Washington Health Law Manual — Fourth Edition

Washington State Society of Healthcare Attorneys (WSSHA)

Chapter 8:

Federal and State Fraud and Abuse Prohibitions

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Gavin is an associate in Davis Wright Tremaine's nationally recognized healthcare practice. He helps physicians, hospitals, health systems, and other private entities navigate the complexities of healthcare regulation and enforcement. In particular, he offers advice on general regulatory compliance, fraud and abuse, provider contracting, corporate and medical staff governance issues, and other emerging issues in digital privacy and telemedicine. Gavin brings a strong legal writing background to the firm, having served on the executive board of Washington Law Review, the University of Washington School of Law's flagship legal journal, and as a legal writing fellow during law school. Prior to joining the firm, Gavin worked in the Washington State Attorney General's office.

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David is a partner with Perkins Coie, LLP and chairs the firm's Healthcare Industry Group. For over three decades, David's practice has focused on representing health care clients in litigation and counseling involving regulatory compliance, contracts and reimbursement, including false claims, anti-kickback laws, physician self-referral, Medicare and Medicaid, antitrust, scientific misconduct and licensing issues.

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Ross Siler focuses his practice on healthcare litigation and regulatory matters, government investigations, and consumer protection cases. He has represented clients in large-scale investigations and suits brought by the Washington Attorney General's Office and U.S. Attorney's

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Miriam Swedlow is an associate who works with health systems, hospitals, and healthcare professionals, helping them to navigate the complex federal and state regulatory framework and find solutions that allow them to focus on providing exceptional care to patients. Miriam's nursing background gives her the ability to see issues through both a legal and clinical lens. Her fluency in clinical matters and her ability to see things from her client's perspective allow her to develop solutions that work in the real world. Miriam has experience with regulatory and litigation matters, including alternative payment models, physician contracting and compensation, False Claims Act, Anti-Kickback, Stark Law, EMTALA, peer review and quality improvement committees, medical staff privileging and complaints, professional licensing and complains, certificate of need, and healthcare antitrust.

CHAPTER OUTLINE

WA Health Law Manual – Fourth Edition - Federal and State Fraud and Abuse Prohibitions

8.1 Chapter Summary

Almost all health care providers participate in federal or state programs related to the delivery of and payment for health care services, predominantly the Medicare and Medicaid programs. Participation in these programs requires compliance with a broad array of regulatory requirements, many of which restrict business arrangements that are common and lawful in other industries. The so-called "fraud and abuse" laws are a complex web of overlapping and sometimes inconsistent prohibitions set forth in federal and state statutes and regulations. These laws address activities such as billing, filing of claims, financial arrangements among health care providers, suppliers and individuals or entities in positions to refer health care items or services, and relationships with government program beneficiaries. Violations of these laws can result in severe civil and criminal sanctions, including civil monetary penalties, treble damages, exclusion from health care program participation, and criminal fines and imprisonment.

Health care fraud is likely to continue to be a major government enforcement priority now that the health care industry has become the largest employer in the United States, surpassing manufacturing and retail. In 2018, the Department of Justice reported that for every dollar spent on anti-fraud efforts, it gets a return of more than $4, making health care fraud prosecutions a lucrative investment for the government.[1]

Given this enforcement climate, health care providers and their legal counsel should seek to understand and comply with the applicable laws. A government investigation of a health care provider for suspected health care fraud (whether or not it results in any adverse action or findings) can have significant consequences, such as reputational harm, impeding financing or future transactions, and expenditure of significant financial and human resources that would be better spent providing health care services to patients.

This chapter focuses on the Washington State health care fraud and abuse laws and provides a brief overview of various federal fraud and abuse laws. Note that there are numerous references available to health lawyers on the federal fraud and abuse laws, including treatises devoted to single statutes.[2] In addition, as healthcare laws and requirements are constantly changing, practitioners should consult industry guidance frequently for updates on fraud and abuse laws and other regulatory developments.

8.2 Overview of Federal Fraud and Abuse Laws

The federal fraud and abuse laws and regulations go by common names such as the Anti-Kickback Statute, the Stark law, the False Claims Act, and the Civil Monetary Penalties Law.[3] These laws are intended to protect the integrity of the Medicare, Medicaid, and other federal health care programs by prohibiting conduct such as fraudulent or abusive billing practices, submission of improper claims for reimbursement, activities that may improperly induce referrals of business

[1] DEP'T OF HEALTH AND HUMAN SERVICES AND DEP'T OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2017 at 8 (Apr. 2018), https://oig.hhs.gov/publications/docs/hcfac/FY2017-hcfac.pdf.

[2] *See*, *e.g.*, JOHN T. BOESE, CIVIL FALSE CLAIMS AND QUI TAM ACTIONS (4th ed. 2011); HEALTH CARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES, ABA HEALTH LAW SECTION (3d ed. & Supp. 2018).

[3] *See* 42 U.S.C. § 1320a-7b(b), 42 U.S.C. § 1395nn, 31 U.S.C. §§ 3729 *et seq*. & 42 U.S.C. § 1320a-7a.

paid for under the programs, and arrangements between and among providers, suppliers, patients, and referral sources that may give rise to inappropriate financial incentives and/or taint clinical decision-making.

The task of evaluating risk under these laws is complicated by the fact that many fraud cases are based upon interpretive rules promulgated by governmental agencies and formal and informal subregulatory policies produced by the governmental and non-governmental [4] agencies that administer the Medicare, Medicaid, and other federal health care programs. It is important, therefore, to have a working knowledge of the applicable laws, regulations, subregulatory guidance and industry-standard reimbursement practices.

For purposes of the law, the term "fraud" generally means an intentional misrepresentation of material facts. Fraud consists of intentional deception or misrepresentation that an individual knows to be false, made with knowledge that the deception could result in some unauthorized benefit to the individual or to some other person. Examples of fraud in federal health care programs include: (a) billing for services not rendered; (b) misrepresentation of services rendered; (c) deliberate application for duplicate reimbursement; and (d) false or misleading entries on provider cost reports.

The legislative history of the fraud and abuse prohibitions suggests that Congress intended for providers or suppliers that bill Medicare or Medicaid to "have an affirmative duty to ensure that the claims for payment which they submit, or which are submitted on their behalf by billing clerks or other employees, are true and accurate representations of the items or services actually provided."[5]

8.2.1 Federal Criminal Prohibitions: The Federal Medicare-Medicaid Anti-Fraud and Abuse Statute

The federal Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977 address various criminal prohibitions and resulting penalties that may be invoked against persons involved with the Medicare and Medicaid programs. The law prohibits many types of fraudulent or abusive conduct:

(a) knowingly and willfully making or causing to be made false statements in an application for benefits or for purposes of determining rights to payment;[6]

[4] The Centers for Medicare and Medicaid Services ("CMS") has overall administrative responsibility for the Medicare program but contracts with private entities (often private insurance companies) to serve as Medicare administrative contractors, or "MACs," that work directly with providers and beneficiaries on a day-to-day basis. The Medicaid program in Washington State (known as "Apple Health") is administered by the Washington State Health Care Authority ("HCA"), which likewise contracts with private and public entities, such as behavioral health organizations, to coordinate certain aspects of Medicaid care.

[5] H.R. REP. NO. 100-391, , pt. 1, at 534 (1987).

[6] 42 U.S.C. §§ 1320a-7b(a)(1)-(2).

(b) concealing or failing to disclose knowledge of the occurrence of any event affecting a person's right to any benefit or payment, with the intent to fraudulently secure such benefit or payment in an amount greater than is due;[7]

(c) when submitting a claim on behalf of another, knowingly converting payments to the use and benefit of an individual other than the one for whom the person was acting;[8]

(d) submission of claims for physician services where the provider is not a licensed physician;[9]

(e) knowingly and willfully making or causing to be made a false representation concerning the conditions of operation for purposes of qualifying for Medicare or state health plan certification;[10] and

(f) paying or receiving remuneration in connection with the referral of Medicare or Medicaid business[11] (the so-called "Anti-Kickback Law").

The law also sets forth criminal sanctions for: (i) knowingly and willfully charging Medicaid a rate in excess of a state-established rate;[12] (ii) conditioning a Medicaid patient's stay at a facility upon receiving consideration in addition to the Medicaid payments;[13] and (iii) knowingly, willfully and repeatedly violating terms of Medicare assignment.[14]

The law provides for substantial criminal penalties upon conviction of any violation. For conduct determined to be a felony, the violator may be sanctioned by a fine of up to $100,000 and up to 10 years in prison, or both.[15] For misdemeanors, the penalty may include a fine not to exceed $20,000 and imprisonment for up to one year.[16]

Other criminal statutes that are not health care specific but are often used in health care fraud prosecutions include the False Statements Act,[17] the criminal False Claims Act,[18] and the mail fraud and conspiracy statutes.[19]

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[7] 42 U.S.C. § 1320a-7b(a)(3).
[8] 42 U.S.C. § 1320a-7b(a)(4).
[9] 42 U.S.C. § 1320a-7b(a)(5).
[10] 42 U.S.C. § 1320a-7b(c).
[11] 42 U.S.C. § 1320a-7b(b).
[12] 42 U.S.C. § 1320a-7b(d)(1).
[13] 42 U.S.C. § 1320a-7b(d)(2).
[14] 42 U.S.C. § 1320a-7b(e).
[15] 42 U.S.C. § 1320a-7b.
[16] *Id.* The criminal prohibitions apply to violations involving virtually all "federal health care programs," including without limitation the Medicare and Medicaid, TRICARE/CHAMPUS, and Railroad Retirement programs. The single exception to the definition of "federal health care programs" involves the Federal Employee Health Benefit Plan.
[17] 18 U.S.C. § 1001.
[18] 18 U.S.C. § 287.
[19] 18 U.S.C. §§ 371 and 1341.

8.2.2 Anti-Kickback Statute

The federal Anti-Kickback Statute ("AKS") addresses improper financial arrangements made in connection with the referral of federal health care program business. The statute makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration in connection with referring an individual for medical items or services for which payment may be made by any "federal health care program," including Medicare and Medicaid.[20] Violation of the law is a felony, punishable with up to ten years imprisonment and/or $100,000 fine.[21] The Department of Health and Human Services Office of Inspector General ("OIG") can also pursue civil penalties of up to $100,000 per violation plus three times the amount of any government overpayment. In addition, violation can result in exclusion from federal health care programs, including Medicare and Medicaid, and collateral consequences such as loss of state licensure, hospital privileges and participation in managed care contracts. Finally, Anti-Kickback Statute violations can also result in civil monetary penalties, discussed below.[22]

The AKS contains specific statutory exceptions that limit its scope, and OIG has promulgated additional prosecutorial "safe harbors,", which include exceptions for arrangements such as bona fide employment relationships, space and equipment leases, discounts and price reductions, investment interests, personal services arrangements, and arrangements involving the subsidy of physician electronic health records, to name a few.[23] An arrangement that fully satisfies all elements of an applicable exception or regulatory safe harbor is immunized from prosecution, even

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[20] 42 U.S.C. § 1320a-7b(b) provides that:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person--
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

[21] *Id*. The Bipartisan Budget Act of 2018 increased the criminal penalty to $100,000 (from $25,000) and the maximum sentence to ten years (from five years). These increased penalties and sentence provisions apply to violations committed after February 9, 2018.

[22] *See* note 55, *infra*.

[23] For a complete list, see 42 U.S.C. § 1320a-7b(b)(3) & 42 C.F.R. § 1001.952.

if the parties intend to (and do in fact) refer federal health care program items or services to each other. Failure to comply with an exception or safe harbor does not necessarily mean that an arrangement is unlawful, but it does mean that the government will evaluate the arrangement under the totality of the facts and circumstances to determine whether a violation exists and it may subject the participants to complex litigation with the government or private parties under a statute whose breadth and vagueness gave rise to the need for exceptions and safe harbors in the first place.

Courts have interpreted the AKS to impose liability where just one purpose of the remuneration was to induce referrals of services covered in whole or in part by a federal health care program, even where other lawful reasons for the arrangement exist.[24] In addition, prior to the Patient Protection and Affordable Care Act ("ACA"),[25] it was the law in the Ninth Circuit that the government must show that a party engaged in the prohibited activity with the *specific intent* to disobey the AKS.[26] The ACA amended the AKS to partially overrule *Hanlester*, however, by specifying that "a person need not have actual knowledge of this section [the AKS] or specific intent to commit a violation of this section."[27] As a result, while specific intent to violate the AKS is no longer an element of liability, the government still must show that a party intended to act unlawfully.[28]

The ACA also specifies that any claim to the federal government that includes items or services "resulting from" a violation of the AKS constitutes a "false or fraudulent claim" under the False Claims Act, thereby exposing AKS violators to penalties and treble damages for each of potentially innumerable claims.[29]

8.2.3 False Claims Act

The federal False Claims Act ("FCA"),[30] though not limited to activities involving health care fraud and abuse, is a significant enforcement tool frequently used by the Department of Justice ("DOJ") and the OIG. The statute combines penalties "essentially punitive in nature"[31] with a relatively relaxed standard of proof.

The FCA prohibits, among other things, the "knowing" submission of a false claim, the knowing use or submission of a false statement in order to get a false claim paid, or a conspiracy to defraud the United States by getting a false or fraudulent claim paid. [32] The statute also provides that the FCA is violated if the entity "knowingly makes, uses, or causes to be made or used, a false record

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[24] *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985), *cert. denied*, 474 U.S. 988, 106 S. Ct. 396 (1985). The Ninth Circuit has adopted the *Greber* reasoning in *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).
[25] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).
[26] *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995).
[27] 42 U.S.C. § 1320a-7b(h).
[28] See *Gonzalez v. Fresenius Med. Care N. Am*., 689 F.3d 470, 476 (5th Cir. 2012).
[29] 42 U.S.C. § 1320a-7b(h).
[30] 31 U.S.C. §§ 3729-33; *See also* Program Fraud Civil Remedies Act of 1986, 31 U.S.C. §§ 3801 *et seq.,* which permits federal agencies responsible for federally funded programs to impose civil penalties on persons or entities that knowingly submit false claims that are valued at or below $150,000. In addition, federal criminal statutes exist related to False Statements (18 U.S.C. § 1001) and False Claims (18 U.S.C. § 287).
[31] *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1998 (2016) (quoting *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784 (2000)).
[32] 31 U.S.C. §§ 3729(a)(1)(A)-(C).

or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[33]

Significantly, "knowingly" does not require that a person actually "know" of the false claim submission. Rather, a person only need have acted "in deliberate ignorance" or "reckless disregard" of the truth or falsity of the information.[34]

FCA liability can exist not only for affirmative misrepresentations on claims submitted to the government (*e.g.*, a physician bills code X to Medicare when service Y was actually provided), but also for implied certifications of compliance with various laws and regulations that apply to the provision of health care services. Given the enormity of this body of legal requirements, courts have struggled to define the legal standard for determining when compliance with a particular law or regulation is considered "material" to the government's decision to pay for a claim (and thus potentially actionable as false).[35] The U.S. Supreme Court has emphasized that this "materiality" requirement is "rigorous" and "demanding"[36] and that the FCA "is not an all-purpose antifraud statute … or a vehicle for punishing garden-variety breaches of contract or regulatory violations."[37]

In addition to penalizing submission of claims known to be false at the time of submission, the FCA also contains a "reverse false claims" provision that prohibits the knowing concealment or avoidance of an obligation to pay or transmit money or property to the Government.[38] As a practical matter, this applies to situations where a provider becomes aware of receiving an overpayment from a government health care program but does not take appropriate action to identify and timely refund those payments. The ACA added additional clarity on this issue by adding a statutory provision stating that failure to report and return an overpayment within 60 days of identification creates an "obligation" under the FCA, which then triggers the "reverse false claims" provision of the FCA for knowing concealment or avoidance of "an obligation to pay" money to the government.[39]

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[33] 31 U.S.C. § 3729(a)(1)(G).

[34] 31 U.S.C. §§ 3729(b)(1)(A)-(B) provides:

> For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information –
>
> (1) has actual knowledge of the information;
>
> (2) acts in deliberate ignorance of the truth or falsity of the information; or
>
> (3) acts in reckless disregard of the truth or falsity of the information, and requires no proof of specific intent to defraud.

[35] 31 U.S.C. §§ 3729(a)(1) & (b)(4).

[36] *Escobar*, 136 S. Ct. at 2002-03.

[37] *Id.* at 2003 (internal quotations and citations omitted).

[38] 31 U.S.C. § 3729(a)(1)(G).

[39] *See* 42 U.S.C. § 1320a-7k(d). "Overpayment" is defined as "any funds that a person receives or retains under [Medicare] or [Medicaid] to which the person, after applicable reconciliation, is not entitled[.]" 42 U.S.C. § 1320a-7k(d)(4)(B).

Sanctions for violating the FCA are severe and include per claim civil penalties of between $11,181 and $22,363, adjusted for inflation most recently effective January 29, 2018,[40] as well as treble (3x) damages suffered by the government.[41] Thus, the civil exposure for violation of the FCA, particularly given the repetitive nature of health care billing, can easily become astronomically high.

The FCA also creates a private right of action for persons who have information regarding a violation of the law.[42] The law permits a whistleblower (or "*qui tam* relator") to file suit on behalf of the government against the alleged perpetrators of the fraud, and then provides the government with an opportunity to intervene and take over the litigation of the case. The statute provides a significant financial incentive for whistle-blowing activity; a successful whistleblower is entitled to 15% to 25% of any FCA recovery if the government intervenes in the case, and 25% to 30% of any recovery if the government declines to intervene.[43]

FCA actions are filed "under seal" and are not matters of public record while the DOJ determines whether it will intervene in the case and take over the litigation. Although the statute states that the government must decide whether to intervene within 60 days after it receives the complaint and material evidence and information, courts are permitted to, and routinely do, grant extensions of time to the government for good cause to complete its investigation and make a decision about intervention.[44] The government's intervention decision can have important implications: statistics show that the government recovered nearly $2 billion in fiscal year 2018 from cases in which it intervened, as compared to $119 million in cases in which it declined to intervene.[45] As a result, health care providers ensnared in in an FCA case will seek to convince the DOJ that it should not intervene in the matter.

The FCA also contains an anti-retaliation provision that provides a cause of action for individuals who have suffered retaliation (including being discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in employment) as a result of actions taken in "furtherance" of an FCA action or "other efforts to stop [one] or more violations" of the Act.[46] Remedies for violation include reinstatement, double back pay damages, and attorney fees and costs.

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[40] 31 U.S.C. § 3729(a)(1)(G); Civil Monetary Penalties Inflation Adjustment, 83 Fed. Reg. 3944 (Jan. 29, 2018). In the Medicare context, the courts have calculated penalties using each invoice (and not each line item) as a separate false claim. *See Cantrell v. N.Y. Univ.*, 326 F. Supp. 2d 468, 470 (S.D.N.Y. 2004) ("One invoice constitutes one false claim, even though it contains numerous individual entries, and a false claim is made when the invoice is presented for payment."); *See United States v. Krizek*, 111 F.3d 934 (D.C. Cir. 1997).

[41] 31 U.S.C. § 3729(a)(1)(G).

[42] 31 U.S.C. § 3730(b).

[43] 31 U.S.C. §§ 3730(d)(1)-(2).

[44] 31 U.S.C. §§ 3730(b)(1)-(2).

[45] *See* https://www.justice.gov/civil/page/file/1080696/download?utm_medium=email&utm_source=govdelivery; *see also* 31 U.S.C. § 3730(b) & (d). Note that there may be substantial procedural and jurisdictional impediments to *qui tam* actions, particularly if the allegations have been publicly disclosed prior to the filing of the action. 31 U.S.C. § 3730(d)(1).

[46] 31 U.S.C. § 3730(h).

8.2.4 Stark Physician Referral Prohibitions

The law commonly referred to as the "Stark" law (after the former congressman from California, Pete Stark), prohibits physicians from making referrals for certain "designated health services" to entities with which the physician (or the physician's immediate family member) has a "financial relationship," unless an exception applies. Designated health services are defined as: (i) inpatient and outpatient hospital services; (ii) clinical laboratory services; (iii) physical therapy services; (iv) occupational therapy services; (v) outpatient speech-language pathology services; (vi) diagnostic radiology services; (vii) durable medical equipment and supplies; (viii) parenteral and enteral nutrients equipment and supplies; (ix) prosthetics, orthotics, and prosthetic devices; (x) home health services; (xi) outpatient prescription drugs; and (xii) radiation therapy services and supplies.

The Stark law is a purely civil statute that prohibits physician referrals for designated health services reimbursed under the Medicare program where a financial arrangement fails to satisfy an exception.[47] Penalties for violations of the Stark Law include denial of payment for the designated health services provided; refund of monies received by physicians and facilities for amounts collected; payment of civil penalties of up to $15,000 for each service that a person "knows or should know" was provided in violation of the law and three times the amount of improper payment the entity received from the Medicare program; exclusion from the Medicare program and/or state healthcare programs including Medicaid; and payment of civil penalties for attempting to circumvent the law of up to $100,000 for each circumvention scheme.

Unlike the FCA and AKS, the Stark law is a strict liability statute and, therefore, no intent to violate the law is needed. This means that liability can be found for even purely technical or ministerial issues, such as the failure to obtain a signature on a lease.

Given the law's strict liability and the potentially devastating financial consequences of non-compliance, Centers for Medicare & Medicaid Services ("CMS") has developed a special self-disclosure protocol for providers who have discovered Stark law violations and wish to make a voluntary disclosure and resolve their repayment obligations with CMS. CMS developed the Self-Referral Disclosure Protocol ("SRDP") in response to a directive in the ACA for the agency to create a voluntary disclosure mechanism for Stark law violations, and an explicit grant of authority to reduce amounts due and owing as a result of Stark law violations.[48] Since 2017, CMS has settled 280 SRDP disclosures with a wide settlement range ($60 - $1,195,763).[49] Providers who

[47] Where a prohibited financial relationship exists, physicians and suppliers are prohibited from (1) making referrals of Medicare-Medicaid business for designated health services, and (2) billing for such services. In general, the penalty for violating the referral prohibitions is denial of Medicare and Medicaid payment. 42 U.S.C. § 1395nn(g)(1). Under certain conditions involving knowing circumvention schemes, civil monetary penalties and program exclusion may also be imposed.

[48] Patient Protection and Affordable Care Act § 6409.

[49] *See* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html.

wish to make a voluntary disclosure through the SRDP are instructed to use the special form available on CMS's website.[50]

While the CMS protocol is limited to potential Stark law violations, the OIG has a similar self-disclosure protocol with a broader scope, applicable to providers who have discovered potential fraud— "matters that, in the disclosing party's reasonable assessment, potentially violate Federal criminal, civil, or administrative laws for which CMPs are authorized."[51] OIG originally created its self-disclosure protocol in 1998 and revised it in 2013.[52] Since 2013, OIG has settled more than 400 disclosures, ranging in amount from $10,000 to more than $8 million.[53] As with the CMS protocol, OIG directs providers to use a particular disclosure form available on its website.[54]

The Stark law statutory and regulatory exceptions are numerous and complex and have been proposed, finalized, and refined continuously since the proposal of the first "Stark II" rules in 1998.[55] Thus, simply staying abreast of regulatory changes and agency interpretations of the rules can be a full-time occupation for health care professionals and their lawyers.

8.2.5 Civil Monetary Penalties

Health care providers or suppliers may also be subject to substantial civil monetary penalties under the Civil Monetary Penalties Law ("CMPL").[56] Significantly, the CMPL adopts the FCA's definition of "knowingly," and thus penalties can be imposed in situations where there was no actual knowledge that the underlying conduct was prohibited.[57] The administrative nature of the penalties also means that determinations of liability are made by an administrative law judge (and not a jury).

The CMPL authorizes the Secretary of Health and Human Services to assess civil monetary penalties of thousands of dollars per item or service improperly delivered or furnished, plus an assessment of up to three times the amounts improperly *claimed* (not necessarily paid) for each such item or service.[58] These administrative remedies may be imposed for the following acts, among others:

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[50] *CMS Voluntary Self-Referral Disclosure Protocol,* https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html.
[51] *U.S. DEP'T OF HEALTH & HUMAN SERVICES,* UPDATED OIG'S PROVIDER SELF-DISCLOSURE PROTOCOL, at 3 (Apr. 17, 2013), https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.
[52] *Id*., at 1.
[53] *See* https://oig.hhs.gov/fraud/enforcement/cmp/psds.asp.
[54] OIG Provider Self-Disclosure Protocol, https://forms.oig.hhs.gov/forms/Self-Disc-Form-Protocol.aspx.
[55] As originally enacted (*i.e.*, "Stark I"), the Stark law applied only to clinical laboratory services. The statute was amended in 1993 to include ten additional categories of designated health services ("Stark II").
[56] 42 U.S.C. § 1320a-7a.
[57] 42 C.F.R. § 1003.110. Thus, the government could seek CMPL penalties from a person against whom it has asserted a violation of the AKS, where proof sufficient to obtain a criminal conviction may be lacking.
[58] 42 U.S.C. § 1320a-7a(a).

(1) presenting or causing to be presented a claim under any federal health care program which the person knows or should have known was false or fraudulent, or for services not provided as claimed;[59]

(2) making a claim while being or having been excluded from the health care program;[60]

(3) violating Medicare assignment agreements;[61]

(4) providing false or misleading information which could influence a hospital discharge decision;[62]

(5) arranging for or contracting with an individual or entity that the person knows, or should know, is excluded from participation in federal health care programs;[63]

(6) committing acts in violation of the AKS;[64] or

(7) knowingly submitting an improper claim under Stark, where the person knows that a principal purpose of the financial arrangement is to evade the self-referral prohibitions.[65]

The doctrine of vicarious liability generally applies to CMPL violations, and thus a principal is strictly liable for civil money penalties arising from violations committed by an agent, such as an employee acting within the scope of his or her employment.[66]

8.2.6 Federal Health Care Program Exclusion Authority

Perhaps the most powerful arrow in the government's quiver is its ability to exclude health care providers from participation in governmental programs such as Medicare and Medicaid. The term "exclusion" means that no payment may be made under any federal health care program for any items or services either rendered by the excluded party, or rendered on the order of, or under the supervision of, an excluded physician, provided the person furnishing the item or service knew or had reason to know of the exclusion.

The federal government has broad authority to exclude providers from participation in federal programs as a penalty for having engaged in certain prohibited conduct. "The purpose of exclusion is to protect the Medicare, Medicaid, and all Federal health care programs from fraud and abuse, and to protect the beneficiaries of those programs from incompetent practitioners and from

[59] 42 U.S.C. §§ 1320a-7a(a)(1)(A) & (B).
[60] 42 U.S.C. § 1320a-7a(a)(1)(D).
[61] 42 U.S.C. § 1320a-7a(a)(2).
[62] 42 U.S.C. § 1320a-7a(a)(3).
[63] 42 U.S.C. § 1320a-7a(a)(6).
[64] 42 U.S.C. § 1320a-7a(a)(7). This provision therefore establishes so-called "intermediate sanctions" (civil fines) for violations of the (criminal) provisions of the AKS. Violators may be fined up to $100,000 for each act, plus three times the amount of the kickback that was alleged to have been offered, paid, solicited or received. Moreover, these penalties may be imposed without the necessity of obtaining a criminal conviction.
[65] 42 U.S.C. §§ 1395nn(g)(3)-(5).
[66] 42 U.S.C. § 1320a-7a(a)(l).

inappropriate or inadequate care."[67] Exclusion is mandatory upon a felony conviction of fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in connection with the delivery of health care items or services, for any criminal conviction involving an act or omission relating to an item or service delivery to a government-funded health care program, or for convictions relating to patient neglect or abuse or unlawful acts related to controlled substances.[68] The Secretary retains discretion to exclude a provider in other situations, such as convictions relating to the obstruction of an investigation or audit, submitting claims for excessive charges that do not rise to the level of fraud, failure to disclose statutorily required information, and failure to provide required access to records.[69]

In general, the minimum exclusion period for mandatory exclusions is five years,[70] and three years for permissive exclusions.[71] The Secretary may impose longer or shorter exclusion periods, however, to account for aggravating or mitigating circumstances.

Although exclusions of large institutional providers are less common, the OIG frequently excludes individuals for participation in federal health care programs following fraud-related convictions and similar circumstances. Excluded individuals are prohibited from receiving payment from a federal health care program for any services furnished, prescribed, or ordered. This prohibition on receiving federal payments extends to anyone who employs or contracts with an excluded individual, or a hospital or provider where the excluded individual provides services.[72] Therefore, it is imperative for entities who employ or contract with individuals to provide health care related services to regularly screen all such individuals against the list of excluded individuals and entities ("LEIE") maintained by OIG at https://exclusions.oig.hhs.gov/.

Short of exclusion or debarment, Medicare contractors and state Medicaid agencies may suspend or withhold payments under the respective programs without a prior hearing where there is "reliable information" that an improper payment exists (Medicare) or "a credible allegation" of fraud or willful misrepresentation (Medicare and Medicaid).[73] Payment suspensions can have devastating consequences for health care providers who rely heavily on federal program patients, as suspensions can continue for extended periods of time (often for the duration of a protracted government investigation) and carry few meaningful appeal rights.[74]

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[67] *Anderson v. Thompson*, 311 F. Supp. 2d 1121, 1124 (D. Kan. 2004).
[68] 42 U.S.C. §§ 1320a-7(a)(1)-(4).
[69] 42 U.S.C. §1320a-7(b).
[70] 42 U.S.C. § 1320a-7(c)(3). The Secretary may waive the exclusion where the targeted individual or entity is a sole community physician or sole source of "essential specialized services" in a given community. 42 U.S.C. § 1320a-7(c)(3)(B).
[71] 42 U.S.C. § 1320a-7(c)(3)(D).
[72] *See* https://oig.hhs.gov/faqs/exclusions-faq.asp.
[73] Medicare regulations authorize an intermediary or carrier to suspend payments without first notifying the provider or supplier under certain circumstances. *See* 42 C.F.R. §§ 405.371, 405.372. In addition, federal Medicaid regulations permit state Medicaid agencies to withhold program payments from a provider without first granting administrative review (subject to contrary state laws) where there is reliable evidence of fraud or willful misrepresentation by the provider. 42 C.F.R. § 455.23.
[74] *See, e.g., Guzman v. Shewry*, 552 F.3d 941, 950 (9th Cir. 2009).

8.2.7. 60-Day Report and Return Obligations

As noted in Section 8.2.3 above, section 6402 of the Affordable Care Act created an express obligation to report and return overpayments received from federal health care programs within 60 days of identification. This obligation is commonly referred to as the "60-Day Rule."[75] "Overpayment" is defined as "any funds that a person receives or retains under [Medicare] or [Medicaid] to which the person, after applicable reconciliation, is not entitled."[76] Failure to report and return the overpayment within 60 days of identification creates an "obligation" under the FCA, which then triggers the "reverse false claims" provision of the FCA for knowing concealment or avoidance of "an obligation to pay" money to the government.

CMS to date has promulgated regulations interpreting the 60-Day Rule for Medicare Part B as well as Medicare Parts C & D payments (but not yet for Medicaid).[77] An overpayment is considered identified when a person "has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment."[78] CMS has emphasized that "reasonable diligence" includes both proactive, good faith compliance measures to monitor receipt of overpayments as well as reactive and timely good faith investigation in response to "credible information" of potential overpayments. CMS has also emphasized that providers have an obligation to consider the broader universe of claims when it identified a single overpaid claim, stating that the "reasonable diligence" standard requires a provider "to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim."[79] Moreover, the provider is responsible for reporting and returning any overpayments that have been received within six years of the date it was identified.[80]

An overpayment is not technically "identified" until it is quantified.[81] Statistical sampling, extrapolation methodologies and other methodologies may be used to determine the amount of the overpayment rather than reviewing every claim. When a provider becomes aware of "credible information" that suggests an overpayment may have occurred, they have an obligation to conduct a reasonable inquiry to determine whether, in fact, an overpayment occurred. Absent extraordinary circumstances, CMS has stated that reasonable diligence can be shown through "a timely, good faith investigation of credible information," which is at most six months from receipt of credible

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[75] 42 U.S.C. § 1302a-7k(d).
[76] 42 U.S.C. § 1302a-7k(d)(4)(B).
[77] 42 C.F.R. § 401.305 & 42 C.F.R. §§ 422.326 & 360.
[78] 42 C.F.R. § 401.305(a)(2) & 42 C.F.R. §§ 422.326(c) & 360(c). It should be noted that one federal court has invalidated the regulation's definition of "identified" for Medicare Part C plans because it effectively introduces a negligence standard into a fraud prohibition, extending "far beyond the False Claims Act and, by extension, the Affordable Care Act."
UnitedHealthcare Ins. Co. v. Azar, 330 F. Supp. 3d 173, 191 (D.D.C. 2018).
[79] Medicare Program; Reporting and Returning of Overpayments, 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016) (to be codified at 42 C.F.R. pts. 401 & 405).
[80] 42 C.F.R. § 401.305(f). This time frame mirrors the general statute of limitations for FCA claims and is at odds with the four-year Medicare claims reopening window.
[81] Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844, 29923-24 (May 23, 2014) (to be codified at 42 C.F.R. pts. 417, 422, 423 & 424); 81 Fed. Reg. at 7659.

information giving rise to the investigation.[82] Unusually complex investigations may justify a time frame in excess of six months.[83]

8.3 Washington State Anti-Kickback, Self-Referral, and False Claims Statutes

Washington State law contains several provisions applicable to kickbacks, rebates, self-referrals and submission of false claims, many of which are analogous to the federal prohibitions discussed above. An understanding of the scope of these laws is necessary in order to fully advise Washington health care providers of fraud and abuse risks attendant to a given arrangement.

8.3.1 Anti-Rebating Statute (Chapter 19.68 RCW)

Washington has a brief but opaque statute aimed at prohibiting improper self-referrals of health care services.[84] This law, commonly referred to as the "anti-rebating statute," is intended to guard against payment of unearned, secret profits in connection with the furnishing of medical services by a person licensed by the state to practice "medicine and surgery."[85] RCW 19.68.010 provides, in a single run-on sentence:

> It shall be unlawful for any person, firm, corporation or association, whether organized as a cooperative, or for profit or nonprofit, to pay, or offer to pay or allow, directly or indirectly, to any person licensed by the state of Washington to engage in the practice of medicine and surgery, drugless treatment in any form, dentistry, or pharmacy and it shall be unlawful for such person to request, receive or allow, directly or indirectly, a rebate, refund, commission, unearned discount or profit by means of a credit or other valuable consideration in connection with the referral of patients to any person, firm, corporation or association, or in connection with the furnishings of medical, surgical or dental care, diagnosis, treatment or service, on the sale, rental, furnishing or supplying of clinical laboratory supplies or services of any kind, drugs, medication, or medical supplies, or any other goods, services or supplies prescribed for medical diagnosis, care or treatment.

The law contains an exception for financial interests in an entity that furnishes clinical laboratory or other services prescribed for medical, surgical, or dental diagnosis.[86] In order to qualify for the exception, a physician must:

(1) Affirmatively disclose to the patient, in writing, the fact that he or she has a financial interest in the entity to which the physician is referring the patient;

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[82] 81 Fed. Reg. at 7662.
[83] *Id*. at 7662.
[84] *See* Chapter 19.68 RCW.
[85] *See* Wash. AGO 1988 No. 28 at 3 (Nov. 14, 1988) (citing *Recent Development*, 45 Wash. L. Rev. 838, 839 (1970)).
[86] *See* RCW § 19.68.010(2).

(2) Provide the patient with a list of effective alternative facilities;

(3) Inform the patient that he or she has the option to use one of the alternative facilities; and

(4) Assure the patient that he or she will not be treated differently by the physician if the patient chooses one of the alternative facilities.[87]

The anti-rebating statute "is not intended to prohibit two or more licensees who practice their profession as copartners to charge or collect compensation for any professional services by any member of the firm, or to prohibit a licensee who employs another licensee to charge or collect compensation for professional services rendered by the employee licensee."[88]

In 2013, the Washington legislature amended Washington's Anti-Rebate Statute to ensure that its prohibitions do not apply to any activity that fits within a safe harbor of the federal Anti-Kickback Statute or otherwise does not violate the AKS. RCW 19.68.900 provides that the anti-rebating statute may not be construed "to limit or prohibit the donation of electronic health record technology or other activity by any entity, including a hospital . . . that operates a clinical laboratory, when the donation or other activity is allowed by or otherwise does not violate" the AKS or its implementing regulations.[89] RCW 19.68.900 includes one exemption: it "does not apply to an entity which principally operates as a clinical laboratory licensed or certified under section 353 of the public health service act, 42 U.S.C. Sec. 263a, or other applicable Washington state law."[90]

Violation of the anti-rebating law constitutes unprofessional conduct and may serve as the basis for license suspension or revocation.[91] A violation is also a criminal misdemeanor.[92] To date, we are not aware of any state enforcement actions brought based upon this statute, but the Washington State Attorney General (AG) has issued a number of advisory opinions on the scope of the statute.

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[87] RCW § 19.68.010.
[88] RCW § 19.68.040.
[89] RCW § 19.68.900 includes the following findings of legislative intent:
(1) The legislature recognizes the complexity of the health care delivery system and the need to provide a clear and consistent regulatory framework to enable health care providers to manage their operations in an efficient and effective manner. The legislature also recognizes that the donation of electronic health records systems reduces health care costs, promotes patient safety, and improves the quality of health care.
(2) To further the important national policy of promoting the widespread adoption of electronic health records systems, the federal antikickback statute and the rules adopted to implement the statute contain a safe harbor that allows the donation of electronic health records systems. The federal statute and rules also contain additional safe harbors to preserve a variety of other activities which, in many cases, improve access to health care. For health care entities other than clinical laboratories, the legality of all of these arrangements is currently in question.
(3) The legislature is adding language to chapter 19.68 RCW to clarify existing law and ensure that, except with respect to arrangements involving an entity which principally operates as a clinical laboratory, it is interpreted in a manner consistent with the federal antikickback statute.
[90] RCW § 19.68.900(2).
[91] RCW §§ 19.68.020-030.
[92] RCW § 19.68.010(3).

In addition, the statute has been invoked by parties in private litigation, often as a means to invalidate an existing contractual arrangement, with three resulting Supreme Court opinions.[93]

8.3.1.1 Attorney General Opinions

The AG's five opinions concerning chapter 19.68 RCW address the law's applicability to various professional arrangements, including the ownership of a nursing home by a licensed physician, a referral arrangement between an optometrist and an ophthalmologist, an infusion therapy company, and a referral arrangement between a physician and a pathologist.

Wash. AGO 1975 No. 24 (Nov. 28, 1975)

In its first opinion regarding chapter 19.68 RCW, the AG addressed whether the anti- rebating law prohibits a physician from owning part or all of a nursing home in which the physician is responsible for patient care. The AG concluded that the physician ownership did not *per se* implicate the statute: "Simply stated, it is not ownership that is restricted by the law but rather the physician's financial benefit derived from referring or supplying patients."

In addressing whether chapter 19.68 RCW prohibits a physician from receiving a profit from "furnishing" medical care at the nursing home, the AG drew a distinction between receiving a profit in connection with the "referral of patients" and receiving a profit in connection with "furnishing" care. Thus:

> Provided that there is no referral, a physician may receive a financial benefit when the institution in which he has a financial interest furnishes services or goods that are not prescribed by the physician. The physician can also receive a financial benefit for services performed by him or rendered by a licensed employee of the physician.
>
> Conversely, however, a physician is not entitled to receive a financial benefit from the services or goods furnished to patients of an institution in which the physician holds some ownership interest when the physician prescribes the services or goods that the institution furnishes to the patient, or when the physician refers the patient to the institution.

Further, RCW 19.68.010 prohibits a physician "from receiving, directly or indirectly, any valuable consideration as the result of either the sale, rental or other furnishing to the patient of any goods, services or supplies prescribed for medical diagnosis, care or treatment or the referral of the patient to any person or firm." Thus, if the physician is "furnishing" medical supplies or services to a patient, the "physician can only furnish such supplies or services at the actual cost thereof."

[93] *See* Section 24.3.1.2 ("Judicial Interpretation") below.

Wash. AGO 1988 No. 28 (Nov. 14, 1988)

In its second opinion, the AG addressed whether an agreement by an optometrist to refer patients to an ophthalmologist for surgery with the understanding that the referring optometrist would provide post-operative care violated chapter 19.68 RCW or RCW 18.130.180(21) (unprofessional conduct for any license holder by violation of RCW 19.68).[94] The AG's interpretation of the statute did not preclude this type of referral because each party performed services the provider was licensed to perform and billed only for those services; therefore, it did not result in any actual rebate or unearned charges.

In reaching that conclusion, the AG first reviewed the legislative intent articulated in RCW 19.68.040, namely, to protect the public from hidden or inflated charges by health care professionals. In light of that intent, the AG focused on whether the optometrist or the ophthalmologist would profit from services other than those they themselves actually rendered. The AG concluded that "[t]he referral does not, by itself, result in any hidden or inflated charges, unnecessary surgery or care, or profits for services not rendered by the referring professional."

Wash. AGO 1992 No. 30 (Dec. 22, 1992)

In this opinion, the AG addressed three questions: (1) does chapter 19.68 RCW prohibit physicians from referring their patients to an infusion therapy company where the physicians are shareholders; (2) does the answer to question (1) change if the physicians supervise the infusion therapy services; and (3) does chapter 19.68 RCW prohibit a physician from receiving a set fee from the infusion therapy company for providing services to the company's patients?

In response to the first question, the AG relied upon the Washington Supreme Court's decision in *Day v. Inland Empire Optical, Inc.*[95] (discussed below). The AG saw little difference between the practice described in question (1) and the practices found to be illegal in *Day*. Thus, a physician referring his or her patient to an infusion therapy company where the physician holds stock would violate chapter 19.68 RCW.

Regarding the second question, the AG concluded that to avoid violating the anti-rebate statute, the services of the infusion therapy company's nurses must be deemed to be those of the supervising physician, the physician's partner, or the physician's employee. In order for a nurse's services to be considered those of the physician's employee, the physician must exercise actual and exclusive control over the nurse's performance. Mere "supervision" by the physician would not be enough.

As to the third question, the AG determined that the anti-rebating statute does not prohibit an infusion therapy company from paying a physician for services as long as the physician actually performs the services, receives fair market value payment for the services, and does not receive duplicate payment from other sources. Although the opinion did not address physician ownership

[94] The opinion also addressed the Medical Disciplinary Board's authority related to the practice of optometry and the scope of practice and post-operative responsibilities of ophthalmologists; however, these issues are not relevant to the discussion of RCW 19.68.

[95] 76 Wn.2d 407, 456 P.2d 1011 (1969).

in the infusion therapy company under this scenario, the AG presumably assumed that the referring physician did not have an ownership interest in the company. If he or she had such an interest, then the AG likely would have opined that the physician would be prohibited from making a profit on services or supplies that the physician had prescribed or furnished under the same reasoning described above in Wash. AGO 1975 No. 24.

Wash. AGO 2005 No. 13 (Sept. 8, 2005)

State Representative Eileen Cody (D) requested an opinion to examine the practice of physicians billing patients or insurers for services provided by independently practicing pathologists to whom the physician referred patients. Pathologists would indirectly bill for their services by sending bills to the referring physicians who would then charge patients or insurers for the services. In some instances, the physicians charged amounts greater than what they paid to the pathologists for the services.

This opinion addressed (i) whether chapter 19.68 RCW prohibits a referring physician from marking up to a patient a pathologist's charge to the referring physician for diagnostic or screening services performed or supervised by a pathologist on the patient's tissue specimen, where the pathologist is neither employed nor supervised by the referring physician; and (2) whether chapter 19.68 RCW prohibits a referring physician from billing for diagnostic or screening services performed or supervised by an independently practicing pathologist on a patient's tissue specimen – even if the referring physician does not mark up the charges.

The AG answered the first question yes, and the second question no. The AG cited the legislative intent section of the law, the Washington Supreme Court's opinion in *Day*, and the AG's own 1992 Opinion, AGO 1992 No. 30. The AG determined that 19.68 RCW does not prohibit a physician from billing for a pathologist's services where those charges are "merely being passed through the pathologist to the referring physician, and then to the patient." Conversely, where the physician is paid more than warranted for the pathology services, an inference would arise that the excess fees represented a rebate, refund, commission, unearned discount or profit in connection with the referral of patients. To avoid this inference, the AG concluded that "pass through" charges should be specifically identified as relating to pathology services, and the referring physician is not permitted to mark up the pathologist's charges.

The AG's opinion is consistent with the Supreme Court's reasoning in *Wright v. Jeckle* (discussed below), decided only one year later in 2006. Both opinions indicate that physicians should earn a profit only from services they actually render. While *unearned* profits from referrals to third parties are prohibited under the anti-rebating statute, physicians are not prohibited from profiting from their own treatment of patients or providing goods or services to their patients.

Wash. AGO 2012 No. 7 (Nov. 20, 2012)

In this opinion, the AG was asked whether the anti-rebate statute permitted a Washington licensed clinical laboratory to lawfully make a monetary donation to a physician to cover 85 percent of the software cost of that physician's electronic health record (EHR) when the physician's office that was the recipient of the EHR donation either continues a referral arrangement with the laboratory or subsequently initiates an arrangement for the referral of specimens to the donating laboratory

for analysis. The AG found that the arrangement would violate the statute. In response to that opinion, the Washington Legislature enacted RCW 19.68.900 to clarify the law's reach.

8.3.1.2 Judicial Interpretation

To date, there are no reported state enforcement actions against providers under the anti-rebating statute. The case law analyzing RCW 19.68 involves private actions brought by competing providers or by the physician's patients.

i. *Day v. Inland Empire Optical, Inc.*, 76 Wn.2d, 456 P.2d 1011 (1969)

In *Day*, physician benefit from a referral relationship with an adjacent optical shop was challenged. The defendant physicians prescribed eyeglasses that were dispensed at a physically adjacent optical shop operated as a separate corporation which the physicians owned and controlled. Signage in the defendants' offices indicated the location of the adjacent shop, and the physical layout of the offices directed patients past the shop.

The trial court held that the circumstances created an unlawful "referral of patients" to the optical shop within the meaning of the statute and entered a decree directing the defendant to divest itself of ownership of the optical shop, restraining the optical shop from filling any prescription for eyeglasses written by the defendant physicians as long as the physicians held a financial interest in the shop, and prohibiting the defendant physicians from referring patients to any optical shop in which they had a financial interest.

In affirming the trial court's findings, the Supreme Court found that the physicians' ownership interest in the optical dispensing company constituted compensation under the anti-rebating statute.[96] Further, the location of the optical company in relation to the physicians' offices and the signs directing patients past the optical company constituted "referrals" to the optical store under the statute.[97] The Court also affirmed the findings of a violation of the rebate statute, RCW 19.68.010, but modified the decree. The Court held that it was permissible for the defendant doctors to own stock in a dispensing optical shop, provided they did not attempt to refer patients to the shop, directly or indirectly, by sign, symbol, gesture, or physical arrangement of their offices.[98]

ii. *Wright v. Jeckle*, 158 Wn.2d 375, 144 P.3d 301 (2006)

In 2006 the Supreme Court issued its decision in *Wright v. Jeckle*,[99] the first reported decision interpreting 19.68 RCW in 37 years. In *Wright*, several patients filed a lawsuit against their physician, Dr. Milan Jeckle, who operated a medical clinic in the Spokane Valley.[100] Dr. Jeckle dispensed, at a profit, the prescription drug commonly known as "fen-phen" to patients seeking to lose weight.[101] The patients alleged that Dr. Jeckle violated the Consumer Protection Act (CPA),

[96] 76 Wn.2d at 418-19.
[97] *Id.* at 418.
[98] 76 Wn.2d at 420-21.
[99] 158 Wn.2d 375, 144 P.3d 301 (2006).
[100] *Id.* at 377.
[101] *Id.*

RCW 19.86.020, by engaging in "deceptive acts" in trade or commerce, and that he breached his fiduciary duty to them. The plaintiffs alleged that the alleged violations of RCW 19.68.010 were *per se* deceptive acts violative of the CPA.[102]

In a unanimous opinion, the Court held that RCW 19.68.010 did not prohibit Dr. Jeckle from furnishing prescription diet drugs to his patients at a profit.[103] The Court concluded that RCW 19.68.010 does not prevent a patient from paying a health care provider for services rendered or prescriptions received.[104] The statute was found to not prevent a health care provider from making a profit on furnishing care or goods to patients.[105] Instead, when read in context, RCW 19.68.010 prohibits taking an "unearned . . . profit" or "kickback" from a third party.[106] The Court reasoned that the purpose of the anti-rebating law was not to prevent medical professionals from profiting from the goods and services that they provide, but to prevent kickbacks.[107] Thus, RCW 19.68.010 prohibits licensed practitioners from doing two things: paying anything of value in return for a referral, and receiving anything of value in return for referring patients (*i.e.*, making or receiving kickbacks).

iii. Columbia Physical Therapy, Inc., P.S. v. Benton Franklin Orthopedic Associates, P.L.L.C., 168 Wn.2d 421, 228 P.3d 1260 (2010)

Most recently, in *Columbia Physical Therapy, Inc., P.S. v. Benton Franklin Orthopedic Associates, P.L.L.C.*,[108] the Supreme Court held that the anti-rebating statute exempts from its coverage profits earned by an employee of a firm that flow to the firm's owners, provided that the owners practice in the firm. Benton Franklin Orthopedic Associates (BFOA), a physician-owned orthopedic professional limited liability company in Kennewick, Washington, employs several physical therapists who work in a facility separate from that occupied by the BFOA physicians. According to BFOA, the practice advises patients who require physical therapy services of BFOA's ownership interest in the physical therapy facility and provides a list of alternative physical therapy providers. Columbia Physical Therapy ("Columbia") is a professional services corporation owned by physical therapists that also employs physical therapists through several offices, including one in Kennewick. Columbia sued BFOA, alleging that BFOA violated the anti-rebate statute, as well as the corporate practice of medicine doctrine, the Professional Service Corporation Act (PSCA), and the Consumer Protection Act (CPA).

With regard to the anti-rebating statute, the Court distinguished BFOA's employment of physical therapists from the ophthalmologists' ownership interest in the optical dispensing company in *Day*. Unlike in *Day*, where the ophthalmologists owned a *separate* entity that operated as an optical shop, BFOA's referring physician members provided professional services through the *same* firm as the physical therapists to which they referred patients. Because the physician-members of BFOA practiced as part of the same firm as the physical therapists, the profits from professional

[102] *Id.* at 388.
[103] *Id.* at 385.
[104] *Id.* at 381.
[105] *Id.*
[106] *Id.*
[107] *Id.* at 382.
[108] 168 Wn.2d 421, 228 P.3d 1260 (2010).

services rendered by employed physical therapists were not "unearned" and, therefore, were not barred by the anti-rebating statute.

8.3.2 State Anti-Kickback and Self-Referral Law (RCW 74.09.240)

RCW 74.09.240 prohibits providers from offering or receiving remuneration in return for the referral of Medicaid services. These provisions closely track the language of the federal Anti-Kickback Statute.[109]

The statute prohibits any person, including any corporation, from soliciting or receiving any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind

(a) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made by the Washington Medicaid program, or

(b) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made by the Washington Medicaid program.

The statute further prohibits any person, including any corporation, from offering or paying any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

(a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made by the Washington Medicaid program, or

(b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made by the Washington Medicaid program.

Subsection (4) provides exceptions for a discount or other reduction in price obtained by a provider of services or other entity if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity, and for amounts paid by an employer to an employee for employment in the provision of covered items or services.

Violation of RCW 74.09.240(1) or (2) is a felony and punishable by a fine of up to $25,000. The penalty provisions supersede the criminal provisions of RCW 19.68, but they do not preclude administrative proceeding under that statute.

The statute was amended in 1995 to include prohibitions on physician referrals patterned after the federal Stark law. Subsection (3) prohibits physicians from self-referring a Medicaid client for certain "designated health services" to a facility in which the physician or an immediate family

[109] 42 U.S.C. § 1320a-7b(a).

member has a financial relationship, including whether a compensation arrangement or an ownership or investment interest.

"Designated health services" means:

(i) clinical laboratory services;

(ii) physical therapy services;

(iii) occupational therapy services;

(iv) radiology including magnetic resonance imaging, computerized axial tomography, and ultrasound services;

(v) durable medical equipment and supplies;

(vi) parenteral and enteral nutrients equipment and supplies;

(vii) prosthetics, orthotics, and prosthetic devices;

(viii) home health services;

(ix) outpatient prescription drugs;

(x) inpatient and outpatient hospital services;

(xi) radiation therapy services and supplies.

The statute provides an exception for any situation covered by a general exception specified in the federal Stark law (42 U.S.C. § 1395nn) and authorizes the adoption by rule of amendments to the Stark Law enacted after July 23, 1995.

As of April 3, 2019, no reported case interprets these subsections of this statute.

8.3.3. Medicaid False Claims (RCW 74.09.210 and RCW 74.66)

State statutes governing the Washington Medicaid program have long prohibited fraudulent billing to the Medicaid program. RCW 74.09.210, enacted in 1979, prohibits any person or legal entity from obtaining Medicaid benefits or payments in an amount greater than allowable through false statements, misrepresentations, concealment of material fact or other fraudulent scheme or device. Knowing violators of that prohibition are subject to repayment of excess benefits or payments plus interest and civil penalties not to exceed treble damages. The prohibitions in this section may be enforced criminally or civilly and may be enforced by private parties or local governments that contract with the State for this purpose.

In 2006, Congress enacted certain provisions of the Deficit Reduction Act of 2005 that created certain financial incentives to states to adopt false claims statutes modeled after the federal False Claims Act to address Medicaid false claims, specifically in the form of an enhancement to the

state share and a reduction of the federal share of any recovery made under a qualifying state law.[110] In response, in 2012 the Washington legislature enacted the Washington State Medicaid False Claims Act ("Medicaid FCA"), which provides that a person is liable to the government entity for a civil penalty, plus three times the amount of damages that the government entity sustains because of that person's act, if the person: knowingly presents, or causes to be presented, a false or fraudulent Medicaid claim for payment or approval; knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent Medicaid claim; has possession or control of property or money used, or to be used, by the government entity and knowingly delivers, or causes to be delivered, less than all of that money or property; is authorized to make or deliver a document certifying receipt of property used, or to be used, by the government entity and with intent to defraud, makes or delivers the receipt without completely knowing that the information on the receipt is true; knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the government entity who lawfully may not sell or pledge property; knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to transmit money or property to the government entity, or knowingly conceals, avoids, or decreases an obligation to transmit money or property to the government entity; or conspires to commit the aforementioned violation(s).[111] In 2018, to continue to qualify for the additional ten percent share of state Medicaid fraud false claims act recoveries afforded by the federal deficit reduction act, the Legislature pegged the amount of the civil penalty to the inflation-adjusted penalty amounts under the federal FCA, 31 U.S.C. § 3729(a), currently between $10,957 and $21,916 per claim.[112]

The court may assess not less than two times the amount of damages that the government entity sustains if the court finds that: the person furnished the state Attorney General with all information known about the violation within 30 days after first obtaining the information; the person fully cooperated with the Attorney General's investigation; and when the person furnished the Attorney General with the information, no criminal prosecution, civil action, or administrative action had commenced under the Medicaid Fraud False Claims Act with respect to the violation, and the person did not have actual knowledge of the existence of an investigation into the violation.[113]

The proceeds of cases under the Medicaid FCA and RCW 74.09.210, are deposited into the state Treasury in a discrete account that is to be used for providing Medicaid services, improper payment enforcement and certain other specified state health care initiatives.[114]

Like the federal FCA, the Medicaid FCA allows for a private person (*qui tam* relator) to a civil action in the name of the state for a violation of the statute. The relator must serve a copy of the complaint and written disclosure of substantially all material evidence on the Washington Attorney General and must file the complaint under seal. The complaint remains under seal for at least 60 days and may not be served on the defendant until the court so orders. The Attorney General may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence. If the Attorney General does not proceed with the action prior to the

[110] 42 U.S.C. §1396h.
[111] RCW 74.66.020.
[112] RCW 74.66.020(1).
[113] RCW 74.66.020(2).
[114] RCW 74.09.215.

expiration of the 60-day period or any extensions obtained, then the relator has the right to conduct the action.[115]

If the Attorney General proceeds with a *qui tam* action under the Medicaid FCA, the relator must receive between 15% and 25% of the proceeds, based on the extent of the relator's contribution. When the action is one that the court finds to be based primarily on disclosures of specific information not provided by the relator, the court may reduce the award to an amount not to exceed 10% of the proceeds, taking into account the significance of the information and the role of the relator. If the Attorney General elects not to intervene in the action, the relator shall receive an amount that the court decides is reasonable of between 25-30% of the proceeds.[116]

8.3.3.1. Judicial Interpretation and Enforcement

As of April 1, 2019, no reported court opinion has substantively interpreted either RCW 74.09.210 or RCW 74.66.

Since August 1978, Washington has had a Medicaid Fraud Control Unit (MFCU) charged with the investigation and prosecution of fraud against the state's Medicaid program. The MFCU has a "limited but vital mission to detect, deter, and prosecute the specialized areas of medicaid fraud, abuse, and neglect in Washington's medicaid system," and to ensure that federal program integrity standards for Washington's Medicaid program are met.[117] Now housed within the office of the attorney general, the MFCU has three dozen staff members, including multiple attorneys, investigators, analysts, and financial examiners.

The attorney general is statutorily required to report annually the results of implementing the Medicaid FCA.[118] In the report most recent to this edition of the chapter (2018), Washington's MFCU reported 530 open investigations, three indictments, four convictions, and 15 civil settlements and judgments.[119] Recoveries totaled $12,343,705 in 2018, nearly all of which came from global recoveries in civil cases involving the DOJ and multiple states; less than $75,000 resulted from purely local cases generated solely under Washington statutes.[120]

Effective January 1, 2019, Washington amended its Medicaid State Plan to require that, as a condition of payment, any entity "that receives or makes annual medical assistance payments under the State Plan of at least $5,000,000 must comply with the requirements of section 1902 of the Social Security Act" by establishing, adopting, and disseminating written policies about the FCA for all its employees, contractors, and agents.[121] Any such agency must also submit "an

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[115] RCW 74.66.050.
[116] RCW 74.66.070.
[117] RCW 74.67.005.
[118] RCW 74.66.130.
[119] *See* https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/expenditures_statistics/fy2018-statistical-chart.pdf.
[120] *Id*.
[121] *See* https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/WA/WA-18-0038.pdf.

attestation under penalty of perjury to the State to verify the entity has compliant written policies, and that they have been disseminated as required."[122]

8.3.4 Criminal Statutes Relating to False Claims and Statements (RCW 48.80.030 and 74.09.230)

RCW 48.80.030 broadly prohibits persons from making health-care related false claims to insurers, health maintenance organizations, health care service contractors and self-funded plans. The act prohibits persons from knowingly presenting false claims or making false statements related to claims for health care payment. In addition, the law prohibits persons from concealing or failing to disclose information in order to obtain health care payment.

The statute provides:

(1) A person shall not make or present or cause to be made or presented to a health care payer a claim for a health care payment knowing the claim to be false.

(2) No person shall knowingly present to a health care payer a claim for a health care payment that falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards. Each claim that violates this subsection shall constitute a separate offense.

(3) No person shall knowingly make a false statement or false representation of a material fact to a health care payer for use in determining rights to a health care payment. Each claim that violates this subsection shall constitute a separate violation.

(4) No person shall conceal the occurrence of any event affecting his or her initial or continued right under a contract, certificate, or policy of insurance to have a payment made by a health care payer for a specified health care service. A person shall not conceal or fail to disclose any information with intent to obtain a health care payment to which the person or any other person is not entitled, or to obtain a health care payment in an amount greater than that which the person or any other person is entitled.

(5) No provider shall willfully collect or attempt to collect an amount from an insured knowing that to be in violation of an agreement or contract with a health care payer to which the provider is a party.

(6) A person who violates this section is guilty of a class C felony punishable under chapter 9A.20 RCW.

(7) This section does not apply to statements made on an application for coverage under a contract or certificate of health care coverage issued by an insurer, health care

[122] *Id*.

> service contractor, health maintenance organization, or other legal entity which is self-insured and providing health care benefits to its employees.[123]

This statute may be used in conjunction with other criminal statutes or despite the filing of civil actions addressing similar conduct.[124] As of April 3, 2019, no reported case interprets this statute.

RCW 74.09.230 prohibits a person, including a corporation, from knowingly making false statements related to services reimbursed under any state medical care program such as Medicaid. While the language of this provision tracks the federal False Claims Act in some respects, it is a criminal statute that is separate and apart from the civil Medicaid FCA, discussed above.

The statute provides:

Any person, including any corporation, that

> (1) knowingly makes or causes to be made any false statement or representation of a material fact in any application for any payment under any medical care program authorized under this chapter, or
>
> (2) at any time knowingly makes or causes to be made any false statement or representation of a material fact for use in determining rights to such payment, or knowingly falsifies, conceals, or covers up by any trick, scheme, or device a material fact in connection with such application or payment, or
>
> (3) having knowledge of the occurrence of any event affecting (a) the initial or continued right to any payment, or (b) the initial or continued right to any such payment of any other individual in whose behalf he has applied for or is receiving such payment, conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount or quantity than is due or when no such payment is authorized, shall be guilty of a class C felony: PROVIDED, That the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.[125]

8.3.4.1 Judicial Interpretation (RCW 74.09.230)

i. State v. Quinn, 43 Wn. App. 696, 719 P.2d 936 (1986)

In *State v. Quinn*, the defendant physician was charged with knowingly submitting false medical claims payable under Medicaid, as well as theft. The defendant allegedly engaged in double billing, submission of false diagnoses to assure payment, and submission of false claims for lab tests. The physician did not seriously contest the lawfulness of the alleged practices but contended that the practices were those of his office staff acting on their own. A jury convicted him on 15 of 16 counts of submitting false claims and two counts of theft.

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[123] RCW 48.80.030.
[124] RCW 48.80.050.
[125] RCW 74.09.230.

The physician challenged the jury verdict on appeal; however, the appellate court upheld the judgments, finding that there was sufficient evidence to submit the matter to the jury—even without direct evidence that the defendant directed that billings be handled in a manner that violated the statute.

ii. State v. Wright, 183 Wn. App. 719, 334 P.3d 22 (2014).

This case involved the prosecution of a caregiver for theft and submitting false medical claims to the Medicaid program. On appeal, the defendant claimed there was not sufficient evidence to support a conviction for Medicaid fraud because the inaccurate written time sheets she submitted to the state were not relied upon in her application for payment as they were submitted after payment. The appellate court upheld the jury's verdict, noting that the time sheets provided circumstantial evidence sufficient to prove that the defendant knowingly made false statements in billings that she had submitted before payment by telephonic means. The court also held that the statutes criminalizing first degree theft and Medicaid fraud were not concurrent and, thus, did not constitute the same criminal conduct for sentencing purposes.

iii. State v. Thompson, 192 Wn. App. 733, 370 P.3d 586 (2016)

In *State v. Thompson*, a caregiver appealed her conviction of theft and submission of false statements to the Medicaid program arguing that the convictions violated her right against double jeopardy. The defendant claimed the two false statement offenses merged with her conviction for theft. The appellate court found that the convictions did not constitute double jeopardy because the underlying statutes have independent purposes and effect.