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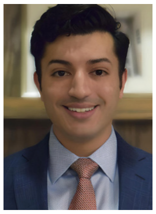


JAIME L.M. JONES
Partner

AHSIN AZIM
Associate

PAUL E. KALB
Partner

BRENNA E. JENNY
Partner

All with Sidley Austin LLP

In DOJ Crosshairs

Rethinking Commission-Based Deals With Independent Contractors

Pharma companies should review their commission-based compensation arrangements with independent contractors to address enforcement risk under the Anti-Kickback Statute, in light of recent Department of Justice enforcement

Commission-based compensation arrangements with both employees and independent contractors have long been common in the life sciences industry, particularly with respect to field sales forces. However, while the federal Anti-Kickback Statute (AKS) and its implementing regulations offer protection for employee compensation, including commissions, analogous compensation arrangements with independent contractors cannot always satisfy a safe harbor to the AKS. Although commissioned-based compensation relationships with independent contractors in the life sciences industry have historically rarely formed the basis for enforcement actions, the Department of Justice (DOJ) has increasingly targeted such arrangements under the AKS and the federal False Claims Act (FCA). DOJ's recent actions suggest that commission-based compensation arrangements with independent contractors present a growing compliance risk for life sciences companies. However, there are steps organizations can take in order to minimize the risk of DOJ scrutiny and liability.

THE AKS AND SAFE HARBORS

The AKS prohibits knowingly and willfully offering or paying remuneration "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering" any federally reimbursable item or service.[1] However, amounts paid by an employer to an employee (who has a bona fide employment relationship with such employer) are protected under the statute and a regulatory safe harbor (the employee safe harbor).[2] There is also a regulatory safe harbor under the AKS protecting personal services furnished by non-employees, so long as the following standards are met:

- The agreement is set out in writing and signed by the parties.
- The agreement sets forth the exact services required to be performed.
- The term of the agreement is not less than one year.
- The methodology for determining the compensation is set in advance and is consistent with fair market value in arm's-length transactions. Further, it is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid, or other federal healthcare programs.
- The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.
- The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.[3]

Commission-based compensation arrangements with an independent contractor sales force often fall outside the four corners of this safe harbor because commission payments commonly vary with the volume or value of items sold.

DOJ SENDS A WARNING SHOT FOLLOWING WIN IN FOURTH CIRCUIT CASE

In *United States v. LaTonya Mallory*, DOJ intervened in an FCA suit filed against a blood testing laboratory, its owner, and leadership from the lab's independent contractor sales company, BlueWave.[4] There were three theories of alleged AKS violations at issue in the case: 1) "processing and handling" fees paid by the lab to ordering physicians; 2) commission-based compensation paid by the lab to BlueWave for sales of the lab's blood tests; and 3) commission-based compensation paid by BlueWave to its independent contractor sales representatives.

DOJ's complaint-in-intervention took aim at the lab's contract with BlueWave, which included a monthly base fee plus a percentage-based commission on revenue generated from sales of the lab's tests to physicians in BlueWave's territory. DOJ pointed out that as an independent contractor, BlueWave

> “Reliance on a theory of prohibited ‘recommendations’ raises important questions about First Amendment protections for truthful, non-misleading speech”

could not take advantage of the employee safe harbor and that the arrangement did not satisfy all of the requirements of the personal services safe harbor, including that compensation for the services performed not take into account the volume or value of referrals. DOJ also asserted that for the same reasons, the commission-based compensation BlueWave paid to its own independent contractor sales force violated the AKS. At trial, a jury concluded that the defendants violated the FCA through violations of the AKS.

The Fourth Circuit Court of Appeals affirmed the jury verdict, and in announcing the appellate win, DOJ's press release broadly characterized commissions that are volume-based—and thus not safe harbored—as unlawful, asserting that the arrangements at issue “constituted ‘remuneration’ intended to induce BlueWave's sales representatives to sell as many blood tests as possible,” and furthermore the AKS “prohibited BlueWave from paying its salespeople for recommending the tests.”[5]

STRAYING FROM PAST PRACTICE

DOJ's press release in the BlueWave case contains broad generalizations about the unlawfulness of commission-based compensation arrangements that do not fit a safe harbor, characterizations that appear to represent a troubling departure from past practice and suggest that at least some within DOJ have grown more interested in scrutinizing financial arrangements between life sciences companies and their independent contractor sales personnel.

DOJ's announcement deviates from the more nuanced, facts-and-circumstances analysis that the Department of Health and Human Services Office of Inspector General (OIG) has articulated when assessing the legality of sales-force compensation arrangements that do not satisfy a safe harbor. OIG has identified certain “suspect characteristics” that “appear to be associated with an increased potential for program abuse,” including:

- “Compensation based on percentage of sales.”
- Promotion of items or services that are separately billable.
- Direct billing of federal healthcare programs by the seller.
- “Direct contact between” the seller's sales agents and federal healthcare program beneficiaries or physicians who can order the seller's items.
- Use of sales agents who are healthcare professionals (e.g., so-called “white coat marketing”).[6]

Although the facts in the BlueWave case are consistent with many of OIG's “suspect” factors, DOJ's description of the misconduct in the press release adopts a much blunter approach than OIG's more nuanced framework of analysis. Indeed, OIG has explained that while it will subject arrangements to greater scrutiny when more factors are present, a violation of the AKS is still contingent on the requisite intent to induce referrals.

DOJ's press release is also in tension with First Amendment protections. AKS enforcement actions often focus on remuneration offered or paid in exchange for purchases of federally reimbursable items and services. However, in this case, the less frequently litigated “arranging for or recommending” language formed the crux of the government's case. Reliance on a theory of prohibited “recommendations” raises important questions about First Amendment protections for truthful, non-misleading speech. DOJ has historically exercised its enforcement discretion under the AKS in a way that seems to steer clear of potential First Amendment battles over truthful speech that recommends products. This is particularly true following certain high-profile losses in enforcement actions in the context of alleged off-label promotion, in which defendants have raised First Amendment defenses. However, notably, while First Amendment defenses were briefly raised at the district court level, they were not presented to or resolved by the Fourth Circuit.

OTHER ENFORCEMENT DEVELOPMENTS

Since the BlueWave case, DOJ has continued to pursue enforcement actions premised on commission-based compensation arrangements with independent contractors. In January 2022, DOJ announced an FCA settlement of over $1.1 million to settle kickback allegations, which, among other things, involved independent contractors.[7] In April, DOJ announced that it filed a related complaint against other participants in the same purported scheme, including two laboratory CEOs and one hospital CEO, alleging FCA violations based on patient referrals in violation of the AKS and the Stark Law, as well as claims otherwise improperly billed to federal healthcare programs for laboratory testing.[8] The complaint alleges that a hospital violated the AKS by paying commission-based compensation to independent contractor recruiters to arrange for and recommend healthcare professionals' (HCPs') referrals of blood tests at the hospital. The recruiters then allegedly “kicked back” some of the hospital's payments to the referring HCPs, in the guise of investment distributions from a management services organization. In May 2022, DOJ announced that it amended its complaint to add six additional physicians in Texas who allegedly also participated in this scheme.[9]

Even before these high-profile DOJ actions, relators filing *qui tam* complaints under the FCA have incorporated allegations relating to commission-based compensation arrangements with independent contractors. The current environment may lead to an increase in such claims. For example, in a *qui tam* complaint originally filed under seal in February 2016 and unsealed earlier this year, the relator alleged, among other violations, that the relationships between the defendant "and its sales representatives are illegal because [the defendant] hires its sales representatives on an independent contractor basis and pays them commissions in violation of the Anti-Kickback Statute."[10] In particular, the allegedly unlawful arrangements were "based on the volume of overall sales each [sales representative] generated" and were not set in advance.[11] Although DOJ declined to intervene in the case, and it is not yet clear whether the relator intends to litigate on his own, the complaint highlights the growing attention this theory of liability is attracting not only from the government but from the whistleblower's bar.

COMPLIANCE CONSIDERATIONS

The evolving enforcement landscape around commission-based compensation arrangements counsels in favor of life sciences companies revisiting such arrangements to ensure they are consistent with current risk-tolerance levels. Despite increased scrutiny, commission-based compensation arrangements with independent contractors may be defensible, but robust compliance controls are necessary, and companies should take steps to ensure that, where possible, these arrangements comply with an AKS safe harbor.

Where arrangements cannot be safe harbored, it is more important than ever to confirm that sales practices more broadly do not implicate the areas of concern that traditionally increase the risk of attracting enforcement scrutiny. For example, in the BlueWave case, although DOJ targeted commission-based compensation arrangements, the government's primary concern appeared to be that the defendants were encouraging physicians to order medically unnecessary laboratory tests.

However, allegations premised on medical necessity can be challenging to prove, particularly in light of ongoing judicial disagreement over the appropriate standard of proof under the FCA for "false" claims allegedly based on a lack of medical necessity. Because of the breadth of the AKS's prohibition on exchanges of remuneration, this law can be an attractive way to target promotional practices DOJ considers concerning for other reasons.

As a result, life sciences companies with commission-based compensation arrangements that cannot be safe harbored should ensure that their compliance programs have adequate guardrails in place to address traditional areas of concern for the government, such as promoting medically unnecessary items or promotional statements that are potentially misleading. Thoughtful incorporation of data analytics into a compliance program, for example, identifying and further investigating outliers receiving relatively high levels of incentive compensation, can further help mitigate risk.

The recent enforcement focus on compensation arrangements with sales contractors increases risk related to practices that have long been common in the life sciences industry. This risk is best controlled by structuring compensation arrangements where possible to comply with the AKS's personal services safe harbors and otherwise to avoid conduct that may enhance the government's concerns about an underlying financial arrangement and draw enforcement scrutiny. PE

About the Authors

Jaime L.M. Jones *is global co-leader of Sidley Austin LLP's Healthcare practice and a member of the Global Life Sciences Leadership Council,* ***Paul E. Kalb****, MD, is a partner in Sidley Austin LLP's Healthcare and Global Life Sciences practices and former head of the firm's Healthcare & FDA group,* ***Brenna E. Jenny*** *is a partner in Sidley Austin LLP's Healthcare and Global Life Sciences practices, and* ***Ahsin Azim*** *is an associate in Sidley Austin LLP's Healthcare practice.*

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