Compliance For Office-Based Interventionalists: What To Watch Out For

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April 5, 2019

Financial Disclosure

- I am a partner in the Healthcare and FDA Practice of Arnold & Porter, LLP in D.C.
- A & P represents
  - Physicians who perform outpatient/office interventional procedures
  - Manufacturers of devices used by interventionalists
  - Companies who may provide services to interventionalists

What's on the Government's Radar:

- Waivers of Co-Insurance
- Professional Interpretation Services Agreements
- Patient Transportation
- Screening Programs
- Marketing, Entertainment, and Gifts to Referring Physicians
- Medical Necessity & Upcoding
- Leases with Referring Physicians
- Employing or Contracting with Excluded Staff

False Claims Cases

US ex rel. Shawnea Howerton v. Covidien

- Alleged kickbacks to vascular surgeons
- Provided marketing support and set up venous ultrasound program on behalf of physician to perform ultrasounds on patients in other physician offices and in the community
- Physician would read ultrasound and was guaranteed referral of “qualifying” patients
- Physician promised to use Covidien ClosureFast Endovenous RFA catheters
- Settlement: Covidien paid $17 million

US ex rel. James Cesare v. Skyline Urology

- Whistleblower was coding expert hired by practice to audit coding for compliance with applicable laws
- Alleged improper use of modifier 25
  - Alleged that the E/M visits billed to Medicare with modifier 25 were not separately identifiable and were included in the surgical global (78% error rate)
- Auditor informed practice of his findings and practice did not change its coding patterns and did not refund the alleged overpayments to Medicare
- Settlement: Skyline Urology paid $1.85 million

MedStar Health

- Settlement: $35 million
- Allegations of kickbacks in the form of improper remuneration to a cardiology practice in order to obtain referals:
  - Managed care guidance agreements
  - Outcomes data research
  - Numerous Administrative services agreements
    - Reasearch
    - Cath lab
    - Echo
    - EP Lab
    - Professional edcuation

Self-Disclosures to the OIG

Improper Billing for Non-invasive Vascular Studies

- After it self-disclosed conduct to OIG, St. Agnes Healthcare, Inc. d/b/a St. Agnes Hospital (St. Agnes), Maryland, agreed to pay $257,594.16. OIG alleged that St. Agnes submitted improper claims for a combination of CPT codes 93965 (noninvasive physiologic studies of extremity veins, complete bilateral study) and 93970/93971 (duplex scan of extremity veins, complete bilateral study/unilateral or limited study) for the same patient on the same date of service when the codes represent technologies that serve the same diagnostic purpose.

Improper Remuneration to Physicians

- After it self-disclosed conduct to OIG, Union Hospital of Cecil County, Inc. (Union), Maryland, agreed to pay $457,213.07. OIG alleged that Union: (1) paid remuneration to physicians in the form of free support services provided by three physician assistants; and (2) paid remuneration to cardiologists in the form of free support services provided by a nurse practitioner.
- After they self-disclosed conduct to OIG, Cancer Treatment Centers of America Global, Inc., Et Al., headquartered in Florida, agreed to pay $8,220,814.50. OIG alleged that CTCA paid improper remuneration to physicians in exchange for their referrals to CTCA's hospitals.

Background Checks

- After it self-disclosed conduct to OIG, IHC Health Services, Inc. d/b/a Intermountain Medical Center (IMC), Utah, agreed to pay $68,204.85 OIG alleged that IMC employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

Rental Arrangements

- After it self-disclosed conduct to OIG, Gastroenterology Associates of Piedmont, P.A. (GAP), North Carolina, agreed to pay $188,900.89. OIG alleged that GAP and its predecessor received remuneration from two anesthesia practices in the form of rent and free anesthesia-related drugs and supplies when the anesthesia practices provided anesthesia services through their employed and contracted anesthesiologists or certified registered nurse anesthetists at GAP's endoscopy centers.

Improper Modifiers; Lack of Supervision

- After it self-disclosed conduct to OIG, McBride Clinic Orthopedic Hospital, LLC d/b/a McBride Orthopedic Hospital (McBride), Oklahoma, agreed to pay $414,649.91. OIG alleged that McBride improperly submitted claims to Federal health care programs for: (1) professional services related to surgeries performed by two employee-physicians improperly appended by Modifier 51, 58, and/or 59; (2) professional and facility fees related to post-surgical patient visits performed by a licensed practical nurse without physician supervision; and (3) evaluation and management services performed by an employee-physician during office visits improperly appended by Modifier 25 and/or billed as split/shared.

Unusual Arrangements

- After it self-disclosed conduct to OIG, San Juan Regional Medical Center, Inc. (SJRMC), New Mexico, agreed to pay $50,000. OIG alleged that SJRMC paid remuneration that was above fair market value to a physician and his wife for land that was leased pursuant to a ground lease.
- After they self-disclosed conduct to OIG, Wahiawa Hospital Association and Wahiawa General Hospital (collectively, "Wahiawa"), agreed to pay $100,000. OIG alleged that Wahiawa provided remuneration to a family health center by leasing office space at below fair market value.
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Any Trends Suggesting At Risk Targets?

- Physician entrepreneurship and third party arrangements seem to be key factors in several cases leading to personal liability
  - Physicians looking for other sources of revenue and taking more risk
  - Improper relationships with industry
- Allegations of wrongdoing that are largely within physician's control either through clinical control or business control

Offering Professional Interpretation Services

- Best option is to bill separately for professional interpretations
  - Referring Physician bills for the technical component
  - You bill for the professional component
- Alternatively, reform your arrangement
  - Enter into a written agreement that describes the arrangement
  - Charge a fair market value fee
  - Require the referring physician to bill for the services in compliance with the Medicare Anti-Markup Rule and other requirements (referring physician cannot bill Medicare for more than what you get paid)

Offering Screening Services

- You may offer screening services as part of a disease awareness campaign or a health fair
- You may not offer free screening services at your referring physician's offices
- You may not pay for marketing materials promoting your referring physicians or the availability of screening services at their office
- You may educate your referring physicians about why screening is important for certain patients
- You may not schedule patients for follow-up diagnostic tests or procedures on the same day
- You may perform screening services on appropriate patients
- Monitor your utilization rates

Marketing to Your Referring Physician

- No de minimus standard under the AKS
- Stark law de minimum exception allows up to $416 per physician (2019)
- Limit expenses to modest tokens
- You may not distinguish based on volume of referrals
- You should develop marketing guidelines and limits
- You should track your marketing expenses and educate your staff

Audits: High Utilization

- OBLs have high volume and could appear as utilization outliers
  - More likely to be audited (postpay or prepay)
- While you cant prevent an audit, you can maximize the possibility of having a low error rate
  - Know the applicable coverage policy requirements (e.g., coverage may require CLI to support medical necessity of procedure)
  - Ensure the medical record includes documentation of objective symptoms
  - If using walking distance as a measure, document how far the patient can walk
  - Be sure to instruct patients on diet and exercise as conservative treatment and document in the record
  - Adequately document medications in the medical record
  - Specifically document why patient has CLI (e.g., ulcer, gangrene, change in skin color/cool skin)
  - Specifically state that due to deterioration continued conservative care would be futile
  - Copy and paste EMR's do not help – need individual documentation at each visit

Comply with the Audit

- If you don't submit records, the claim will be denied as an error ("no records submitted") –
- Fill out the appeal form
- Send in all records, 1 year or more including follow-up after procedure
- Highlight the pertinent language in record that supports medical necessity
- Include cover letter that focuses reviewer on what is important – don't leave it to chance that the reviewer will "figure it out"
- If enough money is at issue. hire a lawyer to assist especially with the second and third level of appeal (i.e., the QIC appeal because no new evidence is allowed when you appeal to the ALJ so you must make sure record is complete for QIC appeal)

Thank You

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The Anti-Kickback Statute

- The Federal Anti-Kickback Statute prohibits individuals or entities from:
  - Knowingly or willfully
  - Offering, paying, soliciting or receiving
  - “Remuneration”
  - Directly or indirectly
  - Where one purpose is to induce or reward business reimbursed under Federal healthcare programs
- Safe harbors available
- Sanctions can include criminal penalties, civil liability under the False Claims Act, and exclusion from federal healthcare programs

The Stark Law

- The Stark Law is a strict liability statute
- Unless an exception applies, if a physician (or an immediate family member) has a financial relationship with a entity that furnishes or bills Designated Health Service (DHS):
  - The physician cannot refer DHS to the entity and
  - The entity cannot bill for the DHS
- Penalties include:
  - Denial of payment for services provided
  - Refunds of amounts collected
  - Civil monetary penalties (up to $15,000 for each prohibited referral; up to $100,000 for a circumvention scheme) (as distinguished from the AKS)
  - Exclusion from Medicare/Medicaid
  - Potential FCA liability

The False Claims Act

- Prohibits the knowing submission of false claims or the use of a false record or statement for payment with government funds
  - "Knowing" includes actual knowledge, deliberate ignorance and reckless disregard for the truth or falsity of the information
- Covers claims presented to any health care program funded in whole or in part by federal funds
- Actions may be brought by private persons
- Penalties:
  - Monetary penalties of between $10,957 and $21,916 per claim (increases every year), plus 3 times the damages sustained by the government
- Collateral Penalties from OIG and other agencies:
  - Possible exclusion from federal health care programs and from employment by entities receiving federal health care funds
  - Professional license sanctions
  - Loss of entity accreditation/certification

Waiving Patient's Co-Insurance

- A Physician Practice
  - Routinely tells their patients they do not personally have to pay for their services and that insurance pays for their services in full
  - Submits bills to Medicare for the services it performs
  - Doesn't collect the 20% co-insurance from the patient

Handling Co-Insurance

You may not:

- Promise patients that you will not collect the co-insurance
- Routinely offer waivers of co-insurance; waivers should be rare and incidental

You may:

- Develop a financial hardship policy
- Obtain documentation from the patient demonstrating his/her financial hardship
- Offer waivers consistent with the policy
- Apply policies to all patients (Medicare, Medicaid, commercial insurance)

Employed Physicians

- Many employed physicians are paid based on a percentage of collections – including collections from diagnostic tests ordered by the employed physician
  - Stark Law requires that the employed physician personally performs the service
  - Employed physicians rarely perform the technical component
  - In such cases compensation must be based on professional component only

Providing Free Patient Transportation

- A Physician Practice
  - Provides free transportation to patients before and after surgery
  - Notes it as a benefit when promoting the practice's services
  - Promotes it to referring physicians
  - Informs patients when they call to schedule their surgery

Providing Patient Transportation

- Final Regulations Established a Safe Harbor:
  - Must have a policy that is applied uniformly and doesn't take into account past or future volume or value of Federal health care business
  - Limit assistance to within 25 miles in urban areas and 50 miles in rural areas
  - Air, limousine, ambulance services excluded but could be allowed on case-by-case basis
  - Must be established patient – previous appt or has selected physician on own initiative
  - No public marketing to the public but may inform patients on targeted basis and may not advertise other services to the patient during the transportation

Government Intervened in a Qui Tam

- Alleges that the physician practice performed medically unnecessary procedures and tests
  - Deficient documentation
  - Routinely waived co-payments
  - Billed for an “unrealistically high percentage of expensive procedures”
  - “Nearly all patients receiving . . . diagnostic scans also received interventions”
  - Upcoding

Avoid Paying Millions to Resolve Medical Necessity Allegations

- Conduct billing and coding audits
  - Conduct internal audits on a periodic basis
  - Consider engaging an outside consultant to conduct an audit
- Timely refund any known overpayments
  - Proposed regulations provide 60 days to refund
- Make sure your staff is trained
- Stay on top of coding, coverage and payment changes

Leases with Referring Physician

- Physician Practice leases space from a referring physician
- No signed written lease exists
- Physician Practice has paid $20 per sq. ft. for years and doesn’t know whether it is fair market value
- Referring physician sends patients to the Physician Practice for ultrasound tests

Handling Leases

- You may enter into written leases that are commercially reasonable
- You may pay Fair Market Value (FMV) rent
- You may obtain FMV support for the rental rate
  - Make sure the appraisal or comparables is for the same type of lease (gross, triple net, etc.)
- You may include an option to renegotiate rental rate if market conditions change or rent is no longer FMV
- You may evaluate your leases on a periodic basis to confirm rent is still FMV and terms are commercially reasonable

Handling Employee Hires

- Screen every new staff member
- Screen existing staff on a periodic basis
- If you find a staff member is an excluded list, the staff must stop providing services to federal program patients
- Evaluate whether you need to make a disclosure or refund an overpayment
- It isn't enough to ask your employees to certify that they are excluded
  - It's your obligation to check the exclusion lists