



COLA APPROVED IN PENNSYLVANIA

Effective July 1997, the State of Pennsylvania officially approved COLA under its laboratory licensure program. This approval, coupled with COLA's approval under the federal CLIA requirements, means that laboratories in Pennsylvania can comply with both CLIA and State laboratory licensing standards by obtaining COLA accreditation.

Since 1975, the State of Pennsylvania has required solo-practicing physicians, group practices, independent laboratories, community hospitals, and ambulatory facilities to obtain a State license to operate a laboratory.

Prior to 1997, laboratories enrolled with COLA for CLIA compliance were also subject to a State survey to determine compliance with the State's requirements.

To simplify this duplicative survey process, COLA and the Pennsylvania Department of Health, with the strong support of the Pennsylvania Society of Internal Medicine, the Pennsylvania Academy of Family Physicians, and other physician organizations in the state of Pennsylvania worked together to change the process. This shared commitment led to COLA's approval in the state.

Benefits of COLA

COLA's accreditation program offers physicians these key benefits:

1. The opportunity for each laboratory to conduct a comprehensive Self-Assessment questionnaire to help prepare for the COLA on-site survey. COLA evaluates the completed Self-Assessment and responds quickly to the laboratory with an educational step-by-step plan to improve your lab's quality if deficiencies are found. You can then correct deficiencies before the on-site survey.

2. On-going support from our staff of trained medical technologists accessible through the COLA Information Resource Center toll-free number.
3. Timely and reliable information regarding regulations related to laboratory testing and practice-based medicine, including OSHA, the Stark Amendments (i.e., self-referral issues), and others, not just CLIA and State regulations.
4. Easy-to-use educational and technical materials to assist physicians in conducting good laboratory practices and in meeting COLA standards.
5. A competitive edge in the managed care environment in which demonstrating quality is increasingly important to laboratories.
6. COLA's Board of Directors are practicing physicians who set policies that are sensitive to the needs of their peers. Because COLA is a physician-directed, physician-run organization, you can be assured that our standards are fully compliant with CLIA requirements while they fairly promote good laboratory practice.

Is Cost a Concern?

COLA May Be Less Expensive!

COLA's laboratory accreditation program is less expensive or, at a minimum, cost-competitive for most laboratories. COLA accredits physician office laboratories, independent laboratories, community hospitals, and ambulatory facilities.

COLA accreditation offers many value-added benefits that will save you time and money in establishing and maintaining a quality laboratory.

Pennsylvania state licensure fees are based upon the following fee schedule. Level I laboratories do not pay any state fees. Level II laboratories pay a \$25 state application fee. Only Level III (most complex) laboratories are subject to a state license fee of \$100 per specialty, per year.

To find out what your savings might be with the COLA accreditation and education program, please call us toll-free at (800) 981-9883.

Questions and Answers about the COLA Accreditation Program in Pennsylvania

Q: If I'm accredited with COLA, will I continue to be regulated under two systems?

A: YES. Your laboratory will continue to be subject to both CLIA and State regulations. However, COLA's agreement with the State will help to reduce your regulatory burden. Because COLA-accredited laboratories are deemed by CMS to be in compliance with CLIA, and are approved under the State's laboratory licensure program, COLA's survey of your lab will satisfy the routine on-site survey element of both the CLIA and State regulations. (Note: 2.5% of accredited labs are surveyed each year by the State as part of COLA's validation with CMS. COLA can provide helpful information in the small likelihood your laboratory is chosen for a validation survey.)

Q: Can I switch to COLA if I've already paid my CLIA fees?

A: YES. You can switch to COLA accreditation with no penalty at all. Officials with the CLIA program have assured us that labs that have paid their CLIA compli-

ance fees but have not yet received their next inspection can have those fees refunded. In order to switch to COLA, all you'll need to do is fill out our simple, half-page application, then notify the Pennsylvania Bureau of Laboratories in writing of your intention to seek accreditation with COLA and request a refund of applicable fees. The Bureau of Laboratories can be contacted at P.O. Box 500, Exton, PA, 19341-0500, telephone (610) 363-8500. If you have questions regarding switching to COLA, please call our Information Resource Center toll-free at (800) 981-9883.

Q: Why should I switch to COLA?

A: With state approval, physicians in Pennsylvania will reap the full benefits of COLA accreditation. COLA's commitment to physician education and promoting quality laboratory medicine are greatly augmented by a positive and proactive working relationship with the State.

Q: Where can I call if I have questions?

A: Please call us if you have any questions about COLA's approval in Pennsylvania or would like to see if COLA accreditation is the right option for you. Our expert team is available to help you toll-free at (800) 981-9883.