

The New Laboratory Director Accreditation Guidelines:

*What Every Hospital Administrator
Needs To Know*



May 11-12, 2006
Hyatt Regency O'Hare Hotel
Rosemont, IL.

sponsored by



Health Care Development Services, Inc.

The conference faculty welcomes you to a comprehensive review of newly focused accreditation guidelines for Laboratory Directors in hospital and healthcare system settings. Not since the development of federal CLIA regulations have hospital administrators needed to be alerted to assure that Laboratory Director responsibilities are appropriately apportioned, and that hospital policies, protocols, and contracts relating to the Laboratory Director position do not pose any risk or liability for the hospital.

**FINAL CLIA RULES
RESOURCE BOOK**

Provided by
American Hospital Association
and
Health Care Development
Services, Inc.
1988

A recent series of events produced a large number of questionable hospital laboratory test results, compromised quality control checks and balances, and generated subsequent accreditation organization, and state and federal investigations. Those events resulted in significant changes in how certain accrediting organizations inspect and evaluate hospital laboratories. In addition to now performing unannounced inspections, each accreditation organization will more carefully assess the role and responsibilities of the Laboratory Director as the individual ultimately responsible for overall laboratory quality. Conference attendees will learn how CAP, CLIA, JCAHO, and state Departments of Health inspectors will evaluate the Laboratory Director's role and responsibilities, as well as how these organizations will examine the effectiveness of tasks apportioned to appropriate laboratory staff.

These specific, detailed inspection guidelines also mean more risk and regulatory compliance. Conference attendees will learn from the former General Counsel of the American Hospital Association how the accreditation guidelines for Laboratory Director pose potential liability to hospitals including possible sanctions and whistleblower activity. Other legal topics to be presented include essential contractual issues that must be negotiated for hospital Laboratory Director relationships.

The faculty member representing the Clinical Laboratory Management Association (CLMA) will discuss her organization's position regarding the development of partnerships to share many of the Laboratory Director responsibilities. The faculty member who represents the American Association for Clinical Chemistry (AACC) will review circumstances where specially certified PhDs may be appointed to the hospital Laboratory Director position. Since CLIA regulations provide for the delegation of many Laboratory Director responsibilities, hospital and healthcare system faculty will share their real world experiences of how hospital administrators, Laboratory Directors, Administrative Laboratory Directors, and supervisory personnel have forged effective, successful organizational relationships to provide Laboratory Director services and meet regulatory and accreditation standards.

We hope you can join us for this timely and important educational conference.

Who Should Attend

The authority to assure appropriate Laboratory Director responsibilities ultimately resides with hospital administrators in a joint effort with laboratory administrators and Directors. Therefore, team attendance is encouraged. Hospitals and healthcare systems will benefit from attendance by:

- Chief Operating Officers
- VP's Professional/Ancillary Services
- Laboratory Medical Directors/Pathologists
- Administrative Laboratory Directors
- PhDs
- Healthcare System Legal Counsel
- Consultants

Thursday, May 11th » Day One Morning

7:30 am – 8:30 am **Registration and Continental Breakfast**

8:30 am **Welcoming Remarks and Industry Overview**

- *Describe industry factors that influenced expansion of accreditation guidelines for Laboratory Directors.*
- *Review how Laboratory Director delegated responsibilities affect hospital laboratory organizational reporting relationships.*
- *Summarize potential liability and contract issues that impact hospitals and pathology groups.*

Mr. Barry Portugal

President

Health Care Development Services, Inc.

**The Accreditation Organizations' Perspective:
Laboratory Director Accreditation Guidelines**

- *Describe factors that influenced expanding criteria for Laboratory Director role and responsibilities.*
- *Explain how surveyors will evaluate the effectiveness of Laboratory Director delegated responsibilities.*
- *Summarize key Laboratory Director responsibility deficiencies found during inspections, and give examples of successful plans of correction.*

9:15 am **The CLIA Experience With Laboratory Director
Role and Responsibilities**

Ms. Judy Yost

Director, Center for Laboratories

US Department of Health & Human Services

10:00 am **Break**

10:30 am **College of American Pathologist's Accreditation
Guidelines: Laboratory Director Role
and Responsibilities**

Bruce Williams, MD

Chair, Commission on Laboratory Accreditation

College of American Pathologists

11:15 am **The JCAHO Perspective:
Laboratory Director's Role and Responsibilities**

Ms. Margaret Peck

Executive Director of Laboratory Accreditation

Joint Commission on Accreditation of Healthcare Organizations

12:00 pm **Lunch**

Thursday, May 11th » Day One Afternoon

1:30 pm **Laboratory Directorship: A Functional Approach To Role and Responsibilities**

- *Review CLMA's position statement on laboratory managerial functions and duties.*
- *Review the relevancy of CLMA's position statement and functional approach to today's regulatory and operational environment.*
- *Identify alternatives in selecting an appropriate framework for laboratory directorship.*

Ms. JoAnne Milbourn

President Elect
Clinical Laboratory Management Association

2:15 pm **The Role of PhDs as Laboratory Directors**

- *Cite the professional qualifications required for PhD scientists to serve as Laboratory Directors of laboratories performing high complexity testing.*
- *Describe the approximate size of the resource pool and the key sources to use when a hospital administrator wishes to appoint a PhD as Laboratory Director of their institution's laboratory.*
- *Explain the necessary areas of experience and expertise of PhDs who are professionally qualified to serve as Laboratory Directors of laboratories performing high complexity testing.*

Stephen Kahn, PhD

Director of Laboratories
Loyola University Medical Center

3:00 pm **Break**

3:30 pm **The Hospital Laboratory Management Team: A Challenged Future**

- *Understand the future challenges to laboratory technology, workforce, demand, and financial issues.*
- *Describe the alignment of professional, programmatic, and system needs.*
- *Crafting of win-win-win solutions.*

Mr. John Duval

Chief Executive Officer
Medical College of Virginia

4:15 pm **Question and Answer Session**

5:00 pm **Adjourn**

5:30 pm **Reception**

Friday, May 12th » Day Two

7:00 am **Continental Breakfast**

8:15 am **Day One Review | Mr. Barry Portugal**

8:30 am **Notes From a Traveling Pathologist:
When You've Seen One Lab, You've Seen One Lab**

- *Recognize the role of the Laboratory Director in assuring compliance with accrediting and regulatory requirements.*
- *Understand the importance of effective, active communication between the Laboratory Director and hospital administrators, and between the Laboratory Director and the laboratory staff to achieve quality and regulatory compliance.*
- *Understand the need to identify institutional impediments that interfere with quality services or accreditation requirements and identify processes to remove impediments.*

Stanley Geyer, MD
Chairman of Pathology
Intermountain Healthcare
Urban Central Region Hospitals

9:30 am **Administrative Directors' Perspectives:
Delegated Laboratory Director Responsibilities**

- *Describe the negotiation process with the Laboratory Directors and hospital administrators.*
- *Differentiate Laboratory Director delegated responsibilities.*
- *Summarize an approach to trust building.*

Ms. Irina Lutinger
Senior Administrative Director, Clinical Laboratories
New York University Medical Center

Mr. Paul Spivey
Administrative Director of Pathology,
Laboratory Medicine, Imaging, and Infusion Clinic
Saint Mary's Hospital and Medical Center

10:30 am **Break**

11:00 am **Contract and Liability Issues Between
Hospitals and Laboratory Directors**

- *Understand current regulatory context within which clinical laboratory leadership issues arise.*
- *Understand liability risks and regulatory compliance. Focus includes understanding of continuing government focus on false claims liability, self-referral, anti-kickback, intermediate sanctions and whistleblower activity.*
- *Understand essential contractual issues that must be negotiated and memorialized in Laboratory Director relationships.*

Mr. Fred Entin
Partner
Foley & Lardner

12:00 pm **Question and Answer Session**

1:00 PM **Adjourn**

Hotel Accommodations

The conference will be held at the Hyatt Regency O'Hare Hotel, 9300 W. Bryn Mawr Avenue, Rosemont IL. The Hotel is just minutes from O'Hare airport. The hotel operates a complimentary shuttle every 15 minutes on the hour 24/7.

Sleeping rooms may be reserved directly with the Hotel by calling 800-223-1234. Be sure to say you're attending the "New Laboratory Director Accreditation Guidelines" conference to qualify for the special meeting rate of \$165 single or double (plus taxes). This rate applies from Wednesday, May 10 through Saturday, May 13, 2006. The deadline to guarantee the conference rate is April 19, 2006, providing group room block is not filled. If the room block is filled, rooms are subject to availability at regular rates.

Travel Arrangements

Frosch Travel of Deerfield, IL has been appointed the travel agency for this conference. Frosch Travel will offer airline reservations at the lowest applicable fare for refundable and non-refundable tickets. Frosch Travel will make travel arrangements, and will email confirmation of E-tickets. Please contact Ms. Pat Williams at 800-323-1276 from 9 AM to 5:00 PM CST, Monday – Friday. You may also contact Pat at pwilliams@froschtravel.com. Please specify you're attending The New Laboratory Director Accreditation Guidelines conference.

Continuing Education

AACC: This conference is approved by the American Association for Clinical Chemistry (AACC) for a maximum of 10 ACCENT Category 1 credits. ACCENT credits are also recognized by the state of California licensees and Florida for continuing education in clinical laboratory science.

ACHE: This program may be eligible for advancement or recertification by ACHE members.

CAP Accreditation: This conference has been planned and implemented in accordance with the Essential areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the College of American Pathologists (CAP) and Health Care Development Services, Inc. The College of American Pathologists is accredited by the ACCME to provide continuing medical education for physicians.

CME Designation: The CAP designates this educational activity for a maximum of 9.25 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in this conference.

P.A.C.E. Credit: Health Care Development Services, Inc. is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E. Program. This conference is approved for 11 contact hours of continuing education.

Special Needs

If you need assistance with special arrangements such as dietary restrictions or accessibility, please call us at 888-522-6747.

4 Easy Ways to Register

1. Online: at www.hcdsinc.com/seminar

3. Fax: 847-498-3264

2. Phone: 888-522-6747

4. Mail: Health Care Development Services, Inc.
3100 Dundee Rd Suite 116
Northbrook, IL 60062

Registrant Information

Name: _____

Title: _____

Organization: _____

Address: _____

City: _____ State: _____ Zip: _____

Email: _____ Phone: () _____

Fax: _____

Additional Registrants From the Same Institution:

Name: _____ Title: _____ Email: _____

1: _____

2: _____

3: _____

4: _____

Registration Fees

Early bird rates are available if the registration form and full payment are received by March 31.

Discounts are available for members of AACC, ACHE, APF, ASCLS, ASCP, CAP, CLMA, and HFMA.

Discounts are also available for two or more registrants from the same institution.

| Conference Rates | #Attendees | Early Bird <i>Before March 31</i> | Regular <i>After March 31</i> | Sub-Totals |
|---|-------------------|---|---|-----------------------|
| Initial Registrant | _____ | \$745 | \$795 | \$ _____ |
| Initial Registrant (Member of an organization listed above) | _____ | \$645 | \$695 | \$ _____ |
| Additional Registrants from same institution | _____ | \$545 | \$595 | \$ _____ |
| Audio CD/Handouts | _____ | *\$155 Audio CD of Speaker Presentations (if attending conference) | | \$ _____ |
| | _____ | *\$325 Audio CD of Speaker Presentations and Complete Set of Handouts (if not attending conference) | | \$ _____ |
| *Includes shipping | | | | Total \$ _____ |

Payment Information

Your registration will be confirmed only after payment in full has been received.

A check is enclosed, payable to Health Care Development Services, Inc.

I authorize you to charge: Visa Mastercard AMEX Discover

Card Number: _____ Expiration: _____

Print name as it appears on card: _____

Signature: _____

Policies

Cancellation Policy: Health Care Development Services, Inc. guarantees a refund, less a \$125 administration fee, if written notification is received on or before April 28. Verbal cancellations are not accepted. Cancellations received after April 28 are not eligible for refund. You may always send a substitute.

Confirmation Policy: All registrations will be confirmed within five business days of receipt of the registration form and payment. If you do not receive a confirmation, please call 888-522-6747. Please do not mail registration forms without payment.

For more information: Call 888-522-6747, or visit www.hcdsinc.com/seminar