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Compliance Today - March 2022
Co-management agreement pitfalls and best practices: A case study

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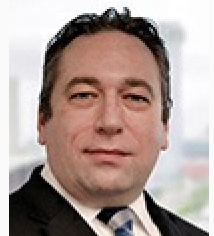

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There has been much discussion in the healthcare industry over many years regarding how healthcare entities and providers can partner to create efficiencies and value in medical services. Some of these efforts culminated in the Department of Health & Human Services' (HHS) 2018 "Regulatory Sprint to Coordinated Care," which resulted in significant changes to the federal Anti-Kickback Statute (AKS) and the Physician Self-Referral Law (Stark Law) regulations. Another way that healthcare providers traditionally coordinate services is through co-management agreements.

The term co-management can refer to a number of practically different but conceptually related arrangements. Perhaps the most traditional example is a hospital contracting with a physician group to co-manage a service line. In this form of agreement, the hospital typically manages the administrative aspects of the practice, while the physician group focuses on the clinical aspects of the practice, particularly patient care. Another example is an arrangement between providers to co-manage different aspects of patient care. For example, a specialist may provide surgical care, and then refer the patient back to their primary care provider for post-surgical monitoring.

Co-management is a common and accepted practice, but that does not mean that it is without risk to the partnering entities. Although HHS has recognized that some forms of co-management agreements are acceptable and some state laws specifically validate the practice, this does not immunize the parties from compliance risks. The particular characteristics of a co-management arrangement may still subject the participants to scrutiny under, for example, the AKS and the Stark Law. These laws are intended to protect federal healthcare programs and their beneficiaries from the influence of money on the referral of program business, which could result in overutilization and other issues. Co-management agreements, by their nature, involve the sharing of responsibility for patient care and can be susceptible to these concerns. This article reviews HHS's general acceptance of co-management agreements in both of the contexts described above, discusses a recent federal case out of the Middle District of Tennessee that identifies certain problematic aspects of one particular co-management arrangement, and provides best practices and considerations for structuring and executing co-management agreements that fall on the right side of the regulatory divide.

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HHS and state acceptance of co-management arrangements

HHS has issued guidance demonstrating acceptance of different types of co-management agreements. For example, Section 40.4(B) of Chapter 12 of the *Medicare Claims Processing Manual* provides codes and modifiers for physicians to use when billing claims for less than a full global surgery package.[1] In the example provided in the *Medicare Claims Processing Manual*, Dr. Jones bills the surgical procedure code using a -54 modifier, indicating 60 days of post-operative care, while Dr. Smith bills for 30 days of post-operative care for the same procedure using a -55 modifier. This illustrates a typical instance of patient co-management where physicians share responsibility for post-surgical care.

States too have acknowledged the propriety of patient co-management. For example, Tennessee's regulations governing the practice of optometry specifically provide for the co-management of patients following eye surgery. The regulations define co-management as "[t]he cooperative and active participation in the delivery of services and treatment to patients between optometrists and other health care providers."[2] Tennessee further provides that (1) the decision to receive co-managed care rests solely with the patient but should be made in consultation with the patient's physicians; (2) an optometrist may provide follow-up care for a patient's surgical eye problem; and (3) the optometrist should provide a report to the surgeon of all post-operative care rendered.[3]

HHS also has recognized the usefulness and propriety of co-management agreements in the hospital context. In 2012, the HHS Office of Counsel to the Inspector General (OCIG) opined that hospital co-management agreements can have "legitimate business and medical purposes" by increasing efficiency, reducing waste, and increasing profitability.[4] OCIG considered a scenario in which a large, rural hospital in a medically underserved area was paying compensation to a cardiology group based on the group's implementation of "certain patient service, quality, and cost savings measures." As part of this arrangement, the cardiology group performed services in the hospital's catheterization labs and referred patients to the hospital for inpatient and outpatient procedures. The agreement between the hospital and the cardiology group had a term of three years, and it contained two fee arrangements: a guaranteed and fixed payment per year and a potential capped annual performance-based payment (based on employee satisfaction, patient satisfaction, quality of care, and implementation of cost savings procedures).

While recognizing that hospital co-management agreements can have benefits, OCIG also expressed its concerns that these arrangements could lead to poor patient care resulting from: "(i) stinting on patient care, (ii) 'cherry picking' healthy patients..., (iii) payments to induce patient referrals, and (iv) unfair competition among hospitals." It found that the particular arrangement at issue was not illegal because (1) it had "not adversely affected patient care"; (2) the risk of a specific cost-savings measure being used in a medically inappropriate circumstance was low; (3) the financial incentive was "reasonably limited in duration and amount"; and (4) receipt of a performance fee was predicated on a physician not taking certain specified actions that are detrimental to a patient's health.

OCIG also found that there was no intent that the arrangement result in illegal remuneration. In making this determination, OCIG noted several elements of the payment arrangements that supported this finding: (1) the payments made under the arrangements constituted fair market value (FMV) for many different types of medical services; (2) the compensation paid under the agreement did not vary with the number of patients treated; (3) there were limited providers in a limited geographic area; (4) the specific measures included in the agreement indicated that the purpose was to improve quality, not reward referrals; and (5) the agreement was written and limited to a three-year period. Thus, OCIG provided some indicators of a legal co-management arrangement, without fully defining what a legal co-management agreement looks like.

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United States of America v. Southeast Eye Specialists

Federal court decisions considering the propriety of co-management agreements are limited, but one district court recently issued a rare opinion in this area. In *United States of America et al. v. Southeast Eye Specialists PLLC et al.*, Chief Judge Waverley Crenshaw, Jr. of the Middle District of Tennessee denied the defendants' motion to dismiss a False Claims Act (FCA) case centered around a series of patient co-management arrangements.[5] In the qui tam case, the plaintiffs contend that the defendants are violating the FCA via illegal kickbacks to optometrists to induce them to refer their patients to the defendants' surgical centers in violation of the AKS. The defendants' primary defense was that they use a lawful, referral-based co-management structure.

The plaintiffs allege that the defendants offer several different financial inducements that make it lucrative for optometrists to refer their patients only to the defendants' surgical centers. These financial inducements included "freebies" (free continuing education, dinner and drinks, lunches, baseball games, golf outings, and other events), a co-management model (in which the ophthalmologist performing the surgery receives 80% of the fees, and the referring optometrist providing follow-up care receives 20% of the fees), and "up-selling" (an optometrist convincing a patient to purchase premium, instead of standard, lenses receives a bonus of $150 or more from the defendants).

In denying the defendants' motion to dismiss, the court rejected the defendants' argument that "co-management is a *legal* practice approved by CMS [Centers for Medicare & Medicaid Services]." It recognized that "defendants are undoubtedly correct that the CMS allows for co-managed care in the sense that global surgery packages covering surgery and aftercare are permissible" but cautioned that this was "a far cry from endorsing all forms of co-management...let alone one that offers improper inducements to others to share in the fees as alleged."

The district court next rejected the defendants' argument that they could not be providing a prohibited remuneration because they were only providing the *opportunity* to earn a co-management fee. The court explained that giving even an opportunity to earn money can be an inducement and that the plaintiffs had pled that inducement had in fact occurred. It noted that "the [AKS] does not require evidence of a 'quid pro quo' in the sense that each bribe must successfully generate referrals." Essentially, the allegations supported a finding at the motion-to-dismiss stage of an illegal co-management structure because "in exchange for a package of goodies including the 80/20 percent fee split, optometrists are lured into sending their patients to Defendants' eye surgeons."

The court distinguished the co-management structure at issue in *Southeast Eye* from the co-management relationship that a prior OCIG advisory opinion, issued in 2011, found permissible. In the 2011 opinion, there were (1) no written or unwritten agreements with optometrists regarding co-management; (2) patients were notified about additional fees; and (3) the surgical group certified that, upon patient request, it would transfer a patient back to their optometrist.[6] In contrast, in *Southeast Eye*, there was a "blanket arrangement where transfers were prearranged without patient's acquiescence, and patient[s] were not informed about the premium lens fees paid to their optometrists."[7]

Finally, the defendants argued that they could not be found to have "willfully" violated the law because they believed they were in compliance with relevant guidelines for co-management agreements. The court was not persuaded by this argument, explaining that the AKS does not require actual knowledge of the statute or specific intent to violate it, and the plaintiffs can just generally aver intent to survive a motion to dismiss. The court further ruled that "the evidentiary value of an alternative explanation means less in the context of an [AKS] case" because "Circuits that have addressed the issue have uniformly held that if at least one purpose of the remuneration is in return for a referral, then the statute has been violated." It is noteworthy that this is the first

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time that a district court in Middle Tennessee has seemingly adopted the one-purpose rule for AKS cases.

Potential pitfalls of co-management agreements

The district court's decision in *Southeast Eye* provides some additional indications of potentially problematic practices surrounding co-management arrangements. The primary concern, as in all AKS cases, is remuneration that is directed toward an individual or entity that is in a position to generate federal healthcare business for the payer. *Southeast Eye* warns that federal and state regulatory acceptance of co-management in general will not necessarily protect any particular arrangement. If there is money going to a referral source, the conduct is subject to scrutiny.

Remuneration also includes any other form of valuable consideration, such as free or discounted continuing education seminars, dinners, and sporting events. These types of remuneration—the court referred to them alternatively as "goodies" and "freebies"—have long been scrutinized in AKS and Stark Law investigations. Just last year, OCIG issued its first special fraud alert in over six years. The alert addressed speaker programs and associated perks, particularly those hosted or sponsored by pharmaceutical or medical device companies.[8]

Another potential issue is inconsistency. The court in *Southeast Eye* observed that "almost a third of [the defendants'] cataract surgeries are not co-managed."[9] Though the court took this as an indication that some of the plaintiffs' claims about "blanket" co-management may be somewhat overstated, it could also raise a question of why some cataract surgeries were co-managed and some were not. Depending on the nature of any particular arrangement, a whistleblower or the government may argue that a lack of consistency in a practice's approach to co-management may be an indicator of improper motivations in cases that were co-managed.

Co-management best practices

Co-management agreements and arrangements, while prevalent and permissible, must be commercially reasonable, and any compensation exchanged must be at FMV. While this statement and the above pitfalls may seem elemental, some basic guardrails should not be overlooked when establishing or reviewing a co-management arrangement. Some fundamental questions to consider in whether the arrangements are *commercially reasonable* include:

- Does the arrangement satisfy a legitimate business need of the parties?
- Is the referring party the best or only party to deliver the services to satisfy the need?
- Are the services (and fees) tailored and limited so that there is no question about their purpose and intent?
- Would the arrangements be reasonable or attractive if no referrals were received?

It is always wise to use the services of an independent third-party valuation expert to confirm that the amounts paid are consistent with FMV and prices that would be paid to other well-qualified parties that are not in a position to make the referrals.

A party must perform services that are of bona fide value and that are truly needed by the other party. When the party performing is a physician or physician group that also is supplying referrals, the arrangement cannot be a disguised or concealed plan to reward the referrals' sources. So a baseline question to ask is: Could the legitimate needs of the recipient be satisfied by a party that is not the source of the referrals? In a patient co-management case like *Southeast Eye*, patient post-surgical care needs may be equally or better served by their primary care physicians, but is any remuneration and any other perks and benefits sufficiently limited and tied to the value of the services to make the relationship pass muster? Certainly the court in *Southeast Eye* did not believe that this

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question was one that could be addressed at a motion-to-dismiss stage. That opinion teaches that co-management agreements and arrangements do not offer a bulletproof, scrutiny-free, or blanket way to align referring parties and those who are recipients of those referrals.

Conclusion

Regulatory guidance regarding particular aspects of patient and healthcare facility co-management agreements are limited, and case law addressing such arrangements and their treatment under the FCA, the AKS, and the Stark Law is also scarce. The recent *Southeast Eye* decision from the Middle District of Tennessee provides at least one example of a court declining to dismiss FCA allegations relating to co-management that contained at least some traditional indicia of kickbacks. Referring back to the fundamentals of AKS compliance may seem rote to those with significant experience in this area, but healthcare practices and entities continue to run afoul of the AKS and the Stark Law. It remains important to scrutinize business relationships on the front end, before the Department of Justice and whistleblowers get to scrutinize them on the back end.

Takeaways

- Co-management is a common and accepted practice recognized by federal and state regulations and guidance, but that does not mean that it is without risk to the partnering entities.
- The particular characteristics of a co-management arrangement may still subject the participants to scrutiny under, for example, the Anti-Kickback Statute and the Stark Law.
- *United States of America et al. v. Southeast Eye Specialists PLLC et al.* is a recent example of a federal court declining to dismiss a whistleblower complaint alleging that certain aspects of patient co-management agreements violated the Anti-Kickback Statute.
- Co-management agreements and arrangements must be commercially reasonable, and any compensation exchanged must be at fair market value.
- A party must perform services that are of bona fide value and that are needed by the other party; the arrangement cannot be a disguised or concealed plan to reward the referrals sources.

1 Centers for Medicare & Medicaid Services, "Chapter 12 - Physicians/Nonphysician Practitioners," § 40.4, Medicare Claims Processing Manual, Pub. 100-04, revised July 25, 2019, https://www.cms.gov/files/document/medicare-claims-processing-manual-chapter-12.
2 Tenn. Comp. R. & Regs. 1045-02-.11(1)(a)(1).
3 Tenn. Comp. R. & Regs. 1045-02-.11(1)(c).
4 U.S. Department of Health & Human Services, Office of Inspector General, "OIG Advisory Opinion No. 12-22," January 7, 2013, https://oig.hhs.gov/documents/advisory-opinions/658/AO-12-22.pdf.
5 United States of America et al. v. Southeast Eye Specialists PLLC et al., No. 3:17-CV-00689, 2021 WL 5150687 (M.D. Tenn. Nov. 5, 2021).
6 Department of Health and Human Services, Office of Inspector General, "Advisory Opinion No. 11-14," October 7, 2011, https://oig.hhs.gov/documents/advisory-opinions/629/AO-11-14.pdf.
7 United States of America et al. v. Southeast Eye Specialists PLLC et al., WL 5150687, 10.
8 Chris Sabis, "HHS-OIG Issues First Special Fraud Alert in Six Years: A Warning for Healthcare Providers Participating in Sponsored Speaker Programs," Sherrard Roe Voigt & Harbison (blog), November 18, 2020, https://srvhlaw.com/blog/hhs-oig-issues-first-special-fraud-alert-in-six-years-a-warning-for-healthcare-providers-participating-in-sponsored-speaker-programs/.

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9 United States of America et al. v. Southeast Eye Specialists PLLC et al., WL 5150687, 9.

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