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Top Compliance Challenges for Laboratories

What are the priorities for a laboratory compliance officer in an increasingly challenging and competitive environment?

In the January 2009 issue of *G-2 Compliance Report* an article titled "Lab Compliance Officers Face Host of Challenges" focused on the results of a survey of lab compliance officers conducted by Washington G-2 Reports and Laboratory Management Support Services (LMSS) of Phoenix. Nearly half of the survey respondents were from hospital outreach labs and 22 percent from independent labs. As vice president and chief compliance officer for Pathology Associates Medical Laboratories (PAML) in Spokane, Wash., as well as for PAML's five joint ventures with hospitals, I have the unique responsibility of overseeing compliance for the two types of labs that comprise nearly 75 percent of those who responded. The effort to "do the right thing right" in any laboratory setting continues to be a challenge and these are some of the key issues I face. Some are very specific current issues, while others are continual and critical needs.

New/Revised ABN

When the Centers for Medicare and Medicaid Services (CMS) published the revisions to the Advance Beneficiary Notice (ABN; Form R-131) in March 2008, this set off a challenge to all labs that provide services to Medicare beneficiaries. Although the form itself appeared to look fairly similar to the former R-131-L, in fact, there were some significant changes that would impact lab employees obtaining the ABN, the lab's physician clients, and the Medicare beneficiaries themselves.

Although the initial mandatory implementation date had been set for Sept. 1, 2008, CMS later extended that date to March 1, 2009, in response to a number of lab industry requests, and that extra time was definitely needed.

The major changes from the R-131-L and its requirements include:

- ❖ The requirement that a cost estimate be listed for each test on the ABN and be within 25 percent or \$100 of the eventual cost charged to the patient;
- ❖ A third option for the Medicare beneficiary to choose from concerning their liability for payment;
- ❖ The requirement that the beneficiary not only sign but also insert the date on the ABN; and
- ❖ The prohibition from using the beneficiary's social security number or HCIN as the identifier on the ABN.

Among the challenges faced by labs, including PAML:

- ❖ Revision/reprinting of paper ABNs and subsequent retrieval of outdated forms prior to March 1;
- ❖ Reprogramming of electronic ABN programs that are the lab's product or working with laboratory information service (LIS) vendors to ensure their programming would be updated by March 1;
- ❖ Determining method for providing cost estimates in the field (i.e., in a pa-

tient service center or physician/client office) for each test; and

- ❖ Education of lab and physician office staff who may need to obtain an ABN, as well as the Medicare beneficiaries who would need to choose one of the three options for payment for their testing.

Now that the March 1 implementation date has passed, it will be important for all labs to monitor the success rate in obtaining valid ABNs so that additional training needs may be identified.

Physician Signature on Lab Orders

The requirement for documentation of the physician's intent to order a lab test has long been a challenge for laboratories as a lab typically relies on the properly completed requisition or an electronic order from the physician's electronic medical record (EMR) as its valid order. CMS, through the fiscal intermediary, carrier, or A/B Medicare administrative contractor, may require that this order also be documented in the patient's medical record along with the medical necessity for the order.

In the past year this was further complicated when a CMS transmittal was published that appeared to require that the physician's signature actually be on the requisition (a practice rarely in place at most labs). The subsequent publication of Transmittal 94 in August 2008 attempted to clarify this requirement by stating: "While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed," along with medical necessity documentation. So the challenge remains that even with the physician signature on the requisition, the lab's reimbursement may depend entirely on the physician's charting practices.

Contracts With Sources of Referral

A key component of successful clinical laboratory outreach programs is the building of relationships with physicians,

clinics, hospitals, long-term care facilities, etc. (collectively "potential sources of referral"). These relationships may be simple and straightforward as serving as the reference laboratory by performing testing on samples sent into the lab from the ordering provider's office or facility or they may involve the leasing/subleasing of space for a patient service center, the provision of phlebotomy services in the provider's office, or the provision of connectivity to facilitate the ordering of lab tests and/or the delivery of lab reports between the provider's electronic medical record (EMR) and the LIS.

These relationships all must be evaluated under both the Anti-Kickback Statute and the Stark laws. These regulations and laws are ever changing and can be complex, so consulting with an attorney with expertise in this area may be prudent.

For instance, in October 2008, a clarification to the Stark Law was published that requires that all applicable agreements with sources of referral (either directly or indirectly) must be fully executed (i.e., signed by both parties) prior to the date upon which the space is occupied (if a patient service center lease or sublease) or the services are first provided (if an in-office phlebotomy arrangement).

Monitoring the Effectiveness of the Lab's Compliance Program

Since the Office of Inspector General's (OIG) Compliance Program Guidance for Clinical Laboratories was published in 1998, labs have known that a critical component of any compliance program is the auditing and monitoring of the effectiveness of the program. Whether this is done by the compliance officer/department, internal or external auditors, or department managers, the scope and details of the review/audit should be clear and well-defined and the reporting mechanism well-documented with appropriate action plans in place should any deficiency be found. As mentioned earlier, having a working relationship

with an attorney with expertise in health care law and in particular with laboratory issues is prudent. An effective compliance program involves regular review and audit of laboratory operations and may include:

- ❖ Completion rates for mandatory new employee, annual employee education/training in general compliance topics, as well as specific topics for identified “high-risk” departments;
- ❖ “Order to Report to Claim” audits, which would include not only confirming that the tests that were ordered were those that were performed and those for which a claim was filed, but also whether the ICD-9 code/diagnosis narrative on the requisition was the same as on the claim, whether an ABN was needed and a valid ABN executed, whether a Medicare Secondary Payer questionnaire was completed, etc.; and
- ❖ Verification that new/revised/deleted CPT codes are reflected in the current chargemaster as of January 1 of each year and also that any changes in methodology during the year have resulted in updates to the chargemaster if needed.

Other review/audit subjects that should be considered:

- ❖ Referred test review to determine whether the laboratory falls within the provisions of the “70/30 rule” by referring less than 30 percent of testing to other laboratories so that the lab can bill Medicare directly;
- ❖ Test utilization review that compares the 30 most frequently billed tests for the year to the previous year’s volume of those tests and the probable cause for any increase greater than 10 percent;
- ❖ Review of contracts with sources of referral (e.g., patient service center leases, phlebotomy services) for appropriate execution of the contract, compliance with the terms of the contract, verification of fair market value (if applicable), etc.;

- ❖ If applicable, review of standing orders related to documentation of specific patient/specific test(s)/specific time interval, as well as annual (at a minimum) review/renewal by the ordering provider; and
- ❖ If applicable, review of billing for end-stage renal disease (ESRD) patient testing or long-term care/skilled nursing facility patient testing for compliance with the unique and specific billing rules for these patient types.

Keeping Current With Compliance Changes and Challenges

Lastly, there is an ongoing need to have resources available for timely and accurate information regarding changes that have been made or may be contemplated by CMS, the OIG, local fiscal intermediary, carrier or A/B Medicare administrative contractor (MAC), or other agencies with jurisdiction over laboratory practices. There are a number of excellent sources for this information:

- ❖ Listservs available through CMS and OIG that are free and send regular notifications via e-mail on a variety of subjects: (www.cms.hhs.gov/AboutWebsite/EmailUpdates/list.asp) or (<http://oig.hhs.gov/maillinglist.asp>);
- ❖ Review of the annual OIG Work Plan, which is typically published in the fall of each year and gives insight into various projects to be addressed by the OIG the following fiscal year, including those that may involve laboratories;
- ❖ Laboratory-specific newsletters/publications such as *G-2 Compliance Report* and *National Intelligence Report*;
- ❖ Laboratory industry conferences (in-person or via video/audio conference), which provide sessions devoted specifically to compliance issues including those sponsored by IOMA, the Dark Report, American Association for Clinical Chemistry (AACC), American Society for Clinical Laboratory Science (ASCLS), the Clinical Laboratory Management Association (CLMA), and others; and

- ❖ Networking with peer laboratories to share best practices, helpful tips, and tools for conducting relevant reviews and audits, as well as education and training materials.

One Final 'Need'

Many laboratories have a person serving as compliance officer or compliance coordinator who moved into that role at the inception of that lab's compliance program (perhaps as far back as 1998 when the OIG compliance guidance document was published). In those situations, the person has had the advantage of learning about laboratory compliance from its beginning as a formal program and then

growing in their knowledge and expertise as laboratory compliance requirements became more well-defined and more resources for training became available. The "need" now is for more laboratory professionals to be positioned through training and experience to acquire that same level of expertise so as to continue to grow and expand the compliance programs for a new generation of laboratorians and to prepare them to face any new challenges posed by compliance regulations.

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