Lab Outreach Pass-Through Billing Arrangements:

Where the Risk Lies

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Agenda

- Common Outreach and Reference Laboratory Practices
- What is Hospital Pass-Through Billing?
- Describe Various Scenarios – The Good vs the Bad
- Structuring your Reference Lab Arrangements

IMAGINE YOU ARE AN INSURER

- A small, 29 bed rural hospital, submits nearly $34 million in outreach laboratory test claims in only 120 days

- A small, 25 bed critical access hospital submits more than 10,000 claims/mo for laboratory testing over a 16-month period and generates over $21 million (or $1.35 million per month) as a result
  - Prior to their “arrangement”, they billed on average 72 laboratory claims per month for an average monthly reimbursement of $1,300

- A hospital is paid an average of $2,250 per claim for urine and blood toxicology testing it did not perform. The performing laboratories would have only received approximately $120 for the same testing had they billed the payer directly

What We Are Used To
Lab Outreach as a Common Practice

- Laboratory Outreach has been a common practice for decades
- Marketing to community physicians for testing of non-hospital patients
- Pass-through billing, sometimes known as account billing or client billing, is a billing model that has been around for years
- Pass-through billing arrangements are commonly identified basically where laboratory testing claims are billed by an entity (HOSPITAL) different than the one that performed the testing (REFERENCE LAB)
- The Hospital provider often purchases Ref Lab testing services at a discount, marks up the price, and rebills the purchased services to patients and payors
  - Often permissible as a reference laboratory arrangement, but in some cases, payor policies or federal or state laws may prohibit the mark-up practice.

Common Reference Lab Practices

- The large national reference laboratories often have patient service centers (PSCs) in locations convenient to their physician clients and near hospitals
- Payors often prefer a large number of PSCs to be considered in-network or exclusive.
- These large reference laboratories may even contract with the hospitals to do their STAT testing locally onsite at the hospital laboratory location with the understanding that other more esoteric testing be sent on to their reference laboratory

NEW Pass-Through Billing Practices

- New form of pass-through billing arrangements-- are frequently “partnerships” between hospitals and outside entities, such as reference labs or lab management companies
- These arrangements often appear to target small, rural hospitals or hospitals which may be in need of capital, and typically only apply to services reimbursable by commercial payors
- Regardless of their in-network or out-of-network status, the reference laboratory claims alone would have less favorable reimbursement than a hospital payor contract reimbursement
- As Hospitals are used to such client bill pass-through arrangements with their national reference laboratories, fraudulent pass-through arrangements are often confusing for many hospitals that may not even realize they are being deceived into unlawful practice
- Payors are standing up to the form of pass-through billing where the sole purpose is to take advantage of favorable in-network payment rates

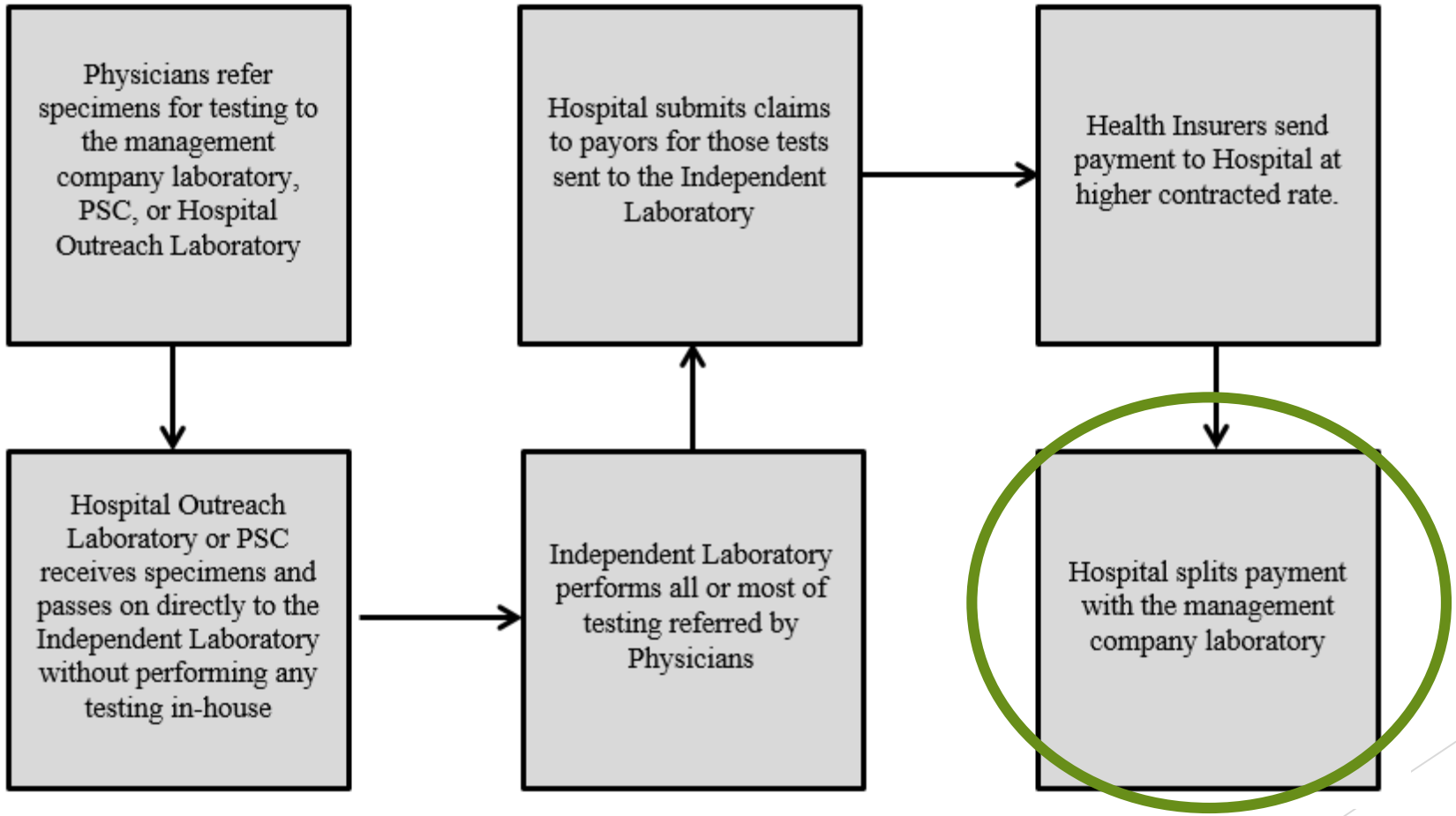
Why Targeting Rural Hospitals?

Medicare Reference Lab Exceptions: impose billing limitations on reference laboratory arrangements by prohibiting a Hospital from billing under the Clinical Laboratory Fee Schedule for diagnostic tests performed by a reference laboratory **unless** the following criteria are satisfied:

- the referring laboratory is located in (or is part of) a rural hospital;
- the referring laboratory and the reference laboratory are under some form of common ownership;
- the referring Hospital laboratory does not refer more than 30% of its clinical laboratory tests out to a reference laboratory during the year (not including referrals under the common ownership exception)

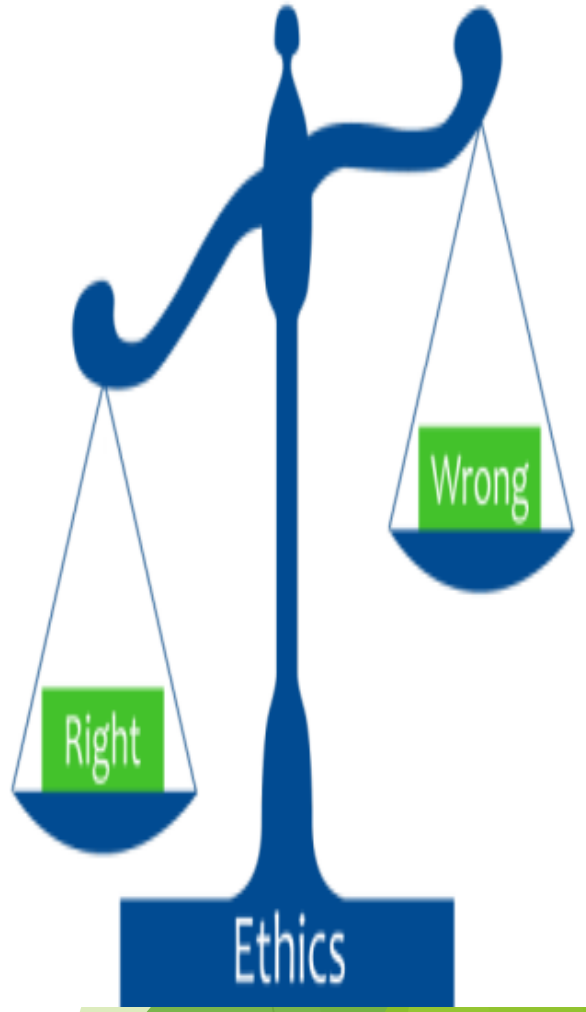
- Management companies target the rural hospitals to take advantage of this rural hospital exception when courting them to a pass-through billing arrangement
- Although the arrangement appears to satisfy the exception on its face, the fact that there is usually no nexus between the hospital and the patient for whom testing is performed calls the arrangement into question.

Common Pass-Through Scenario



Where the RISKY Business Lies

- The “partner” company helps to set-up the laboratory outreach programs in mostly rural hospitals for the ***sole*** purpose of receiving and processing specimens and for the pass-through billing arrangement
- Payors pay a hospital for a test they did not perform, at a higher contracted rate than the payor would have paid for the same test had the performing independent laboratory billed for the test themselves directly to the payor
  - This scheme also increases the patient’s responsibility due to the more inflated pricing, where the arrangement is solely for the financial gain of the “partner”
- Hospital laboratories are used as fronts to conceal the identity of the management company laboratories that performs the testing
  - The CLIA number of the performing laboratory is not accurately depicted on the claim or the report
- Once the hospital receives payment from the insurer, the hospital then splits the revenue profits according to an agreement with the management company/laboratory “partner”
  - Paid referring providers kickbacks to induce them to refer laboratory specimens
- No laboratory testing is ever performed by the hospital laboratory and is instead ***solely*** performed by the management company’s related independent reference laboratory
  - New tests may be added to the hospital's menu to capture profits from referrals from the hospital's partner; Involves testing which the hospital has not performed previously



Regulatory Implications of Hospital Pass-Through Billing Arrangements

- In addition to the various legal issues, these arrangements are clearly attracting the attention of state and federal regulators and private and commercial payors
  - Under these arrangements, such a drastic change in Hospital's overall revenues brings increased scrutiny
- Fraud and Abuse
  - Medicare Reference Laboratory Exceptions
  - Anti-Kickback Statute (AKS)
  - Stark Law
  - False Claims Act
- State and Payor Issues
  - Direct Bill and Anti-Markup Laws
  - Payor Contracts

Federal Fraud and Abuse Concerns

Anti-Kickback Statute (AKS): prohibits payment, receipt, offering or solicitation of remuneration in exchange for the referral of services or items reimbursed by the Medicare or Medicaid programs. 42 U.S.C. § 1320a-7b

- Hospital pass-through billing arrangements can implicate the AKS in a number of ways:
  - The revenue split between the hospital and the performing laboratory or laboratory management company can be considered an inducement in exchange for receipt of the referral
  - The hospital is paying the laboratory or management company for referring the specimen to the hospital and the hospital will bill for laboratory services it did not perform.
  - Any remuneration offered to the ordering providers to induce them to refer the testing to the laboratory in question would be considered a kickback or Stark violation in violation of federal law.
    - This is why these arrangements typically exclude services reimbursable by a government payor (i.e., Medicare, Medicaid, Tricare, CHAMPUS, and Medicare Advantage).
    - Although, many states have similar laws applicable to all payor categories

Federal Fraud and Abuse Concerns

Stark Law: The federal physician self-referral law prohibits a physician from making a referral for certain designated health services reimbursable by Medicare or Medicaid to an entity with which the physician has a financial relationship. 42 U.S.C. §1395nn

- A hospital pass-through arrangement could implicate the Stark Law if it includes referrals by a physician to a laboratory that will share a portion of the revenue received for performing the laboratory services with the referring physician

False Claims Act (FCA): a provider may be liable 1) knowingly presents (or causes to be presented) a false or fraudulent claim for payment; (2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (3) conspires with others to commit a violation of the FCA (4) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money or transmit property to the Federal Government. False claims are subject to recoupment and can create both civil and criminal liability for the billing provider.

- The FCA generally only applies to claims submitted to a federal program for reimbursement.
- Many states have their own equivalent of the FCA, which would false claims from being submitted to private payors as well.

State and Payor Concerns

- **Eliminating services reimbursed by a government payor is not enough to mitigate the risks associated with these arrangements**, and there are still significant state and payor issues to consider. Again, most states have Stark, AKS, and FCA equivalent laws that would apply
- *Direct Bill and Anti-markup Laws*
  - Many states have statutory restrictions on pass-through billing and markup, although some of the provisions only relate to professional component services and not technical component
  - There are four categories of state regulations:
    - direct billing, anti-markup, disclosure, and unregulated.
      - In direct billing states, laboratories (and, in some states, other third parties) are required to bill payors directly for the services they perform.
      - In anti-markup states, a provider that purchases laboratory services is prohibited from marking up the cost of such services above the amount he or she paid to the laboratory.
      - In disclosure states, the purchaser must disclose the name of the selling laboratory, the amount paid for the laboratory service, and the amount of any markup.
  - It is worth noting that in many states, hospitals are specifically exempted from direct billing and anti-markup regulations. This is another angle through which hospital pass-through arrangements are marketed.

Increased Scrutiny and Recoupment

- Payors regularly monitor provider reimbursement trends.
- Concerning when a payor reimburses a high volume of claims in a short period of time for a hospital located in a rural area where there could not possible be such a demand for laboratory services.
- Increasing enforcement by payors to recoup amounts reimbursed under a hospital arrangement under theories of breach of contract, fraud, civil conspiracy, negligent misrepresentation, and unjust enrichment
- The billing hospital will be directly liable for any recoupment claim successfully brought by a payor related to the billed tests in question since it is the hospital that billed the services and has a contract with the payor. This means that the hospital, and not the management company/laboratory, will be the subject of any recoupment action based upon theories such as lack of medical necessity – an increasingly common basis for recoupment actions

Noteworthy Examples

- RightCHOICE Managed Care, Inc. v. Hosp. Partners, Inc.
- Blue Cross Blue Shield of Mississippi v. Sharkey-Issaquena Community Hospital
- Aetna, Inc. v. People's Choice Hospital, LLC
- Blue Cross Blue Shield of Georgia v. Chestatee Regional Hospital
- Sonoma West Medical Center (Anthem)
- LifeBrite Hospital Group of Stokes LLC (Blue Cross Blue Shield of North Carolina)
- Bay Area Regional Medical Center (Aetna)

LAWSUIT!

Commercial Payors Fight Back Examples

- **BLUE CROSS BLUE SHIELD OF LOUISIANA - Specific Provider Manual Instructions: Pass-Through Billing Not Permitted.** Pass-through billing occurs when the ordering provider requests and bills for a lab service, but the lab service is not performed by the ordering provider or the CLIA-certified lab owned and operated by the ordering provider. The expectation is that we will receive lab claims billed from:
  - The performing provider at a CLIA-certified lab, owned and operated by the ordering physician, or
  - The ordering provider who owns and operates a CLIA-certified lab, or
  - An in-network reference lab
- **Blue Cross and HMO Louisiana - do not permit pass-through billing. Only the performing provider should bill for these services.** You may only bill for lab services that you perform in your office. Providers may bill for the following indirectly performed services:
  - The service of the performing provider is performed at the place of service of the ordering provider and is billed by the ordering provider, or
  - The service is provided by an employee of a physician or other professional provider (e.g. physician assistant, surgical assistant, advanced practice nurse, clinical nurse specialist, certified nurse midwife or registered nurse first assistant), who is under the direct supervision of the ordering provider and the service is billed by the ordering provider.

How to Reduce your Risk
Considerations in Structuring Outreach Lab

- Have the CLIA number and address printed on the report to the provider of the lab which actually performs the testing
- The hospital performs onsite 70% of the testing that it is billing
- Comply with any applicable state or commercial payor requirements for non-Medicare work
  - Any remuneration exchanged with the hospital, the performing laboratory, the management company (if applicable), and the referring provider must be structured in a manner that satisfies applicable Stark Law exceptions (again, this only applies if doctor is receiving remuneration) and AKS safe harbors, as well as any state law equivalent
  - Applicable state law must be consulted to determine whether the hospital is even permitted to bill and markup the cost of services for services it does not personally perform
  - the terms of the hospital's payor agreements must be carefully analyzed to determine whether such an arrangement is even permitted under the contract
- The revenue received as payment by the hospital is never split as part of the arrangement with the reference lab.
- The hospital laboratory pays the independent laboratory fair market value for the testing performed, and such payment must exceed the cost for the laboratory to perform the test.
- The arrangement should be reviewed by an attorney well-versed in healthcare regulatory issues to verify that the arrangement complies with applicable federal and state laws and regulations, as well as with the terms of the hospital's payor agreements.

Other Reference Lab Arrangement
Ask the question?

- What's the motivation and rationalization?
- Is the arrangement too good to be true?
- Does the claim accurately reflect arrangement by showing the name of the lab performing the testing?
- Do the payment claims comply with relevant billing and payment rules, including the hospital's participation agreements with private insurers?
- Is there a reasonable basis for the hospital to bill for tests for which it claims payment?
- Will related compensation arrangements violate applicable federal or state anti-kickback statutes? Who is marketing the services?
- Will the billing arrangement accommodate requirements to which the hospital is subject such as outpatient bundling or the 3-day DRG window?
- Considered business issues such as financial exposure from recoupment actions or adverse actions taken by a private insurer?