



Compounding The Kickback Problem

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Compounding The Kickback Problem

Compounding pharmaceuticals, specific drugs for specific patients, offers tremendous benefit. The problems arise when the benefit is for the prescribing physician. Then, we're dealing with analyses under the federal Anti-Kickback Statute (AKS), the Stark Law, and their state law counterparts.

A recent federal appellate court opinion highlights what everyone (okay, just those not willing to lie to themselves) already knew but many (those willing to lie to themselves) were unwilling to admit: That it can be a violation of the AKS to receive something of value when simply serving as a gatekeeper for a patient's previously existing choice.

Let's stick with the compounding pharmacy example, at least for the moment:

Setting aside a plethora of issues from the distinction between compounding and manufacturing, to issues of direct patient solicitation, there are some in the compounding pharmacy business who believe that it's okay to market specific compound medications directly to patients, using networks of physicians to rubber-stamp that pesky necessity, the prescription.

Often, the physicians in the network receive payment from the unlicensed pharmaceutical manufacturer compounding pharmacy for, essentially, issuing a prescription for the compounded drug in response to the patient's request. How, those physicians tell themselves, can authorizing what the patient already wants, "Miracle Compounded Drug X," from Lucky Larry's Pharmacy in Leucadia, CA, be a referral to Lucky Larry?

Here's where the cautionary tale of Kamal Patel, M.D. (U.S. v. Kamal Patel), comes into play. The unfortunate Dr. Patel wasn't involved with compounding, he was involved in a home health care services kickback scheme. But the lesson is equally applicable.

Dr. Patel is an internal medicine physician. He routinely treated elderly patients, Medicare beneficiaries. He regularly prescribed home health care services to his patients. There was no allegation that he ever made any improper prescription for any service.

Due to the defection of a number of its partners who took a large portion of the existing business with them, the remaining owners of a home health care agency, Grand Home Health Care, made overtures to pay Dr. Patel a bounty per each of his patients who received home care from Grand.

Importantly, at least to Dr. Patel's failed defense and to the fact situation, as it is akin to the compounding pharmacy example, it was the patients who chose to obtain home healthcare from Grand, it was not Dr. Patel who chose Grand as the provider.

The fact that a patient chooses a specific home health care service is not sufficient for the service to receive payment from Medicare. Instead, there must be a certification (essentially a prescription) by a physician. Dr. Patel signed the certifications that those patients required care from the home health care agency they chose, that is, from Grand.

The government brought charges against Dr. Patel under the AKS. The essential language of the AKS is "whoever knowingly and willfully solicits or receives any remuneration (including any kick-back, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program [shall be guilty of a felony]."

Dr. Patel argued that there was no referral: It was the patients who independently chose Grand. He never gave any input to influence their choice. Therefore, he argued that he could not be guilty of an AKS violation.

On the other hand, the government argued, and the court agreed, that "refer" includes not only a doctor's recommendation of a provider, but also a doctor's authorization of care by a particular provider.

Even though Dr. Patel played no role in his patients' initial selection of Grand or their decision to continue using Grand, by certifying their care at Grand, Dr. Patel chose whether his patients could go to Grand at all. In the words of the court, "Patel acted as a gatekeeper to federally-reimbursed care. Without his permission, his patients' independent choices were meaningless."

Dr. Patel then tried the "no harm, no foul" defense: He argued that by certifying the patient's decision to use Grand, he did not cause the federal government to pay Grand any more than it would otherwise have to pay for home health care. After all, there was never any question that he had ever certified a patient for home health services who did not actually require home health services.

February 29, 2016

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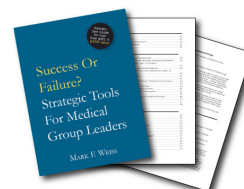
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However the appeals court correctly pointed out that even if the Medicare system suffered no losses in this instance, the danger of fraud at the certification stage is quite clear. "A physician could refuse to certify a patient to a patient-chosen provider unless the provider paid the physician a kickback. This behavior could increase the cost of care. It could also contravene the second purpose of the AKS -- protection of patient choice -- by interfering with the patient's choice if the selected provider refused to pay."

The appellate court upheld the trial court's decision that Dr. Patel had violated the AKS. Dr. Patel was sentenced to 8 months in prison plus 200 hours of community service, and ordered to forfeit \$31,900 of kickback payments.

Dr. Patel's certification, that is, prescription, of home health care services from a patient-selected provider, is no different from another physician's prescription of a compounded drug from a patient-selected pharmacy.

If that pharmacy, like Grand, made payments to the physician to induce that prescription (whether it's blatantly offered as by Grand or whispered sotto voce in terms of payment for "something" that is actually for nothing) then both the physician and the pharmacist may be headed off to join Dr. Patel in the federal penitentiary for violating the AKS.

[Although it does nothing to change the analysis, physicians considering borderline deals of all sorts often ask questions (which they intend as statements) akin to, "how will they ever find out?" Perhaps Dr. Patel or the folks at Grand Home Health Care will let you know of one common way: The feds initially investigated Grand and its owners. To reduce their own exposure, Grand's owners flipped on Dr. Patel and wore a "wire" to record their communication.]

There are many legitimate ways for physicians to increase their practice income. They include, depending on state law, investments in compounding pharmacies and the direct dispensing of pharmaceuticals. But any deal must be structured in compliance with the AKS. And then, of course, also in compliance with other applicable laws, from Stark to state law considerations.

Go ahead, I encourage you, think entrepreneurially. But please be smart about it.

Upcoming Webinars Announced

Stay tuned for two upcoming webinars with Mark Weiss:

"Understanding The OIG Advisory Opinion Process"

"Is Your Medical Group A Business or A Club"



Wisdom. Applied. 85 - Climate Change and Hospital-Controlled Medicine

I'm not a climate change denier. After all, it's cooler out now that it's winter than it was just a short time ago when it was summer.

All Things Personal

Sometime last year, my wife bought me, via a Groupon, a Zoom teeth whitening treatment at a dentist's office. I finally used it earlier this month.

The Zoom dentist paid Groupon a fee to facilitate the sale, at \$98, of a treatment regularly priced at more than \$400. The whole point of this was to garner new patients from those showing up for the whitening.

So why is it that I never saw the dentist, only a technician, over the hour-plus that I was in his office. Why is it that no one even mentioned to me what their other services are? Why is it that no one even asked if I have a regular dentist?

They wasted the entire marketing opportunity created by the Groupon.

I know that most professionals hate "selling" because they somehow believe that it cheapens them. But that's not at all true and it's certainly not true about the Zoom dentist or he wouldn't have done a Groupon deal to begin with. He was just lazy, or overextended, or stupid.

The fact is that we all "sell." We sell ourselves on an idea. You sold your way into your present job or position. And, the fact of the matter is that you have lots of opportunities to sell - yourself, your own services, your medical group's or business' services - on a daily basis.

You might as well do it right.

You don't have to become an over-aggressive used car salesman. Simply explaining what you do can be a form of selling. Being polite can be a form of selling. So, too, of course, can be making suggestions as to future treatment.

Everyday encounters, from the scheduled, like the Zoom appointment, to the far more random, present opportunities to create new relationships, to sell more of your services, to even make new friends.

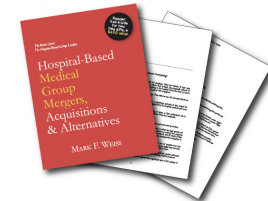
Consider those opportunities as resources that shouldn't be wasted.

disruptive ventures. Yet at the same time, the future of healthcare offers medical groups tremendous opportunity.

This small book is a collection of essays, of thoughts as tools for your success. Read. Think. Succeed. Repeat.

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Hospital-Based Medical Group Mergers, Acquisitions & Alternatives



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Some days, it seems as if everyone, from anesthesia or vascular surgery practices, is talking about selling their larger group, to private equity investors, or to a hospital.

The reality is that some practices can be sold, some can be sold, and some have nothing to sell.

The reality also is that there are a number of strategic a practice sale.

A perfect storm of factors is accelerating the market for based medical group mergers and acquisitions.

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Directions: Clarity For Medical Group Leaders



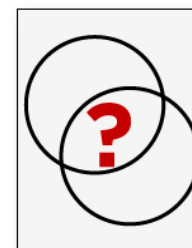
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The healthcare market is changing rapidly, bringing new problems.

How can you find a solution, how can you engage in the development of strategy, and how can you to plan your, group's, future without tools to help clarify your think

Directions is a collection of thoughts as thinking tools, to instruct, inform, and even more so, cause you to give instruct and inform yourself.

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Mark's article **Impending Death of Hospitals: Will Your Anesthesia Practice Survive?** was published in the winter 2016 volume of *Communique*. Read or download [here](#).

Mark was quoted in the article **Practice Patterns Change While Outcomes Remain Steady Among Older Anesthesiologists**, published in the December 2015 issue of *Anesthesiology News*. Read or download [here](#).

Mark's article **Anesthesia Group Mergers, Acquisitions and (Importantly) Alternatives** was published in the summer 2015 volume of *Communique*. Read or download [here](#).

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Mark was quoted in the article **Anesthesiology Acquisition Rate Still at Fevered Pace**, published in the July 2015 issue of Anesthesiology News. Read or download [here](#).

Mark's article **Seeking Certainty In Radiology: Mergers, Acquisitions and Alternatives** was published in June 2015 on Imagingbiz.com. Read or download [here](#).

Mark's article **Give Disruptive Docs the Boot** was published in the April 2015 issue of Outpatient Surgery. Read or download [here](#).

Mark's article **Do You Make This Mistake Concerning Customer Value?** was published in the April 2015 issue of Anesthesiology News. Read or download [here](#).

Mark's article **Do You Make This Mistake Concerning Customer Value?** was published in the March 2015 issue of General Surgery News. Read or download [here](#).

Mark's article **McDonald's and Delivering Anesthesia Group Value** was published on AnesthesiologyNews.com on December 30, 2014. Read or download [here](#).

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2. Be a guest on "Wisdom. Applied. Podcast."

Although most of my podcasts involve me addressing an important point for your success, I'm always looking for guests who'd like to be interviewed about their personal and professional achievements and the lessons learned. [Email](#) me if you're interested in participating.

3. Book me to speak to your group or organization.

I've spoken at dozens of medical group events, healthcare organization events, large corporate events, university-sponsored events, and private, invitation-only events on topics such as The Impending Death of Hospitals, the strategic use of OIG Advisory Opinions, medical group governance, and succeeding at negotiations. For more information about a custom presentation for you, [email](#) my Santa Barbara office staff.

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