



# FAST FACTS 3

## FINAL STARK I REGULATIONS

### **When Were the Final Regulations Published?**

On August 14, 1995, the Department of Health and Human Services (HHS) published final regulations implementing the Stark law. The Stark I law was enacted in 1989 and effective January 1, 1992. The law prohibits physicians from referring their patients to a laboratory with which they or an immediate family member has an ownership or compensation arrangement.

### **Does the Federal Law Apply to All My Laboratory Referrals?**

No. The federal prohibition on referrals applies to Medicare and Medicaid beneficiaries only, not patients covered by other third-party private insurance. You should, however, check with your local state medical or specialty society organization regarding any possible state laws which prohibit referrals to laboratories in which you have an ownership. For example, state self-referral bans in California and New York apply to all payers, not just Medicare and Medicaid.

### **Are Any Referrals Exempt from the Ban?**

Yes, in-office ancillary testing. In 1989 Congress provided a key exemption from the ban on referrals when it established the law—the ban does not apply to “in-office ancillary laboratory services.” This exemption was written into the law so that solo-practicing physicians and group practices could continue to provide convenient in-office testing to their patients.

### **What is the Definition of In-Office Ancillary Services?**

In-office ancillary services are defined by the law as services which are personally performed by one of the following:

- The referring physician; or
- A physician who is a member of the same group practice as the referring physician; or
- An individual who is directly supervised by the referring physician or, in the case of group practices, by another physician member of the same group practice. “Directly supervised” is defined as on-site and immediately available during testing.

In addition, to qualify for the in-office ancillary exemption, the laboratory services must be provided in the same building as the referring physician, or in the case of group practices, in the same building as the practice or another building that is used by the group practice for providing ancillary services.

Finally, laboratory services billed to Medicare and Medicaid must be billed by the referring physician, the group practice of which the referring physician is a member or by an entity that is wholly owned by the physician or the physician’s group practice.

### **What Does Direct Supervision Mean?**

In order to meet the direct supervision requirement the physician must be present in the office suite and be immediately available to provide assistance to the technician during the time testing is being performed for his or her patients.

### **What Additional Criteria Must Group Practices Meet to Qualify for the Exemption?**

If a group practice wants to qualify for the exemption, it must meet the following criteria:

- Be legally-organized as a partnership, professional corporation, foundation, not-for-profit corporation or similar association;
- Substantially all (defined by the new regulations as at least 75 percent) of the patient care services of the group practice members must be furnished through the group;
- Patient care services (meaning more than just laboratory) must be billed in the name of the group; and
- Amounts received treated as receipts of the group.

### What About Shared Labs?

Although HHS does not establish a specific exemption for shared laboratories, the Agency does clarify that certain shared laboratory arrangements could qualify for the general in-office ancillary exemption discussed above. To qualify for the in-office ancillary exemption each physician involved in the arrangement must comply with the location, direct supervision and billing criteria of the in-office ancillary exemption.

HHS gives the following example of an arrangement that would qualify:

- Physicians A, B and C each have their own practices in the same building,
- Each physician “directly” supervises the laboratory staff during testing for his or her patients, and
- Each physician bills individually for the services provided.

HHS gives the following example of an arrangement which would not qualify:

- Ten individuals have their own practices on different floors and the laboratory they share is located in the basement;
- The physicians do not directly supervise the laboratory staff when testing is performed on their own patients; and
- The laboratory itself bills Medicare or Medicaid.

This arrangement is problematic on two counts:

- 1) According to HHS, the fact that the physicians involved in the shared laboratory arrangement are not on the same floor as the laboratory makes it difficult for the physicians to directly supervise laboratory staff.
- 2) The laboratory (rather than the individual physicians) bills Medicare and Medicaid.

### Are There Special Provisions for Rural Laboratories?

Yes. The law also exempts from the referral ban physician ownership and referral to laboratories located in rural areas (defined as located outside a Metropolitan Statistical Area). To qualify for the rural exemption, at least 75 percent of the clinical laboratory services must be furnished to individuals who reside in a rural area.

### Does HHS Plan to Retroactively Enforce the New Regulations?

Yes and no. HHS has the authority to retroactively enforce the Stark law. However, HHS states in the final rule that “any sanctions that can only be applied as a result of clarification or interpretation of the statute through this rule will, of course, be applied on a prospective basis beginning with the September 13 effective date of the final regulations.”

Given the need for regulatory guidance on the shared lab issue, COLA understands that HHS will not retroactively sanction physicians in shared laboratories for any prohibited referrals associated with the shared laboratory arrangement.

### Other Issues?

There are numerous complexities associated with the final regulations. Not addressed here are the general exceptions for compensation arrangements, additional exceptions for certain ownership/investment arrangements and state referral laws which may affect your practice. Before making any business decisions intended to respond to the final Stark I regulations, physicians are encouraged to talk with their attorney and their national medical or specialty society organization for more information. COLA is not able to give legal advice!

### How Should I Register My Shared Laboratory for CLIA or COLA?

Publication of the final Stark regulations does not change the way HCFA certifies shared laboratories. Like COLA, HCFA certifies the laboratory, not the individual practices involved in the shared laboratory arrangement. Shared laboratories apply for one CLIA number, receive one biennial on-site survey and must only enroll in proficiency testing one time.

For more information about shared laboratories, please call the COLA Information Resource Center at (800) 981-9883 to request a complimentary copy of CLIA Fact Sheet #4, “How To Register Your Shared Laboratory With HCFA.” It can be faxed to you the same day.