Vendor relationships face increased government and public scrutiny

It looks like Medicare Compliance Alert’s warning that contracting with pharmaceutical and device manufacturers may put you at risk of violating the anti-fraud laws (MCA, 3/23/09) came in the nick of time. The government has begun to crack down on physicians who partner with the manufacturers.

What’s worse: Many of these relationships may end up on the Internet, making it easy for the government, your patients, and your colleagues to see what these vendors are paying you (see story, pg. 2).

The government has traditionally targeted the manufacturers, with impressive results. Several device manufacturers, such as Zimmer and Smith & Nephew, signed deferred prosecution agreements and corporate integrity agreements to settle fraud allegations relating to their hip and knee implants, according to attorney Lisa Taylor, Stern & Kilcullen, Roseland, N.J.

The pharmaceutical industry has also been targeted by the government. Example: Eli Lilly and Pfizer both agreed this year to pay million-dollar fines to settle fraud charges regarding drug marketing. The U.S. Attorney’s office for the District of Massachusetts announced Feb. 25 that it filed a complaint against Forest Laboratories for paying kickbacks to physicians.

Why physicians should be concerned

Physicians should not ignore these developments because they see themselves as too small to be on the government’s radar. The government has announced it is now going after physicians who partner with the manufacturers, says attorney Judith Waltz, with Foley & Lardner, San Francisco. “There is a concern that the payments [to doctors] are excessive or a sham, and influence their decision-making,” she points out.

“It’s a logical corollary. There’s a need to look at both sides of the relationship,” notes attorney Andrew Wachler, Wachler & Associates, Royal Oak, Mich.
The risks of being in a fraudulent deal include civil and criminal penalties and exclusion from the Medicare and Medicaid programs. You can be sued by patients who claim that the vendor’s money influenced your clinical decision-making. Your state licensing board can also go after you for violating ethical standards, warns attorney William Mandell, Pierce & Mandell, Boston.

The government has begun to issue subpoenas to physicians who have contracts with vendors, says Taylor. Based on the information received from either the subpoenas or from the vendors themselves, the government is also sending “pre-demand” letters to physicians, inviting them to enter into a deal with the government before it commences an administrative proceeding or other action against them, says Taylor.

If that wasn’t bad enough, many of your vendor relationships may now be available to the public on the Internet. There has been a big push in 2009 for greater transparency regarding these contracts. Some initiatives to disclose manufacturer-physician deals, such as those by the associations PhRMA and AdvaMed, are voluntary.

But many aren’t. Several manufacturers that have settled with the government have been required to post on their Web sites the names of physicians they paid and how much they paid them. Columbia’s, Stanford’s and Johns Hopkins University’s medical centers, in what has become a trend, announced in April that they will provide online disclosure of their faculty’s consulting activities and/or ban them from consulting or accepting gifts from the industry.

Sens. Charles Grassley (R-Iowa) and Herb Kohl (D-Wis.) introduced federal legislation this year to require manufacturers to publicly report money they give to doctors; some states, such as Massachusetts, also require disclosure.

Many of these consulting, research and other arrangements with pharmaceutical and device manufacturers are legal and helpful to the industry, points out Mandell. However, they will no longer be secret, and physicians will be held accountable, says Taylor. “There’s potential exposure, but don’t panic. Use this as an opportunity to check what you’re doing,” she suggests.

“Industry relationships are under attack and observation [and doctors are at risk of running into legal trouble]. No one wants to be that doctor,” says Mandell.

7 steps to deal with closer scrutiny of vendor deals

To protect yourself in light of the surge of government and public interest in your deals with device

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and pharmaceutical manufacturers, you should:

1. **Look at the deal objectively and see if it’s compliant.** Make sure you’re being paid fair market value for your services and that you actually provide those services, says attorney Andrew Wachler, Wachler & Associates, Royal Oak, Mich. (MCA, 3/23/09). If the deal is not legally compliant, and you can’t get the vendor to change it, consider terminating the relationship. “Even if you’re not [currently] in the crosshairs of a prosecutor or whistleblower, you don’t want to be party to a relationship like that,” says attorney William Mandell, Pierce & Mandell, Boston. “And even if the doctor isn’t the target, you might be dragged in as a potential witness. That’s not a great place to be, either,” he adds.

2. **Follow whatever disclosure requirements apply to you.** If you’re on the faculty of a university or on medical staff of a health system that requires disclosure of your vendor relationships, make sure you do that, says attorney Judith Waltz, with Foley & Lardner, San Francisco. If your state, board of medicine or professional society requires you to report, make sure you comply.

3. **Assume your vendor relationships will be in the public domain and view them in their totality.** “If you have 25 relationships and get six figures a year [from them], is that what you want people to know?” asks Mandell.

4. **Keep an eye on developments,** such as new investigations of your vendor partners, new requirements of providers you’re affiliated with, and new state and federal laws. “2009 is a year of revolution [in this arena],” says Mandell.

5. **If you are involved in research or trials of a product or drug,** such as a patent or royalty, have a carve out for your own use of the product, suggests Wachler. “It shows that you’re not being paid on the volume of what you’re ordering,” he explains.

6. **Be prepared for fallout from colleagues,** who may question why you accepted money from vendors, especially if you didn’t disclose it to your partners or run it by your department chair, says Lisa Taylor, with Stern & Kilcullen, Roseland, N.J.

7. **If you receive a subpoena or pre-demand letter from the government,** talk to an attorney before proceeding. “Take it seriously,” says Waltz. One physician she knows who received a pre-demand letter and responded without proper assistance got slammed. “The physicians said, ‘but that OIG girl sounded so nice,’” Waltz warns.

**Dear Reader: 8 things you need to know about RACs**

(continued from page 1)

- **Look at the information your RACs will use.** Amy Reese, project officer for Medicare’s Region C, directed listeners to the same sources RACs will use to determine the issues they’ll audit: Reports regularly released by the OIG as well as Comprehensive Error Rate Testing reports and issues identified during the RAC demonstration. **Example:** Duplicate claims were one of the top physician errors identified during the demonstration. Reese also recommended internal audits to spot potential vulnerabilities.

- **Watch for Remittance Advice Code N432.** It means your claims have been adjusted based on a recovery audit. If the RAC performs an automated review of your claims, this will be the only way you’ll know.

- **There’s no limit to the number of times a RAC can perform an automated review.** As a result, there’s no limit to the number of times a RAC can find you owe Medicare money.

- **Make sure your RAC has your contact information.** If the RAC wants to perform a complex review of claims, it will send a medical request letter to the billing provider address on file with your carrier.

    One caller from an organization with multiple sites wanted to know if the RAC would send letters to their administrative office. Another wanted to know if the RAC could send letters to more than one location. In both instances, RAC representatives said they probably wouldn’t be able to do that.

- **The discussion period does not halt recoupment.** The discussion period is unique to the RAC program and allows providers under complex medical review to state their case to the RAC without having to file an appeal, explained Commander Kathleen Wallace, project officer for Region D. Once you receive the review results letter the discussion period begins. “Call, use that time to find out what you need to send to support your claim,” Wallace advised. If the claim isn’t resolved in your favor, you’ll need to return the money or file an appeal.

- **The discussion period is not a set period of time.** There were a number of questions about the discussion period during the Q & A session of the call. While the time to discuss the RAC’s findings begins when it issues the review results...
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letter, it **ends** when the RAC sends your files to your carrier, Wallace said. Depending on how quickly your RAC moves, you could have a very small window in which to start a conversation.

**Your RAC shouldn’t lump denials Part A and Part B claims together.** A few callers wondered if the RAC’s discovery of errors in a hospital’s claims would mean the associated physician services would also be denied. CMS has warned the RACs “not to automatically deny a Part B claim associated with a Part A denial,” Reese explained.

**RACs have the same incentives to find underpayments** as they do overpayments. They receive the same amount no matter what type of error they uncover.

**On the Internet:**

7 tips to deal with Medicaid’s enforcers

Even as providers brace themselves for more Medicare enforcement, Medicaid is ramping up its own anti-fraud initiatives (MCA, 4/20/09).

To prepare for the potential Medicaid fraud investigations and enforcement from the Medicaid Integrity Program (MIP), you should:

1. **Review your policies for compliance with your state’s Medicaid program.** “Be prepared for increased activity [regarding your Medicaid billing],” says Bill Hammock, vice president and senior consultant for Marsh USA, Nashville. Audit your Medicaid claims to see if there are any irregularities or patterns.

2. **Watch for differences between Medicare and Medicaid programs.** The enrollments in the programs differ, as do some of the billing requirements, says attorney Judith Waltz, formerly with CMS and now with Foley & Lardner in San Francisco. RACs and Medicaid Integrity Contractors (MICs) operate under different procedures. **Example:** The new limits on RACs regarding the number of medical records that can be requested in a time period don’t currently apply to the MICs, points out Jennifer O’Brien, former compliance officer for a Minneapolis health system and now an attorney there with Halleland Lewis Nilan & Johnson.

3. **Don’t assume you can fly under the radar.** While some Medicaid providers had been treated gently by the state because there were no other Medicaid providers in town or they treated a particularly needy Medicaid patient group, CMS is not likely to cut providers slack for those reasons, says consultant Kip Piper, President, Health Results Group, Washington, D.C.

4. **Screen potential employees and contractors.** You need to ensure you don’t hire any individuals or entities who have been excluded from the Medicare or Medicaid programs. Any work performed by excluded people or entities is not reimbursable and any such payments are considered overpayments subject to recoupment. This is a big deal to CMS, says David Frank, Director of the Medicare Integrity Group for CMS in Baltimore.

5. **Keep an eye on developments in your state.** **Example:** North Carolina Medicaid has posted on its Web site that it will be contacting Medicaid providers in North Carolina regarding provider audits and provided a fact sheet regarding the MICs.

6. **If your state provides Medicaid compliance guidance, use it.** New York has published such guidance, and other states are considering doing so, says Waltz. This will help you comply with requirements and identify your state’s areas of focus. Also look at state Medicaid alerts and other information.

7. **Review denied Medicaid claims.** Determine the reason for the denial, and correct the problem. Denied claims can trigger an MIP audit, says Waltz. Look especially for denials that recur, say in coding or medical necessity.

On the Internet:

Enrollment hurdles raise doctors’ burdens

Tightening the standards and rules you face when you enroll in Medicare is one of the key ways the government can fight fraud, according to Lewis Morris, Chief Counsel for the HHS Office of Inspector General. Unfortunately, that could raise the regulatory burden for you.

“New providers and suppliers should be subject to a provisional period during which they are subject to enhanced oversight, such as prepayment review and payment caps,” Lewis told the Senate subcommittee on Federal Financial Management, Government Information, Federal Services and International Security on April 22. “The cost of this screening could be covered by application fees,” Morris said. These comments were part of Morris’ prepared testimony.
While Morris’ comments provide a glimpse of what the future of enrollment might look like, the present contains enough problems for providers. Durable medical equipment suppliers and independent diagnostic testing facilities aren’t the only providers receiving extra scrutiny, warns Belinda Holmes CPC, senior medical consultant with Kerkering, Barbe rio & Co. in Sarasota, Fla. “They’re really coming down on the physicians as well.”

One of the key reasons CMS wants to tighten enrollment is to weed out rouge providers, says Danielle Trostorff, shareholder with Baker Donelson in New Orleans. Medicare Administrative Contractors (MACs) will check the OIG exclusions list, make sure the provider is really licensed and verify his credentials. “It also allows CMS to capture overpayments,” Trostorff says. If a provider tries to re-enroll and he has outstanding overpayments, “They’ll reject you.”

Even the troubled economy is creating enrollment woes for providers. One client had his payments suspended when his bank merged with another, Holmes says. “The bank sent a letter to every entity that made automatic deposits or withdrawals from the bank’s accounts as a courtesy.” This included Medicare, which paid the provider via electronic funds transfer. Medicare suspended his payments upon receipt of the letter.

**Note:** The enrollment anti-fraud initiative means you’re more likely to receive a revalidation request, Holmes warns. Carriers need to enter providers into the national Provider Enrollment Chain Operation System (PECOS), Holmes explains. PECOS enables enrollment data to be linked nationwide. “Revalidation is not an update saying everything is the same,” Holmes says. You have to start from step one. While carriers are holding off on issuing mass revalidation request, they are looking for excuses to get individual doctors to do so.

**Example:** A doctor receives paper checks, then moves and doesn’t notify the carrier in a timely fashion. “You’ll get caught because they do not forward payments,” Holmes says. “Your payments will stop and they’ll ask you to revalidate.”

**Watch out for these 4 common enrollment mistakes**

There’s no way for the enrollment divisions of carriers and Medicare Administrative Contractors (MACs) to tell innocent mistakes from step one in a scheme to defraud the program.

As a result, experts say if you are enrolling for the first time or notifying your MAC of some change at your practice, you are far more likely to have your enrollment denied or rejected and your ability to bill Medicare placed on hold until the MAC is absolutely certain you should be receive payments.

**Note:** Because the process is so complex, Trostorff highly recommends PECOS online. The system will pick up certain errors, Trostorff says. “It will trigger you to fill out required information.”

“It’s like ‘Mission Impossible’,” Holmes says. “The lasers form a web to detect intruders, but honest providers have to get through the web as well.” Make sure you don’t trigger a loss of revenue by avoiding these 4 common mistakes:

**Bad timing:** If your enrollment is incomplete, the MAC will send a letter asking for the additional information, says Wayne van Halem, principal of The van Halem Group, LLC in Atlanta. Providers have a very narrow window in which to respond to these requests: 30 days from the date on the letter – not the postmark or the date it arrives at your office, Holmes notes.

“If they don’t respond, either the application is denied (for new enrollees) or their billing privileges are revoked (for enrolled providers),” van Halem says.

**Missing documentation:** The application and the requirements to submit an enrollment are extensive, van Halem notes. The MAC will want copies of all professional school degrees or certificates, professional licenses and/or evidence of qualifying course work to a copy of the confirmation letter from the IRS. The IRS CP-575 form can create a huge headache for providers, Holmes says. It can take a few weeks to get the letter from the IRS so if you start the enrollment process and you don’t have it on hand, your MAC will kick out your application.

**Business name mismatch:** “The biggest issue I see is a mismatch between the business name the IRS has on file and the rest of the documentation the provider has on hand,” Holmes says. To make matters more confusing, what the IRS has on file may not match the information you submitted when you incorporated. Holmes gives the example of an instance where the IRS truncated a provider’s name. However, even a difference in punctuation can cause problems. “When the IRS data doesn’t match, you have appeal to the IRS,” Holmes says. “This can take weeks and your application will get dropped.” A provider’s best bet is to make sure the IRS doesn’t have conflicting information on file well before he needs to enroll.

**Too many chefs:** Practices have to have a point person for enrollment and credentialing, Holmes says. Not only will this increase the chance that a request from the MAC’s enrollment division is handled in a timely fashion, it can eliminate the risk that the MAC will receive conflicting information, which can stop the process cold.

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**On the Internet:**
The when and how of patient notification

Physicians who have an ownership interest in a hospital may need to tweak their work flow before the second week of June. A Change Request recently issued by CMS will require doctors to inform patients of their financial relationships with hospitals when they refer a patient to the facility. CMS expects hospitals to police physicians and pull staff membership and admitting privileges when doctors don’t comply (MCA, 4/20/09).

Here are 5 tips D.C.-based attorneys Don Romano of Arent Fox and Lisa Ohrin of Sonnenschein, Nath & Rosenthal shared for keeping your patients informed:

1. **Make it part of your standard operating procedure**, Ohrin suggests. A physician could give the disclosure to every patient, just to make sure he’s covered, Ohrin says.

2. **Timing is crucial.** The physician must give the patient the notification at the time of the referral, Romano says.

3. **Keep it simple.** The notice should be written in easy to understand language, Ohrin says. Don’t get carried away with detail, just give the information required by the rule: You have an ownership interest in the hospital where you’re referring the patient.

4. **Create a pre-printed form.** To make sure you’re completely covered, Ohrin suggests a pre-printed disclosure form that states you have an ownership interest in the hospital with blanks for the date, patient’s name, hospital name and the procedure you’re referring the patient for. Don’t forget to give the patient time to ask questions, Ohrin adds.

5. **Hang on to a copy,** Romano advises. After you’ve answered any questions the patient might have, get them to sign the form and make a copy.

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**Q&A**

**FOR THE ANONYMOUS CO: YOUR QUESTIONS ANSWERED HERE**

**OIG says free transportation to visitors possible**

**Q** We want to offer free transportation to friends and family of our patients. Will this violate the anti-kickback rules?

**A** It depends on how your program is structured. Ordinarily the OIG has concerns about providing free transportation, since they’re sometimes an integral part of schemes that lead to inappropriate steering of patients, overutilization, and the provision of medically unnecessary services.

However, the OIG recently approved a free transportation program for friends and family of residents of a skilled nursing facility (SNF). In an Advisory Opinion published March 13, the OIG said the SNF’s program wouldn’t constitute grounds for the imposition of civil monetary penalties and that the OIG would not impose administrative sanctions.

**Note:** The OIG distinguished this program from problematic free transportation programs, such as providers offering patients free limousine services, providers inducing referrals from physicians by offering the physicians’ patients free transportation, or patients being offered free transportation for services of questionable necessity. The SNF’s program passed muster because:

- It’s being offered to friends and families of all of the SNF’s residents, not just Medicare or Medicaid beneficiaries.
- The transportation will be by van, not limousine, and generally only to and from the SNF and various public locations, not door-to-door service to people’s homes.
- The service will only be offered and advertised locally.
- The SNF certified that local public transportation in its city is limited, and a part of its primary service area is separated from it by a toll bridge.
- The arrangement will give the residents increased companionship from friends and family, which is consistent with the SNF’s mission to provide quality care.
- The cost of the transportation won’t be claimed on any bill or cost report or otherwise shifted to any federal health care program.

While the Advisory Opinion only applies to the SNF that requested it, it provides guidance on how the OIG would view other free transportation programs.

**On the Internet:**


Have a question you’d like to ask anonymously? Send it to jkyles@decisionhealth.com. Medicare Compliance Alert will not print any information that could identify your organization or your client.
Case #10: The Case of the False Problem Oriented Service

The client: A large integrated health system in the Northeast.

The audit: System-wide audit of internal medicine and family practice.

The compliance risk: Physical exams performed without a patient problem or complaint billed using Problem Oriented E/M codes (99201-99215) instead of preventive codes (99381-99397) to financially benefit patients and/or the practice.

Background:
An essential requirement to bill CPT codes 99201-99215 to Medicare is that the patient has an illness or injury that supports the service. Annual physical exams or preventive physical exams are billed with preventive service codes 99381-99397 and Medicare does not cover these codes.

The providers we spoke with were aware of the difference between the services, yet chose to bill Medicare incorrectly because they were acting as a financial advocate for themselves or the patient.

Based on years of performing audits for primary care physicians, we believe a significant number of services billed as problem oriented are actually annual physicals or complete physical exams. This billing exposes a practice to allegations of Medicare fraud.

The investigation:
The client wanted a solely prospective investigation without looking back at past claims – even if a significant error is uncovered. Turning a blind eye in cases such as these are ill-advised and could raise significant problems when uncovered during a CMS audit.

Recommended Corrective Action Plan:
One of the most common services provided by primary care physicians is the “Complete Physical Exam” (CPE). There is wide variation in the content and extent of “physicals” and the coding must reflect any variation.

Let’s assume the physician’s charges are as follows:
- 99397 – Annual physical for an established patient age 65 or older, $150
- 99213 – Problem-oriented service based on a low complexity of decision making, $50

Note these modifiers:
- 25 – Significant, separately identifiable E&M service was performed on the same day as other services or minor surgical procedure.
- GA – Medicare may deny a service as not reasonable and necessary and there is an Advance Beneficiary Notice on file.
- GY – Service is statutorily excluded from Medicare.

Here are some billing scenarios we advised the client to implement:

CPE, no symptoms, no pre-existing conditions
The physician should bill 99397-GY (diagnosis code V70.0) and charge $150. Since the patient did not present with any symptoms and pre-existing conditions were not addressed at this visit, the service must be coded as a physical even if an abnormality is discovered during the review of systems or physical examination. The doctor may bill at the time of service.

CPE, patient complaint of symptoms or pre-existing conditions addressed
A pre-existing problem evaluated during the preventive service that is significant enough to require additional work (history, exam, and medical decision making) should be separately coded with the appropriate E/M code. Insignificant or trivial problems not requiring additional work should not be separately reported.

The charge for the E/M portion of the visit should be deducted from the usual charge for the preventive service. Assuming a mid-level E/M service, the physician should bill as follows:

(continued on page 8)
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Case Files

(continued from page 7)

- 99213-25, $50
- 99397-GY, $100

The total charge for the visit would be $150, and the patient would pay for the entire preventive visit and the deductible of the covered service.

Brief or reduced physical exam
If a patient presents for an annual check-up but the service provided does not justify the usual charge for a physical exam, the physician still needs to code the preventive service when appropriate. Since the type of service provided has been reduced at the election of the physician, he/she may add the 52 modifier to the preventive medicine code.

Physicians should develop a fee for this reduced physical exam. Charges for separately billable problem-oriented E/M codes and screening services (e.g., G0101, Q0091, and G0102) must be subtracted from the charge for the reduced physical.

Patient with Extensive Problems or Pre-existing Conditions

By contrast, if the patient has multiple problems and/or new complaints, such that the problem-pertinent E&M service justifies a 99215 level of care, the physician may choose between coding the visit as follows:

- 99214-25 and 99397-GY or
- 99215. In this case, Medicare considers the additional preventive services a duplication of the work required justifying the 99215 level of care. You may never bill 99215 and 99397 together on the same date of service.

Note: If the evaluation and management of a complex patient requires more time than usual, the doctor may bill 99354 (prolonged service). In order to use this code, the physician’s face-to-face time must exceed the typical time associated with the E/M code by 30 minutes or more and be clearly documented. Medical necessity must be met for all prolonged services codes. Don’t forget, time alone does not indicate medical necessity. In this instance, the CPE is considered bundled into the problem-oriented E/M and prolonged service codes.

Sean M. Weiss, vice president & chief compliance officer of DecisionHealth can be contacted directly at sweiss@dhpfessionalservices.com or at 770-402-0855. DecisionHealth Professional Services, is a service of DecisionHealth and provides full-scale medical consulting services in the areas of practice management, compliance and coding as well as health law services. To learn more about our services visit us at www.dhprofessionalservices.com or contact us at 888-262-8354.

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