

# STATE OF TELEHEALTH IN SOUTH CAROLINA

## FRAUD & ABUSE ISSUES IN TELEHEALTH

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# State of Telehealth In South Carolina: What's New?

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ Proposed legislation (S.1035 & H.5162) proposes a definition of telemedicine:
- ▶ “Telemedicine means the practice of medicine using electronic communications, information technology, or other means between a licensee in one location and a patient in another location with or without an intervening practitioner.”

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ New Bill (S.1035 and H.5612)
- ▶ The purpose is to facilitate the use of telemedicine in SC
- ▶ A physician/patient relationship established solely by telemedicine must adhere to the same standard of care as a traditional face-to-face establishment.
- ▶ Must maintain records
- ▶ Must adhere to standards of practice improvement and monitoring outcomes

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ Must conduct an appropriate evaluation prior to diagnosing (questionnaire without evaluation prohibited)
- ▶ Must verify patient identity and inform patient of the professional's credentials
- ▶ Must ensure availability of follow up care

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ Prescribing with establishment of a physician patient relationship by telemedicine only :
  - ▶ Schedule II & III not permitted
  - ▶ Exceptions:
    - ▶ as authorized by the Board
  - ▶ No “lifestyle” replacement therapies:
    - ▶ hormone replacement
    - ▶ Birth control
    - ▶ Erectile dysfunction
    - ▶ Abortion drugs

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ Must maintain confidentiality of records
- ▶ If the patient has a primary care physician (PCP) for the same ailment, then the PCP record and the telemedicine provider's record constitute one record
- ▶ Must discuss with patient the value of having a PCP and assist by providing options
- ▶ Train staff on telemedicine equipment

# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ Modifies statute that limits prescribing without a personal examination by adding a new exception:
- ▶ “prescribing for a patient for whom the licensee has established a physician-patient relationship solely via telemedicine so long as the licensee complies with Section 40-47-37.” S.C. Code Ann. § 40-47-113(B)



# UPDATE ON TELEHEALTH LEGISLATION/REGULATION

- ▶ New Board of Medical Examiner's Advisory Opinion on prescribing for Hospice Care Patients – February 1, 2016
- ▶ Licensed physicians who are employees of/contract with a Medicare-certified hospice program may prescribe up to a 14-day supply of medications for a certified hospice patient for the purpose of controlling symptoms prior to establishing a traditional patient/physician relationship by direct physical examination
- ▶ Not meant for routine use
- ▶ Prescribing narcotics as above is not misconduct.

# WHY WORRY ABOUT FRAUD & ABUSE?

- ▶ Health care is one of the most regulated industries on the planet
- ▶ Fraud and abuse rules are applicable in a variety of clinical settings and apply to countless types of financial arrangements like telehealth
- ▶ Many fraud and abuse statutes or regulations have very draconian and financially devastating penalty schemes
- ▶ Defending fraud and abuse allegations can be very expensive and very disruptive

# TELEHEALTH & FRAUD & ABUSE

- ▶ Telehealth expands potential financial and clinical relationships that implicate fraud & abuse laws
- ▶ Telehealth expands potential billing and collection issues that implicate fraud & abuse laws
- ▶ By expanding access to different providers, telehealth could also expand exposure to fraud & abuse laws

# Health Care Fraud Enforcement is BIG Business for Washington

- ▶ Over the last three years (2013-2015), DOJ claims to have recovered an average of \$6.10 for every dollar of funding that Congress has appropriated for health care fraud enforcement
- ▶ OIG claims to have almost \$17 to \$1 return on investment based on their recovery
- ▶ Health care fraud is a popular subject and gets bipartisan support in Congress

# Recent Enforcement Facts In FY 2015

- ▶ 983 new criminal health care fraud investigations
- ▶ 613 defendants convicted of health care fraud related crimes
- ▶ 808 new civil health care fraud investigations
- ▶ 4,112 individuals and entities excluded in FY 2015
  - ▶ Over 20% increase from FY 2013

# Recent Enforcement Facts

- ▶ During FY 2015, the Federal government won or negotiated over \$2.4 billion in health care fraud judgments and settlements
- ▶ The total recovered by the administration's health care fraud enforcement efforts over the last 5 years amounts to over \$16.2 billion

# WHAT FRAUD AND ABUSE LAWS MAY APPLY?

- ▶ Stark Law
- ▶ Federal Anti-Kickback Law
- ▶ Federal False Claims Act
- ▶ Reverse False Claims - 60 day Rule
- ▶ State Self-Referral and Anti-Kickback Law
- ▶ Federal and State Billing Requirements
- ▶ HIPAA / Privacy Rules
- ▶ Licensing / Scope of Practice

# Stark Law Prohibition

- ▶ If a Physician (or family member) has a financial relationship with the entity, the Physician may not refer Medicare/Medicaid patients to the entity for “Designated Health Service” (DHS)
- ▶ Entity may not bill for that DHS service, unless an applicable exception exists



# STARK SANCTIONS



- ▶ Denial of payment (expectation of refund)
- ▶ \$15,000 per occurrence
- ▶ \$100,000 per arrangement of "scheme"
- ▶ Governmental health care program exclusion

# Designated Health Services

- ▶ Designated Health Services includes:
  - ▶ Clinical laboratory services
  - ▶ Physical therapy services
  - ▶ Occupational therapy services
  - ▶ Radiology services (including MRIs)
  - ▶ Radiation therapy services and supplies
  - ▶ Durable medical equipment and supplies
  - ▶ Inpatient and outpatient hospital services
- ▶ Designated Health Services also determined by CPT codes

# Stark Exceptions Include:

- ▶ Personal Services arrangements
- ▶ Office/equipment rentals
- ▶ Employment
- ▶ Electronic Prescribing arrangement
- ▶ Electronic Health Records arrangement

# Anti-kickback Statute

- ▶ Criminal statute
- ▶ Prohibits a person from knowingly and willingly soliciting or receiving any remuneration in return for referring an individual for medical care if that individual pays for the service by way of any federal health care program (42 USC §1320a-7b)
- ▶ Intent-based statute



# Anti-kickback Statute

- ▶ Easier to understand and prosecute than Stark violation, but harder to prove
- ▶ Violation occurs if "**one purpose** of the payment was to induce future referrals" U.S. v. Kats, 871 F.2d 105 (9<sup>th</sup> Cir. 1989)
- ▶ ACA lowered the intent standard:
  - ▶ Person need not have actual knowledge of the AKS or specific intent to violate the AKS.
- ▶ Anti-kickback may become a bigger part of enforcement efforts now.

# Anti-kickback Statute

- ▶ Penalties
  - ▶ Imprisonment for up to 5 years, \$25,000 fine, or both
  - ▶ Exclusion from participation in government programs
  - ▶ Civil monetary penalties up to \$50,000 per violation



# ANTI-KICKBACK SAFE HARBORS

- ▶ Similar to Stark exceptions
- ▶ If you do not qualify for each element it does not mean that there is an Anti-kickback Statute violation, just don't get benefit of safe harbor protection
- ▶ Lease arrangements
- ▶ Personal services arrangement
- ▶ Electronic prescribing arrangement
- ▶ Electronic health records arrangement

# Anti-kickback Statute v. Stark Law

## Anti-kickback

- ▶ **Penalties:** five years imprisonment and/or \$25,000 fine
- ▶ Applies to everyone
- ▶ Law contains an “intent” element
- ▶ Is a criminal statute
- ▶ Behavior or relationships falling out of a safe harbor may nonetheless be legal

## Stark

- ▶ **Penalties:** Denial of payment, \$15,000 per occurrence, \$100,000 per arrangement or “scheme”, or governmental health care program exclusion
- ▶ Applies to physicians only
- ▶ Less “intent” needs to be proven, supposed strict liability
- ▶ Civil Statute
- ▶ Failure to meet every element of the exception = violation



# STARK & ANTI-KICKBACK

- ▶ Telehealth can expand the potential application of these laws to new arrangements involving telehealth referrals
- ▶ Should look at telehealth arrangement like any other physician arrangement or arrangement that could involve referrals

# Stark and Anti-kickback Violations Can Implicate False Claims Act

- ▶ Anti-kickback and Stark violations can, and many times do, lead to violations of the False Claims Act
- ▶ Theory – Since claim based on referral in violation of Anti-Kickback or Stark, the claim should never have been submitted
- ▶ Claim based on improper referral = false claim
- ▶ This growing trend is developing through whistleblower claims

# False Claims Act Penalties

- ▶ Statutory per claim penalties of between \$5,500 and \$11,000
- ▶ Treble damages
- ▶ Attorney fees
- ▶ Exclusion from Medicare/Medicaid program

# Whistleblowers and False Claims Cases

- ▶ The Department of Justice encourages whistleblowers to bring allegation of FCA
- ▶ If successful, whistleblowers can be eligible for between 15-25% of the Government's recovery plus attorney fees
- ▶ In recent cases, whistleblowers have been physicians, hospital executives, nurses, compliance offices and consultants



# SUMMARY OF OIG ADVISORY OPINIONS ON TELEMEDICINE

## Advisory Opinion 11-12

- ▶ OIG, approved of health system's provision of neuro emergency protocols, and consultations with stroke neurologists via telemedicine technology to community hospitals.
- ▶ Provided 1) neuro emergency telemedicine technology 2) neuro emergency clinical consultation, 3) acceptance of neuro emergency transfers 4) neuro emergency clinical protocol and medical education.
- ▶ Implicates Anti-kickback Statute, but OIG said it was allowable.



# FRAUD AND ABUSE CONSIDERATIONS

- ▶ Issue – A telemedicine provider and its customers (i.e., participating distant sites) are potential sources of referrals of Federal health care program business to one another. As such, the exchange of anything of value between them potentially implicates the Anti-kickback Statute and Stark Law.
  - ▶ Most fraud and abuse issues unique to telemedicine relate to the infrastructure, equipment, and support needed to operate a telemedicine service.
  - ▶ Example: Provision of free telemedicine equipment to originating locations.
- ▶ The OIG's "longstanding and clear" position on free or below-market items or services to actual or potential referral sources is that such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. OIG Advisory Opinion No. 11-12 (Aug. 6, 2011).

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ However, the OIG distinguishes between free or below-market services that are integrally related to a provider's service and those that are not. OIG Advisory Opinion No. 12-19 (Nov. 30, 2012).
- ▶ This means that the item or service offered (e.g., telemedicine equipment) can be *used only as part of the underlying service* being provided (e.g., telemedicine), such that the free or below-market items or services appear to have no independent value apart from the underlying service. *Id.*
- ▶ Where the item or service has no independent value apart from the services being provided, the preamble to the 1991 safe harbor states, its purpose is not to induce any act prohibited by the anti-kickback statute. Fed. Reg. 35,952, 35,978 (July 29, 1991).

# FRAUD AND ABUSE CONSIDERATIONS

- ▶ Additionally, the following is a compilation of safeguards that should be put in place that are aimed at reducing the risk of improper payments for referrals of Federal health care program business and derived from OIG opinions on telemedicine or arrangements analogous to telemedicine:
  - ▶ No obligation for local site to refer to distant site
  - ▶ No additional payment, beyond a consultation fee, for physicians to provide telemedicine services
  - ▶ No referral restrictions on physicians at distant site
  - ▶ Customers targeted based upon need and access, not referrals
  - ▶ Each party covers its own marketing costs
  - ▶ Cost of the equipment is not billed to any patient or third party payor
  - ▶ Equipment is
    - ▶ used exclusively for the telemedicine service, and
    - ▶ an integral part of the physician's use of the service
  - ▶ Expectation of less cost to the Federal health care programs



# S.C. Provider Self-Referral/ Anti-Kickback Statute

- ▶ Elements:
  - ▶ Health care provider
  - ▶ Provider has investment interest in Entity
  - ▶ Referral of patient by provider to Entity
- ▶ If above elements are present, referral violates Act unless exception is met.
  - ▶ Exceptions:
    - ▶ Provider directly provides services in Entity or supervises services
    - ▶ Investment is in particular publicly traded company

# Focus on Individuals

- ▶ Individuals increasingly targeted for civil and criminal prosecution and exclusion
- ▶ Yates Memorandum: allows government to charge executives with a criminal charge
  - ▶ If executive had authority/responsibility to prevent, detect or resolve misconduct affecting public welfare and failed to do so
- ▶ Mistakes are being prosecuted as civil or criminal offenses
- ▶ Responsible Corporate Officer Doctrine

# How Are You Most Likely to Violate Stark, Anti-kickback, or False Claims Laws

- ▶ Compensation methodology not appropriate
- ▶ Payments are made without documentation of work performed
- ▶ Services that are not well-documented could be deemed suspicious by federal investigators
- ▶ Most likely to be a technical violation
  - ▶ Contract not executed or contract has expired
  - ▶ Payment not consistent with FMV
  - ▶ Lack of FMV documentation

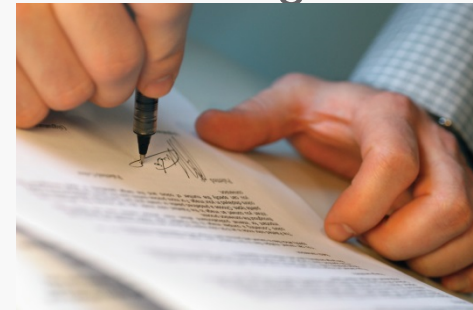
# How Are You Most Likely To Get Caught

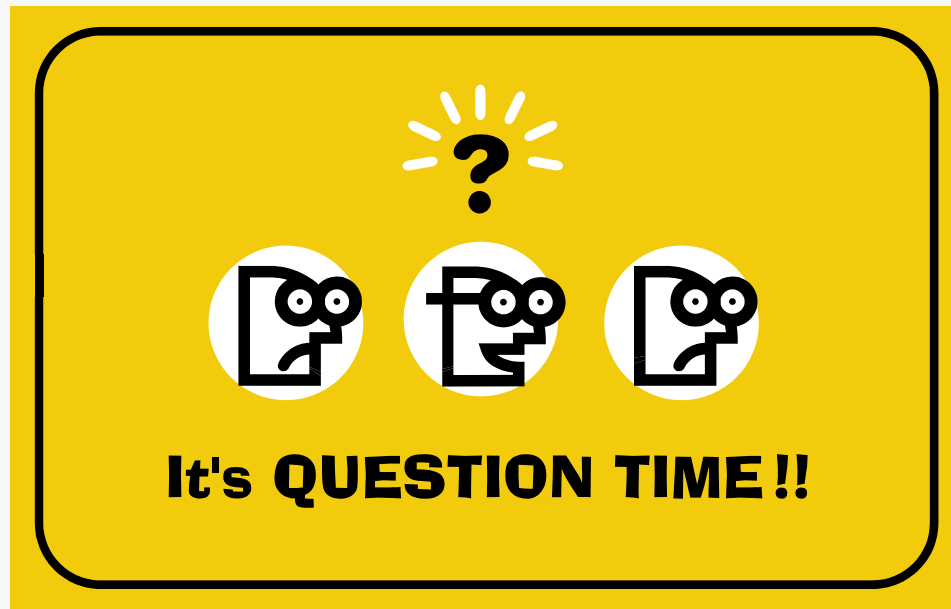
- ▶ Competitors
- ▶ Disgruntled employee (or former employee) = whistleblower
  - ▶ Be wary of disruptive physician. The number of physician relators is on the rise.
- ▶ Government audit



# KEY THINGS TO KEEP IN MIND

- ▶ Document all financial relationships with physicians in written agreements
- ▶ Do not make payments to referral without documenting
  - ▶ Existence of written agreement
  - ▶ Documentation that services were performed
  - ▶ Documentation that services are being paid for once
  - ▶ Documentation that the compensation is consistent with FMV and terms are commercially reasonable
- ▶ Keep list of physician contracts updated







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