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MEDICARE COMPLIANCE:

What Type of Anti-fraud Program Fits Your POL?

In the nationwide crackdown on fraudulent coding, billing, and marketing of laboratory testing services reimbursed under federally-financed programs, government authorities expect labs of all types and sizes to have an effective voluntary compliance program which corrects and prevents fraud and abuse.

At the same time, the government expects each lab to customize its program in light of individual needs and financial realities, such as client and payor mix, billing procedures, sales-marketing, profile pricing, and business arrangements with outside providers, suppliers, and vendors.

Guidance on the major elements a lab compliance program should address is presented in the model plan released by the HHS Office of Inspector General. That plan, while specific and wide-ranging in its recommendations, is “not all-inclusive,” the OIG warns, and labs should consider “any and all areas where abuse may be prevalent including, for example, anti-kickback [law], Stark self-referral issues and CLIA requirements.”

So, how much leeway do physician office laboratories (POLs) have in shaping a compliance program?

General Principles

The answer to this question is broadly thus: the program should be devised to ensure compliance with all laws and regulations—federal, state, and local—applicable to the lab’s legal structure and scope of operations. The purpose is to establish the POL as an honest, trustworthy partner with which the government can do business.

Ideally, the POL’s compliance code of conduct should be part of a broader compliance program overseeing all

interactions between the physician practice and health-care programs with federally-financed services. Many lab compliance issues are similar to those in other aspects of a physician practice, such as proper coding/billing for physicians’ services, refunds of overpayments, Stark self-referral limits on designated health services and avoiding inducements and remuneration which are prohibited under anti-kickback law.

For the POL compliance program, the OIG’s model lab plan can be used as a checklist to determine at least the minimum required. That plan is emphatic on areas where action is expected—not just to correct fraud, but also to prevent it from happening in the first place, whether by intent, by mistake, or by inadvertence.

The model plan, however, is a guide, not a recipe. A small in-office lab which performs tests mainly for the practice’s patients will need a much less comprehensive compliance program than a large group practice lab serving the group’s own patients as well as outside physician clients.

Does this mean that recommendations in the model don’t have to be followed? No. They do have to be addressed, but not necessarily followed to the letter. The guiding principle is: first consider, then meet the expectations underlying the OIG’s recommendations.

POLs may find that a particular approach to a compliance objective suits them better than the OIG’s example. For instance, the OIG advises labs to have a hotline for anonymous reporting of compliance problems. This makes sense in a large, multi-site regional independent facility, but not in small or mid-size local in-office labs. What POLs need to consider is the OIG’s objective: to

assure an open line of communication so that individuals can anonymously report problems, without fear of retaliation, to those responsible for ensuring compliance. It's up to the POL to decide how best to achieve this open line of communication.

Moreover, each POL must determine how it will respond to the problems identified. These problems will need to be investigated and resolved. In most of the recent settlements reached between large independent lab companies and the government over false claims and kickback charges, former employees alleged their warnings of suspect practices went unheeded, prompting them to file whistleblower lawsuits to halt wrongdoing. Each POL should have an internal mechanism to handle and remedy problems.

If a POL decides that one or more of the recommendations in the OIG model plan don't apply, the reason(s) should be documented. This is important, health law experts advise, should any enforcement action be launched against the lab in an area which is covered in the OIG's model plan but not in the lab's compliance program. In other words, it's up to the POL to justify why it decided not to follow the government's suggestions.

Finally, POLs must meet the government's expectation that the compliance program is "effective." This can be measured by the following: the program targets any and all areas of the POL operations where fraud and abuse are likely to occur; compliance policies and procedures are implemented, updated, communicated, and enforced; improper conduct is corrected and appropriate disciplinary action is taken; the program's impact is monitored, and results are regularly reported and acted upon. Beware of cosmetic or "paper" programs; in the OIG's view, these are worse than having no program at all because they impugn the lab's "good faith."

The cornerstone of an "effective" compliance program is explicit endorsement and support from the top of the organization. Individuals who are assigned responsibility for running the program should have sufficient authority and resources to make it work, and should enjoy direct access to the top to report on and discuss compliance issues. Personnel should understand that compliance is a condition of employment and a factor in promotions to supervisory or managerial positions; moreover, personnel should understand that non-compliance will be disciplined, up to and including termination.

Physicians who run the practice have a clear-cut incentive to ensure that the POL compliance program measures up to the "effectiveness" standard. That's because they bear ultimate responsibility for its success or failure. It is they who are most at risk when wrongdoing occurs, especially if due diligence could have prevented it.

The following scenarios illustrate these general principles. Each assumes that the patients involved are Medicare/Medicaid beneficiaries and that the practice complies with Stark self-referral requirements and any related exception.

Scenario 1

A POL serves only the physicians' patients and limits its testing menu to CLIA waived tests. It accepts no referrals and thus doesn't market its services. The physicians order individual tests by checking them off on a superbill that acts as a proxy for the requisition form.

Many of the OIG's model plan recommendations don't pertain to this POL and thus don't have to be part of its compliance program as long as the lab keeps operating as described. Examples of the recommendations that don't apply: requisition design (only individual tests are listed by the physicians who order them and oversee the lab); panel and profile offerings (it has none); disclosures and notices to physician clients (it has none); billing of automated multichannel tests (it offers none); reliance on standing orders (it uses none).

For this POL, the most pertinent compliance recommendations in the OIG plan are: periodic training of coding/billing personnel; proper selection, use, and updating of CPT, HCPCS, and ICD-9 codes; adherence to government billing rules and, where applicable, OIG fraud alerts; retention of appropriate and legally required records; and compliance with CLIA standards for waived testing.

Scenario 2

A POL provides testing for the physicians' own patients and also performs testing on specimens referred by other physicians in the area. For its own patients, the practice's physicians have created a custom panel of tests, including automated multichannel chemistries. But recognizing that Medicare plans to eliminate current automated profile codes CPT 80002-80019 and HCPCS G0058-G0060 at the start of 1998, the POL has decided that as of a specific date it will offer outside referring physicians only CPT-defined test panels (80050-80092 and HCPCS G0095-G0098); all other tests will be ordered individually. This is evident on the uniform requisition form the POL uses with all its physician clients. The POL uses no standing orders. Though accepting referrals from outside physicians, the POL has no other financial ties with them.

As in Scenario 1, many of the OIG's model plan recommendations aren't relevant to this POL. The compliance program should cover the areas cited in Scenario 1. The OIG's advice regarding automated test profiles does not pertain since the only profiles used are customized by

the physicians for their patient population needs; the presumption is that the physicians have full knowledge of the component tests and their medical necessity.

Because of this POL's acceptance of referral work, the compliance program should, however, include safeguards to ensure that bills are submitted only for medically necessary tests (as a general rule) and that all CLIA, Medicare/ Medicaid, and Stark requirements are satisfied. Even though physician clients can order only Medicare-recognized panels (singly coded and presumed to be medically necessary), the POL should, in line with the OIG's suggestions, send notices to these clients reminding them that when ordering these panels for which Medicare payment will be claimed, each of the tests must be medically necessary for the patient. Similar advisories should be printed on the requisition forms.

Operationally, the program should be more formalized and comprehensive than that in Scenario 1. It should include most, if not all, of the OIG's suggestions for compliance program design and implementation (see below).

Scenario 3

A large multispecialty group practice lab serves a network of the group practice's sites in the community as well as nursing homes served by the practice's physicians, and performs testing on referral from various sources with which it has various financial arrangements. The lab offers current CPT test panels, standard profiles, and profiles customized at the request of physician clients (often including automated multichannel chemistry tests). The lab vigorously markets its services throughout the community.

Of all the scenarios presented, this lab's compliance program should be the most comprehensive. It should carefully consider all the OIG model plan recommendations, especially those relating to requisition design; ordering of automated multichannel chemistries; annual notices and disclosures to physicians clients; fair and honest marketing and profile pricing; and monitoring test utilization of referral sources. If this lab decides not to adopt any one of the OIG's recommendations, it definitely should document and be able to defend such a decision.

Conclusion

Though no deadline is set for formulating or refining a lab compliance program, it's better to do it sooner, not later. Should fraud be detected in a POL without a program, it's already too late. An effective program can help in case of any investigation or settlement. Though it's not an ironclad guarantee of immunity, it can be a factor in mitigating the formidable legal risks: criminal and civil prosecution, hefty fines, and exclusion from doing business with Medicare and Medicaid.

A compliance program should be developed in concert with appropriate legal counsel. Of special concern are areas where the program touches on sensitive issues, such as disciplinary action against employees, protecting patient privacy/confidentiality when reporting on the compliance effort, and satisfying the government's requirements for disclosure of misconduct and refunds of overpayments. The attorney-client privilege and the attorney work privilege are important protections that the POL should not forfeit, say legal experts.

Medicare Compliance for Clinical Laboratories, published by Washington G-2 Reports, provides detailed information about the OIG Model Code of Conduct and Medicare billing compliance.

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