

A New Tool For Assessing Kickback Risks In Health Marketing

By **Elisha Kobre** (April 30, 2025, 5:39 PM EDT)

A frequently recurring question under the federal Anti-Kickback Statute concerns when payments by healthcare providers to marketers or advertisers cross the line from legal marketing or advertising activities into unlawful referral payments — i.e., payments prohibited by the AKS because they are made to induce a person to refer an individual for items or services for which payment may be made under a federal healthcare program.

An April 14 decision by the U.S. Court of Appeals for the Seventh Circuit in *U.S. v. Sorensen*, reversing a conviction after trial of a durable medical equipment distributor, explores the outer boundaries of the AKS as applied to marketing and advertising by healthcare companies. The opinion distills the most important federal appellate decisions in this area into a useful pair of core considerations courts use to distinguish between legitimate marketing services and unlawful referral fees.



Elisha Kobre

These basic elements are: (1) whether the marketers or advertisers have an existing or special relationship with the physician or other decision-maker such that the marketer is positioned to exert undue influence on the decision-maker; and (2) whether, in actuality, the physician or ultimate decision-maker exclusively, or nearly so, does in fact make the referrals.

The first of these elements will, of course, always be met when the payee is the ultimate decision-maker, for example where payment is made to a prescribing physician. In that case, the payee obviously has a special existing relationship with himself.

These factors come into play where the payee is not the decision-maker. In those cases, *Sorensen* and other key cases show that exposure under the AKS strongly depends on the nature of the relationship between the marketer and decision-maker, including the influence a marketer may have with the decision-maker, and whether the actual referral rate confirms the undue influence.

U. S. v. Sorensen

Mark Sorensen operated a Medicare-registered distributor of durable medical equipment. To obtain customers, he paid marketing firms to publish advertisements for orthopedic braces. Sales agents from these marketing companies, after speaking with the patients and obtaining their consent, faxed prefilled but unsigned prescriptions forms to the patients' physicians.

The prescription forms contained Sorensen's companies' name and corporate logo and listed the medical devices to be ordered. Critically, the doctors who received these unsigned prescription forms declined 80% of the orders sent by one of the marketing companies and regularly ignored forms sent by the other. If a physician signed and approved a prescription, however, the marketing companies would receive payment based on the number of leads that each generated.

The court started with the obvious premise that, where the payee is a physician, a payor's intent to induce a referral may be clear because "physicians have significant power to guide patients to specific providers and to approve care."

But in a case like *Sorensen's* — where the payments are to nonphysician marketers — the court

found the critical consideration whether the marketer "leverages fluid, informal power and influence over health care decisions."

Analyzing the existing case law, the court ultimately determined, for two reasons, that the marketers in Sorensen did not leverage such power and influence, but simply engaged in aggressive advertising permissible under the AKS.

The Marketer-Decision-Maker Relationship and Marketer Influence

First, there was no evidence that the marketers took advantage of existing relationships with patients or other healthcare providers. This distinguished the case from an earlier Seventh Circuit decision, *U.S. v. Polin* in 1999, where payments were made to a sales representative whose recommendations on pacemaker monitoring services "had never been overruled by a physician during his 14 year career."

The salesperson payee in *Polin* was therefore the de facto decision-maker, wielding such influence that the physicians' approval "seemed to be more of a formality or rubber stamping" of the sales representative's referral.

The Sorensen court also relied on a decision from the U.S. Court of Appeals for the Fifth Circuit, *U.S. v. Shoemaker* in 2014, reversing an acquittal on grounds similar to *Polin* where a nurse staffing business paid a hospital executive in exchange for pressuring the executive to exploit his personal access to contracting authorities at the hospital. Both the salesperson in *Polin* and the hospital executive in *Shoemaker* exercised substantial influence over the respective decision-makers.

Further illustrating the importance of the relationship between a marketer and decision-maker was last year's Fifth Circuit decision in *U.S. v. Marchetti*, where the court found most of the defendant's actions not violative of the AKS because there was no evidence that he "exercised any impermissible influence on those who make healthcare decisions on behalf of patients." As Marchetti explained:

If Marchetti "improperly influenced" doctors, this case is open and shut. But the government does not provide a drop of color as to what Marchetti's influence looked like. Plainly, not every sort of influence is improper. (What are advertisers hired to do anyway?) Ultimately, the government fell short in providing any detail on the key relationship: the relationship between Marchetti and relevant decision-makers.

The Referral Rate as Measure of Influence

Second, the absence of undue influence by the marketing companies in Sorensen was confirmed by the fact that 80% of the blank prescriptions sent to physicians by one of the marketers were declined and many sent by the other marketer were never returned. As Sorensen noted, this was a far cry from *Polin*, where the salesperson's recommendations were never in his 14-year career rejected.

The Sorensen court likened its facts to yet another key Fifth Circuit decision in this area, *U.S. v. Miles*, where the court reversed the convictions of home healthcare company executives who paid a marketing firm to supply promotional materials — literature, business cards and the occasional plate of cookies — to doctors' offices.

The government in *Miles*, as in Sorensen, failed to adduce any evidence that the doctors exclusively chose the defendants' healthcare services. To the contrary, at least one doctor regularly chose from among numerous alternatives.

Takeaways

The Sorensen decision's crystallization of existing case law on the meaning of the term "refer" in the AKS is decidedly pro-defense.

First, the court's formulation in Sorensen that the AKS "primarily targets payments to individuals with influence over or access to patients that lets them control or influence the patients' choices about medical care" is a narrow view of the purpose of the AKS.

Indeed, the Seventh Circuit itself, in a 2015 case, *U.S. v. Patel*, citing guidance from the U.S.

Department of Health and Human Services, stated more broadly that the purpose of the AKS is to "protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services."

The court's formulation is likely to be cited by the defense bar as cabining the reach of the AKS.

Second, the court's emphasis on a special relationship leading to undue influence over the relevant decision-maker as a key factor in determining whether a payment was made to induce a referral will likely pose a significant hurdle for the government.

In many cases, marketers will have little or no relationship with the prescribing physicians or patients themselves. The government in many cases has pursued even such marketing schemes. And it of course remains unclear what level of influence will be undue for AKS liability as required by the court in Sorensen.

Third, many marketing cases involve successful referral rates similar to or even less than those in the Sorensen case, making that element likewise difficult for the government to meet.

It is notable that the Sorensen court's fairly narrow interpretation of the term "referral" in the marketing and advertising context is at odds with the Seventh Circuit's much broader interpretation of that term in the Patel case, which presented the question of whether a physician refers a patient for home healthcare services when he or she merely authorizes or reauthorizes the services, but has no role in the patient's selection of the provider or decision to continue using the provider.

The court in Patel took a broad approach, holding that the word "referral" is commonly used in a way that extends to a physician's certification or recertification that a patient requires Medicare-reimbursed care, even without steering the patient to a particular provider.

This was so even though a majority of Kamal Patel's patients continued to use providers other than the one from which Patel received remuneration. The Patel court further noted that a narrow definition of the term would defeat the central purposes of the AKS.

Taken together, the Sorensen and Patel cases counsel a contrast between the AKS treatment of physicians and other relevant decision-makers — who will be broadly deemed to have made a referral by taking steps to facilitate federally paid-for healthcare services — and nonphysicians or others without decision-making authority, where the government will be required to meet the higher burden of proving undue influence.

Conclusion

Sorensen and the cases leading up to it demonstrate that the two principal considerations in determining whether payments to marketers or advertisers in the healthcare context are unlawful under the AKS are: (1) whether the marketer has a special or existing relationship with the relevant decision-maker such that the marketer can exercise undue influence over the decision to refer; and (2) whether the undue influence is confirmed by a high actual referral rate.

In Sorensen, the Seventh Circuit's distillation and application of the key cases in this area will be a crucial tool in evaluating the potential AKS implications of marketing and advertising in the healthcare sector.

Elisha Kobre is a partner at Sheppard Mullin Richter & Hampton LLP.

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