

Telemedicine Fraud and Abuse Under the Microscope

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Douglas Grimm & Hillary Stemple

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Douglas Grimm is a partner in Arent Fox's Health Care group who previously served as a former Chief Operating Officer of multiple acute-care hospitals throughout the United States. Douglas focuses his practice on the representation of hospitals and health care systems with an emphasis on regulatory counseling in the areas of compliance planning, government investigations, health information privacy and security, reimbursement issues, health information technology, telemedicine, peer review/medical staff and certificates of need, development of new service lines, licensure and provider enrollment, and insurance issues.



Hillary Stemple is an associate in Arent Fox's Health Care group where she represents health care providers, including hospitals and health care systems, pharmaceutical and device manufacturers, and telemedicine companies. Hillary regularly advises clients on compliance with health care fraud and abuse laws, with an emphasis on the Stark law and anti-kickback statute. She also counsels clients on internal and external investigations, particularly investigations related to the False Claims Act, as well as on reimbursement issues, licensing requirements, and other compliance matters.

Overview

- Fraud and Abuse Rules of the Road
- Implications for:
 - Direct to Consumer (i.e., cash pay)
 - Commercial Payers
 - Federal Payers (e.g., Medicare, Medicaid, Tricare)
- Recent Enforcement Trends and Actions

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Rules of the Road

Overview of the Fraud and Abuse Rules Governing Telemedicine



Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- › Prohibits a physician from referring Medicare or Medicaid patients for designated health services (“DHS”) to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies
- › Prohibits the entity from submitting claims to Medicare or Medicaid for services resulting from a prohibited referral
- › Strict liability statute – must meet all elements of an exception or the statute has been violated

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Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- › Civil liability (not criminal)
- › Potential Penalties
 - Overpayment/refund obligation
 - False Claims Act liability
 - Civil Monetary Penalties
 - Exclusion
- › Government interpretation of the law is evolving
 - HHS vs. DOJ

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Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Physician (or immediate family member)
- Financial relationship
- DHS entity
- Referrals by physician for Medicare or Medicaid services
- Strict liability

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Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Different exceptions for ownership and/or compensation arrangements; common exceptions in telemedicine include:
 - Employment relationships
 - Personal services arrangements
 - Space and equipment leasing arrangements
 - Fair market value (“FMV”) compensation arrangements
 - In-office ancillary services
 - Indirect compensation arrangements
 - Electronic prescribing and electronic health records items and services
- Exceptions generally require:
 - Signed, written agreement
 - Commercially reasonable, FMV compensation
 - Compensation does not reflect the volume/value of referrals

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Federal Laws – Stark Law (42 U.S.C. § 1395nn)

- Example of arrangement implicating the Stark law:
 - Hospital engages a physician (or physician group) to provide on-call telestroke services
 - Arrangement includes compensation for physician's services and equipment to facilitate the telestroke assessment
 - HIPAA-secure transmission? Encryption?
 - Any referrals by physician to the hospital for DHS implicate the Stark law (whether or not related to telestroke services)

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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Prohibits the knowing and willful offer or payment of or the solicitation or receipt of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients)

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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- › Criminal law
- › Applies to payers and recipients of kickbacks
- › Each party's intent is a key element of their liability under the AKS – only “one purpose” needs to be to induce the purchase of a product or service or to reward referrals
- › Certain “safe harbor” protections (42 C.F.R. § 1001.952)
- › Penalties include criminal (jail) and civil (monetary) penalties, and FCA liability



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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- › Elements of an AKS violation
 - Remuneration
 - Offered, paid, solicited, received
 - To induce or reward referrals of Federal health care programs – Medicare, Medicaid, and TRICARE
 - Knowingly and willfully
 - “One-Purpose” test



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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

➤ “Remuneration”

- Cash
- Free equipment
- Excessive compensation for medical directorships or consultancies or compensation where no legitimate services are provided
- Provision of office assistance
- Certain reimbursement services
- Free rent
- Expensive hotel stays, meals, travel, etc.



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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

➤ AKS Safe Harbors

- No liability if all elements of safe harbor are met
- BUT ... not an automatic violation if activities do not fit squarely in a safe harbor
- The closer an activity or arrangement comes to satisfying the requirements of a safe harbor, the safer the activity or arrangement

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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Examples of common AKS Safe Harbors for Telemedicine:
 - *Bona fide* employment
 - Personal services contracts
 - Leases for space or equipment
 - Electronic prescribing and electronic health records items and services
- Common requirements for safe harbor protections:
 - Agreement covers all services to be provided by one party to another
 - Aggregate services provided do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose
 - Aggregate compensation, set in advance, consistent with FMV, not determined in a manner that takes into account the volume or value of referrals or other business generated

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Federal Laws – Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- Example of arrangement implicating the AKS:
 - Pharmacy enters into arrangement with physician group to have physicians provide assessments of pharmacy patients via telemedicine as part of pharmacy's expansion into primary care services
 - Pharmacy compensates physicians and provides equipment to facilitate telemedicine consultations
 - Physicians may refer patients to the pharmacy for fulfillment of prescriptions, but referrals aren't required under the terms of the arrangement

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OIG Advisory Opinions

- › Provide guidance on OIG's interpretation of AKS
- › Binding only as to requesting parties, but can provide guidance with respect to similar factual situations
- › OIG approved 5 telemedicine-related opinions
 - AKS implicated by the arrangements, but no sanctions
- › After 7-year lull, a new telemedicine Advisory Opinion was issued on May 24, 2018

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Advisory Op. 98-18

Facts

- › Sublease arrangement involving ophthalmologist subleasing equipment to optometrist
- › Optometrist sent images to ophthalmologist for interpretation
- › Ophthalmologist provided free consultations via telemedicine

Analysis

- › Sublease ok – all elements of equipment safe harbor were met
- › Free telemedicine consultations were remuneration
- › Arrangement approved because optometrist would not advertise or bill for consults and patients free to choose any ophthalmologist

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Advisory Op. 04-07

Facts

- Health system develops telemedicine program for specialist consultation services for low-income children in rural areas
- School nurses visit with children and consult with specialists via telemedicine
- Consults not reimbursable under Medicaid or CHIP

Analysis

- Remuneration included: free telecomm equipment to the schools; free consults for the patients; additional opportunities for consulting practitioners to earn professional fees (future opportunities)
- Low risk b/c services not billable
- Safeguard: students needing follow-up referred to local provider
- Public benefit in access to services for low-income children

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Advisory Op. 11-12

Facts

- Health system provides emergency telestroke consults to community hospitals
- System provides: technology, consults, clinical protocols, training, education, and commitment to accept transfers
- Hospitals provide: communication lines, connectivity, and CT scanners
- Hospitals are referral source for the health system

Analysis

- Safeguards include: no required referrals, patient freedom of choice, participating hospitals not included in program based on referral history
- Medicare is not billed so less risk to federal health care programs
- Benefits include: improved quality of care and patients receiving treatment sooner (rather than needing to be transferred to health system)

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Advisory Op. 18-03 (NEW)

Facts

- FQHC “look-alike” to provide county health clinic technology-related equipment and services to facilitate telemedicine encounters with county clinic’s patients
- Items and services paid for using State Department of Health grant
- Telemedicine items and services used only for encounters related to HIV prevention, including prescription of meds for pre-exposure and post-exposure prophylaxis
- County clinic could use telemedicine items to refer to FQHC-like provider or other providers
- Both parties may submit claims to federal payers

Analysis

- Safeguards against patient steering, including no referral requirements between parties or to a provider’s pharmacy
- None of the telemedicine technology would limit or restrict compatibility with other technologies
- Unlikely to increase costs to federal payers because billed items/services would have been provided regardless of the arrangement
- Increased access to preventative services primarily benefit patients, not the providers

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Federal Laws – False Claims Act (31 U.S.C. § 3729 *et seq.*)

➤ Prohibitions include:

- Knowingly submitting or causing to be submitted false or fraudulent claims
- Knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim

➤ Penalties

- Treble damages
- Penalties currently \$11,181 - \$22,363 per false claim (as adjusted annually)

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Federal Laws – False Claims Act (31 U.S.C. § 3729 *et seq.*)

- ▶ Examples of potential FCA violations related to telemedicine:
 - Referrals made in violation of Stark law or AKS
 - Claims submitted to Medicare where patient was not located at a qualifying originating site
 - Claims submitted to Tricare for prescriptions where doctors did not properly consult with the Tricare beneficiary (e.g., by consulting with the patient over the telephone rather than via a real-time A/V consult)

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State Laws

- ▶ State law versions of:
 - Stark Law (prohibition against self-referral)
 - Anti-Kickback Statute (often including prohibitions against “fee splitting”)
 - False Claims Act
- ▶ Scope of state laws vary
 - Medicaid-only
 - Medicaid and commercial
 - Commercial
 - “All-payer”

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State Laws

- Telemedicine laws
 - Establishing the requirements for the practice of medicine via telemedicine, including the requirements for a valid telemedicine visit in the state
- Corporate Practice of Medicine

How the Governing Laws Affect Different Telemedicine Models

Implications for reimbursement by different payers

Direct-to-Consumer Model

- Federal laws generally not implicated
 - But, companies should take steps to ensure patients aren't submitting claims for reimbursement, which could implicate federal laws
- State “all-payer” laws may cover cash-only models
 - Implications if company has an arrangement for services with another company (e.g., pharmacy, DME)

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Direct-to-Consumer Model

- Telemedicine laws
 - Board of Medicine administrative sanctions
 - Loss of license
 - Potential reporting to National Practitioner Data Bank
- Corporate Practice of Medicine laws
 - Penalties are state-specific
 - Criminal, civil, administrative

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Commercial Payer Model

- › State laws (depending on scope of the laws)
 - Penalties vary by state, but may include criminal, civil, or administrative penalties
 - Potential state FCA liability
- › Network contract requirements
- › Telemedicine reimbursement laws (e.g., state parity laws)
- › Telemedicine laws
- › Corporate Practice of Medicine laws

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Federal Payer Model

- › Federal laws
 - Possible criminal, civil, and administrative
 - FCA liability
- › State laws (including Medicaid)
- › Telemedicine laws
- › Corporate Practice of Medicine laws

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Recent Enforcement Trends and Actions

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Enforcement Trends

- As federal dollars spent on telemedicine increase, enforcement actions will increase
- Unnecessary prescription of compounded drugs and DME are currently significant targets

Compounding Pharmacy, Executives, and Private Equity Settlement

- September 2019
- \$21.36M to resolve allegations that pharmacy, Diabetic Care Rx LLC (aka Patient Care America (PCA)), PCA's CEO and former VP of Operations, and PE firm Riordan, Lewis & Haden Inc. (RLH) violated the FCA through a kickback scheme intended to generate referrals for pain creams for TriCare patients
- PCA allegedly paid kickbacks to “marketers” to target military members for the pain creams; the marketers paid telemedicine physicians who prescribed the pain cream without assessing the patients through a valid patient encounter (assessments involved only a telephone call or, in some cases, no actual involvement with the patients)
- RLH, which managed PCA, allegedly knew of the scheme and agreed to the plan to pay the outside marketers

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Indictments in \$1.2 B Fraud Scheme Involving Telemedicine and DME Prescriptions

- April 2019 DOJ announcement
- Charges filed against 24 telemedicine and DME executives and physicians, including CEOs and COOs of telemedicine companies, and owners of DME companies
- Scheme involved marketers for the DME companies reaching out to Medicare beneficiaries and offering “free or low cost” back, shoulder, wrist, and knee braces; the marketing companies paid the DME companies to secure referrals and DME companies paid physicians to write the prescriptions, regardless of medical necessity and without a valid telemedicine encounter
 - At most, patient encounters involved a brief telephone call

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Indictments and Guilty Pleas in \$1B Fraud Scheme Involving Telemedicine

- › October 2018 DOJ announcement
- › Telemedicine company, HealthRight LLC and its CEO pleaded guilty to felony conspiracy and wire fraud charges related to a scheme in which the company allegedly fraudulently solicited insurance information and prescriptions for the pain cream from patients across the country
- › Telemedicine physicians approved the prescriptions
- › Charges pending against multiple compounding pharmacies and 4 individuals associated with the pharmacies
- › Scheme also involved significantly marking up the cost of the pain creams, where the elevated costs were then charged to private insurance companies
- › Insurers ultimately paid \$174M for prescriptions
- › Telemarketer involved in scheme paid \$2.5M in August 2019 to resolve claims

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Medicare Requirements

- › Generally 5 conditions for coverage under Medicare
 - Beneficiary is located in qualifying rural area (HPSA)
 - Beneficiary is located at a qualifying “originating site”
 - Services provided by 1 of 10 eligible “distant site practitioners”
 - Beneficiary and distant site practitioner communicate via interactive, real-time A/V communication
 - CPT/HCPCS code for the service is included on list of covered Medicare telehealth services

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OIG Review of Medicare Payments for Telehealth Services

- Added to OIG Work Plan in 2017

- OIG Report issued April 2018: “CMS Paid Practitioners For Telehealth Services That Did Not Meet Medicare Requirements”

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OIG Review of Medicare Payments for Telehealth Services

- Findings:
 - 31 out of 100 claims did not meet Medicare requirements
 - 24 claims unallowable because beneficiaries received services at non-rural originating sites
 - 7 claims billed by ineligible institutional providers
 - 3 claims for services to beneficiaries at unauthorized originating sites
 - 2 claims for services provided by unallowable means of communication
 - 1 claim for noncovered service
 - 1 claim for services provided by a physician located outside the U.S.

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OIG Review of Medicare Payments for Telehealth Services

➤ Findings:

- By extrapolation, improperly paid estimated \$3.7 million during the audit period (2014-2015)
 - Dollar amount is relatively low, but accounts for approximately 27% of all Medicare dollars spent on telehealth services during the audit period
 - Compare to 9.51% overall error rate for FY 2017 (July 1, 2015 – June 30, 2016)

➤ OIG recommended CMS:

- Conduct periodic postpayment reviews of telehealth services
- Work with Medicare contractors to implement required telehealth claim edits listed in Claims Processing Manual
- Offer education and training to practitioners on Medicare telehealth requirements

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CONTACT INFO

Douglas Grimm

douglas.grimm@arentfox.com | (202) 857-6370

Hillary Stemple

hillary.stemple@arentfox.com | (202) 350-3638

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