COMPLIANCE ROUND-UP

Therapy in Home Health, Streamlining Medicare and Medicaid Rules, EHR Incentive Program, and OIG Advisory Opinions

October 25, 2011

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Today's Faculty

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Compliance Round-Up: Changing Format

- Between now and December 31, 2011 we will be working on revising the webinar format
- The name is changing to “Compliance Round-Up”
- Will remain twice per month but will tackle a host of compliance areas and provide a broader scope of updates
- November 8 webinar will have a brand new look and format and we will kick off the re-boot with a run-down of the recently released OIG Workplan for FY 2012

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Compliance Round-Up: Webinar Overview

- Scope of Webinar topics to be discussed include:

  1. AKS & Stark Law,
  2. HIPAA,
  3. RAC,
  4. Medicare,
  5. Compliance Program tips, and
  6. Other compliance subjects

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Compliance Round-Up: Webinar Overview

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

- Administrative Matters
  - 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
  - We will le all of you try it out for the next three months at no additional charge
  - If you like the revised format, you can review your subscription as of January 1, 2012

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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)

- We will be spending October building the new format with a re-boot for the November and December trial period
  - We will be adding faculty to the program to bring additional perspectives
  - We welcome all suggestions for topics!

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Today's Topic and Agenda

- Senate Finance Committee Report on Therapy Utilization in Home Health
- CMS Issues Proposed and Final regulations to Streamline Medicare and Medicaid Rules
- EHR Incentive Programs
- OIG Advisory Opinions

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Therapy Utilization in Home Health

- Therapy utilization in home health episodes has long been an area of suspected abuse.

- In May 2010, the scrutiny reached a new level when the Senate Finance committee launched an investigation into the therapy utilization practices of the four largest publicly traded home health providers in the country(Amedisys, LHC Group, Gentiva and Almost Family). Followed WSJ investigation

- On October 3, 2011, the U.S. Senate Finance Committee released a 670-page report outlining the results of its investigation.

- Findings=the agencies intentionally manipulated therapy utilization during home health episodes to improve their financial performance.

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Therapy Utilization in Home Health

- APTA and the four home health providers have issued press releases and responses disputing Senate Finance Committee's findings and affirming their commitment to compliance

- Nonetheless, indicative of future scrutiny by investigators, including RACs, ZPICs

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Streamlining Medicare & Medicaid Rules

- In January, 2011, President Obama issues Executive Order 13563 entitled “Improving Regulation and Regulatory Review.”

- In response, CMS recently announced one final rule and two proposed rules aimed at streamlining Medicare and Medicaid regulations

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Streamlining Medicare & Medicaid Rules

- In the final rule, CMS revised ASC conditions for coverage to allow patient rights information to be provided to the patient, the patient's representative, or the patient's surrogate "prior to the start of" the surgical procedure rather than "in advance of the date of" the procedure.
- CMS stated that this revision "will provide the patient, the patient's provider of transportation, and the ASC with the flexibility of having the surgical procedure completed on the same day the notice of patient rights is provided, when appropriate."

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Streamlining Medicare & Medicaid Rules

- The first proposed rule (76 Fed. Reg. 65891 (Oct. 24, 2011), entitled "Reform of Hospital and Critical Access Hospital Conditions of Participation," includes revisions to the Hospital COPs, including
  - Removing the requirement that a hospital have a single director for outpatient services,
  - Permitting one governing body to oversee multiple hospitals in a single health system,
  - Allowing CAHs to provide laboratory and radiology services under arrangements, and
  - Allowing hospital patients to take certain self-administered drugs on their own without immediate supervision by a nurse

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Streamlining Medicare & Medicaid Rules

- The other proposed rule, "Regulatory Provisions to Promote Program Efficiency," affects a variety of healthcare facilities, including ESRD facilities, OPOs, and ASCs.
- Among other things, this proposed rule would
  - eliminate automatic deactivation of a Medicare provider number for providers and suppliers that have not submitted a claim in twelve consecutive months,
  - eliminate the list of specific emergency equipment ASCs must have on hand, and
  - revise ESRD Conditions for Coverage to limit the applicability of the National Fire Protection Agency's 101 Life Safety Code to certain ESRD facilities.

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EHR Incentive Program

- On October 17, 2011, CMS issued an email providing additional information about the EHR Incentive Program Attestation.

- The email update is available at http://www.cms.gov/EHRIncentivePrograms/Downloads/Meaningful_Use_Attesting_to_the_data.pdf

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EHR Incentive Program

In order to attest, successfully demonstrate meaningful use and receive incentive payments, eligible hospitals must agree that the information submitted:

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

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Recent OIG Advisory Opinions

- A look at 4 OIG Advisory Opinions released in the past 30 days and the impact on health care compliance and billing

- Adv. Ops:
  - Sept 30: Modification of Advisory Opinion 07-06
  - Oct 7: Advisory Opinion 11-14
  - Oct 11: Advisory Opinion 11-15
  - Oct 18: Modification of Advisory Opinion 07-18

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OIG Advisory Opinions

- In the new program format, we will regularly update subscribers on all Advisory Opinions released by OIG & CMS
- The Advisory Opinion commentary will be indexed on our website starting January 2012
- Our goal is to provide a quick overview of the issues covered by the Advisory Opinion and practical take-away points
- Advisory Opinion topics are not always immediately relevant but keeping up on the ones released will help compliance programs relate them to issues when they arise

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OIG Advisory Opinions

- Today we will spend some time explaining Advisory Opinions and why they are important to monitor and to provide a baseline

- This sessions can be referenced in the future for anyone in your organization who wants an overview of what Advisory Opinions are

- In the future we will talk directly about the recently issues Advisory Opinions and not go over the basics of the process each time

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Differences between AOs issued by OIG and CMS

An important note:

- OIG issues advisory opinions on arrangements which potentially impact the **anti-kickback statute** and associated **civil monetary penalties**

- CMS issues advisory opinions on arrangements which potentially impact the physician self-referral law (**Stark Law**)

In both instances, if OIG or CMS does not approve an arrangement, there are implications for penalties and billing

Today we will focus on OIG Advisory Opinions

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Links

- OIG Advisory Opinion Man Page
  - http://oig.hhs.gov/compliance/advisory-opinions/index.asp
- FAQs:
  - http://oig.hhs.gov/faqs/advisory-opinions-faq.asp
- Checklist:
  - http://oig.hhs.gov/fraud/docs/advisoryopinions/prechecklist.htm

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What is an Advisory Opinion?

- "[A] **legal opinion** issued by OIG to one or more requesting parties about the application of the OIG's fraud and abuse authorities to the party's existing or proposed business arrangement. An OIG advisory opinion is legally **binding on [HHS] and the requesting party or parties**. It is not binding on any other governmental department or agency. A party that receives a favorable advisory opinion is protected from OIG administrative sanctions, so long as the arrangement at issue is conducted in accordance with the facts submitted to the OIG. **However, no person or entity can rely on an advisory opinion issued to someone else**."

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Requesting an Advisory Opinion

- Submitted in writing to OIG
- OIG charges $86 per hour for reviewing the Advisory Opinion
- Parties may request an estimate of cost
- Estimated response time for issuing advisory opinion is 60 days

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Requesting an Advisory Opinion

- May cover proposed arrangements or existing arrangements
- Organization must be prepared to unwind the arrangement if disapproved
- Advisory Opinion is published, but names redacted
- They can be useful tools, but tread carefully!

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Modifications to Advisory Opinions 07-06 & 07-18

- OIG rarely “revises” a previously issued Advisory Opinion, but recently they revised two:
  - Sept 30: Modification of Advisory Opinion 07-06
  - Oct 18: Modification of Advisory Opinion 07-18
- In both instances, the OIG allowed the arrangement and approved **charitable subsidies** to Medicare beneficiaries
- Since both of the modifications are similar, we will deal when them first

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(Revised) Advisory Opinion 07-06

- Facts:
  - Original Advisory Opinion 07-06 (July 27, 2007) allowed a hospital's charitable foundation to provide assistance in cost-sharing and premium payments to financially needy individuals with **specific chronic diseases**
  - Party requested OIG to comment on the foundation adding targeted assistance for Medicare beneficiaries with specific chronic diseases

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(Revised) Advisory Opinion 07-06

- OIG Ok'd the arrangement:
  - As long as there is no intent to induce or reward referrals
  - All eligible individuals are reviewed for assistance (everyone treated equally)
  - It would extend financial assistance only in connection with disease states for which at least two different products from two different manufacturers are supported by the funds.
- Importantly:
  - "OIG's conclusion might differ if the [the subsidy] included single-product or single-manufacturer disease states."

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(Revised) Advisory Opinion 07-18

- Facts:
  - Original Advisory Opinion 07-18 allowed a foundation "to cover copayments, deductibles, and co-insurance associated with certain **high-cost drugs used to treat specified diseases**."
  - Party asks OIG to consider modification which allows:
    - move towards a specialty therapeutics model such that its disease funds would only offer assistance to patients prescribed treatment with specialty therapeutics; and
    - enroll certain pharmacies as "Participating Pharmacies" through which claims could be processed more efficiently.
  - Note: "Specialty therapeutics are costly medications with particular features that complicate their use (e.g., the medications may require physician administration,…or their effective use may require significant patient education)."

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(Revised) Advisory Opinion 07-18

- OIG Ok'd it because:
  - The funds would be used to subsidize specialty therapeutics which "include at least two specialty therapeutics, marketed by different manufacturers. " OIG noted: "In fact, the majority of funds on the list include at least four specialty therapeutics."
  - Decisions about which diseases to address would be based on an independent assessment by the Foundation's Board of Directors.
  - "Any duly licensed pharmacy capable of dispensing specialty therapeutics and equipped to appropriately exchange information with the Foundation for claims processing would be permitted to enroll as a Participating Pharmacy."

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Advisory Opinion 11-14 (Oct. 7, 2011)

- Facts:
  - Requester is an ophthalmology group
  - Medicare pays for **conventional lens** as part of cataract surgery but does not pay for premium lens
  - Premium lens attempt to help repair near and intermediate distance issues
  - If a patient wants a premium lens, Medicare will pay for the surgery the cost of a conventional lens but Medicare will not pay for:
    - The difference between the convention and premium lens
    - Extra services and diagnostic tests associated with the premium lens
  - **Physician group proposes to ask patients wanting premium lenses to pay a flat $500 to cover the extra services**
  - And physician group wants to promote this with optometrists
  - Question: If an optometrist promotes the attractive flat rate to patients will this provide the optometrist with lucrative additional charges for premium lens maintenance when the patient returns to the optometrist post-surgery?

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Advisory Opinion 11-14

- OIG Ok'd the arrangement:

- The Requestor would have no written or unwritten agreements to co-manage patients with (referring) optometrists. Instead, the Requestor would explain to all patients that they may receive their post-surgical care from the Requestor or from their referring optometrist, following a determination of clinical appropriateness—an option that the referring optometrist may have already presented to the patient.

- Second, the Requestor would inform patients receiving Premium Lenses that, if they choose to return to their optometrist for post-operative care, the optometrist may charge them for any services related to the Premium Lens that the optometrist may deem necessary. By informing the patient of potential additional charges that the patient would not incur by receiving follow-up care with the Requestor, the Requestor actually reduces the likelihood that the patient will choose to return to the referring optometrist.

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Advisory Opinion 11-14

- OIG Ok'd the arrangement:

- Third, the increased costs associated with a Premium IOL are not covered by the Medicare program. Although the Medicare program does cover the cost of medically necessary cataract surgery (including facility and physician services) up to the cost of, and for services associated with, a Conventional IOL, as noted above, we have relied on the Requestor's certification that it complies with all applicable Medicare billing and coding requirements, including requirements regarding splitting the global fee. Thus, the fact that the Requestor would co-manage a beneficiary receiving a Premium IOL with an optometrist who may charge the beneficiary for additional, non-covered services provided would not increase costs to the Medicare program.

- Finally, the Requestor also certified that it would transfer a patient back to his or her optometrist only upon the patient's request. Explaining a patient's options for post-surgical treatment providers, including the potential for incurring additional fees by returning to the optometrist, and complying with the patient's decision, would not constitute prohibited remuneration to induce the optometrists' referrals under the anti-kickback statute.

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Advisory Opinion 11-15 (October 11, 2011)

- Facts:
  - Requester is an LLC owned by a physician
  - The LLC would contract with a to-be-determined anatomic pathology lab
  - The path lab would enter into a management agreement with the LLC (i.e., LLC would manage the path lab)
  - The path lab would pay the LLC a **set-in-advance percentage of the path lab's revenue as compensation**
  - The LLC would offer investment interests to physicians with no obligation to refer
- OIG did not like the proposal

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Advisory Opinion 11-15

- "The OIG has in past publications warned the public about arrangements in which a health care provider expands into clinical diagnostic laboratory services by contracting with an existing provider of that laboratory services to operate a newly formed laboratory subsidiary on essentially a turn-key basis."

- "The Proposed Arrangement is the converse of such an arrangement; rather than contracting with an existing provider to obtain turn-key laboratory services for which a physician-owned entity would bill Federal health care programs, the Requestor, a physician-owned entity, would contract to provide such services to an entity that would, in turn, bill Federal health care programs." (emphasis in original)

- **Key Point:** "[T]he income of the physician-owned entity would vary with the volume or value of referrals from physician investors. We therefore evaluate the Proposed Arrangement for compliance with any applicable safe harbor, and for the potential for abuse."

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Advisory Opinion 11-15

- **Conclusion:** "[T]he usage fees to be paid by the Path Lab to the Requestor under the Management Contract would take into account the volume or value of business generated for the Path Lab by the New Physician Investors in the form of laboratory specimen referrals directed to the Path Lab. This fee structure would effectively link the New Physician Investors' profit distributions to the laboratory business they send the Path Lab, posing considerable risks of overutilization of laboratory services, distorted medical decision-making, and increased costs to Federal health care programs."

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Follow-Up

- Questions?

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- Next Lecture:

Tuesday, November 8, 2011

12pm CT/1pm ET

OIG FY 2012 Workplan!

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