



HOW TO PROPERLY REGISTER YOUR SHARED LABORATORY WITH CMS

Shared laboratories generally involve two or more independently practicing physicians who share the costs of laboratory equipment and staff, with each physician billing separately for the tests they perform for their own patients.

The Centers for Medicare and Medicaid Services (CMS) has released guidelines to its regional offices and state survey offices about shared laboratories and CLIA numbers. Shared laboratories in New York must be state-licensed and are considered independent laboratories.

Over the past few years, physicians involved in shared laboratories have registered in a variety of ways with CMS for CLIA purposes. Some physicians involved in shared laboratories registered separately, obtained their own CLIA numbers, and enrolled in proficiency testing (PT) multiple times for the same laboratory. Others filed jointly and requested that the laboratory be considered as a single site for CLIA certification purposes.

Current CMS policy requires shared laboratories to obtain a single CLIA number. Shared laboratories must designate one physician as the laboratory director. The laboratory will be subject to a single biennial inspection, will pay one compliance fee, and will only be required to enroll in proficiency testing one time.

To file an amended CMS-116 form for your shared laboratory you must do the following:

1. Obtain a new CMS-116 form on-line or from your state survey office.
2. In "Section VIII - Nonwaived Testing" use the total nonwaived test volume for all the physicians using the laboratory for their patients when calculating the "Annual Test Volume" for each specialty/sub-specialty (do not count quality control tests and PT specimens). Also, check the boxes for all the specialties/subspecialties performed by the physicians using the laboratory. In Section XII - Individuals Involved in Laboratory Testing include the total number of laboratory personnel involved in the laboratory.
3. Write the words "shared laboratory" in bold letters across the top of the CMS-116 form
4. Designate one physician as the laboratory director and use his/her CLIA number and federal tax identification number (if applicable) to complete

"Section I - General Information" of the CMS-116 form. The designated laboratory director should sign the newly completed 116 form.

5. Attach a cover letter indicating the names and CLIA numbers of the additional physicians involved in the shared laboratory arrangement.
6. In the cover letter, include the name and telephone number of the contact person in your office in case the state survey agency has questions.
7. Send the amended form and cover letter to your state survey agency.
8. Send a copy to your accreditation organization if you are accredited, or in the process of obtaining accreditation.
9. Retain a copy of the form and letter for your records.

Your laboratory will then receive a primary CLIA number for the shared laboratory to be used by all the physicians for billing Medicare and Medicaid. Your individual CLIA numbers will be terminated. It is important that you contact your PT program and, if accredited, your accreditation organization to provide them with your primary CLIA number.

Shared laboratories which do not file an amended CMS-116 form will be asked to complete the form during their next biennial on-site inspection.

One clarifying point: physicians who perform testing in their own office in addition to utilizing the shared laboratory must also register their own laboratory for CLIA purposes. For example, if physicians perform waived testing in their own office in addition to utilizing the shared laboratory for more extensive laboratory work, they have to obtain a certificate of waiver.

This fact sheet does not address issues related to billing practices for shared laboratories. Proper registration under CLIA does not exempt laboratories from the referral prohibition under the Stark law. Physicians involved in shared laboratory arrangements should review the final Stark regulations to make sure they are in compliance with the law.

COLA has developed an informative Fast Facts on the final Stark regulations which may be helpful--*Fast Facts #3 -- Final Stark Regulations.*