



Have policy, procedures, provider checks to protect from vendor kickback scandals

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A sensational case involving kickbacks to doctors from a pharmaceutical company serves as a warning: Without effective policy and procedures for providers' financial relationships with vendors, you risk serious damage to your practice.

Several former executives of Insys Therapeutics are accused of various crimes including violation of the anti-kickback statute for what the grand jury indictment portrays as a massive campaign to induce providers to improperly prescribe – in return for improper payments – fentanyl spray, a powerful opioid. The case is now being tried in U.S. District Court in Boston.

Prosecutors charge that Insys' "Speaker Program events," which were portrayed for reporting purposes as legitimate educational presentations for which providers were paid, "were often just social gatherings at high-priced restaurants that involved no education and no presentation" and sometimes no legitimate attendees at all.

Providers are mentioned in the indictment as "co-conspirators" and are left anonymous, identified only as numbered "practitioners." For example, "Practitioner #3" operator of a large pain management clinic in Saginaw, Mich., is praised for his corruption in an Insys internal communication mentioned in the indictment: "It's the [Practitioner #3s] of the world that keep us in business, lets [sic] get a few more and the rest ... of this job is a 'joke.'"

There are also what sound like HIPAA violations: "To accomplish this, Practitioner #8 routinely assembled the medical charts of each patient for whom he prescribed the fentanyl spray and gave them to the sales representative or to a company employee assisting the sales representative," the indictment says.

Might these providers expect a call from the feds, and possibly state authorities, in the near future? "It seems prosecutors have been reluctant to go after the providers in these cases," says Kevin Campbell, a partner at Bradley Arant Boult Cummings in Nashville. "They're going after the sales reps and managers who are orchestrating the scams. But you can't count on that — the anti-kickback statute works in both directions. It's just as illegal to receive kickbacks as to dispense them." Also, don't forget about whistleblowers who may turn over the rock on your misbehaving providers.

What to do?

The potential for mischief — not to mention indictments and blowback for the practice — leads some attorneys to advise a hard no-vendor-payments policy. "The easy answer to this and best practice for a physician, in my opinion, is to avoid any and all [appearances of or potential for] kickback relationships in their practice," says James Smeriglio, associate attorney at Jordan Law FL, P.A. in Orlando, Fla. "While this may be overly cautious, it's simply not worth the headache, publicity or legal fees that could potentially be incurred if someone ever blew the lid off of such an agreement and filed a class action suit."

On the other hand, "you'll still have doctors talking with reps," says Glenn P. Prives, attorney with McElroy, Deutsch, Mulvaney & Carpenter LLP in Morristown, N.J. "The reality is pharmas and their reps will always try to talk with doctors. It's not realistic to stop those conversations, so you need a policy" for gifts and payments.

Have a policy

Jay Anstine, a health care corporate compliance expert in Fort Collins, Colo., recommends a policy covering "anyone doing business with the practice." The practice should make clear what gifts and payments are unacceptable, using Stark law, anti-kickback statute and other relevant laws like the Sunshine Act as guidelines. For example, medical staff incidental expenses such as parking covered by a vendor should not exceed the \$34-per-instance limit under Stark.

The policy "should also spell out the process for approval to give or receive such a gift," says Anstine — that is, how much discretion the practice gives each provider to make these decisions. It would cover, for example, training encounters to which vendors often invite providers — which "could range from a modest lunch-and-learn brought in to the practices to lodging and travel expenses at a distant location."

This not only lets the providers know what's expected of them; it also protects the practice in the event of a problem. Part of the purpose is to "shift responsibility onto the rogue employee," says Eric Fader, partner with the Rivkin Radler firm in New York. "If the provider's going to go rogue, even if he's been trained not to, as long as the company's doing what it's supposed to do, then at least the entity won't take the fall."

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4 anti-kickback tips

Check on your providers. Your compliance officer should be at least surveying doctors in your practice, says Prives: "Require them to attest in writing that nothing was received or, if it was, to turn over documentation" on their payments. "Periodic required disclosure of financial arrangements might discourage [illicit] behavior and also identify issues so that you can screen them away from decision-making where they do have a financial tie," says Campbell.

You could even monitor a provider's prescribing habits, he suggests, "and look to see if certain drugs are being prescribed in an outlier manner" that correlate with the provider's financial ties.

Check Open Payments. CMS will send you emails when the Open Payments data that vendors have reported to CMS on their payments to providers is available to check, says Anstine; it usually becomes public towards the end of June each year (PBN 1/12/15). This launches a process that allows providers to dispute the data, but managers might want a peek, too.

"Checking the database will help ensure that the data being reported by vendors about your physicians is accurate," says Anstine. "Also it will help ensure on the practice side that your physicians are being transparent with what they've received or any investments interests they may have in a pharmaceutical company or medical device manufacturer."

Don't forget your own state laws, which can in some cases be more restrictive than federal ones, says Prives. Last year, for example, New Jersey passed a new regulation "that strictly limits what kind of benefits doctors can receive — and that includes even 'independent agents' of pharmas" who are not directly employed by them, says Prives. "Now there's very little they can give to a doctor. It covers meals and even the little things like pens and notepads with the company logo. And it hits speaker fees at even legitimate events."

Redirect potential whistleblowers. "Any large company that doesn't have a whistleblower hotline or some mechanism like that is making a big mistake," says Fader. The idea is to intercept and deal with complaints — including complaints about doctors getting shady compensation — before they turn into a legal nightmare for the company.

Resource:

- **U.S. Department of Justice case information,** United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor: www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and



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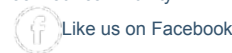
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