

Some Laws Affecting Healthcare Transactions



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(10-15)

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Overview

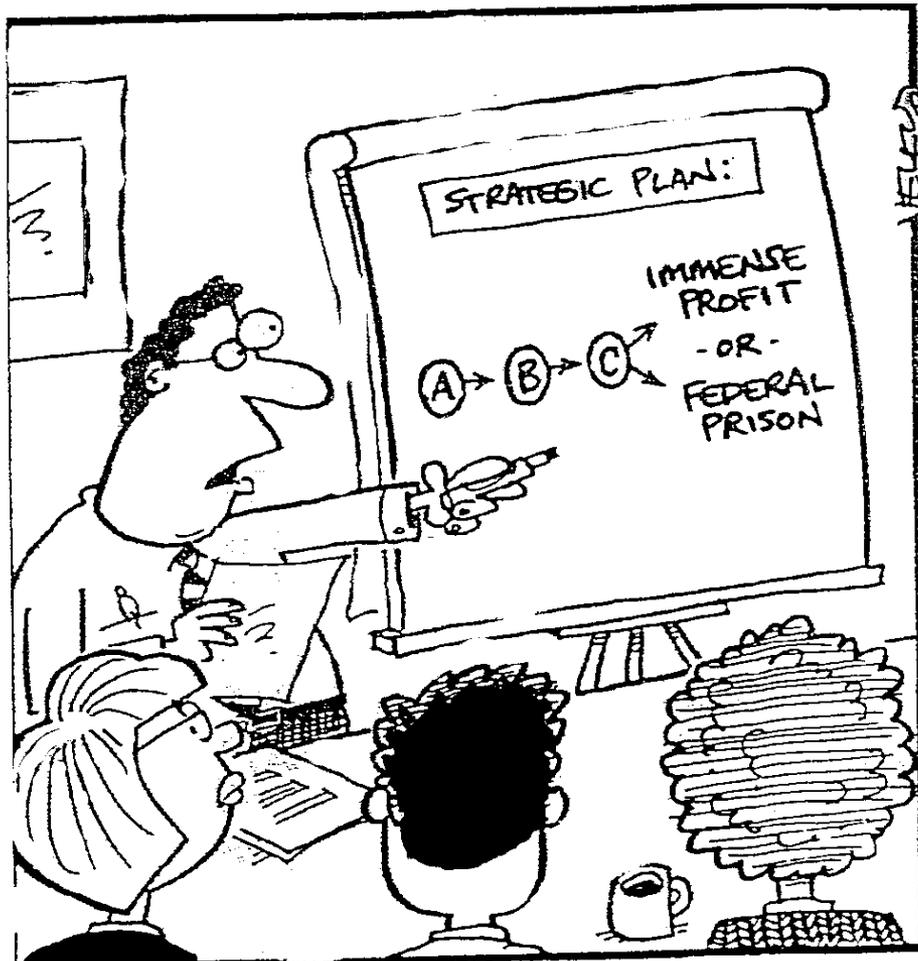
- **Fraud and abuse laws**
 - Anti-Kickback Statute
 - Stark
 - Civil Monetary Penalties Law
 - State laws
- **HIPAA**
 - Business Associate Requirements
- **Corporate practice of medicine**

AGENDA

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-
-



Fraud and Abuse Laws



“Stay with me now, people, because in step C, things get a bit delicate.”

- False Claims Act
- Anti-Kickback Statute
- Ethics in Patient Referrals Act (“Stark”)
- Civil Monetary Penalties Law



WARNING

Anytime your client wants to:

- **Give anything to induce or reward referrals, or**
- **Do any deal with a referral source.**

Anti-Kickback Statute (42 USC 1320a-7b; 42 CFR 1001.952)



Anti-Kickback Statute

- **Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless fit within regulatory safe harbor.**
 - Applies to anyone.
 - Applies to any form of remuneration, i.e., anything of value.
- **Test: Statute violated if “one purpose” is to induce improper referrals. (*U.S. v. Greber* (3d Cir. 1985))**
- **Ignorance of the law is no excuse.**

Anti-Kickback Statute

- **Penalties**

- 5 years in prison
- \$25,000 criminal fine
- \$50,000 penalty
- 3x damages
- Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.102)

- **Anti-Kickback violation = False Claims Act violation**

- Lower standard of proof
- Subject to False Claims Act penalties
- Subject to qui tam suit.
- Must repay amounts received improperly.

(42 USC 1320a-7a(a)(7))

- **OIG Self-Disclosure Protocol: minimum \$50,000 settlement.**



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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, October 22, 2014

DaVita to Pay \$350 Million to Resolve Allegations of Illegal Kickbacks

DaVita Healthcare Partners, Inc., one of the leading providers of dialysis services in the United States, has agreed to pay \$350 million to resolve claims that it violated the False Claims Act by paying kickbacks to induce the referral of patients to its dialysis clinics, the Justice Department announced today. DaVita is headquartered in Denver, Colorado and has dialysis clinics in 46 states and the District of Columbia.

The settlement today resolves allegations that, between March 1, 2005 and February 1, 2014, DaVita identified physicians or physician groups that had significant patient populations suffering renal disease and offered them lucrative opportunities to partner with DaVita by acquiring and/or selling an interest in dialysis clinics to which their patients would be referred for dialysis treatment. DaVita further ensured referrals of these patients to the clinics through a series of secondary agreements with the physicians, including entering into agreements in which the physician agreed not to compete with the DaVita clinic and non-disparagement agreements that would have prevented the physicians from referring their patients to other dialysis providers.

Anti-Kickback Statute

- Applies to any form of remuneration, i.e., anything of value.
 - Money
 - Free or discounted items, services, gifts or perks (e.g., free use of hospital services, equipment, space)
 - Contract compensation structures that pay based on referrals.
 - Business opportunities
 - Waivers of copays or deductibles
 - Overpayments or underpayments (paying more or less than fair market value)

Anti-Kickback: Safe Harbors

- Anti-Kickback Statute contains regulatory safe harbors at 42 CFR 1001.952.
 - To be safe, must comply with all elements.
 - Not required to fit within safe harbor.
- Safe harbors include:
 - Bona fide employment contracts
 - Personal services contracts
 - Leases for space or equipment
 - Acquisition of physician practices
 - Investments in healthcare entities
 - Others
- *Structure deals to comply with AKS!*



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Advisory Opinions

Act (42

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if you act consistently with favorable advisory opinion.

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certain privileged, confidential, or financial
e specified by the requestor.

Ethics in Patient Referrals Act (“Stark”) (42 USC 1395nn; 42 CFR 411.351)



Stark Self-Referral Law

- If a physician (or their family member) has a financial relationship with an entity:
 - The physician may not refer patients to that entity for designated health services (“DHS”), and
 - The entity may not bill Medicare for such designated health servicesunless arrangement structured to fit within a regulatory exception.

Stark Self-Referral Law

- **Penalties**
 - No payment for services provided per improper referral.
 - Repayment of payments improperly received within 60 days.
 - Civil penalties.
 - \$15,000 per improper referral/claim
 - \$100,000 per scheme
- **Stark violation is also likely a False Claims Act violation**
 - Penalty of \$5,500 to \$11,000 per claim
 - Exclusion from Medicare and Medicaid
 - Qui tam lawsuit
 - Must repay amounts improperly received



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"Even for well-intentioned healthcare providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous exposure."

Judge Albert Diaz

\$237 million Tuomey judgment upheld by federal appeals court

By [Lisa Schencker](#) | July 2, 2015

(This story was updated at 4:45 p.m. ET)

A federal appeals court on Thursday upheld a \$237 million False Claims Act verdict against [Tuomey Healthcare System](#) in Sumter, S.C. The sum is believed to be the largest ever levied against a community hospital and exceeds the hospital's annual revenue.

"We are disappointed," said Tuomey President and CEO Michelle Logan-Owens in the statement responding to the [decision reached by the 4th U.S. Circuit Court of Appeals \(PDF\)](#).

Tuomey said it would continue settlement discussions with the government and consider its legal options moving forward.

"However, for more than 100 years we have been providing healthcare services in

Stark Safe Harbors

- Stark contains regulatory safe harbors.
 - To receive benefit, must comply with all elements.
- Safe harbors include:
 - Referrals within a group
 - Ownership or investment in rural providers
 - Bona fide employment contracts
 - Services contracts
 - Leases for space or equipment
 - Acquisition of physician practices
 - Medical staff incidental benefits
 - Professional courtesy
 - Recruitment
- ***Structure physician transactions to comply with Stark!***

Civil Monetary Penalties Law (42 USC 1320a-7a)



Civil Monetary Penalties Law

Prohibits specified conduct, e.g.,

- **Submitting false or fraudulent claims, or claims for unnecessary services.**
- **Offering inducements to Medicare program beneficiaries to get them to purchase items.**
 - Waivers or copays
 - Free or discounted items or services
- **Offering incentives to physicians to reduce services payable by government programs.**
 - Gainsharing programs
 - Share of profits of department
- **Contract with excluded entity.**
 - Employees, providers, contractors

Civil Monetary Penalties Law

- **Penalties generally include:**
 - \$2,000 to \$50,000 fines
 - 3x amount claimed
 - Exclusion from government programs
- **CMPL violations may also violate:**
 - False Claims Act
 - Anti-Kickback Statute
 - Stark

Health Insurance Portability and Accountability Act ("HIPAA") (42 CFR part 164)



HIPAA Privacy and Security Rules

- Health care providers and their business associates must:
 - Protect the privacy of protected health info (“PHI”).
 - Secure patient’s electronic PHI by adopting specified safeguards.
 - Give patients certain rights concerning their PHI.
 - Report breaches of unsecured info within 60 days to:
 - The affected individual.
 - HHS.
 - Local media if breach involves > 500 persons.

Civil Penalties (45 CFR 160.400)

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none">• \$100 to \$50,000 per violation• Up to \$1.5 million per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none">• \$1000 to \$50,000 per violation• Up to \$1.5 million per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none">• \$10,000 to \$50,000 per violation• Up to \$1.5 million per type per year• Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none">• At least \$50,000 per violation• Up to \$1.5 million per type per year• Penalty is mandatory

Civil Penalties

Data Breach Results | x

www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/jointbreach-agreement.html

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Data Breach Results in \$4.8 Million HIPAA Settlements

New York and Presbyterian Hospital

New York and Presbyterian Hospital (NYP) has agreed to pay OCR \$3,300,000 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, and will adopt a corrective action plan to evidence their remediation of these findings.

- [Read the Resolution Agreement](#)

Columbia University

Columbia University (CU) has agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules, including a \$1,500,000 monetary settlement and corrective action plan to address deficiencies in its HIPAA compliance program.

- [Read the Resolution Agreement](#)

HIPAA

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Criminal Penalties

(42 USC 1320d-6(a))

- Applies if employees or others obtain or disclose protected health info from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	<ul style="list-style-type: none">• \$50,000 fine• 1 year in prison
Committed under false pretenses	<ul style="list-style-type: none">• 100,000 fine• 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	<ul style="list-style-type: none">• \$250,000 fine• 10 years in prison

Business Associate Obligations

- **Execute and comply with the terms of the business associate agreement with covered entity.**
 - Must contain certain terms required by HIPAA.
- **Comply with the Security Rule.**
 - Appoint security officer.
 - Perform and document a risk assessment.
 - Implement required safeguards.
 - Execute agreements with subcontractors.
 - Maintain written policies and procedures.
 - Train personnel.
- **Comply with minimum necessary standard.**
- **Report breaches of unsecured PHI to covered entity.**

OCR Sample BAA Language

Business Associate Contracts - Windows Internet Explorer provided by Holland and Hart, LLP

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/contractprov.html

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Business Associate Contracts

SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS

(Published January 25, 2013)

Introduction

A "business associate" is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of a covered entity that involve access by the business associate to protected health information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract a

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Summary of the HIPAA Security Rule

Corporate Practice of Medicine



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Corporate Practice of Medicine

- In some states, physicians may not be employed by corporations.
 - Concern that non-physicians may influence physician conduct.
 - Medical practices acts interpreted to prohibit corporations from “practicing medicine” through employed physicians.
 - Statutes prohibit physicians from practicing medicine as an employee of corporation.
E.g., California, New York, Texas, Idaho, etc.
- Penalties may include fines, adverse licensure actions, or injunctions to stop practice.

Corporate Practice of Medicine



“It is well established that no unlicensed person or entity may engage in the practice of the medical profession through licensed employees; nor may a licensed physician practice as an employee of an unlicensed person or entity. Such practices are contrary to public policy.” (*Worlton v. Davis*, 73 Idaho 217, 249 P.2d 810 (1952))

Corporate Practice of Medicine

- CPOM is usually subject to exceptions.
 - Statutes expressly allow or contemplate that certain entities may employ physicians (e.g., hospitals, managed care organizations, other licensed entities).
 - Professional corporations, professional limited liability companies, etc.
- CPOM usually does not apply to independent contractors.
- CPOM usually does not apply to midlevels.
- *Physicians and corporations employing physicians must beware CPOM when practicing across state boundaries.*

Questions?



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Health Care Transactions: Beware Stark, Kickbacks, and More

Author(s) - [Kim Stanger](#)
Holland & Hart News Update

9/10/2012

Anytime you structure a transaction involving healthcare providers, you must beware federal and state statutes unique to the healthcare industry, including laws prohibiting illegal kickbacks or referrals. Those laws may affect any transactions between health care providers, including employment or service contracts, group compensation structures, joint ventures, leases for space or equipment, professional courtesies, free or discounted items or services, and virtually any other exchange of remuneration. Violations may result in significant administrative, civil and criminal penalties. The Affordable Care Act ("ACA") dramatically increased exposure for violations by expanding the statutory prohibitions, increasing penalties, and imposing an affirmative obligation to repay amounts received in violation of the laws.¹ The following are some of the more relevant traps for the unwary.

Anti-Kickback Statute ("AKS"). The federal AKS prohibits anyone from knowingly and willfully soliciting, offering, receiving, or paying any form of remuneration to induce referrals for any items or services for which payment may be made by any federal health care program unless the transaction is structured to fit within a regulatory exception.² An AKS violation is a felony punishable by a \$25,000 fine and up to five years in prison.³ Thanks to the ACA, violation of the AKS is an automatic violation of the federal False Claims Act⁴, which exposes defendants to additional civil penalties of \$5,500 to \$11,000 per claim, treble damages, and private qui tam lawsuits.⁵ The AKS is very broad: it applies to any form of remuneration, including kickbacks, items or services for which fair market value is not paid, business opportunities, perks, or anything else of value offered in exchange for referrals. The statute applies if "one purpose" of the transaction is to generate improper referrals.⁶ It applies to any persons who make or solicit referrals, including health care providers, managers, program beneficiaries, vendors, and even attorneys.⁷ Despite its breadth, the AKS does have limitations. First, it only applies to referrals for items or services payable by government health care programs such as Medicare or Medicaid.⁸ If the parties to the arrangement do not participate in government programs or are not in a position to make referrals relating to government programs, then the statute should not apply. Second, the statute does not apply if the transaction fits within regulatory exceptions.⁹ For example, exceptions apply to employment or personal services contracts, space or equipment leases, investment interests, and certain other relationships so long as those transactions satisfy specified regulatory requirements.¹⁰ Third, interested persons who are concerned about a transaction may obtain an Advisory Opinion from the Office of Inspector General ("OIG") concerning the proposed transaction. Past Advisory Opinions are published on the OIG's website, www.hhh.oig.hhs.gov/fraud. Although the Advisory Opinions are binding only on the parties to the specific opinion, they do provide guidance for others seeking to structure a similar transaction.

Ethics in Patient Referrals Act ("Stark"). The federal Stark law prohibits physicians from referring patients for certain designated health services to entities with which the physician (or a member of the physician's family) has a financial relationship unless the transaction fits within a regulatory safe harbor.¹¹ Stark also prohibits the entity that receives an improper referral from billing for the items or services rendered per the improper referral.¹² Unlike the AKS, Stark is a civil statute: violations may result in civil fines ranging up to \$15,000 per violation and up to \$100,000 per scheme in addition to repayments received for services rendered per improper referrals.¹³ Repayments can easily run into thousands or millions of dollars. Stark is a strict liability statute; it does not require intent, and there is no "good faith" compliance.¹⁴ Stark applies only to financial relationships with physicians, i.e., M.D.s, D.O.s, podiatrists, dentists, chiropractors, and optometrists¹⁵, or with members of such physicians' families; it does not apply to transactions with other health care providers. Finally, unlike the AKS, Stark applies only to referrals for certain designated health services, ("DHS"), payable by Medicare;¹⁶ it does not apply to referrals for other items or services. If triggered, Stark applies to any type of direct or indirect financial relationship between physicians or their family members and a potential provider of DHS, including any ownership, investment, or compensation relationship.¹⁷ Thus, the statute applies to everything from ownership or investment interests to compensation among group members to contracts, leases, waivers, discounts, professional courtesies, medical staff benefits, or any other transaction in which anything of value is shared between the parties. If Stark applies to a financial relationship, then the parties must either structure the arrangement to fit squarely within one of the regulatory safe harbors¹⁸ or not refer patients to each other for DHS covered by the statute and regulations.

Civil Monetary Penalties Law ("CMP"). The federal CMP prohibits certain transactions that have the effect of increasing utilization or

costs to federally funded health care programs or improperly minimizing services to beneficiaries.¹⁹ For example, the CMP prohibits offering or providing inducements to a Medicare or Medicaid beneficiary that are likely to influence the beneficiary to order or receive items or services payable by federal health care programs, including free or discounted items or services, waivers of copays or deductibles, etc.²⁰ This law may affect health care provider marketing programs as well as contracts or payment terms with program beneficiaries.²¹ The CMP also prohibits hospitals from making payments to physicians to induce the physicians to reduce or limit services covered by Medicare.²² Thus, the CMP usually prohibits so-called "gainsharing" programs in which hospitals split cost-savings with physicians.²³ Finally, the CMP prohibits submitting claims for federal health care programs based on items or services provided by persons excluded from health care programs.²⁴ As a practical matter, the statute prohibits health care providers from employing or contracting with persons or entities who have been excluded from participating in federal health care programs.²⁵ Violations of the CMP may result in administrative penalties ranging from \$2,000 to \$50,000 per violation.²⁶

State Anti-Kickback, Self-Referral, or Fee Splitting Statutes. Many states have their own versions of anti-kickback²⁷ or self-referral laws²⁸ that must also be considered. State versions vary widely; they may or may not parallel federal versions. In addition, most states also prohibit fee splitting or giving rebates for referrals, which might also apply to some transactions between referral sources.²⁹ Providers should check their own state statutes to ensure compliance.

Medicare Reimbursement Rules. The Centers for Medicare & Medicaid Services ("CMS") has promulgated volumes of rules and manuals governing reimbursement for services provided under federal health care programs. The rules govern such items as when a health care provider may bill for services provided by another entity, supervision required for such services, and the location in which such services may be performed to be reimbursable. In addition, the amount of government reimbursement may differ depending on how the transaction is structured, e.g., whether it is provided through an arrangement with a hospital or by a separate clinic or physician practice. The rules concerning reimbursement and reassignment should be considered in structuring health care transactions if the entities intend to bill government programs for services or maximize their reimbursement under such programs.

Corporate Practice of Medicine Doctrine ("CPOM"). Some states impose the so-called "corporate practice of medicine" doctrine by statute or case law, i.e., only certain licensed health care professionals (e.g., physicians) may practice medicine; corporations may not employ physicians to practice medicine due to the risk that such an arrangement would improperly influencing medical judgment.³⁰ There are often statutory exceptions, e.g., professional corporations or employment by hospitals or managed care organizations. In those states that apply or enforce the CPOM, transactions may need to be structured around the CPOM, including services contracts with physicians or other healthcare providers.

Certificates of Need ("CON"). Finally, to avoid over-saturation and resulting overcharges, some states require that providers obtain a certificate authorizing the construction or expansion of certain types of facilities, e.g., hospitals, ambulatory surgery centers, or skilled nursing facilities.³¹

Conclusion. The foregoing is only a brief summary of some of the more significant laws and regulations that may affect common health care transactions. As in all cases, the devil is in the details (as well as the Code of Federal Regulations and CMS Medicare Manuals). Providers and their advisors should review the relevant laws and regulations whenever structuring a health care transaction, especially if that transaction involves potential referral sources or implicates federal health care programs.

Endnotes

¹ 42 U.S.C. § 1320a-7k.

² 42 U.S.C. § 1320a-7b(b).

³ 42 U.S.C. § 1320a-7b(b)(2)(B).

⁴ Patient Protection and Affordable Care Act Pub L. No. 111-148 § 6402(f)(1), 124 Stat. 119 (2010); see 31 U.S.C. § 3729 *et seq.*

⁵ See, e.g., 42 U.S.C. § 1320a-7a(5); 42 U.S.C. § 1320a-7(b)(7); 31 U.S.C. § 3729-3733; *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

⁶ *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied* 474 U.S. 988 (1985).

⁷ *United States v. Anderson*, Case No. 98-20030- 01/07 (D. Kan. 1998).

⁸ See 42 U.S.C. § 1320a-7b(b)(2)(B).

⁹ 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.

¹⁰ 42 U.S.C. § 1320a-7b(3); 42 C.F.R. § 1001.952.

¹¹ 42 U.S.C. § 1395nn; 42 C.F.R. § 411.351 *et seq.*

¹² 42 C.F.R. § 411.353(b).

¹³ 42 U.S.C. § 1395nn.

¹⁴ See 42 C.F.R. § 411.353(a)-(b).

¹⁵ *Id.* at § 411.351.

¹⁶ The "designated health services" covered by Stark include clinical laboratory services; physical therapy, occupational therapy and speech-language pathology services; radiology and other imaging services; radiation therapy; durable medical equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; inpatient and outpatient hospital services; and parenteral and enteral nutrients. *Id.* at § 411.351.

¹⁷ *Id.* at § 411.351.

¹⁸ *Id.* at § 411.355 to 411.357.

¹⁹ 42 U.S.C. § 1320a-7a.

²⁰ 42 U.S.C. § 1320a-7a(a)(5).

²¹ See OIG Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries" (August 2002); OIG Special Fraud Alert, "Routine Waiver of Part B Co-Payments/Deductibles" (May 1991).

²² 42 U.S.C. § 1320a-7a(b).

²³ See, e.g., OIG Special Fraud Alert, "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999).

²⁴ 42 U.S.C. § 1320a-7a(a)(1)(C) and (2).

²⁵ OIG Special Advisory Bulletin, "The Effect of Exclusion from Participation in Federal Health Care Programs (Sept. 1999)." ²⁶ See *id.* at § 1320a-7a(a) and (b).

²⁷ See, e.g., Colorado Revised Statutes ("CRS") § 25.5-4-305; Idaho Code ("IC") § 41-348(1); Nevada Revised Statutes ("NRS") 439B.420; New Mexico Statutes Annotated ("NSMA") §§ 30-41-1 to -3, and 30-44-7(A)(1); Utah Code § 26-20-4.

²⁸ See, e.g., CRS § 25.5-4-414; NRS. 439B.425; New Mexico Administrative Code ("NMAC") 439B.5205-.5408; NMSA §§ 24-1-5.8(C)(6); NMAC 7.7.2.8(B)(3) and 7.7.2.8(N); Utah Code §§ 58-67-801, 58-68-801, 58-69-805.

²⁹ See, e.g., CRS §§ 12-36-125 and 12-36-126; IC § 54-1814(8)-(9); NMSA §§ 61-6-15(D).

³⁰ See, e.g., CRS §§ 12-36-117(m) and 6-18-301 *et seq.*; *Worlton v. Davis*, 73 Idaho 217, 221, 249 P.2d 810 (1952).

³¹ See, e.g., NRS 439A and NAC 439A.

For questions regarding this update, please contact

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