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Enforcement Trends Part I: “Hot” Compliance and Other Legal Issues (PLUS Common Mistakes that Radiology Businesses Make)

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Disclosure

- NONE.



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Learning Objectives

- The world of radiology is rapidly and constantly changing. Change is resulting from more than just clinical and business considerations. Compliance and other legal considerations are forcing radiology businesses to change how they operate and their views on what can, or should, be done to survive and, hopefully, succeed. Moreover, legal considerations are having a much larger impact on the business of radiology than they have in the past.
- At the conclusion of this session attendees will be able to:
 - Spot “hot” compliance and other legal issues.
 - What is meant by “hot” in this context.
 - Based on a couple of recent real-world/real-time case examples, see how to avoid some of the most common compliance mistakes that your radiology business may be making.
 - With a better ability to issue-spot, be able to more effectively manage for today and plan for the future as laws evolve.

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Issue-Spotting “Hot” Compliance and Other Legal Issues

- Use of RPA's and RA's.
- Correct PTAN.
- Electronic signatures on orders.
- “Automated reads.”
- PQRS/MIPS.
- Pre-authorization.
- Out-of-network and balance billing.
- Social media.

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Recent Real-World/Real-Time Case Examples

- Pelvic ultrasound orders.
- Various Stark Law violations.



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Use of RPA's and RA's

- Radiology practitioner assistants (“RPA’s”) and radiology assistants (“RA’s”) are not recognized Medicare Part B suppliers.
- Regardless of whether employed by the radiology group or by a hospital, if you bill for what they do as if the supervising physician performed the service, then you have a problem:
 - The physician didn’t perform the service, the RPA or RA did.



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Correct PTAN

- Sometimes, a non-radiologist physician owner of an imaging center will try to bill for the professional services using her/his Provider Transaction Access Number (“PTAN”).
- HOWEVER, if a radiologist provided the service, must bill using her/his PTAN.



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Electronic Signatures on Orders

- If a test is electronically ordered, the order needs to say “electronically signed by . . .,” otherwise, not a valid order.
- Imaging center needs to maintain a signature log if you get unrecognizable signatures.
 - Note that the program integrity manual doesn’t require this.



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“Automated Reads”

- If a radiologist is going to bill for the professional component, she/he needs to have provided a full interpretation as and to the extent required under Medicare and any other payor requirements.
- **WHAT DOES THIS MEAN?**



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PQRS/MIPS

- Must assure that all of the extensive information you are required to provide is fulsome and accurate.
- The consequences of not doing so could be HUGE:
 - Best case: reduction or loss of Medicare reimbursement.
 - Worst case: false claim and/or de-participation.



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Pre-Authorization

- The potential legal problems these kinds of arrangements can create, and the factors supporting the OIG's favorable conclusion:
 - First, would not target any particular referring physicians, and would be made available on an equal basis to all patients and physicians, without regard to any physician's overall volume or value of expected or past referrals.
 - Second, certain safeguards implemented:
 - No payments to referring physicians, and no ancillary agreements with referring physicians that might otherwise reward referrals.
 - No assurances to physicians or patients that pre-authorization would be successful.
 - Only minimal necessary information would be collected and provided to insurers, and all applicable privacy laws would be complied with.
 - Third, party obtaining the pre-authorization would operate **transparently**.
 - Fourth, party obtaining the pre-authorization has a legitimate business interest in offering uniform pre-authorization services.
 - Only that party's payments are at stake.

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Pre-Authorization (cont'd)

- Practical advice:
 - First, be keenly aware of what local payors require, and what your own payor agreements allow (or prohibit).
 - Use the guidance provided by the OIG Advisory Opinion No. 12-10.
 - And remember the types of things that are still legally problematic.





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Out-of-Network and Balance Billing

- Does your state have laws, and if so, what do they require/prohibit?
- Is legislation already pending or is it being considered for proposal.
 - MUST monitor and advocate.
 - As Shakespeare wrote, “Misery acquaints a man [sic] with strange bedfellows.”
- Be aware of how longstanding laws can have similar effects.
- What’s the interplay with the radiology group’s exclusive provider agreement?
 - Particularly, the payor contracting requirements.

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Social Media

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- Significant areas of potential liability:
 - Privacy.
 - Reputation and “brand risk.”
 - Confidentiality.
 - Ethics.
 - Practice of medicine.
 - FTC guidelines on endorsements and testimonials.
 - Professional Liability.
 - Ownership of health data.
 - Breach of contract.
 - Intellectual property rights.
 - Copyright.
 - Employees and labor relations.
 - Libel.
 - Patient rights.



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Pelvic Ultrasound Orders

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Zwanger-Pesiri Settlement

- Zwanger-Pesiri Inc. (“Z-P”), a Long Island radiology company, pleaded guilty to two counts of health care fraud for illegally performing and billing for procedures that had not been ordered by treating physicians.
- Settlement with the United States and the State of New York for \$2,400,000 in the criminal case and \$8,153,727 to resolve civil liability arising from its fraudulent practices (began as a *qui tam* suit)
- Pled guilty to fraudulently obtaining reimbursements from Medicare and Medicaid by “bundling” the tests it performed, such that when a patient’s treating physician ordered one test to be performed, Z-P would automatically perform a related but unordered test.
 - Specifically for the automatic performance of both a pelvic and transvaginal ultrasound in female patients even though both procedures were not ordered by a treating physician.

(See DOJ Press Release at [https://www.justice.gov/usao-edny/pr/long-island-radiology-company-zwanger-pesiri-inc-pleads-guilty-federal-health-care.](https://www.justice.gov/usao-edny/pr/long-island-radiology-company-zwanger-pesiri-inc-pleads-guilty-federal-health-care))

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The Complaint

- When a patient was sent to Z-P for a transvaginal ultrasound, the patient was automatically scheduled for a transabdominal ultrasound as well (and *vice versa*).
- The lack of documentation to support the scheduling of both procedures was especially apparent when patients were automatically scheduled for both procedures.
- Z-P had programmed its billing system to link transabdominal ultrasounds with transvaginal ultrasounds.
- Z-P referral forms bundled the two tests together so that a referring physician's ability to specify a specific procedure was limited.

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Federal Regulation Requirements

- All diagnostic tests must be ordered by the physician who is treating the beneficiary. 42 CFR 410.32(a).
 - The physician who is treating the beneficiary is the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results of a diagnostic test in the beneficiary's care.
 - Tests not ordered by the treating physician are not reasonable or necessary.
- All procedures performed by an IDTF must be ordered in writing by the physician who is treating the beneficiary. 42 CFR 410.33(d).
 - The order must specify the diagnosis or basis for the test.

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Prohibition on Adding Procedures

- “[T]he supervising physician for the IDTF may not order tests to be performed by the IDTF, unless the IDTF’s supervising physician is in fact the beneficiary’s treating physician.... **The IDTF may not add any procedures based on internal protocols without a written order from the treating physician.**” 42 CFR 410.33(d) (emphasis added).

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Medicare Manual Guidance

- If an interpreting radiologist wants to perform additional tests, (except in limited circumstances) a new order must be obtained from the treating physician. *See Medicare Benefit Policy Manual, Pub. 100-02, Ch. 15, Section 80.6.*
 - For example, if an interpreting physician determines the ordered test is clinically inappropriate, and that a different test should be performed, the interpreting physician may not perform the unordered test until a new order has been received. Section 80.6.2.
- If an ordered test is normal and the interpreting physician believes another diagnostic test should be completed, an order from the treating physician must be received prior to performing the unordered test. Section 80.6.2.
- “[A]n order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner. (*e.g.*, if test X is negative, then perform test Y).” Section 80.6.1.

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Rule for Testing Facility to Furnish Additional Tests

- If the testing facility cannot reach the treating physician, then the testing facility may perform an additional diagnostic test if **all** of the following apply:
 - the testing center performs the diagnostic test ordered by the treating physician;
 - the interpreting physician determines that because of an abnormal result of the diagnostic test performed, an additional test is diagnostically necessary;
 - delaying the performance of the additional diagnostic test would have adverse effect on the care of the beneficiary;
 - the result of the test is communicated to and is used by the treating physician in the treatment of the beneficiary; **and**
 - the interpreting physician at the testing facility documents in his/her report why additional testing was done. Section 80.6.3.

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Interpreting Physician to Furnish Different or Additional Tests

- In certain instances, interpreting radiologists have the authority to alter orders:
 - *Test Design* - unless specified, the interpreting physician may determine the parameters of the diagnostic test (*e.g.*, number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media);
 - *Clear Error* - the interpreting physician may modify an order with clear and obvious errors (*e.g.*, x-ray of wrong foot ordered); or
 - *Patient Condition* - the interpreting physician may cancel an order because of the beneficiary's condition at the time will not permit performance of the test (*e.g.*, a barium enema cannot be performed because of residual stool in colon on scout KUB). Section 80.6.4.

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Pelvic Ultrasounds as an Example

- An order for a “pelvic” ultrasound may be considered a “generic” order for an imaging of the pelvic region and may be accomplished through a transabdominal ultrasound or a transvaginal ultrasound.
 - Sometimes transabdominal and transvaginal ultrasounds are complementary and may be ordered and performed together, but only medically necessary.
 - Often only one of the procedures is medically necessary.
- There may be certain limited circumstances where the “test design” exception would allow for the performance of both the transabdominal and transvaginal ultrasound.
- Can the imaging center document the clinical reasoning and medical necessity of those limited circumstances where both procedures are performed without an order specifying both procedures?
- **WHAT DOES THIS ALL MEAN?**

Various Stark Law Violations

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Stark Law Prohibited Activity

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- “If a physician (or an **IMMEDIATE FAMILY MEMBER** of such physician) has a financial relationship with an entity . . . then the physician may not make a **REFERRAL** to the entity for the furnishing of designated health services (“DHS”) for which payment otherwise may be made” under Medicare (and to some extent Medicaid) **UNLESS AN EXCEPTION APPLIES.**



Stark Law Penalties

- Denial of payment.
- Disgorgement.
- Fine of up to \$15,000 for each service a person “knows or should have known” was provided in violation of Stark.
- Fine of up to \$100,000 for attempting to circumvent Stark for each such circumvention or scheme.
- Exclusion from all federally-funded health care programs.





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Stark Law

Important Definitions

- Financial Relationship: Defined to include any type of ownership or investment interest and any compensation arrangement, *i.e.*, any arrangement involving any remuneration between a physician and an entity, directly or indirectly, overtly or covertly, in cash or in kind.



Important Definitions (cont'd)

- Remuneration: Defined to include any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind, subject to certain limited exceptions.
 - Includes the provision of free fax or computer equipment, unless it can be demonstrated that the equipment is integral to and used exclusively for performing work for the entity that supplied the equipment (*e.g.*, such as computer terminal provided by a lab for the sole purpose of ordering lab tests).
 - But see exceptions for ERx and EHR.

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Stark Law

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Important Definitions (cont'd)

- Designated Health Services: It includes in its definition “radiology and certain other imaging services.”

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Stark Law

Important Definitions (cont'd)

- Referral: Defined more broadly than merely recommending a vendor of DHS to a patient; instead, it is defined as “the request by a physician for the item or service” or the “establishment of a plan of care by a physician which includes the provision of the designated health service.”
 - More later on the “consultation exception” to the referral definition (for a request by a radiologist for diagnostic radiology services, subject to certain requirements).

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“Immediate Family Member”

- How is this relevant:
 - “If a physician (*or an immediate family member of such physician*) has a financial relationship with an entity . . . then the physician may not make a referral to the entity . . .”
- “*Immediate family member or member of a physician's immediate family* means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.”

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“Immediate Family Member” (cont’d)

- Typical facts (imaging center):
 - Radiologist with ownership in an imaging center has an immediate family member who refers to the imaging center.
 - The Stark violation.
- Less obvious facts (hospital):
 - Radiologist, who is a “partner” (owner) in the radiology group, has an immediate family member who refers to a hospital where the group provides the professional interpretations on an independently contracted, split-billed basis.
 - The Stark violation.
- NOTE: the facts usually aren’t static.
- AND: remember the Affordable Care Act’s 60-day repayment rule.

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“Immediate Family Member” (cont’d)

- One solution: remove the radiologists with immediate family members, who are (important) referral sources, from “partner” status.
 - But if you do so, be wary of compensating non-partner radiologists the same as partner radiologists.
- How to address proactively for an imaging center:
 - Don’t accept referrals from immediate family members, at least not for governmental beneficiaries.
 - Create policies and procedures to operationalize the screen.
 - Affirmatively obligate each owning radiologist to notify group of all changes in their immediate family members.
 - Build mechanism within group to monitor and confirm on at least an annual basis.
- How to address proactively at the hospital.
 - Ship out the study and allow an independent contractor radiologist to read and bill for the study.
 - Allow one of the group’s radiologists to read and bill in her/his name for the study.
 - NOTE: all of these solutions need to be reviewed against any exclusive provider agreement that the radiology group has with the hospital.
 - Would the solution cause the radiology group to be in breach?

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Consultation Exception to Referral Definition

- Why is the exception important for radiology groups:
 - Interventional radiologists.
- History of the exception.
- The Stark law applies to referrals, but “referral” does not include a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, and by a radiation oncologist for radiation therapy or ancillary services necessary for, and integral to, the provision of radiation therapy,” if:
 - The request results from a consultation initiated by another physician (whether the request for a consultation was made to a particular physician or to an entity with which the physician is affiliated); and
 - The tests or services are furnished by or under the supervision of the pathologist, radiologist, or radiation oncologist, or under the supervision of a pathologist, radiologist, or radiation oncologist, respectively, in the same group practice as the pathologist, radiologist, or radiation oncologist.

Consultation Exception to Referral Definition (cont'd)

- “Consultation” means a professional service furnished to a patient by a physician if the following conditions are satisfied:
 - The physician's opinion or advice regarding evaluation or management or both of a specific medical problem is requested by another physician.
 - The request and need for the consultation are documented in the patient's medical record.
 - After the consultation is provided, the physician prepares a written report of his or her findings, which is provided to the physician who requested the consultation.
 - With respect to radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided that the radiation oncologist communicates with the referring physician on a regular basis about the patient's course of treatment and progress.”

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Consultation Exception to Referral Definition (cont'd)

- Exception only applies to certain type of services ordered by certain types of physician specialists.
- Must result from a consultation initiated by another physician.
- Consultation definition requires a lot of things to occur:
 - Documentation.
 - Written report to physician who requested the consultation.



Consultation Exception to Referral Definition (cont'd)

- If the “consulting physician” never returns the patient to the care of the physician who requested the consultation, query whether a consultation occurred?
- The relevant types of physician specialties are not defined in the regulations, *e.g.*, who qualifies as a “radiologist” and under what circumstances.
- Query how the exception applies to “interventional radiologists” and ancillary testing ordered by interventional radiologists that are ancillary and necessary to interventional radiology procedures.
 - On the one hand, the plain language of the regulations seems to indicate that the exception could apply, if you carefully comply with the express requirements of the exception.
 - On the other hand, preamble language potentially indicates the contrary. 72 Fed. Reg. 5102, Sept. 5, 2007.
 - Must drill into how the interventional radiologists practice: regional and sometimes generational differences can impact the analysis.
- **WHAT DOES THIS ALL MEAN?**

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Stark Law Exception for Nonmonetary Compensation

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- This exception applies to nonmonetary compensation (*i.e.*, it does not apply to cash or cash equivalents) that is less than an aggregate of \$300 per year if certain conditions are satisfied.
 - Amount is indexed to increase with the Consumer Price Index-Urban All Items (see http://www.cms.gov/PhysicianSelfReferral/50_CPI-U_Updates.asp#TopOfPage (the “CY \$\$\$ Limit”).
 - ***The CY \$\$\$ Limit for calendar year 2016 was \$392.***
 - ***The CY \$\$\$ Limit for calendar year 2017 is \$398.***
- CMS has clarified that the dollar limitation is to be calculated on a calendar year basis.



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Stark Law Exception for Nonmonetary Compensation (cont'd)

- All of the following conditions must be satisfied:
 - The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician,
 - the compensation may not be solicited by the physician or the physician's practice (including employees and staff members), and
 - the compensation arrangement does not violate the anti-kickback statute.

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Stark Law Exception for Nonmonetary Compensation (cont'd)

- The exception now has a limited repayment mechanism to preserve compliance.
- Where an entity has inadvertently provided nonmonetary compensation to a physician in excess of the dollar limit for that year, such compensation is deemed to be within the limit if:
 - the value of the excess nonmonetary compensation is no more than 50 percent of the limit, and
 - the physician returns to the entity the excess nonmonetary compensation (or an amount equal to the value of the nonmonetary compensation) by the end of the calendar year in which the nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier.
- This repayment mechanism may be used by an entity only once every 3 years with respect to the same referring physician.
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