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Can compliance officers unring the bell?

by Charles Oppenheim and Stephanie Gross

Ideally, compliance officers are brought into their organization's discussions about potential business deals at the outset to help ensure they start on a compliant path. Unfortunately, compliance officers are sometimes asked to assess the compliance risks of a proposed deal *after* the parties have already started discussions and negotiations. Naturally, once compliance officers become involved, they dutifully review the preliminary drafts, meeting minutes, PowerPoint presentations, etc., in an effort to assess potential compliance risks. Sometimes, compliance officers are stopped in their tracks because they uncover what appears to be a "smoking gun"—evidence that the parties are motivated to do the proposed deal because of the resulting referrals, thus potentially jeopardizing compliance with the federal Anti-Kickback Statute (AKS). Among other things, the AKS prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration, directly or indirectly, overtly or covertly, in cash or in-kind, as inducement for the referral of patients for items or services for which payment may be made in whole or in part under a federal healthcare program and any state healthcare program.[1]

When this happens, a crucial decision must be made based on an assessment of whether the deal is sufficiently tainted that it must be called off or whether, instead, there is a way to fully address the issues raised by the evidence uncovered and put the deal on a compliant path forward (i.e., "unring" the bell). This article offers some suggestions to help guide compliance officers through that decision-making process.

Key determinations

First, consider the nature, degree, and extent of the evidence uncovered that suggests one or more parties to the proposed deal are motivated by referrals. Does the evidence suggest only that the parties are hoping for or expecting referrals as a result of the deal? Courts have explained that there is nothing wrong with hoping for or expecting that referrals will result from a deal, so long as one party does not pay the other to induce them. As the Tenth Circuit explained in *McClatchey*, "a hospital or individual may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from that doctor, so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals."[2]

The difference might seem like splitting hairs, but it matters what was said, how it was said, and the context in which it was said. If the parties were merely expressing hope or expectation, and/or there are a host of non-referral reasons for the deal, then careful compliance work might put the proposed deal on the right path.

On the other hand, imagine if a medical group were to communicate to a diagnostic imaging facility that (1) it would like the facility to provide free preauthorization services so that the group can reduce administrative headcount by offloading this task to the facility, and (2) if the facility does start providing free preauthorization services, then (but only then) the group will move all of its referrals to that facility. If the facility responds by immediately agreeing to provide free preauthorization services to this group (which are free services the facility has no other reason to perform, and does not and never has provided to anyone else), then this response presumably is based on more than a hope or expectation of referrals. Instead, it is essentially based on an agreement to exchange free services for referrals. This situation must be distinguished from the common and legitimate circumstances where imaging facilities decide to provide free preauthorization without being asked for everyone ordering imaging after the facility determines that the benefit of reducing payment denials exceeds the burden of providing the preauthorization services.[3]

Another key to determining whether one can unring the bell is carefully reviewing and analyzing the non-referral reasons for doing the deal. If there are none, then the bell might be hard to unring. If there are plenty of non-referral related reasons to do the deal—and especially if one or more of these reasons are truly compelling—then it might be easier to unring the bell by excising the referral-related reasons from the consideration used when deciding to move ahead and retaining the other reasons. Consider, for example, if the proposed deal involves meeting a specific community need or defined organizational purpose, developing a new service line, expanding geographically, improving quality of care or patient satisfaction, increasing efficiency, streamlining scheduling, fostering protocol adherence, improving patient access or meeting other specific patient needs, improving provider education or training, increasing access or use of protocols, technology, or other innovations, improving research and development, or even avoiding costs or reducing expenses that otherwise would be incurred.

If one or more substantial reasons (unrelated to referrals) support doing the deal, then consider what remedial steps can reasonably be taken based on the nature of the problematic evidence of the parties being motivated by referrals. Hypothetically, a transactions committee with ultimate decision-making authority for whether to do the proposed deal possibly had a meeting to discuss it while the potential deal was in the early stages of negotiations. Perhaps the meeting of the transactions committee included a presentation prepared by well-intentioned but overeager advocates for the deal that identified increased referrals as one of the benefits resulting from doing the deal. In this example, a remedial step might include providing specific, targeted education and training on the AKS to the transactions committee and explaining to the committee as part of that training that they must not take referrals into account in their future deliberations on the proposed deal or in their ultimate decision-making. Instead, they must evaluate the proposed deal solely based on the non-referral related reasons for doing the deal. Consider having each member commit to that approach, potentially in writing. The compliance training, subsequent deliberations, decision-making process, and the outcome should all be carefully documented. The "bad" evidence that indicated the parties were considering referrals should not necessarily be expunged because that could create the impression of a cover-up. Instead, consider retaining it, together with thorough documentation of the work done to re-educate the decision-makers and correct their decision-making process to ensure only legitimate considerations were taken into account in moving ahead with the deal.

Another way to unring the bell (by nullifying the potential ongoing taint of the problematic evidence of impermissible intent) would be to structure the arrangement to fit entirely within a safe harbor (or statutory exception) to the AKS. If an arrangement satisfies all of the requirements of an applicable safe harbor, then it is immune from scrutiny under the AKS.[4] On the other hand, even if an arrangement cannot fit perfectly within a safe harbor, and thus be immunized from scrutiny under the AKS, risks can potentially be mitigated if the arrangement comes close to meeting the requirements of a safe harbor—especially if additional steps are undertaken to document compliance efforts (e.g., if the parties secure an outside valuation expert to verify that the financial aspects of the arrangement are consistent with fair market value). Some outside valuation experts and consultants will also be willing to evaluate a proposed transaction and opine on whether it is commercially reasonable for the parties to enter the transaction without regard to potential referrals.

Even when efforts are made to unring the bell, for instance, by identifying appropriate non-referral related reasons for a deal, educating decision-makers about appropriate and inappropriate considerations, getting their commitments to use only appropriate criteria to evaluate whether to do the deal, and then documenting the corrective action taken, there can be an ongoing risk that earlier inappropriate discussions will linger and potentially prove problematic. This is especially true if efforts to unring the bell look more like an effort to cover up the prior problematic evidence of intent instead of confronting it head-on and making every reasonable effort to correct it. In one recent case, a federal court considered an internal PowerPoint presentation that identified potential referrals as a justification for a particular transaction, pointing to it as evidence of the defendant's improper intent; however, it was only a draft, and those portions were later stricken. (Notably, the defendants in that case apparently did not engage in additional corrective action to prevent consideration of referrals from guiding future decisions about the deal. The court considered as potential evidence against defendants, the fact that they "struck references to referrals from their internal PowerPoint presentation," which "suggest[ed] they knew consideration of referrals was improper."[5]

Deal or no deal?

One of the toughest calls any compliance officer may ever make is whether to call off a deal or try to salvage it. Sometimes, a compliance officer must simply say no, after determining that a deal is fundamentally tainted by improper intent and cannot safely be resuscitated. Other times, after undertaking a careful and thorough review of the facts and circumstances and then developing and implementing a corrective action plan for moving ahead with the proposed deal, a compliance officer may very well reasonably conclude that a deal can be allowed to move forward, notwithstanding that it might have had a problematic start.

Takeaways

- If compliance officers identify evidence that a proposed deal is intended to increase referrals, they might need to kill it, but they might be able to save it.
- The decision to kill or save a deal will depend on how much the goal of increasing referrals permeates the deal or is tangential to the deal's main purpose(s).
- Simply eliminating evidence that the parties sought to drive referrals is insufficient to save a deal; it could, in fact, be viewed as an attempted cover-up of the deal's actual purpose.
- If there are legitimate non-referral reasons for a deal, then compliance training and reconsideration of the reasons for the deal, and thorough documentation of those corrective actions, might save the deal.
- Fitting within a safe harbor immunizes the deal from scrutiny under the Anti-Kickback Statute, regardless of any evidence the parties seek to drive referrals.

1 42 U.S.C. § 1320a–7b(b) .
2 United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000), cert. denied, 531 U. S. 1015 (2000).
3 U.S. v. Valley Campus Pharmacy, Inc., 2021 WL 5406148 (C.D. Calif. 2021).
4 42 U.S.C. §1320a-7b(b)(3)(E) .
5 Kuzma v. Northern Arizona Healthcare Corporation, 607 F. Supp. 3. 942 (Ariz. 2021).