COMPLIANCE ROUND-UP

December 13, 2011

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Today's Faculty

- Brian Annulis, JD, CHC
  - Partner, Meade & Roach, LLP
  - 773.907.8343
  - bannulis@meaderoach.com
- Ryan Meade, JD, CHRC
  - Partner, Meade & Roach, LLP
  - 773.472.3975
  - rmeade@meaderoach.com
- Steve Weiser, JD, LLM
  - Of Counsel, Meade & Roach, LLP
  - 312.403.4284
  - sweiser@meaderoach.com

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Continuing Goals

- The goals of the Compliance Round-Up Webinars:
  - Teaching/knowledge transfer
  - Keep you up to date on compliance rules
  - Practical points
  - Assist organizations to develop in-house methods of managing
  - Please share your thoughts, suggestions (and criticisms)

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Compliance Round-Up: Webinar Overview

- As always, regularly scheduled Webinars will be supplemented, as necessary, with special “emergency” sessions

- <u>Administrative Matters</u>
  - Each session will continue be 60-75 minutes in duration, including a question and answer session
  - Each session will begin at 12:00 PM CT
  - If you are unable to participate in the live discussion, each session will be recorded and made available in MP3 format

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Today's Topic and Agenda

- OIG Advisory Opinion
  - 11-17
  - 11-18
- Medicare RAC Quarterly Report
- New Demonstration Project
- HIPAA Audits
- Meaningful Use Extension

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG Advisory Opinion 11-17 November 16, 2011

The U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued an unfavorable opinion relating to a proposed arrangement whereby a laboratory management company (Requestor) would provide allergy and immunotherapy testing services to physician offices (the Proposed Arrangement).

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's 1994 Background

The OIG indicated in the 1994 Special Fraud Alert that the provision of phlebotomy services by a clinical laboratory in certain settings would not be construed to constitute illegal remuneration under the federal Anti-Kickback Statute.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's 1994 OIG Fraud Alert

A laboratory may make available to a physician's office a phlebotomist who collects specimens from patients for testing by the outside laboratory as long as:

1. Permitted by State law,

2. The phlebotomist is restricted from performing additional tasks that are normally the responsibility of the physician's office staff

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's 1994 OIG Fraud Alert

The "key" to the Fraud Alert:

- OIG emphasized:

  "While the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's office staff."

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's Advisory Opinion No. 11-17 Facts

Requestor Laboratory would be:

1. Providing all necessary laboratory personnel (including laboratory technicians), equipment, supplies, training and billing and collection to and for the physicians on an as-needed basis (i.e., the physicians would be the laboratory service suppliers); and

2. Assisting the physicians with marketing allergy services to patients by providing "patient education materials" and reviewing patient charts to identify candidates for allergy laboratory services.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's Advisory Opinion No. 11-17 Facts

The physicians would be:

1. Billing federal health care programs and third party payors for the laboratory items and services. The Requestor laboratory would be providing billing and collection services on behalf of the physicians for the allergy testing services.

2. Paying the Requestor laboratory a fee for items and services provided by the laboratory equal to 60% of the physician's gross collections from allergy testing and immunotherapy items and services.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's Advisory Opinion No. 11-17 Facts

Proposed Arrangement does not qualify for safe harbor protection under AKS's personal service agreements safe harbor because:

1. The agreement would not specify the schedule of intervals, the precise interval length, or the charge for such intervals; and

2. The aggregate compensation to be paid under the contract would not be set in advance and would be determined in a manner that take into account the volume or value of the business generated between the parties that is payable by a Federal health care program.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

OIG's Advisory Opinion No. 11-17 OID Determination

The OIG also determined that the Requestor laboratory's fees could not be tied to actual and medically necessary services to be provided by the laboratory to the physicians' patients, such that the proposed arrangement could result in an over-utilization of laboratory services.

The laboratory's receipt of a percentage of fees based on the physicians' collections was also particularly problematic to the OIG.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Key Differences between 1994 Fraud Alert and OIG Opinion 11-17

While proposed arrangements in both the 1994 Fraud Alert and OIG Opinion 11-17 failed to meet personal services safe harbor, the Proposed Arrangement in the latter differs with respect to:

1. The Requestor Laboratory's provision of additional services to the physician's office in addition to phlebotomy services.

2. The Requestor Laboratory's receipt of a percentage of the physicians' collections related to the provision of clinical laboratory services.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

New OIG Advisory Opinion

- On November 30, 2011, the OIG issued a favorable opinion (Advisory Opinion 11-18) relating to a proposed arrangement whereby a vendor of web-based business services to physician practices (Requestor) would provide a referral order transmission and coordination service to healthcare professionals with a transaction-based pricing model (Proposed Arrangement).

- Although the Proposed Arrangement potentially implicates the Anti-Kickback Statute (AKS), OIG concluded that it would not subject Requestor to administrative sanctions under AKS.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

New OIG Advisory Opinion

- OIG has typically been hesitant to grant favorable advisory opinions for arrangements in which there is a per-transaction charge associated with the transmission of referral orders.

- Notable, because Advisory Opinion 11-18 recognizes that healthcare professionals may, in appropriate cases, pay for the fair value of health information exchange and care coordination services that merely facilitate the referral of healthcare items or services or provide additional value in connection with such referrals if those services are unrelated to inducing the referrals.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Medicare RAC Quarterly report

- On November 23, 2011, CMS released Medicare RAC statistics for 4th Quarter of FY 2011

- Available at http://www.cms.gov/Recovery-Audit-Program/03_Recent%20Updates.asp#TopOfPage

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

FY 2011 4th Quarter

	Overpayments Collected	Underpayments Collected	Total Quarter Collections	FY to Date Corrections
Region A (DCS)	$43.3	$5.8	$49.1	$146.3
Region B (CGI)	$60.4	$3.2	$63.6	$170.3
Region C (Connolly)	$65.2	$60.7	$125.9	$260.9
Region D (HDI)	$108.2	$6.9	$115.1	$361.8
Nationwide Totals	$277.1	$76.6	$353.7	$939.4

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

FY 2011 4th Quarter Statistics

- For the final quarter, the recovery auditors identified $353.7 million in claims' corrections, with $277.1 million in overpayments collected and $76.6 million in underpayments returned to providers. This represents a cumulative increase of 22 percent over all corrections identified in the third quarter.

- HDI, the Region D RAC, continues its significant lead among the RACs in identifying overpayments, with $108.2 returned to the Medicare program. This represents slightly over 39 percent of all monies returned in the final quarter of the fiscal year.

- Connolly, the Region C RAC, returned $60.7 million to providers in the final quarter. This number represents more than an eightfold increase from the $7.4 million returned by Connolly in the third quarter. Significantly, this number represents nearly 50 percent of all claims' corrections identified by Connolly in the final quarter of FY 2011.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Top Issues Per Region

- Region A (DCS): Renal and urinary tract disorders (medical Necessity)
- Region B (CGI): Surgical cardiovascular procedures (medical necessity)
- Region C (Connolly): Acute inpatient admission neurological disorders (medical necessity)
- Region D (HDI): Minor surgery and other treatment billed as inpatient (medical necessity)
- No change for Region A and Region D.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

New RAC Demonstration

- CMS also recently announced several new demonstration projects, including one involving recovery auditors

- Beginning January 1, 2012, the Recovery Audit Prepayment Review demonstration will allow Medicare Recovery Auditors (RACs) to review claims **before they are paid** to ensure that the provider complied with all Medicare payment rules. The RACs will conduct prepayment reviews on certain types of claims that historically result in high rates of improper payments. These reviews will focus on seven states with high populations of fraud- and error-prone providers (FL, CA, MI, TX, NY, LA, IL) and four states with high claims volumes of short inpatient hospital stays (PA, OH, NC, MO) for a total of 11 states.

- This demonstration will also help lower the error rate by preventing improper payments rather than the traditional "pay and chase" methods of looking for improper payments after they have been made.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

HIPAA Audits

- In June, HHS awarded KPMG a $9.2 million contract to create an audit protocol and then audit covered entities' and business associates' compliance with the privacy and security requirements of HIPAA.

- The contract calls for as many as **150 audits** of entities varying in size and scope before December 31, 2012.

- Historically, HHS had sought compliance with the Privacy and Security Rules in a mostly reactive manner, initiating investigations largely in response to complaints that it has received.

- But, HITECH required HHS to conduct periodic audits to ensure that HIPAA covered entities and business associates comply with the Privacy and Security Rules

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

HIPAA Audits

- Contract requires KPMG to develop an audit protocol
- The audit protocol will include instructions for auditors, checklists, interview questions, templates for communications and audit reports, and additional elements to target specific types of covered entities (e.g., group health plans) or to tailor the protocol to particular risks that have been identified.
- OCR has not indicated whether the protocol will be made publicly available
- Each audit will include a site visit. OCR has indicated that there will usually be an advance request for documentation so that the audit team can use their time on site to focus on what they need and with whom they need to speak. Documentation is expected within 10 business days of the request.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

HIPAA Audits

- Audits are expected to last 3-10 business days.
- Both CEs and BAs are eligible for audit, although CEs will be the initial focus.
- Intent is to audit as wide a range of types and sizes of CEs as possible.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

How to Prepare?

- Self-Assessment/Readiness Checklist
  - Do you have a health information privacy and security program?
    - Policies
    - Procedures
    - Contract templates
    - Do you have a designated Privacy Officer? A designated Security Officer
  - How is that program implemented by your workforce?
  - Have you conducted the requisite security assessment/risk analysis?
  - Have you updated your program to address breach notification?

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

How to Prepare?

- Self-Assessment/Readiness Checklist
  - Do you have a central repository for BAAs? If not, how will you evidence compliance?
  - Do you perform regular self-assessments?

- Even if you are not an audit target, keep an eye out for public reports. Learn from those audits and modify your practices accordingly.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Meaningful Use Extension

- On November 30, 2011, HHS Secretary Kathleen Sebelius announced her intent to extend the timelines for qualifying for reimbursement incentives available under the "meaningful use" rules to encourage more providers to attest to Stage 1 meaningful use before the end of 2011.

- Under the current requirements, doctors and hospitals that begin participating in the Medicare incentive program in 2011 (i.e., Stage 1 meaningful use) would have to meet new standards (Stage 2) beginning in 2013. If they waited until 2012 to attest to Stage 1 meaningful use, they could qualify for the same reimbursement amount but delay the need for Stage 2 compliance until 2014.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Meaningful Use Extension

- To encourage more Stage 1 use and attestations in 2011, Sebelius announced her plan to amend the rules to allow a 2011 Stage 1 meaningful user to have until 2014 to qualify for Stage 2 and still receive the full incentive payment amounts available under the Medicare program.

- HHS also clarified that providers who attest to having met Stage 1 meaningful use standards in 2011 have until February 28, 2012, to file their attestation and still qualify for 2011 incentive payments.

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Meaningful Use Extension

- SMS also recently published a web-based interactive resource, called "An Introduction to the Medicare EHR Incentive Program for Eligible Professionals" (PDF) to assist physicians and other eligible professionals with the meaningful use rules.

- The tool includes chapters on program basics, eligibility and registration. It also has a description of all of the Stage 1 meaningful-use criteria and advises practitioners on how to choose the optional measures they will use as part of the attestation phase of the program.

- https://www.cms.gov/EHRIncentivePrograms/Downloads/Beginners_Guide.pdf

AEGIS
COMPLIANCE & ETHICS CENTER, LLP

Follow-Up

- Questions?

questions@aegis-compliance.com

audiocourses@aegis-compliance.com

- Next Lecture:

Tuesday, December 27, 2011

12pm CT/1pm ET

Happy Holidays!

AEGIS
COMPLIANCE & ETHICS CENTER, LLP