Agenda

• Federal Regulations for Ordering Diagnostic Tests
• Exceptions
  • Case Study
• Subspecialty Rules
  • Interventional Radiology and Mammography
• Conditional Orders
• Hospital Rule Differences
• Submitted Questions
Diagnostic Tests and Different Settings

• No reimbursement without order
• Orders can be modified
  • Different rules for hospital and nonhospital settings
Orders in Radiology

- Diagnostic Tests must have medical necessity
- Two sets of rules covering Hospitals and Non-Hospitals
  - The Ordering Diagnostic Test Rule
  - Hospital Conditions of Participation
Federal Regulations

• The Social Security Act (42 CFR 410.32)
  • The Ordering Diagnostic Test Rule
• Applies to IDTF and Physician Office Settings
  • Hospital have separate guidelines
Why does this rule exist?

• CMS does not allow radiologists to change the originally ordered test. It reasons that the radiologist may not know the true intent of the order or of previous studies performed on the patient prior to this request. In this case, written or verbal communication must occur prior to the change in order to obtain a new or revised order.
“Treating Physician” Defined

• A physician who furnishes a consultation or treats a patient for a specific medical problem, and who uses the results of a diagnostic test in the management of the patient's specific medical problem.
“Orders” Defined

- CMS defines an order as a written communication (hand delivered or faxed), telephone call, or e-mail to the testing facility by the treating physician/practitioner or his or her staff. If an order is communicated via telephone, both the treating physician and the testing site must document the telephone call in their respective copies of the patient's medical record.

- All orders should be signed by the treating physician to show intent and avoid denials.

- IDTF orders must be in writing
Exceptions

• Three written exceptions
  • Test Design
  • Clear Error
  • Patient Condition
• Abnormal results and need for additional test
• Subspecialties
  • IR and Mammography
Test Design Exception

• Unless specified in the order, the interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test
Test Design Exception: Case Study

- In 2016 Zwanger-Pesiri a NY Radiology company plead guilty to two counts of fraud and paid over $10 million billing procedures that had not been ordered by the treating physician.
- Paid criminal and civil penalties under the False Claims Act and entered an agreement with HHS-OIG to be bound by a Corporate Integrity Agreement for future billing practices.
Zwanger-Pesiri Case Study

• Obvious the ZP was automatically bundling the tests
• No medical necessity documentation
• “Corporate greed must never be a part of medical decision making. HHS-OIG and our law enforcement partners are committed to protecting patient care, and the federally funded health care programs intended for the nation’s most vulnerable citizens.” – Special Agent of Inspector General after the ZP ruling
Test Design Exception: Pelvic Ultrasounds

• “Pelvic US” may be considered generic
  • Accomplished through either a transvaginal or transabdominal
• Sometimes both are complementary and can be performed together
  • Only if medically necessary
• Limited circumstances allowed by the Test Design Exception
Clear Error Exception

• Radiologists may independently alter tests that contain “clear and obvious errors that would be apparent to a reasonable layperson

\[2 + 2 = 5\]
Patient Condition Exception

- Finally, a radiologist may cancel an ordered test when the patient’s condition at the time of testing is such that the originally ordered test cannot be performed.
Abnormal Test Results Exception

• 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.
When in doubt get a new order!
Interventional Radiology

- Interventional radiologists that are performing therapeutic interventional radiology procedures are considered treating physicians by the CMS guidelines.
- Due to the fact that they are considered treating physicians in that circumstance, they have the ability to order additional procedures when clinically warranted.
Mammography Rules

• Regulated by FDA Mammography Quality Standards Act
• Radiologist can convert screening mammogram to a diagnostic mammogram - with reason.
• Computer Aided Detection (CAD) can be used without order
• Radiologist can NOT add a breast ultrasound to a diagnostic mammogram without and updated order
Conditional Orders

• Allowed if on patient by patient basis
• No standing orders and standard protocol
Hospital Services

• Hospital radiologists can order medically necessary tests
• Must have clinical privileges and within state scope of practice
• Within hospitals by laws
Review

• Ordering Diagnostic Test Rule (non-hospital setting)
  • Exceptions and adding an additional test
  • No standing orders
  • DOCUMENT!
• IR and Mammography
• Hospital Setting
Thank you!

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