He’s Making a List, You Should Check It Twice

- Regional Surgery Center (RSC) is a 4 OR multi-specialty surgical facility. Approximately 45% of the patients treated at RSC are Medicare beneficiaries. It has 12 RNs on staff who share responsibility for pre-, intra- and post-operative care of the patients treated at RSC. All the RNs are crossed trained to handle the various types of cases done at RSC.
- RSC has in place the P&Ps necessary for accreditation, but has just started implementing a compliance program. As part of this effort, RSC’s newly appointed compliance officer checks for the first time the OIG Excluded Individuals database to see if any of the RSC employees, surgeons or vendors are on the list.
- Low and behold the compliance officer discovers that one of RSC’s best RNs is on the list.

Now what?

- Speak with the RN as soon as possible to determine why he is on the list.
- If it appears the listing is correct or likely correct, place him on a leave of absence until the situation is sorted out.

Effect of exclusion

- Making a voluntary disclosure
  - OIG Self Disclosure Protocol
Effect of Exclusion

- No payment will be made by any Federal health care program for any items or services furnished, ordered or prescribed by an excluded individual or entity.
- This payment prohibition applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider for which the excluded person provides services, and anyone else.
- The exclusion applies regardless of who submits the claims and applies to all administrative and management services furnished by the excluded person.

Making a Self-Disclosure

- The job duties performed by that individual.
- The dates of the individual’s employment or contractual relationship.
- A description of any background checks that the disclosing party completed before and/or during the individual’s employment or contract.
- A description of the disclosing party’s screening process (including any policy or procedure that was in place) and any flaw or breakdown in that process that led to the hiring or contracting with the excluded individual.
- A description of how the conduct was discovered.
- A description of any corrective action (including a copy of any revised policy or procedure) implemented to prevent future hiring of excluded individuals.

Calculating Damages

- Disclosing party’s total costs of employment or contracting during the exclusion to estimate the value of the items and services provided by that excluded individual.
- The costs of employment or contracting include, but are not limited to, all salary and benefits and other money or items of value, health insurance, life insurance, disability insurance, and employer taxes paid related to employment of the individual.
- This total amount is multiplied by the disclosing party’s revenue-based Federal health care program payor mix for the relevant time period.

Location, Location, Location

- The physician principals of Eye Surgeons PC want to purchase a femtosecond laser for the 2 OR ASC they own.
- The surgeons agree on a technology, but can’t come to a consensus about where to locate the FSL. There are three options under consideration:
  - Install the laser in one of the two ORs. This may require the OR to be enlarged.
  - Install the laser in the open area between the two ORs where staff pass through to access the ORs.
  - Install the laser in an extra exam room in their medical practice office, which is in the same building as the ASC.
**Location, Location, Location**

- What should the surgeons be considering in trying to make a decision?
  - Patient safety
  - State licensure and/or Certificate of Need requirements
  - Malpractice insurance restrictions
  - Medicare’s Conditions for Coverage and third-party accreditation standards

**Time Marches On**

- On April 1st, your head biller returns from a coding workshop sponsored by your local MAC and advises you that, according to the MAC, the practice may not bill for certain diagnostic tests as you have been doing. This advice contradicts the advice you received from your expert billing consultant. The amount you received for the services was about $50,000 for each of the past 3 years, and $250,000 over the past 6 years.

**With Friends Like These . . .**

Five surgeons set up their own ASC. Each contributes $50,000 and each signs a personal guarantee of an additional $250,000. For several years, everything goes well; all of the surgeons are busy, and the ASC is profitable. Each of the surgeons generates more than 1/3 of his income from surgery, consistent with the ASC safe harbor criterion. The value of the ASC to each investor increases dramatically.

Five years later one of the partners decides to slow down. He reduces his schedule to 3 days per week, and performs surgery only on a limited basis. A second partner becomes disabled and is no longer able to perform surgery, but he continues to practice ophthalmology. With the reduction in productivity, the value of the shares in the ASC plummets.

The other three partners decide that it is not fair for each partner to get the same distribution from the ASC when they are clearly contributing more to the profit than the other 2 partners. As they hold the majority of the shares, they demand that their part-time partner sell back 40% of his stock in the ASC and force their disabled partner to divest entirely.

Any problem with this plan?
With Friends Like These...

1. No Problem – While the 3 full-time partners may not win the Nobel Prize for Collegiality and Compassion, this is a business, and it is not fair for the others to profit from their hard work.
2. Problem – They cannot force out the other partners just because those partners are not contributing to the profitability of the ASC to the same degree. They are tying access to shares to volume of referrals, and that is a kickback concern.
3. No problem with respect to the disabled partner. Since he no longer performs surgery at all, he cannot own an interest in the ASC.
4. No problem with respect to the part-time partner if his revenue from surgery drops below 1/3 of his total revenue.
5. It may be a problem - - What does the Partnership Agreement provide?

New Gadgets

- Your ASC has just purchased a femtosecond laser system (FLS) that your surgeons believe will improve the refractive outcomes of their cataract surgery patients. The new technology is quite expensive and while you are eager to assure that your patients get the best possible result, you also wish to recoup your costs by charging patients an additional fee.
- Medicare has stated that utilization of the FLS to perform the standard steps of cataract surgery is covered, but that the imaging function is not when it is used to enhance the placement of a premium IOL.

New Gadgets (con’t)

- The ASC performs approximately 1,000 cataract procedures per year, inclusive of both monofocal and premium IOLs. You estimate that with a $300 per surgery charge, the laser will be paid off in approximately 1 year.
- Thoughts on this business plan?

CMS Guidance

- “If the bladeless, computer controlled laser cataract surgery includes implantation of a PC-IOL or AC-IOL, only charges for those non-covered services specified above may be charged to the beneficiary. These charges could possibly include charges for additional services, such as imaging, necessary to implant a PC-IOL or an AC-IOL but that are not performed when a conventional IOL is implanted. Performance of such additional services by a physician on a limited and non-routine basis in conventional IOL cataract surgery would not disqualify such services as non-covered services.”
Where is the Laptop?

- Eye Care Specialists, PA is a large, multi-location practice. An accounting audit revealed irregularities with the practice finances and an internal investigation found that the practice administrator was embezzling from the practice. The administrator was terminated and his practice laptop retrieved. Concerned that the administrator had access to important practice records as well as personal financial records of the physicians, the practice had a forensic review of the laptop conducted, which showed that the full contents of the laptop had been transferred to three separate external devices in the days just prior to the termination of the administrator.

  What would you do?

The Plot Thickens

- The review of the laptop contents reveals that the administrator appropriated 600 patient medical records, tax records for the physicians and the professional corporation as well as a letter to the Office of the Inspector General alleging the practice has been submitting claims for unnecessary cataract surgery.

  Now what would you do?

1. Contact an attorney
2. Conduct immediate review of the contents of the laptop with special attention to patient health information and key personal information that could be used with identity theft
3. Demand flash drives and affidavit from former administrator that no copies of the data have exist and that no information has been disclosed
4. Consider reporting the theft to the authorities

1. Deal with the unauthorized disclosure of the patient medical records. Must consider both HIPAA privacy rules as well as state rules.
2. Notify individuals whose personal financial information was discovered so that they may take steps to protect themselves from identity theft.
3. Conduct an audit of cataract surgery performed by the practice physicians with particular attention to medical necessity. May want to conduct a general compliance review to determine whether the practice has any other areas of exposure.
Public Service or Criminal Kickback Violation?

- Community Eye Care is a highly respected ophthalmology practice that is active in community service. Each quarter, it sponsors a CE course for all local ODs, providing education on the latest developments in vision care. Some of the attending ODs are referral sources; others are not.
- Speakers at these events frequently are physicians from Community Eye Care, although occasionally, they will invite a competing physician to present when the topic is one where the competing physician is recognized as the real expert.
- Several industry representatives have offered to sponsor the meeting, but the physicians from Community have refused, electing to incur the entire expense on their own. As a result, instead of having steak dinners, the meals are modest, usually sandwiches or a pasta buffet.
- The optometrists attend free of charge.

Any concerns?

1. No, the practice is doing everything right – not limiting the invitation to referring ODs, not accepting money from industry, providing modest meals, and inviting competing physicians to speak when the competition is the expert. It doesn’t get any better than that.
2. Yes, they are providing CE, which is something of value, to referral sources at no charge.
3. Yes, these guys are missing a great opportunity – if they would accept the grant from industry, they could serve steak and generate much more goodwill, and increase their referrals from the local ODs.
4. Any suggestions on how to further reduce the risk?

Just When You Thought It Could Not Get Any Worse

- A physician is under investigation for performing medically unnecessary laser procedures. The procedures are performed in a hospital. The physician billed for his procedures and the hospital billed a facility fee. Both the physician’s claims and the hospital’s claims accurately reflected the service performed.
- The prosecutor has an expert who believes that some of the procedures performed were not consistent with medical necessity, but does not question that the services were performed.
- What theories of liability could the prosecutor pursue?

- Overpayment for the physician’s claims. A dispute between professionals on the basis of medical necessity cannot be the basis for a sanction.
- Civil False Claims for the physician’s claims because the Medicare claim form includes a certification that the services reflected on the claim form are medically necessary, and these were not.
- Civil False Claims for the physician’s and the hospital’s claims. Not only did the physician certify to the medical necessity of his services, but he also caused the hospital to file false claims.
- Item #3 above plus criminal liability, because the physician knew that the services he performed were not medically necessary and, therefore, he knowingly filed false claims.
Marketing Program Landmines

- Eye Associates is approached by a manufacturer of a new drug to treat a chronic eye disease with a special marketing program. Manufacturer will send a COT to the practice for two days to review the records of all current patients with the disease to determine those with clinical findings that indicate they might be candidates to switch from their current Rx to the new drug. There is no charge for the COT’s time. Manufacturer also will provide patient education mailers for the practice to send to the patients identified and pay for the mailing.

What do you think?

Treatment Recommendation vs. Marketing

- With limited exception the Privacy Rules require an individual’s written authorization before his/her PHI may be used or disclosed for marketing communications to the individual.
- Before HITECH: Communications regarding treatment were exempt from the definition of marketing, regardless of whether any remuneration was involved.
- After HITECH: any communication to an individual by a covered entity or its BA about a drug or biologic currently prescribed to that individual does not generally require prior authorization, so long as any financial remuneration provided by the third party whose product is being described is “reasonably related” to the covered entity’s cost of making the communication.

What Communications Qualify?

- Refill reminders for currently prescribed medications
- Communication about generic substitutions for a currently prescribed drug
- Communications about a recently lapsed prescription (with 90 days of lapse)
- Adherence communications

What Communications Do Not Qualify?

- Adjunctive drugs – Communications regarding a drug that may be used in conjunction with a currently prescribed drug or biologic, exception general information (e.g., drug to treat side effects of prescribed drug).
- New formulations – Communications regarding new formulations of a currently prescribed drug or biologic may only be made in a general manner, such as providing information (e.g., liquid rather than pill formulation).
- Switch messaging – Communications encouraging an individual to switch from a currently prescribed drug or biologic to a different drug or biologic do not meet the exception.
Advanced Co-Management

An ophthalmology practice has worked for years co-managing cataract surgery with ODs, properly informing patients about their choice and honoring the patients' decision.

When the patient elects to have a premium IOL implanted, the patient pays an additional $2500 per eye, of which $1000 goes to the ASC for the IOL and $1500 goes to the surgeon for additional diagnostic tests and an extended post operative period to one year, with an anticipated 3 additional post-op visits. When the OD co-manages, the surgeon follows the Medicare guideline and pays 20% of the $1500 to the OD, or $300. The patient is fully informed.

A femtosecond laser has been purchased and the patient charge for premium IOL implants has increased by $500 to $3000. The ODs now expect an additional $100, 20% of the additional $500.

Any problem with the OD logic here? Any other problem?

No - - these guys are doing everything correct. The patient has a choice, is fully informed about charges for which the patient is responsible, and the Medicare 20% co-management rule is followed every step of the way.

Yes - - the ODs are not entitled to receive any amount in connection with the femtosecond laser - - they do not perform any additional services.

Yes - - same as above, but in addition, the 20% Medicare rule does not apply to the diagnostic and other non-covered services that make up the $1500 additional fee for the premium IOL implant. Therefore, the ODs have no right to payment for those services, either.

No - - It's all non-covered, so Medicare doesn't care. Don't worry, be happy.