrutinize the numbers and, if possible, attain review from an objective party before attesting.

Some examples of audit red flags that EPs should avoid in attesting are: patient denominator inconsistencies, such as unique patients on specific measures and comparison of total discharges on cost reports with the number of encounters reported for meaningful use; exemptions inconsistent with patient population, such as exemptions for smoking status from non-pediatric hospitals; and interoperability for EPs with multiple EHR vendors.³⁶ All of these examples have one thing in common: the data would show the error prior to submission. Before submitting, the EP should carefully review the data for red flags.

As with all documentation related to meaningful use, EP clients must retain attestation evidence for six years and save any electronic or paper documentation that supports the attestation. Documentation would include reports from the certified EHR system that validate all CQM data entered during attestation, and that supports the values the EP entered into the Attestation Module of the CMS portal.³⁷

Security risk analysis

Simply installing a Certified EHR does not fulfill the security risk analysis that meaningful use requires. Attorneys must advise EP clients that even with a Certified EHR, EPs must perform a full security risk analysis, also called the risk assessment, addressing all electronic protected health information, not just the information that is included in the EHR. Specifically, the security risk analysis must take into consideration the idiosyncrasies of the specific version of the Certified EHR being used for meaningful use purposes and also address HIPAA security

36 *Medicare & Medicaid EHR Incentive Programs: Audit Information*, eHEALTH: CMS (June 13, 2013), available at www.cms.gov/regulations-and-guidance/legislation/ehrincentive-programs/downloads/vendorworkgroupcall_june13.pdf.

37 *Id.*

issues related to electronic health records generally.³⁸ The risk analysis helps ensure that the EP is compliant with HIPAA's administrative, physical, and technical safeguards by revealing areas where protected health information could be at risk. A helpful security assessment tool can be found on the [federal government's HealthIT website](#).

It is possible for EPs to conduct a risk analysis using internal resources and online tools. EPs should consider, however, whether a thorough and technical risk analysis that will withstand an audit or other compliance review requires objectivity and expertise that may be better obtained from an outside professional. Both CMS and OCR have provided guidance on the security risk analysis requirement through the [Security Risk Analysis Tip Sheet](#) and the [OCR Guidance on Risk Analysis](#).

Documentation of exclusions, transmissions, and attestations

CMS provides further guidance on the need for regularly updating contact information provided in an EP's attestation, as well as the documentation necessary if an exclusion applies to an EP or if an EP uses an intermediary to transmit public health data.

Exclusions

During attestation, EPs can claim exclusions from completing certain meaningful use criteria. If an EP qualifies for an exclusion, the EP does not have to meet that measure to receive a full incentive or avoid penalties. There are no blanket exclusions and each EP must analyze whether they meet the exclusion criteria for each applicable measure. EPs should carefully read and understand the [list of Stage 2 measures and their associated exclusions](#) to determine if any of the exclusions apply to their practice.

38 *The Security Rule*, HHS.gov, www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule (last visited July 15, 2016).

CMS provides extensive guidance and will field questions related to the exclusion process.³⁹ For purposes of anticipating an audit, it is imperative to document communications and directions provided by CMS regarding exclusions.⁴⁰ The final rule for the EHR Incentive Program includes alternate exclusions for certain objectives and measures in 2015 and 2016 where there is no Stage 1 equivalent. Alternate exclusions exist for the computerized provider order entry, electronic prescribing, patient transitions, and for certain public health reporting measures.⁴¹

Transmissions

CMS has provided examples of documentation related to transmissions that should be maintained for audit purposes. If an EP who plans to submit an attestation also plans to use an intermediary (e.g., a health information exchange) to submit public health data, it is prudent to confirm with counsel or CMS that use of the intermediary will allow the EP to meet the meaningful use objectives.⁴² CMS has provided examples of documentation related to transmissions that should be maintained for audit purposes:

- Dated screenshots from the Certified EHR documenting a test submission to an immunization registry or public health agency and showing the result (i.e., successful or unsuccessful).

39 *Frequently Asked Questions (FAQs)*, CMS.GOV, www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/FAQ.html (last visited July 15, 2016).

40 CMS, EHR INCENTIVE PROGRAMS IN 2016: ALTERNATE EXCLUSIONS, *available at* https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_AlternateExclusionsfor2016.pdf.

41 *Id.*

42 *ONC Regulation FAQs*, HEALTHIT.GOV, www.healthit.gov/policy-researchers-implementers/18-question-09-10-018 (last visited July 15, 2016) [hereinafter *ONC Regulation FAQs*].

The documentation should include evidence to support that it was generated for that specific provider's system.⁴³

- A dated record of successful or unsuccessful electronic transmission (e.g., screenshot from another system, etc.). This record should include evidence to support that it was generated for that specific provider.
- A letter or email from an immunization registry or public health agency confirming receipt or failure of receipt of the data submitted electronically. The letter or email should include the date of the submission, the names of the provider and the registry or agency, and the result of the test (i.e., successful or unsuccessful).⁴⁴

CMS has indicated that thus far, auditors have not focused closely on the transmission requirements, as many immunization registries and public health agencies were not prepared to receive the information. As EPs become more sophisticated, however, the focus on the transmission requirements will likely increase.⁴⁵

Attestations

Along with all the other types of documentation discussed here, EPs should maintain a copy of the actual attestation submitted and update all contact information provided during attestation. EPs also should make sure that all contact information provided during attestation (e.g., an email address) is in working order and is being monitored. If an email address is not monitored and auditor communications are not read promptly, this could be very problematic, for obvious reasons.

43 NAT'L LEARNING CONSORT., CHECKLIST FOR CAPABILITY TO EXCHANGE KEY CLINICAL INFORMATION (June 30, 2012), available at <https://www.healthit.gov/sites/default/files/cm14-nlc-checklist-for-capability-to-exchange.docx>.

44 *ONC Regulation FAQs*.

45 *Id.*

For EPs practicing in multiple locations, the EHR Incentive Program presents additional challenges with regard to exclusions, transmission, and attestation. CMS has issued guidance to address these challenges.⁴⁶ The guidance assists EPs in understanding the definition of patient encounters, determining if a location has certified EHR technology, and calculating meaningful use across multiple locations.

Medicaid considerations

Audits and documentation requirements under the Medicaid EHR Incentive Program vary by state.⁴⁷ The state-centric audits typically focus on the number of Medicaid patients served by the attesting EP. Those providers with no history of providing services to Medicaid beneficiaries prior to the EHR Incentive Program may be more likely to be audited.

State Medicaid audits focus on much of the same data as Medicare audits, such as National Provider Identification Number, Tax ID, and ONC Certification Number. In addition, Medicaid auditors review factors such as percentage of services provided to Medicaid members, average length of patient stay, procedures performed, and processes followed.

OIG audits

As described previously, an EP may also face an OIG audit. The purpose of an OIG audit is to audit the state's program for payments of Medicaid incentives. Therefore, the OIG will ask the EP to provide the same types of information the EP may have already provided directly to the state. If an OIG audit finds that the state failed to appropriately establish an EP as a meaningful user, that report would be returned to

46 CMS, GUIDE FOR ELIGIBLE PROFESSIONALS PRACTICING IN MULTIPLE LOCATIONS (EHR INCENTIVE PROGRAMS IN 2015 THROUGH 2017) (2016), available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2016_EPMultipleLocations.pdf.

47 [Untitled table of "estimated dates each State intends to begin accepting registrations for its Medicaid EHR Incentive Program"], www.cms.gov/apps/files/statecontacts.pdf (last updated Aug. 29, 2013, last visited Jul. 24, 2016).

the state, and the state may take action to recover the incentive payment from the EP.

Incentives and Penalties

To secure the maximum incentive, EPs must have commenced meaningful use of a Certified EHR in the first years (i.e., 2011 or 2012) of the meaningful use program. For EPs who received their first payment in 2011 or 2012, that incentive payment was \$18,000. If they continued to qualify, they received smaller amounts in 2012 through 2015 for a total of \$44,000. If an EP did not qualify until 2015, the EP did not receive any incentive payment.⁴⁸

Incentive payments for Medicaid providers are designed differently, with payments spread out over a longer period of time. Medicaid payments are set at \$21,250 the first year and \$8,500 every year after that until the total payout is reached. These providers may have waited to attest until 2016 and still receive incentive payments through 2021, totaling about \$64,000.⁴⁹

In 2015, penalties for Medicare providers who had not met meaningful use or filed for a hardship waiver started taking effect. This penalty was 1% in 2015, 2% in 2016, and will be 3% in 2017, which can add up to a significant amount for EPs who decide not to comply with meaningful use.⁵⁰

Payments received under the Medicare and Medicaid EHR Incentive Programs are subject to federal laws governing fraud and abuse, so providers who submit a fraudulent attestation may be subject to sanctions,

48 *EHR Incentive Payment Timeline*, HEALTHIT.GOV, www.healthit.gov/providers-professionals/ehr-incentive-payment-timeline (last visited Aug. 16, 2016); *Incentives and Penalties*, SA IGNITE, www.saignite.com/resources/meaningful-use-incentives-penalties (last visited July 15, 2016).

49 *Id.*

50 *Medicare and Medicaid EHR Incentive Program Basics*, CMS.GOV, www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/basics.html (last visited Aug. 16, 2016).

including fines and program exclusion, as well as criminal sanctions. If CMS determines that audit failure is due to an EP's knowingly false attestation statements, CMS may refer the issue to the Department of Justice (DOJ), which can seek an indictment. The following case involved a hospital, but illustrates the DOJ's scrutiny of attestations and commitment to using criminal, civil, and administrative enforcement against entities and individuals receiving incentive payments.

A former chief financial officer (CFO) pleaded guilty to falsely attesting to CMS that Shelby Regional—a 54 bed hospital in Texas—met meaningful use requirements for the 2012 fiscal year.⁵¹ Shelby Regional allegedly relied on paper records during that time, and to give the false appearance that the hospital was actually using an EHR, the hospital directed its software vendor and hospital employees to manually input data from paper records into the EHR software, often months after a patient was discharged and after the end of the fiscal year. Based on the false attestation, CMS paid Shelby Regional nearly \$800,000. The former CFO was sentenced to 23 months in federal prison, and Shelby Regional is shutting its doors due in part to the recoupment of meaningful use incentive payments and related penalties.⁵² This case highlights the importance of making certain that all meaningful use objectives are met before attesting to the same.

Appeals of Regulatory Standards and Methods for Meaningful Use

CMS had proposed a limited appeal process for providers challenging a determination that the EP did not meet the regulatory standards and

51 Sarah Beth Smith & Laurence J. Freedman, *Hospital Executive Pleads Guilty to False Meaningful Use Attestation for EHR Incentive Payments*, HEALTH LAW & POLICY MATTERS (Nov. 21, 2014), www.healthlawpolicymatters.com/2014/11/21/hospital-executive-pleads-guilty-to-false-meaningful-use-attestation-for-electronic-health-record-incentive-payments/.

52 *Id.*

methods for meaningful use.⁵³ In the Stage 2 Final Rule, CMS argued that the administrative review process is primarily procedural and need not be specified in regulation. CMS instead indicated it intends to issue guidance regarding types or categories of appeals and accompanying requirements. The proposed administrative appeals process would apply to both Stage 1 and Stage 2 of meaningful use. CMS also proposed three types of permissible appeals: eligibility, meaningful use, and incentive payment. Per the Final Rule, there will not be appeal reconsiderations of incentive payment amounts or recoupments, selection or demonstration of measures, hardship exception, hardship reconsiderations, or payment adjustment determinations.⁵⁴

CMS has explicit instructions related to filing appeals.⁵⁵ For each type of appeal listed below, the appeal must be submitted electronically or postmarked as instructed:

1. **Failed Audit Meaningful Use.** Allows a provider to demonstrate meaningful use by addressing each of the measures failed on audit. Appeals must be filed within 30 days after the adverse audit determination letter. When submitting this type of appeal, EPs may choose to delay repayment of the Medicare EHR incentive payment. If, however, the appeal is denied, failing to return the incentive payment as instructed could result in additional interest payments owed.
2. **Failed Reporting Meaningful Use.** Allows a provider to show that certified electronic health record technology

53 *Appeals*, CMS.gov, www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentive-Programs/Appeals.html (last visited July 15, 2016).

54 Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 3 and Modifications to Meaningful Use in 2015 Through 2017; Final Rules with Comment Period, 80 Fed. Reg. 62761 (Oct. 16, 2015), available at www.federalregister.gov/articles/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications.

55 CMS, ELIGIBLE PROFESSIONAL (EP) APPEAL INSTRUCTIONS, available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Appeal_EP_FilingRequest_Instructions.pdf.

(CEHRT) was used to successfully demonstrate meaningful use but failed due to a reporting issue. Appeals must be filed within 30 days after the attestation deadline.

3. **CQM e-Reporting Meaningful Use.** Allows a provider to show that CQM e-reporting was successful in meeting meaningful use. Appeals must be filed within 30 days after the attestation deadline.
4. **Eligibility.** Allows an EP to show that all EHR Incentive Program requirements were met and that the provider should have been able to register and attest for the Program but could not due to circumstances outside the provider's control. An example includes being unable to register by deadline. Appeals must be filed within 30 days after the attestation deadline.⁵⁶

The date that the appeal and supporting documentation are received will be the submission date. All supporting documentation must be included at the time of submission or it will not be accepted. It is very important to comply with CMS specification submission requirements because documentation not submitted in the required formats may result in either a delayed or denied appeal determination. CMS strongly recommends that submission be accomplished electronically by completing the appeal form, attaching all supporting documentation to an email, and sending it to a designated email account.⁵⁷

Most states have implemented an appeals process for their Medicaid EHR Incentive Programs. Medicaid program participants should contact their state Medicaid agencies for more information about these appeals.

56 CMS, EHR INCENTIVE PROGRAMS APPEALS OVERVIEW (2016), available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/AppealsAudits_EHRAppealsOverview-.pdf.

57 *Id.*

Conclusion

Attorneys can help EPs minimize the impact of an audit through advance preparation. Counsel can assist the EP client in developing a robust compliance folder of documentation and screen shots and a clear vision of how to prepare for and respond to a CMS audit.

Attorneys have a vital role in navigating and researching the applicable statutory regulatory and sub-regulatory requirements for meaningful use. Attorneys can provide proactive compliance assistance through training, education, and development of a governance structure that outlines clear roles and responsibilities for each key component of meaningful use that may be subject to an audit: system monitoring, clinician engagement, training, attestation, and documentation. Attorneys can assist in communications with vendors, registries, CMS, and state Medicaid programs.

A best practice to ensure compliance with the meaningful use program is for the EP to have an objective third party conduct an internal audit of its meaningful use practices and the resulting attestation. This audit should be conducted each year that the attestation is submitted to CMS. For self-auditing EPs, attorneys can assist by drafting or reviewing a self-audit work plan, conducting or assisting with the audit, reviewing all documentation required to support the attestation, assessing the information security controls, and identifying how the EPs can strengthen the current process so that it may hold up under the scrutiny of a CMS audit.

Attorneys can review, organize, and train on the key components of meaningful documentation. These components include proof of ownership of the certified electronic health record technology for all systems, core and menu set percentage measures, core and menu set yes/no measures, and clinical quality measures.

Attorneys can draft and assist with training related to the EP's audit response plan. EPs should have a defined procedure in place to manage the audit process, describing how it will:

1. determine the roles and responsibilities for each phase of the audit outlined;
2. recognize and process CMS audit letters in a timely manner;
3. produce documentation quickly;
4. verify what EHR system was used and the timeframe it was used; and
5. conduct audit response fire drills where team members walk through all the steps that take place beginning with receipt of the audit letter.

In the event of an audit, counsel for EPs should take the lead in evaluating meaningful use audit request letters; reviewing supporting documents for submission in response to an audit request letter; communicating with CMS, its audit contractor, or the applicable State Medicaid Agency to obtain clarification in the audit review process; evaluating audit result letters; identifying the applicable appeals process and key deadlines on appeal; and developing substantive written analysis and arguments for submission on appeal.

Meaningful use standards are complex and dynamic, leading many EPs to sagely seek legal counsel. The earlier counsel are consulted, the better prepared the EP will be for each stage of meaningful use compliance, which will help the EP achieve and maintain meaningful use attestation in the event of an audit.