

Journal of Health & Life Sciences Law

VOLUME 11, NUMBER 1 | OCTOBER 2017

FEATURED ARTICLES

Examining Covert Kickbacks: The OIG Carve-out Rule 1
by Russell Caldwell Ramzel

The National Vaccine Injury Compensation Program and Maternal Immunizations 32
by Emily Marcus Levine and Andrea Sudell Davey

NOTES AND COMMENTS

A Litigation Attorney’s Formula for Changing the Factors that Influence a Patient’s
 Decision to Sue..... 58
by Daniel J. D’Alesio Jr.

PRACTICE RESOURCE

Emerging Duties Under Unsettled Disability Law: Web Access and Service Animals
 in Health Care 80
by Anne Ruff and Adriana Fortune

BRIEF INSIGHTS

Reasonable Limits on Antitrust Liability for Reverse Payment Patent Settlements 108
by Peter A. Hecker

Cybersecurity Report Identifies Unique Challenges to Tackling Cybersecurity
 in Health Care 117
by Deborah R. Farringer

Examining Covert Kickbacks: The OIG Carve-out Rule

Russell Caldwell Ramzel

What is the issue? The Office of Inspector General of the Department of Health and Human Services (OIG) has consistently interpreted the Anti-Kickback Statute to find that arrangements that pay for commercial business while attempting to carve out federal health care program business may nonetheless violate the statute if any potential nexus exists between payments for commercial business and generation of federal health care program business.

What is at stake? Recent changes have increased civil penalties under the False Claims Act, potentially making lawsuits brought by quit tam relators based on anti-kickback violations more lucrative. Health care providers must consider whether the OIG's interpretation of the Anti-Kickback Statute increases the risk of such a lawsuit arising from carve-out arrangements.

What do you need to know? The scope of OIG advisory opinions is limited to the specific facts examined and may be relied on only by the requesting party. Further, the OIG has never determined that a carve-out arrangement violates the anti-kickback statute. Nevertheless, there is a risk that courts will find the OIG's opinions persuasive regarding whether a carve-out arrangement *potentially* violates the statute. Counsel should consider factors the OIG has found suspect or protective in carve-out arrangements.

Russell Caldwell Ramzel, *Examining Covert Kickbacks: The OIG Carve-out Rule*, J. HEALTH & LIFE SCI. L., Oct. 2017, at 1, © American Health Lawyers Association, www.healthlawyers.org/journal. All rights reserved.

Ramzel: OIG Carve-out Rule

CONTENTS

Introduction	3
Increased Enforcement and Larger Penalties Under the False Claims Act.....	4
False Claims Act Lawsuits Based on Anti-Kickback Statute Violations Made Easier	6
The Carve-out Rule	7
Limitations of Advisory Opinions	9
Swapping and Its Relationship to Carve-outs.....	11
Suspect Carve-out Arrangements Examined by the OIG.....	15
Significance of the One Purpose Test—Advisory Opinion 06-02	15
The outer limits of an advisory opinion’s persuasiveness— Advisory Opinions 11-08 and 12-06	18
Incentives to refer federal health care program business— Advisory Opinion 13-03.....	20
Commercial Business Only Arrangements Excepted from the Carve-out Rule	22
Pharmacies and Section 340B of the Public Health Services Act— Advisory Opinion 98-15.....	23
Carve-outs involving little or no federal health care program business ...	23
Dealing with Carve-out Arrangements.....	26
The safe(st) harbor route.....	26
The spectrum of risk and volume	27
Analyze the carve-out arrangement based on swapping arrangement factors	29
Conclusion	30

Introduction

Imagine this not uncommon scenario: A representative of a laboratory attempts to convince Dr. Smith to order more of a certain diagnostic test now that Medicare, Medicaid, and commercial payers have started paying for the test. The laboratory will happily pay a fee to Dr. Smith each time she orders this test for her patients. Dr. Smith knows it is illegal for the laboratory to pay her commissions to reward her for ordering tests for her Medicare and Medicaid patients, so she is hesitant to accept the offer. The representative is empathetic to Dr. Smith's concerns but remains undeterred and offers instead to pay only for the tests she orders for patients who have commercial insurance. Under this arrangement, Dr. Smith would still be able to order the test for her Medicare/Medicaid patients but would not receive a fee or commission for those tests.

Under the Anti-Kickback Statute (AKS), it is a felony for a person to knowingly and willfully offer or pay (or solicit or receive) remuneration “directly or indirectly, overtly or covertly, in cash or in kind” to induce (or reward) referrals or the generation of federal health care program business.¹ Like Dr. Smith, most providers understand that the AKS prohibits direct payment or receipt of remuneration² for referrals or generation of federal health care program business. It is not uncommon, however, for providers to believe that the AKS permits arrangements that exchange remuneration for referrals or generation of *commercial* business, to the exclusion of federal health care program business.

While the AKS on its face does not prohibit the exchange of remuneration for referrals or generation of commercial business, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has consistently interpreted the AKS in its advisory opinions to find that “carving out” federal health care program business from an arrangement that exchanges

1 42 U.S.C. § 1320a-7b(b)(1).

2 “Remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. OIG Advisory Op. No. 12-05, at 3 (Apr. 24, 2012), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-05.pdf>.

remuneration for commercial referrals does not immunize the arrangement from prosecution under the AKS. On the contrary, under the OIG’s “Carve-out Rule,” the exchange of remuneration for commercial business can give rise to the inference that remuneration exchanged for commercial business is actually disguised remuneration for the referral or generation of federal health care program business.

This article will discuss the OIG’s decades-long development of [the so-called Carve-out Rule](#) through its advisory opinions, as well as the [limitations of advisory opinions](#), especially whether a court or jury may rely on them to determine potential AKS liability; the [current environment of increased enforcement and larger penalties](#) as a result of amendments made to the AKS; and the concept of “swapping” and [the OIG’s analysis of swapping arrangements in relation to the Carve-out Rule](#). This article will also review several [suspect carve-out arrangements](#) that were examined by the OIG, as well as [commercial business only arrangements](#) that the OIG excepted from the Carve-out Rule. Finally, the article will provide suggestions on [how a health care provider can respond to an existing or proposed carve-out arrangement](#) to minimize or eliminate her risk of violating the AKS.

Increased Enforcement and Larger Penalties Under the False Claims Act

Recent increased enforcement of the AKS warrants the renewed attention of health care lawyers and health care providers to the Carve-out Rule. On December 14, 2016, the United States Department of Justice (DOJ) reported it had recovered “more than \$4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in fiscal year 2016 ending Sept. 30”³ This represents the third highest annual amount recovered in the history of enforcement of the False Claims Act⁴ (FCA).⁵ Of

3 Press Release, DOJ, Justice Department Recovers Over \$4.7 Billion from False Claims Act Cases in Fiscal Year 2016: Third Highest Annual Recovery in FCA History (Dec. 14, 2016) [hereinafter *Press Release, DOJ*], available at www.justice.gov/opa/pr/justice-department-recovers-over-47-billion-false-claims-act-cases-fiscal-year-2016.

4 31 U.S.C. §§ 3729–33.

5 *Press Release, DOJ*.

that total, health care fraud and abuse cases accounted for over \$2.5 billion.⁶ A total of 570 new referrals, investigations, and qui tam actions alleging health care fraud and abuse were brought in 2016, of which 69 were brought directly by the DOJ and 501 were brought by qui tam relators.⁷ In addition, the DOJ charged 802 and convicted 658 persons of health care fraud-related crimes in 2016.⁸ Many of these cases involved alleged violations of the AKS, which is punishable by criminal fines and up to five years in prison.

Civil enforcement of the AKS occurs mainly through the FCA. The FCA provides that any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval”⁹ to the federal government or a “contractor, grantee, or other recipient” of the federal government for federal funds,¹⁰ or conspires to do so,¹¹ is liable to the federal government for a civil penalty of “not less than \$5,000 and not more than \$10,000” as adjusted for inflation, “plus 3 times the amount of damages which the Government sustains because of the act of that person.”¹² An FCA case may be brought either by the federal government directly¹³ or by a private individual as a qui tam relator on behalf of the federal government.¹⁴ Relators who prevail may receive up to 30% of the amount recovered in the case, depending on whether the federal government decides to intervene in the action and on the source of the allegations in the action.¹⁵ These potential rewards for bringing an FCA action account, in part, for the fact that qui tam relators filed nearly 88% of the FCA cases in 2016.

6 *Id.*

7 CIVIL DIV., DOJ, FRAUD STATISTICS – OVERVIEW: OCTOBER 1, 1987 – SEPTEMBER 30, 2016 [hereinafter 2016 FRAUD STATISTICS], available at www.justice.gov/opa/press-release/file/918361/download.

8 HHS & DOJ, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM: ANNUAL REPORT FOR FISCAL YEAR 2016, at 1 [hereinafter 2016 REPORT] (Jan. 2017), available at <https://oig.hhs.gov/publications/docs/hcfac/FY2016-hcfac.pdf>.

9 31 U.S.C. § 3729(a)(1)(A).

10 *Id.* § 3729(b)(2)(A)(ii).

11 *Id.* § 3729(a)(1)(C).

12 *Id.* § 3729(a)(1)(G).

13 *Id.* § 3730(a).

14 *Id.* § 3730(b).

15 *Id.* § 3730(d).

False Claims Act Lawsuits Based on Anti-Kickback Statute Violations Made Easier

In 2010, the Patient Protection and Affordable Care Act (ACA)¹⁶ made it easier to bring an FCA action based on an AKS violation. First, the ACA reduced the required showing of bad intent. The ACA amended the AKS to provide that a person “need not have actual knowledge of [the AKS] or specific intent to violate” the AKS in order to violate the AKS.¹⁷ Previously, the U.S. Court of Appeals for the Ninth Circuit held that proof of specific intent to violate the AKS was necessary to prove a violation of the AKS.¹⁸ Now, an AKS violation occurs whenever the defendant willfully and knowingly offers, pays, solicits, or receives remuneration intended to induce or reward referrals or the generation of federal health care program business, regardless of whether the defendant is aware of the AKS or that he or she violated the AKS.

Second, the ACA made claims for items and services resulting from a violation of the AKS automatic false claims under the FCA.¹⁹ Previously, the theory of express false certification required the plaintiff to prove that the defendant certified compliance with the AKS *at the time of* claim submission and that compliance with the AKS was material to the federal government’s decision to pay the claim.²⁰ The theory of implied false certification required the plaintiff to prove that the defendant certified compliance with the AKS *at some time prior to* claim submission, such as through provider agreements, and that compliance with these prior false certifications was material to the government’s decision to pay the claim.²¹ The AKS amendments in the ACA eliminated the need to prove false certification in an FCA case based on claims made as a direct result of an arrangement violating the AKS.

16 Pub. L. No. 111-148, 124 Stat. 119 [hereinafter *ACA*].

17 *Id.* at 759 § 6402(f)(2) (codified at 42 U.S.C. § 1320a-7b(h)).

18 *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).

19 *ACA* § 1128J(f)(2).

20 *See, e.g., United States ex rel. Conner v. Salina Reg’l Health Ctr., Inc.*, 543 F.3d 1211, 1217 (10th Cir. 2008).

21 *See, e.g., United States ex rel. Ebeid v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010).

While the intensity of health care fraud enforcement under the Trump Administration remains to be seen, AKS enforcement in 2017 may exceed 2016's \$2.5 billion in health care fraud settlements and may even break the 2012 record of \$3.1 billion.²² Effective February 3, 2017, the DOJ adopted a new rule²³ increasing the minimum civil penalty per violation of the FCA to \$10,957 and the maximum to \$21,916, more than doubling the previous statutory minimum and maximum.²⁴ This change will likely encourage even more cases by qui tam relators who, as noted, bring 88% of health care fraud civil actions. In its Semiannual Report to Congress, the OIG reported 468 criminal actions and 461 civil actions against individuals or entities involved in health care fraud in the first half of Fiscal Year 2017.²⁵ Thus, the federal government is on pace to bring 936 criminal actions in Fiscal Year 2017, which would represent a 16% increase over Fiscal Year 2016.

The Carve-out Rule

Under the Carve-out Rule, remuneration exchanged for commercial business may be considered an indirect covert payment to induce or reward the referrals or generation of federal health care program business prohibited under the AKS.²⁶ The Carve-out Rule is not set forth in any statute or regulation. Rather, the Rule developed through interpretations of the AKS in OIG advisory opinions.

Those advisory opinions and other OIG guidance summarize the Carve-out Rule as follows:

The “carve-out” of Federal business is not dispositive . . . on the question of whether the proposed program potentially violates the [AKS]. The OIG has a long-standing

22 2016 FRAUD STATISTICS.

23 As required by the Federal Civil Penalties Inflation Adjustment Act of 1990, Pub. L. No. 101-410, 104 Stat. 890.

24 Civil Monetary Penalties Inflation Adjustment for 2017, 28 C.F.R. § 85.5.

25 HHS OIG, SEMIANNUAL REPORT TO CONGRESS: OCTOBER 1, 2016 TO MARCH 31, 2017 ix, available at <https://oig.hhs.gov/reports-and-publications/archives/semiannual/2017/sar-spring-2017.pdf>.

26 42 U.S.C. § 1320a-7b(b).

concern about arrangements pursuant to which parties “carve-out” referrals of Federal health care beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements may violate the [AKS] by disguising remuneration for Federal referrals through the payment of amounts purportedly related to non-Federal business.²⁷

The Carve-out Rule, as developed in the advisory opinions, logically follows from the following premises:

1. The AKS prohibits all direct *and indirect*, and overt *and covert*, remuneration exchanged with the intent to induce or reward the generation of federal health care program business.
2. As such, the “source of the funding for a potential kickback payment is not determinative of the intent of the payment.”²⁸ The fact that remuneration exchanged between parties is calculated based on the generation of commercial business is not determinative of whether the exchanged remuneration is in fact intended to reward or induce the generation of federal health care program business.
3. Rather, arrangements that exchange remuneration for the generation of commercial business only “[implicate and]²⁹ may violate the [AKS] by disguising remuneration for Federal referrals through offers or payments of inflated amounts for non-Federal business or simply by offering or paying remuneration for non-Federal referrals to ‘pull through’ the Federal business.”³⁰ The OIG examines such arrangements to determine whether the remuneration exchanged

27 OIG Advisory Op. No. 06-02, at 7 (Mar. 21, 2006), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/ao0602.pdf> [hereinafter *OIG Advisory Op. No. 06-02*].

28 *Id.* at 8.

29 OIG Advisory Op. No. 11-08, at 5 (June 14, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf>.

30 OIG Advisory Op. No. 00-08, at 5 (Dec. 5, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_8.pdf; see also OIG - HHS, Special Fraud Alert: Laboratory Payments to Referring Physicians, 79 Fed. Reg. 40115, 40117 (July 11, 2014).

for commercial business may actually be intended as an indirect and covert payment for federal health care program business.

In its advisory opinions, the OIG has relied on the above premises to determine that it *might* impose sanctions against an arrangement *if any potential nexus exists* between remuneration exchanged for commercial business and the generation of federal health care program business because such payment may be indirect covert payments for federal health care program business.

Limitations of Advisory Opinions

The OIG is limited to determining in an advisory opinion whether (i) the remuneration paid under a proposed arrangement constitutes prohibited remuneration under the AKS,³¹ (ii) the proposed arrangement meets a regulatory or statutory safe harbor to the AKS,³² or (iii) the proposed arrangement constitutes grounds for sanctions under the AKS.³³ The OIG generally may not later impose sanctions against an arrangement if it determines it will not impose sanctions against the proposed arrangement in an advisory opinion.³⁴

Importantly, in its advisory opinions, the OIG never states that arrangements running afoul of the Carve-out Rule necessarily violate the AKS, even though the OIG has repeatedly found that the AKS is implicated by carve-out arrangements and that it will not afford protection against sanctions for such arrangements. As a criminal statute, the AKS requires the parties to have the requisite *mens rea* of “knowingly and willfully” paying or receiving remuneration with the intent to induce or reward the generation of federal health care program business. Even in advisory opinions where the OIG concludes it could impose sanctions against a proposed arrangement because of the Carve-out Rule, the OIG states that any “definitive conclusion regarding the

31 42 C.F.R. § 1008.5(a)(1).

32 *Id.* § 1008.5(a)(2), (3).

33 *Id.* § 1008.5(a)(5).

34 *Id.* § 1008.59(b). An advisory opinion binds the Department unless the OIG later rescinds, terminates, or modifies the opinion, which requires the OIG to provide preliminary notice to the requestor and an opportunity to respond. *Id.* § 1008.45.

existence of an [AKS] violation *requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.*³⁵

Advisory opinions by their nature only address the specific facts presented for review in each opinion. Only “the requestor(s) may rely on an advisory opinion,”³⁶ and “an advisory opinion . . . [does] not bind or obligate any agency” other than HHS.³⁷ In addition, an advisory opinion may not be introduced into evidence by a person who is not a party to the advisory opinion as proof that the person did not violate the AKS.³⁸

Even though the regulations state that no person other than a requestor may rely on an advisory opinion, there is a risk a court or a jury might find the OIG’s advisory opinions persuasive or, in an extremely rare case, even subject to deference. For example, the court in *Zimmer v. Nu Tech Medical* found that while the advisory opinion obtained by a party to that case was not binding, the opinion “as an agency interpretation of the [AKS], is entitled to deference as an ‘informed judgment to which courts and litigants may properly resort for guidance.’”³⁹ Consequently, if a court finds that the OIG has determined that an arrangement has the potential to violate the AKS, the court may give deference

35 OIG Advisory Op. No. 12-06, at 2 (May 25, 2012), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-06.pdf> (emphasis added). In the preamble to the final rule establishing the advisory opinion process, the OIG specifically stated that intent would not be determined through the advisory opinion process: “These regulations are designed to avoid the potential pitfalls of advisory opinions on intent-based statutes, such as the anti-kickback statute. First, it is not practical for the agency to make an independent determination of the subjective intent of the parties based only upon written materials submitted by the requestor. . . . It is most unlikely that written materials prepared by the requestor could encompass all the information necessary to enable the OIG to make a reliable determination of the subjective intent of the parties.” 62 Fed. Reg. 7350, 7351-52 (Feb. 19, 1997).

36 42 C.F.R. § 1008.53.

37 *Id.* § 1008.59(b).

38 *Id.* § 1008.55(b).

39 *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp.2d 850, 856 (N.D. Ind. 1999) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944)) [hereinafter *Zimmer*]; *but see United States ex rel. Perales v. St. Margaret’s Hosp.*, 243 F.Supp.2d 843, 849 (C.D. Ill. 2003) (*finding* OIG opinion letter not entitled to *Chevron* deference, although “may be considered as persuasive precedent”); *United States ex rel. McDonough v. Symphony Diagnostic Servs.*, 36 F.Supp.3d 773, 780 (S.D. Ohio 2014) [hereinafter *Mobilex*] (refusing to find OIG’s definition of swapping in advisory opinion binding on court).

to an advisory opinion⁴⁰ with regard to the determination of that potential, but intent must still be proven to establish a violation of the AKS.⁴¹ However, *Zimmer* gave deference to the advisory opinion at issue in this case *because* a party to the case requested that the advisory opinion be introduced into evidence “so its introduction of and reliance on that opinion is not improper.”⁴² Deference should arguably not be afforded to an advisory opinion in cases where the party seeking to introduce an advisory opinion in a lawsuit is not the party who requested the opinion.

Swapping and Its Relationship to Carve-outs

In the late-1990s, the OIG introduced the concept of “swapping,” where a supplier bills a provider heavily discounted rates for items or services provided by the supplier for which the *provider* bills third-party payers, but the supplier does not offer the discounts if the *supplier* bills third-party payers. In Advisory Opinion 99-13, the OIG examined an arrangement where a laboratory billed federal health care programs and their beneficiaries directly for laboratory services provided to federal health care program patients of hospitals and physician groups.⁴³ For the groups’ and hospitals’ commercial patients, however, the laboratory billed the groups/hospitals for commercial laboratory services, and the group/hospital would then bill commercial payers and patients for those services. Under this arrangement, the laboratory requested approval from the OIG to bill heavily discounted rates to the groups and

40 See, e.g., *Zimmer*, at 856 (While Advisory Opinion 98-1 is not binding authority, “considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer”) (*quoting* *Hanson v. Espy*, 8 F.3d 469, 473 (7th Cir. 1993) (*quoting* *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984))).

41 While giving deference to the OIG’s determination that the arrangement could potentially violate the AKS, the court in *Zimmer* acknowledged that the OIG did not find that the arrangement in question necessarily violated the AKS because a violation of the AKS requires the requisite intent, a determination of which is beyond the scope of the advisory opinion process. *Zimmer*, at 859.

42 *Zimmer*, at 856.

43 OIG Advisory Op. No. 99-13 (Nov. 30, 1999), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_13.htm [hereinafter *OIG Advisory Op. No. 99-13*].

hospitals for commercial patient laboratory services. These discounts would not be available for federal health care program patients.

The OIG concluded that, under the arrangement, a nexus “may exist between the discount to the physicians for non-Federal health care program business and referrals of Federal health care program business,” and that, as such, the arrangement “gives rise to an inference that the laboratory and physician may be ‘swapping’ discounts on [commercial business] in exchange for profitable non-discounted” federal program business.⁴⁴

While a swapping analysis has been applied where a discount is provided for services billed to commercial payers to the exclusion of services billed to federal health care programs, it is typically applied where suppliers propose providing discounts to a nursing facility for Medicare Part A business to secure referrals of the nursing facility’s Medicare Part B or Part D business.⁴⁵ Nursing facilities must pay for all required medical services for a patient in a covered Part A stay within the first 100 days of discharge from a hospital in exchange for Medicare’s per diem rate paid to the nursing facility.⁴⁶ Except for certain excluded services,⁴⁷ a person or entity that provides medical services to a patient in a Part A stay must look solely to the nursing facility for payment and may not bill Medicare or the patient for those services.⁴⁸ In the typical scenario, a supplier of services offers deep discounts to the nursing facility for services for which the nursing facility must pay under Part A consolidated

44 *Id.* (emphasis added).

45 While the OIG has most often analyzed “swapping” arrangements in the context of nursing homes, the OIG still applies the “swapping” analysis where deep discounts in commercial business could affect referrals of non-discounted federal program business in non-nursing home contexts. *See, e.g.*, OIG Advisory Op. No. 13-02 (June 4, 2013) (applying a swapping analysis to a proposed orthotics sales arrangement), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-02.pdf>; OIG Advisory Op. No. 12-09 (July 23, 2012) (applying a swapping analysis to proposed discounts to veterans’ homes), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-09.pdf>.

46 42 U.S.C. § 1395yy(e)(2)(a)(i).

47 *See* 42 C.F.R. § 411.15(p).

48 42 U.S.C. § 1395y(a)(18).

billing, but the supplier bills Medicare its normal higher rates for services provided to those nursing facility residents not in a covered Part A stay.⁴⁹

While discount swapping is not precisely analogous to the situation in which a supplier directly pays remuneration to a provider for commercial business and carves out federal health care program business from the arrangement, the similarities warrant consideration of the OIG's analysis of swapping arrangements when analyzing the Carve-out Rule. The only significant difference between the OIG's swapping analysis and its carve-out analysis are that in a swapping arrangement, the remuneration exchanged between the parties is the money saved by the provider based on the discount offered by the supplier, whereas in a carve-out situation the provider is paid directly for commercial business.

Consequently, the following factors that the OIG considers suspect in swapping arrangements may be viewed as equally suspect when analyzing carve-out arrangements:

1. an exclusive supplier agreement coupled with a discount on services billed by the provider, where the discount is not offered on services billed by the supplier, or, in the case of a carve-out arrangement, coupled with payment for commercial business where payment is not made for federal health care program business; and
2. a discount on services billed by the provider, or, in the case of a carve-out arrangement, payment for commercial business “made in conjunction with explicit or implicit agreements to refer other facility business to the supplier, including Part B or other [federal] health care program business.”⁵⁰

49 See e.g. OIG Advisory Op. No. 99-2 (Feb. 26, 1999), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_2.htm [hereinafter *OIG Advisory Op. No. 99-2*]; OIG Advisory Op. No. 10-26 (Dec. 20, 2010), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-26.pdf>; OIG Advisory Op. No. 11-11 (July 28, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-11.pdf>; see also HHS, Health Res. & Servs. Admin., Notice of Meeting of the Advisory Committee on Organ Transplantation, 73 Fed. Reg. 56832, 56844 (Sept. 30, 2008).

50 *OIG Advisory Op. No. 99-2*.

The ultimate question in a swapping analysis is whether the discount “is tied or linked directly or indirectly to referrals of other Federal health care program business.”⁵¹ Similarly, the ultimate issue in a carve-out analysis is whether any nexus exists between the payments made for commercial business and the federal health care program business generated by the parties.⁵² Like in suspect swapping arrangements, exclusive supply arrangements and implicit or explicit agreements that the provider will send federal health care program business to the supplier in exchange for payments for commercial business can give rise to an inference that such a nexus exists in carve-out arrangements.

The recent decision in *United States ex rel. McDonough v. Symphony Diagnostic Services (Mobilex)* refused to give deference to the OIG’s swapping analysis. The qui tam relator argued that an x-ray provider, Mobilex, violated the AKS by charging nursing homes lower prices for Part A business than it charged for patients not in a covered Part A stay.⁵³ The relator urged the court to find that Mobilex engaged in swapping as defined by the OIG because Mobilex charged less than its total cost, including Mobilex’s overhead, for Part A services.⁵⁴ While the court acknowledged that pricing Part A services too low might implicate the AKS, the court held that even though Mobilex priced its Part A services below its fully loaded costs, there was no evidence that Mobilex priced its Part A services at the lower rates to induce the purchase of other federal health care program business.⁵⁵ Instead, Mobilex presented evidence that it attempted to price its Part A contracts above costs.⁵⁶ Likewise, although a court might agree that an inference may be made in a carve-out case that remuneration exchanged for commercial business is concealed remuneration for federal health care program business, a defendant might be able to overcome this inference by introducing evidence of a different intent for exchange of remuneration for commercial business other than the generation of federal health care program business.

51 *OIG Advisory Op. No. 99-13.*

52 *OIG Advisory Op. No. 13-03*, at 5 (June 7, 2013), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/AdvOpn13-03.pdf> [hereinafter *OIG Advisory Op. No. 13-03*].

53 *Mobilex*, at 775.

54 *Id.* at 780.

55 *Id.* at 781.

56 *Id.*

Suspect Carve-out Arrangements Examined by the OIG

The various advisory opinions in which the OIG has utilized the Carve-out Rule to find that a proposed arrangement posed more than a minimal risk to federal health care programs are summarized below. The biggest obstacle to these proposed carve-out arrangements was that the OIG could not rule out the existence of a nexus between payments for commercial business and the generation of federal health care program business because the parties engaged or could engage in federal health care program business apart from the proposed commercial arrangement.

Significance of the One Purpose Test—Advisory Opinion 06-02

In Advisory Opinion 06-02, a durable medical equipment (DME) supplier proposed to sell and rent DME to physicians and be paid by the physicians pursuant to a fixed fee schedule or at a daily rate.⁵⁷ The physicians would then sell or rent the DME to commercial patients only and bill commercial plans or patients directly for the DME.⁵⁸ For commercial patients only, the DME supplier would provide all billing and collections services for the physicians and would provide the physicians a trained technician to fit and train patients on the DME.⁵⁹ While the physicians would still prescribe the supplier's DME to federal health care program patients, federal health care program business would be carved out of the arrangement, such that the physicians would instruct federal health care program patients to fill their prescriptions from local DME suppliers rather than through the physicians.⁶⁰ Consequently, neither the DME supplier nor the physicians would bill federal health care programs for DME prescribed to the physician's federal health care program patients.⁶¹

⁵⁷ *OIG Advisory Op. No. 06-02*, at 2–3.

⁵⁸ *Id.* at 3.

⁵⁹ *Id.*

⁶⁰ *Id.* at 3–4.

⁶¹ Because the OIG concluded that the proposed arrangement resembled suspect joint ventures, it did not examine whether the proposed arrangement would potentially meet a safe harbor. *OIG Advisory Op. No. 06-02*, at 3.

While the DME supplier certified that all of the various contracts constituting the arrangement would meet applicable safe harbors, except for the rental of DME at a daily rate,⁶² the OIG looked at the multiple contracts as a singular arrangement that had the characteristics of suspect joint ventures previously identified by the OIG in its Special Advisory Bulletin on Contractual Joint Ventures, in which a service provider expands into another line of services at little or no risk,⁶³ except that in this case, federal health care program business was carved out of the arrangement.⁶⁴ Despite this carve-out, the OIG concluded that, because the physicians could still prescribe the supplier's DME to federal health care program patients, the OIG:

... cannot conclude that there would be no nexus between the potential profits physicians may generate from the private pay DME . . . and prescriptions of the [supplier's] products for Federally insured patients. For example, . . . the possibility [exists] that participating physicians *may have an extra incentive to steer [federal program] beneficiaries* to the [supplier's] products . . . [to] potentially secure more favorable pricing on private pay products.⁶⁵

In a marked departure from the swapping analysis discussed [above](#)—which inferred that actual discounts provided for commercial business could be remuneration for federal health care program business—the OIG denied a favorable opinion due solely to the potential that the physicians *might steer* federal health care program patients to the DME supplier to secure more favorable pricing for commercial patients.

The fact that the OIG denied a favorable opinion in this instance does not mean that the proposed commercial business only arrangement would violate the AKS. If the DME supplier and physicians did not have the intent to induce

62 This aspect of the arrangement would not meet the equipment rental safe harbor because the aggregate rental would not be set in advance. *OIG Advisory Op. No. 06-02*, at 3.

63 HHS, OIG, Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures, 68 Fed. Reg. 23148 (Apr. 30, 2003).

64 *OIG Advisory Op. No. 06-02*, at 7.

65 *Id.* (emphasis added).

or reward the generation of federal health care program business through the commercial patient program, then the program would not violate the AKS. The OIG and most federal circuits have, however, adopted the position that if even one purpose of an arrangement is to induce or reward the generation of federal health care program business, then the arrangement violates the AKS, even if the arrangement has other legitimate purposes.⁶⁶

While a criminal conviction under the AKS requires the government to prove beyond a reasonable doubt that at least one purpose of payments made under an arrangement was to induce or reward the generation of federal health care program business,⁶⁷ a civil prosecution under the FCA, based on an alleged violation of the AKS, requires the government⁶⁸ or a qui tam relator⁶⁹ to prove the same only by a preponderance of the evidence.

Even with the lower civil burden of proof, however, the government or qui tam relator must prove by a preponderance of the evidence that at least one purpose of the parties' arrangement was to induce or reward the generation of federal health care program business through payments made for commercial business. Where the parties generate a relatively small volume or value of federal health care program business compared to commercial business, a defendant might successfully argue that the fact that some federal health care program business was generated between the parties is not enough to prove that one purpose of the arrangement was to induce or reward the generation of federal health care program business, but rather proves that the parties did not intend the payments to induce or reward the generation of that business. In

66 See *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20 (1st Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985); *United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011) [hereinafter *Borrasi*]; *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

67 *Borrasi*, at 782.

68 31 U.S.C. § 3731(d).

69 While Section 3731(d) on its face appears to require a court to apply a preponderance of the evidence standard only where the government brings or intervenes in an FCA action, readers should keep in mind that a relator is bringing an action *on behalf of* the government, and courts have applied the same burden of proof to qui tam relators. See *United States ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 714 (7th Cir. 2014).

support of this argument, the defendant could cite the OIG opinions, discussed in detail [below](#), issued for carve-out arrangements that generated little or no federal health care program business.

The outer limits of an advisory opinion’s persuasiveness—Advisory Opinions 11-08 and 12-06

Two OIG advisory opinions in particular—Advisory Opinion 11-08 and Advisory Opinion 12-06—demonstrate how the premises on which the OIG has declined to issue favorable opinions for carve-out arrangements vary greatly, and why those differences will likely affect the potential persuasiveness of each opinion. Advisory Opinion 11-08 involved payments made by a DME supplier to a testing facility, and Advisory Opinion 12-06 involved an arrangement between an anesthesia group and ambulatory surgical centers.

Advisory Opinion 11-08

In Advisory Opinion 11-08, the OIG examined an arrangement under which a DME supplier utilized the staff of independent diagnostic testing facilities (IDTFs) performing sleep studies to educate the IDTFs’ commercial patients who selected the supplier’s DME on the set up and use of the DME. The DME supplier paid the IDTFs a per-commercial patient fee for these services.⁷⁰ Some of the IDTFs were owned by physicians who could prescribe the supplier’s DME. Federal health care program patients were carved out of this arrangement.

The OIG found that “IDTFs participating in the [arrangement] *may still influence referrals of Federal health care program beneficiaries* to the [supplier] for DME” and, consequently, a nexus may exist between the supplier’s payment to the IDTFs for commercial business and the generation between the supplier and the IDTF of federal health care program business.⁷¹ Further, the OIG found that the arrangement did not meet potentially applicable safe harbors

70 OIG Advisory Op. No. 11-08 (June 14, 2011), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf>.

71 *Id.* at 5 (emphasis added).

because it did not specify the exact schedule of services for which payment would be made.⁷²

Advisory Opinion 12-06

In Advisory Opinion 12-06, an anesthesia group contracted to be the exclusive anesthesia services provider for certain ambulatory surgical centers (ASCs). The group proposed to pay the ASCs an anesthesia management fee on a per-commercial patient basis.⁷³ Federal health care program patients were carved out of the arrangement. The OIG concluded that because the anesthesia group was the ASCs' exclusive provider for both federal and commercial patients, "carving out Federally insured patients . . . does not reduce the risk that the [anesthesia group's] payment to the [ASCs] would be paid to induce referrals to the [group] of Federally insured patients."⁷⁴

A comparative analysis of the persuasiveness of Advisory Opinions 11-08 and 12-06

In both opinions, the OIG refused to issue a favorable finding for a proposed arrangement because the Carve-out Rule gave rise to an inference that a per-patient fee for the generation of commercial business was potentially a disguised fee for federal health care program business, but the premise on which the OIG declined to issue a favorable opinion in each case varies greatly and will likely affect the relative persuasiveness of each advisory opinion to a court.

In [Advisory Opinion 06-02](#), recall that the OIG found that a nexus might exist between commercial payments and the generation of federal health care program business when a provider generates federal health care program business where a suspect commercial arrangement exists. In [Advisory Opinion 11-08](#), the fact that the IDTF *might influence* the generation of federal health care program business was, according to the OIG, sufficient to find that

⁷² See 42 C.F.R. § 1001.952(d)(3).

⁷³ OIG Advisory Op. No. 12-06 at 4, available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-06.pdf> [hereinafter *OIG Advisory Op. No. 12-06*].

⁷⁴ *Id.* at 6.

the commercial arrangement had the potential for generating remuneration prohibited under the AKS.

In Advisory Opinion 11-08, the mere possibility of influencing the generation of federal health care program business prevented a favorable finding.⁷⁵ Mere possibility, however, will likely not be sufficient for a judge or jury to find by a preponderance of the evidence that a commercial-only arrangement is intended to unlawfully induce or reward the generation of federal health care program business. At a minimum, a judge likely will require proof that federal health care program business was actually generated between the parties to find intent to induce or reward the generation of federal health care program business through a carve-out arrangement such that a party might be civilly or criminally liable for a violation of the AKS, and, as discussed in relation to [Advisory Opinion 06-02](#), the generation of only a small volume or value of federal health care program business will likely be insufficient.

In Advisory Opinion 12-06, by contrast, the OIG had proof that the ASC generated substantial federal health care program business for the anesthesia group due to the exclusive nature of the arrangement. A jury could easily find a violation of the AKS where the party providing exclusive services for both commercial and federal health care program patients pays the party generating business any type of per-commercial patient fee. Advisory Opinion 12-06 reiterates that the same types of considerations, such as exclusive arrangements being suspect, apply to both carve-out cases and swapping cases.

Incentives to refer federal health care program business—Advisory Opinion 13-03

A clinical laboratory proposed creating a management company to help physician groups set up their own laboratories that would provide services only to commercial patients.⁷⁶ The laboratory would provide the groups with space and management and would lease all personnel and equipment to the groups for the operation of the groups' laboratories. The groups would bill

⁷⁵ See 42 C.F.R. § 1008.5(a)(1).

⁷⁶ *OIG Advisory Op. No. 13-03*, at 2.

commercial patients and payers directly for commercial laboratory services. The groups were free to refer federal health care program business to either the clinical laboratory providing them management services or to any unrelated clinical laboratory. The clinical laboratory would be paid a fixed fair market value fee for managing the groups' laboratories, space, personnel, and equipment with respect to commercial business.⁷⁷

Despite the fact that all remuneration paid by the groups to the clinical laboratory under the arrangement was certified to be fair market value and that each component of the arrangement taken separately would likely meet a safe harbor,⁷⁸ the OIG concluded that the proposed arrangement included suspect remuneration to the physician groups in the form of a "potentially lucrative opportunity to expand into the clinical laboratory business with little or no business risk."⁷⁹ This remuneration offered by the clinical laboratory was not protected by the carve-out of federal health care program business.⁸⁰

The OIG found that under this arrangement, the groups might refer or generate additional federal health care program business for the clinical laboratory to secure better rates for the management, space, equipment, and personnel charged to the groups' laboratories for commercial laboratory services, or simply because the groups may prefer to send all clinical laboratory business to the same laboratory.⁸¹ As such, the OIG could not "conclude that there would be no nexus between the potential profits the Physician Groups may generate from the private pay clinical laboratory business, on the one hand, and orders of the Parent Laboratory's services for Federally insured patients, on the other."⁸²

Advisory Opinion 13-03 raises additional questions about the use of advisory opinions in court. Here, the clinical laboratory did not give discounts

⁷⁷ *Id.* at 3.

⁷⁸ Although the OIG did not reference its prior Special Advisory Bulletin on Contractual Joint Ventures, this arrangement had many of the characteristics of suspect joint ventures discussed in the DME/physician practice joint venture examined in Advisory Opinion 12-06.

⁷⁹ *OIG Advisory Op. No. 13-03*, at 5.

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² *Id.*

and made no payments to the groups to secure the generation of either commercial or federal health care program business. Rather, the clinical laboratory merely provided the means for the groups to profit on commercial laboratory business. If no federal health care program business was ever generated between the parties under the arrangement, it would be very difficult to make a case that the AKS was violated. In addition, it remains an open question whether a court would accept the premise that merely providing the means for a provider to pursue commercial business constitutes the exchange of remuneration under the AKS. Given that the physician groups were paying what was certified to be fair market value for the services provided by the clinical laboratory for commercial business, a counterargument could be made that the physician groups were in fact accepting at least the risk of paying the fair market value fees under the contracts with the clinical laboratory regardless of whether the venture succeeded.

Commercial Business Only Arrangements Excepted from the Carve-out Rule

In four advisory opinions, the OIG decided it would not impose sanctions against carve-out arrangements. In each case, one of the following factors aided the OIG's favorable opinion: (i) the carve-out of certain federal health care program business was required by other applicable federal law,⁸³ or (ii) despite the carve-out of federal health care program business, no—or a limited—nexus existed between payment for commercial business and federal health care program business because the entity receiving payment for commercial business would generate little or no federal health care program business under the commercial business arrangement.⁸⁴

83 OIG Advisory Op. No. 98-15 (Nov. 2, 1998), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_15.htm [hereinafter *OIG Advisory Op. No. 98-15*].

84 OIG Advisory Op. No. 00-01 (Mar. 9, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_1.htm [hereinafter *OIG Advisory Op. No. 00-01*]; OIG Advisory Op. No. 00-08 (Dec. 5, 2000), available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2000/ao00_8.pdf [hereinafter *OIG Advisory Op. No. 00-08*]; OIG Advisory Op. No. 05-12 (Oct. 31, 2005), available at <https://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0512.pdf> [hereinafter *OIG Advisory Op. No. 05-12*].

Pharmacies and Section 340B of the Public Health Services Act—Advisory Opinion 98-15

A university's hemophilia treatment center (HTC) qualified as a covered entity under Section 340B of the Public Health Services Act.⁸⁵ The university proposed an agreement under which a pharmacy would dispense anti-hemophilia factor to the HTC's patients and be paid a fixed amount by the HTC per unit dispensed.⁸⁶ The parties certified that the payment from the HTC to the pharmacy would be fair market value. The arrangement carved out Medicaid fee-for-service patients because Section 340B and Medicaid prohibit dual discounts.⁸⁷

The OIG determined the arrangement would not meet the personal services and management contracts safe harbor because neither the exact schedule of the services to be provided by the pharmacy nor the aggregate compensation under the arrangement would be set in advance. Nevertheless, the OIG would not seek sanctions against the proposed arrangement even though it carved out Medicaid fee-for-service patients because (i) the pharmacy would not set the price for Section 340B drugs or bill federal health care programs for such drugs, (ii) the pharmacy would not be paying the HTC remuneration in the form of below-market value services to secure federal health care program business, and (iii) the exclusion of Medicaid fee-for-service patients was consistent with Section 340B's prohibition against duplicate discounts.⁸⁸

Carve-outs involving little or no federal health care program business

In some cases, the OIG has issued a favorable advisory opinion when a carve-out arrangement involves little or no federal health care program business, as examined in the following advisory opinions involving an auditing company

85 42 U.S.C. § 256b(a)(4)(G).

86 *OIG Advisory Op. No. 98-15*.

87 42 U.S.C. § 256b(a)(5)(A).

88 *OIG Advisory Op. No. 98-15*.

that serviced commercial payers, a non-profit housing referral service, and a group of psychiatrists that wished to establish a pediatric day treatment facility.

An arrangement to audit commercial payers only—Advisory Opinion 00-01

An auditing company worked with commercial payers to reconcile incorrect bills that had been submitted by providers.⁸⁹ The providers paid a percentage of the amount they collected as a result of this reconciliation to the auditing company. The auditing company did not audit bills reimbursed by federal health care programs.

The OIG reaffirmed that arrangements that carve out federal health care program business may “have a ‘spillover’ effect on billing or coding for Federal health care program items or services” and if such effect “is intended by one or both parties, the [AKS] may be implicated.” The OIG nonetheless issued a favorable advisory opinion because the auditing company certified that the arrangement involved absolutely no federal health care program business.

Percentage fee for commercial patient only facilities and fixed fee for facilities with federal health care program business—Advisory Opinion 00-08

A non-profit housing referral service charged any facility that accepted only commercial patients a fee for the referral of each patient based on a percentage of the patient’s first month rent.⁹⁰ The referral service would charge a fixed annual fee for the referral service if the facility accepted any federal health care program business.

The OIG found that the Carve-out Rule in this case would not create an inference that payments for commercial business were potentially payments for federal health care program business. The commercial facilities that paid the referral service a percentage fee served absolutely no federal health care program beneficiaries. There was no nexus between the payments for commercial business to the referral service and the generation of federal health care program business by these commercial-only facilities. The fixed payment made

⁸⁹ OIG Advisory Op. No. 00-01.

⁹⁰ OIG Advisory Op. No. 00-08, at 2.

for the referral services made by all facilities accepting federal health care program business met the requirements for the referral service safe harbor.⁹¹

Joint venture with limited Medicaid reimbursement structure—Advisory Opinion 05-12

A group of psychiatrists with their own patient bases proposed a partnership to establish a pediatric day treatment facility.⁹² The facility would not treat any federal health care program beneficiaries except for patients enrolled in Medicaid health maintenance organizations. Each psychiatrist owner could refer patients to the facility, so the OIG determined that the safe harbor for small entity investments would not apply.⁹³

Even though the arrangement would implicate the AKS, the OIG determined that it would not pursue sanctions. The OIG acknowledged the Carve-out Rule but found that it was unlikely the arrangement was designed (or intended) to channel the generation of federal health care program business because (i) the “facility’s line of business—pediatric psychiatric day treatment—inherently limits the universe of potential Federal health care program patients to children, a group primarily represented in the Medicaid population” and (ii) “the only Federal health care program beneficiaries who will be treated at the facility will be clinically-eligible children enrolled in a Medicaid HMO.” The psychiatrists also had certified that the facility’s Medicaid HMO business would result in no more than two percent of the facility’s revenue.

Much of the above discussion has focused on how the advisory opinions developing the Carve-out Rule have found carve-out arrangements potentially problematic and the potential persuasiveness of these opinions in litigation. The last four opinions discussed might likewise have a persuasive effect if used by a defendant, subject to the limitations of advisory opinions discussed above.

91 42 C.F.R. § 1001.952(f).

92 *OIG Advisory Op. No. 05-12*.

93 42 C.F.R. § 1001.952(a)(2).

Dealing with Carve-out Arrangements⁹⁴

Given the increased enforcement activity by the federal government and qui tam relators for AKS violations, health care attorneys and providers should carefully examine any arrangement that seeks to avoid the AKS by paying only for commercial business and carving out federal health care program business. Regardless of whether an advisory opinion is entitled to deference, there is a possibility that a court or jury reviewing a carve-out arrangement may find the OIG's analysis of the Carve-out Rule, or its opinions protecting certain carve-out arrangements, persuasive in a criminal AKS or a civil FCA case. In any case, if an arrangement does not meet an applicable AKS safe harbor, health care counsel must always keep in mind that the key issue in a case based on an alleged AKS violation is whether one of the parties to the arrangement had the intent to induce or reward the referral or generation of federal health care program business.

Absent contrary evidence, the Carve-out Rule advisory opinions may be persuasive to support an inference that payments made for the generation of commercial business to the exclusion of federal health care program business have the potential to violate the AKS if the requisite intent is present. However, as discussed [above](#), in cases involving the similar theory of swapping, courts have not given deference to the advisory opinions but relied on the evidence introduced by one of the parties showing that the intent of the remuneration exchanged between the parties was not to induce the referral or generation of federal health care program business.

The safe(st) harbor route

If possible, a provider's counsel should ensure that a carve-out arrangement meets all elements of an applicable AKS safe harbor. If a carve-out arrange-

94 State laws, other federal laws, and commercial provider agreements are outside the scope of this article. Providers' counsel should examine any state-specific health care fraud and abuse laws and other federal laws that may potentially impact the analysis of a carve-out arrangement. Likewise, a provider should ensure that none of its agreements with commercial payers forbid the payment of remuneration for the generation of business payable by the commercial payer. A violation of any such clause in a provider agreement may be cause for termination of the provider agreement, which would ultimately frustrate the purpose of a carve-out arrangement.

ment meets the elements, the remuneration exchanged between the parties under that particular arrangement cannot be deemed a criminal offense under the AKS and the remuneration exchanged between the parties cannot be considered remuneration for the purposes of the AKS.⁹⁵ Consequently, meeting the elements of a safe harbor in a carve-out arrangement will prevent the inference that remuneration paid for commercial business under the arrangement is disguised payment for federal health care program business.

Nevertheless, the arrangement between two entities needs to be reviewed *as a whole*, especially where multiple contracts are involved. The OIG has found—and a court could find—that the whole of the arrangement confers some benefit on one of the parties that is greater than the benefits conferred in any individual contract. Even if the component contracts meet a safe harbor, the OIG or a court could find that some benefit conferred by the arrangement as a whole but not by any single contract does not meet a safe harbor and may infer that payments for commercial business under individual contracts are intended to induce or reward the referral or generation of federal health care program business.⁹⁶ Consequently, when reviewing a carve-out arrangement, a provider's counsel should be careful to analyze whether the *overall* contractual arrangement confers a benefit apart from the individual contracts.

The spectrum of risk and volume

If a carve-out arrangement cannot be structured to meet an AKS safe harbor, provider's counsel should use the OIG's Carve-out Rule analysis as a basis for examining the facts and circumstances of the arrangement to determine whether an inference could be made that payments for commercial business are disguised payments for federal health care program business. In other words, based on the Carve-out Rule analysis, a provider's counsel should carefully examine whether and to what extent federal health care program business will be generated between the parties to a carve-out arrangement.

95 42 C.F.R. § 1001.952.

96 See OIG Advisory Op. No. 06-02; OIG Advisory Op. No. 13-03.

The OIG's analysis discussed above indicates a spectrum of risk in relation to carve-out arrangements. At the riskiest end of the spectrum, the inference that payments for commercial business are disguised payments for federal health care program business is most likely to be made when carve-out arrangements require a provider to exclusively use a supplier for certain items or services payable by federal health care programs, regardless of whether the patient is covered by commercial insurance or federal health care programs.⁹⁷

On the other end of the spectrum are carve-out arrangements under which the parties (i) are required by law to carve out federal health care program business,⁹⁸ or (ii) cannot, do not,⁹⁹ or have contractually agreed not to generate federal health care program business within the arrangement. Where other federal law requires a carve-out arrangement, that requirement provides evidence that the carve-out was not made with the intent of circumventing the AKS by covertly paying for federal health care program business through payments for commercial business. Where the parties cannot, do not, or have agreed not to refer or generate federal health care program business between each other, no inference can arise that the parties intended payments to induce or reward federal health care program business. A health care attorney should have little concern about AKS risk if a carve-out arrangement meets one of these elements.

In the middle of the spectrum are carve-out arrangements that have a low volume of federal health care program business generated between the parties either by design¹⁰⁰ or in fact. If a high volume of federal health care program business is generated between the parties, it will be difficult to argue against an inference that payments ostensibly intended for the generation of commercial business were actually intended to generate federal health care program business. The converse is also true. Although the OIG has refused to endorse arrangements where there is a mere chance that payment for the generation of

⁹⁷ See *OIG Advisory Op. No. 12-06*.

⁹⁸ See *OIG Advisory Op. No. 98-15* (carve-out of Medicaid patients required for 340B program).

⁹⁹ See *OIG Advisory Op. No. 00-08* (percentage based contract for referral service limited to commercial-only facilities that would not serve federal health care program beneficiaries).

¹⁰⁰ See *OIG Advisory Op. No. 00-01* (carve-out limited to federal health care program beneficiaries covered by Medicaid HMOs and inherently limited to child beneficiaries).

commercial business *might* generate federal health care program business, the fact that the parties generate a relatively small volume of federal health care program business in relation to commercial business could be found by a court or jury to be persuasive evidence that a carve-out arrangement was not intended by the parties to induce or reward the referral or generation federal health care program business. In at least one instance, the OIG has issued a favorable advisory opinion where the parties generated a relatively small volume of federal health care program business in relation to commercial business.¹⁰¹

Analyze the carve-out arrangement based on swapping arrangement factors

As discussed [above](#), the similarities between the OIG's swapping arrangement analysis and its carve-out analysis are notable. Consequently, a health care attorney should determine whether a carve-out arrangement includes any of the factors the OIG has found suspect in a swapping arrangement. Particularly, a health care attorney should advise against a provider entering into a carve-out arrangement that pays for commercial business where the provider agrees to use the other party exclusively, including for federal health care program beneficiaries. The inference that commercial payments constitute disguised payment for federal health care program business is strongest where the provider agrees to send all federal health care program business to the other party.

Likewise, the health care attorney should identify and avoid any overall arrangement that could incentivize the generation of additional federal health care program business between the parties. The OIG has found such incentives, particularly in cases where the supplier of services who will ultimately bill federal health care programs for the items and services generated by the provider also provides non-federal items and/or services to the provider at a discounted rate.

¹⁰¹ See OIG Advisory Op. No. 00-08.

Conclusion

While the OIG, for the past two decades, has consistently interpreted the Anti-Kickback Statute to determine that arrangements that pay for referrals of commercial business while carving out federal health care program business could potentially violate the statute because a nexus may exist between the commercial payments and the generation of federal health care program business, the ultimate issue in any AKS case is whether at least one purpose of the parties in making the commercial payments was to induce or reward the referrals or generation of federal health care program business. Intent is beyond the scope of the OIG's advisory opinion process. Because the scope of advisory opinions is so limited, their potential persuasiveness in an FCA case or a criminal AKS lawsuit is equally limited. Nevertheless, the OIG's development of the Carve-out Rule indicates that there is a spectrum of risk in carve-out arrangements based on volume of federal health care program business generated between the parties, and there is a risk that a court or a jury could find the OIG's opinions to be persuasive. While the safest course is to structure a carve-out arrangement to meet a safe harbor, if the arrangement cannot be so structured, health care counsel should consider the OIG's opinions developing the Carve-out Rule, the OIG's swapping analysis, and the factors that the OIG has determined favorable and unfavorable along this spectrum. **■**



Russell Caldwell Ramzel is a senior associate in the Tulsa, Oklahoma office of Conner & Winters, LLP. His practice focuses on regulatory compliance and transactional matters within the health care industry. He represents a range of clients within the industry, including hospital systems, psychiatric hospitals, long-term care facilities, pharmacies, and suppliers of health care technologies and services. Contact him via email at rramzel@cwlaw.com.