Pass-Through Billing and Shared Labs

Pass-through billing has mostly passed on.

Pass-through billing is an arrangement between a physician practice and a reference laboratory that allows the physician practice to submit specimens to the reference lab for testing, pay that laboratory directly, and then bill the payer (insurance or patient) for the test, usually at a higher fee. This practice, in which the physician makes a profit for work done by another entity, is prohibited by Medicare and Medicaid.

CMS requires all laboratory tests to be billed by the laboratory that does the work. Some states and some private payers have similar restrictions. Examples are the State of Tennessee, United Healthcare, BCBS of Texas and BCBS of Alabama.

Even when billing only private payers, this could be considered inducement and could be against the law- the Anti-Kickback Statute. This is because the physician would be more likely to send Medicare/Medicaid testing to the laboratory that allows pass-through billing, also known as client or account billing.

The Federal Anti-Kickback Statute

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prohibits "knowingly and willfully offering, paying, soliciting or receiving remuneration to induce referrals...of services covered by Medicare, Medicaid or any federally funded program.." 42. U.S.C. § 1320a-7b(b).

Beyond specific laws and payer restrictions, every clinician should hold themselves and their practice(s) to the highest ethical standards possible. The American Medical Association and the American Society of Clinical Pathology have issued ethical guidelines on arrangements that allow physicians to profit from work done by others when the patient is ultimately the payer.

Exceptions:
1. CMS does allow physicians to purchase the technical component of pathology services but only if the practice reads its own slides. However, the practice can bill only the actual amount it paid the reference lab for the slide preparation.
2. CMS does allow pass-through billing for some drugs, biological and radiopharmaceuticals- a completely difference service.
3. A physician practice may bill for referred tests only if it does not refer more than 30% of the clinical laboratory tests required during the year. This comes under "purchased services" and is allowed only if the reference lab does not also bill for the tests.

Shared Laboratories

Stark laws prohibit a physician from referring patients to an entity in which he or she has a financial stake. Stark applies only to Medicare and Medicaid, but some states such as California and New York have their own regulations which also prohibit self-referrals.

One exception to the Stark Regulation is the in-house laboratory owned by one physician or a group practice. These labs are known as "Physician Office Laboratories" or POLs. Laboratories owned by group practice must be in the same building as the practice or in another building of the same practice.
building used by the group practice for ancillary services.

Group practices must be legally-organized as a partnership, corporation, foundation, not-for-profit corporation or similar association. Substantially all (considered to be at least 75%) of all patient services must be provided through the group; patient care services must be billed in the name of the group, and reimbursement received must be treated as receipts of the group. Laboratories located outside a Metropolitan Statistical area are also exempt, with the caveat that at least 75% of the laboratory services must be provided to individuals residing in a rural area.

A shared laboratory is a clinical laboratory owned by more than one practice operating in the same building, with each physician "directly" supervising laboratory staff while they are running tests for his/her patients, and with each physician billing individually for the tests performed on his/her patients. All participating physicians or physician practices must be on the same floor of the building as the laboratory, so that the supervision requirement can be fulfilled.

CLIA, the Clinical Laboratory Improvement Amendments, includes "shared lab" as an option on its application, form CMS 116, although the regulation does not address shared laboratories. From a CLIA compliance standpoint, there are some recommendations to clarify operational separation of the entities owning and testing in a shared lab:

- There can be only one CLIA certificate and one laboratory director
- The laboratory should, however, enroll in separate proficiency testing programs for each participating practice.
- Other documentation such as manuals, personnel files and quality control records may be shared.

There are some additional arrangements...
that could ultimately be considered shared labs, even though they use it on different days.

- Laboratory space, equipment and maybe even personnel are used by different practices on separate days.
- One practice owns the laboratory but another practice leases the laboratory, including its personnel, on certain days only.

This Week’s Audit Tip Provided by:
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References:
1. "Physicians Should be Wary of Labs Offering Incentives.." Physicians Practice blog, Feb. 27, 2013
2. BCBSTX notices
4. CMS Regulations and Guidance
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