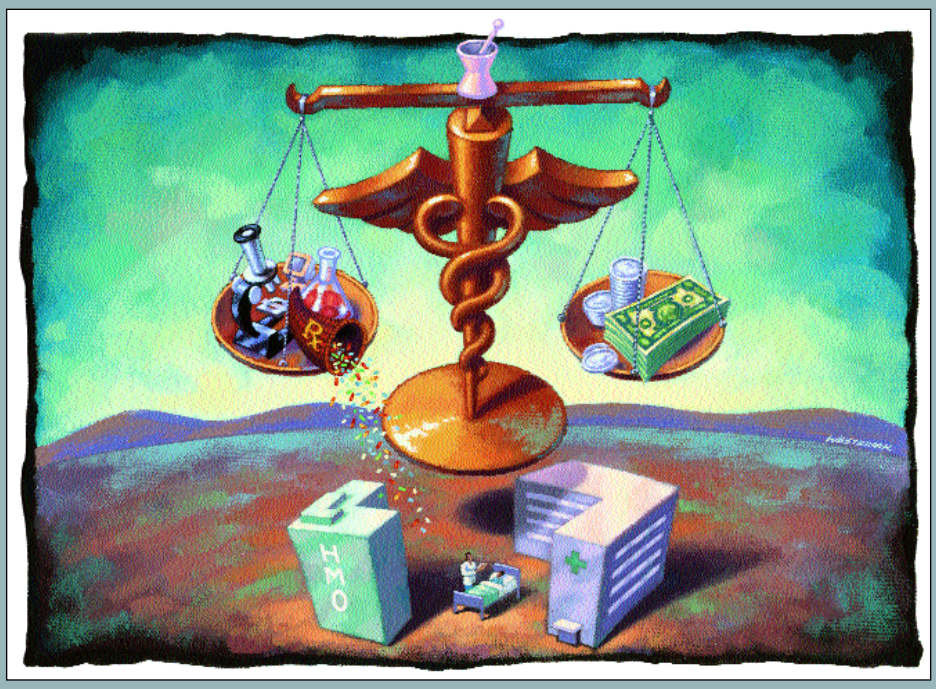
The Second Annual Pharmaceutical Industry Regulatory & Compliance Summit



June 10–12, 2001

Hyatt Regency Crystal City, Arlington, VA

Co-Sponsored by:
Health Care Compliance Association

HCCA

in association with the
Food and Drug Law Institute

FDLI

and *Medical Education Collaborative*
A Nonprofit Education Organization

Featured Speakers:

Anthony O. Boswell, Esq., Corporate Compliance Officer and Corporate Counsel, Laidlaw, Inc.

Charles M. Brock, Esq., Chief Ethics and Compliance Officer, AbbottLaboratories

Oliver M. Johnson, II, Esq., Chief Privacy Officer, Merck & Co., Inc

Paul E. Kalb, MD, JD, Partner, Sidley & Austin

Richard J. Kenny, Jr., Esq., Assistant General Counsel, AstraZeneca Pharmaceuticals, LP

Michael K. Loucks, Esq., Health Care Fraud Chief, United States Attorney's Office, District of Massachusetts

Douglas M. Lankler, Esq., Corporate Counsel, Compliance, Pfizer Inc.

Roger W. Louis, Esq., Chief Compliance Officer, Genzyme Corporation

John Markus, Esq., Senior Vice President, Fresenius Medical Care North America

Vickie McCormick, Esq., Integrity Officer, UnitedHealth Group

Michael B. McCulley, Esq., Assistant General Counsel, Johnson & Johnson

Joseph W. Metro, Esq., Partner, Reed Smith, LLP

Lewis Morris, Esq., Assistant Inspector General for Legal Affairs, Office of the Inspector General, US Department of Health and Human Services

Arjun Rajaratnam, Esq., Compliance Officer, Global Pharmaceuticals, GlaxoSmithKline

Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, HHS-OIG

Brent Saunders, JD, MBA, Director, PricewaterhouseCoopers and Founder, Privacy Officers Association

James Sheehan, Esq., Assistant United States Attorney, United States Attorney's Office, Eastern District of Pennsylvania

Arvin P. Shroff, Ph.D., Arvin Shroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration

Professor Malcolm K. Sparrow, Ph.D., Lecturer in Public Policy, John F. Kennedy School of Government, Harvard University

Robert L. Steinmeier, Corporate 21 CFR Part 11 Program Director, Abbott Laboratories

David Waterbury, Esq., Senior Counsel, Washington State Attorney General's Office, Medicaid Fraud Control Unit

This Program is Made Possible by an Unrestricted Educational Grant Provided by the Following Major Grantor:

PRICEWATERHOUSECOOPERS

The Second Annual Pharmaceutical Industry

The Issue

Over the past few years, the pharmaceutical industry has come under increased scrutiny from the federal government. The US Government and the FDA have begun to more rigorously enforce the rules and regulations that apply to the pharmaceutical industry. Until recently, the majority of the government's enforcement efforts have focused on health care providers. Now pharmaceutical companies are finding themselves under the gun. Pharmaceutical companies are being forced to update their knowledge of existing laws and incorporate them into their business plans as well as create future business plans that comply with the often ambiguous and confusing federal regulations. Critical issues such as drug pricing, sales and marketing practice, conducting clinical trials and a proposed Medicare prescription drug benefit are many topics that will be discussed at this important summit.

The Summit

The Second Annual Pharmaceutical Industry Regulatory and Compliance Summit has been established as a direct result of the heightened need for corporate compliance programs, increased government scrutiny and new regulations being imposed upon the pharmaceutical industry. It will bring together the nation's leaders in the pharmaceutical industry. This three-day conference, sponsored by the Health Care Compliance Association in association with the Food and Drug Law Institute will be held June 10-12, 2001, at the Hyatt Regency Crystal City, Arlington, VA.

Pharmaceutical professionals looking for a comprehensive understanding of the current and future compliance laws and regulations and enforcement initiatives affecting the pharmaceutical industry should plan to attend.

Sponsoring Organizations

The Second Annual Pharmaceutical Industry Regulatory & Compliance Summit is sponsored by:

The Health Care Compliance Association (HCCA), the 501(c)(6) association representing approximately 2000 of the nation's healthcare chief compliance officers. HCCA offers a number of programs. For more information on HCCA, call 1-800-580-8373 or go to the HCCA website at www.hcca-info.org.

In Association with the:

Food and Drug Law Institute (FDLI) is a non-profit institute dedicated to advancing the public health by providing a neutral forum for critical examinations of the laws, regulations, and policies related to drugs, medical devices, other healthcare technologies, and food. For more information call (800) 956-6293 or visit www.fdli.org.

Extensive Written Materials

The Faculty of the Summit will prepare written materials to accompany their presentations, including copies of presentation overheads, slides and related materials that will be included with the summit materials.

Who Should Attend:

Health Care Executives and Board Members
Health Plan, Health System and Physician Organization Medical Directors
Physicians
Pharmacists
Registered Nurses
Purchasers, including Private Employers and Public Purchasers
Pharmaceutical Manufacturers
Generic Pharmaceutical Manufacturers
Site Management Organizations
Clinical Research Organizations
Pharmacy Benefit Management Companies
Health Plans and Health Insurers
Wholesale, Retail, Mail Order and Internet Pharmacies
Health Care Attorneys and In-house Counsel
Compliance Officers
Privacy Officers
Ethics Officers
Pharmaceutical Consultants
Investment Bankers
Venture Capitalists
Health Care Regulators and Policy Makers
Health Services Researchers and Academics

Summit Goals and Objectives

At the conclusion of the Summit, attendees should be able to:

- Discuss the regulators' enforcement initiatives pertaining to the pharmaceutical industry.
- Explain how clinical trials should be conducted and build controls to mitigate potential risk.
- Relate to case studies that demonstrate how multinational corporations expanded their compliance programs to international operations.
- Take appropriate steps if a government investigation is initiated.
- Apply practical tips about implementing compliance programs in Pharmaceutical Companies.
- Understand the FDA labeling and advertising requirements and build compliance programs around those requirements.
- Appreciate the regulations and rules associated with government pricing of pharmaceuticals.
- Understand legal obstacles associated with promoting drugs on the internet and develop strategies to deal with them.
- Learn drug sample regulations and develop strategies for dealing with them.
- Gain appreciation for applicability of HIPAA statute to the pharmaceutical industry and learn compliance strategies.
- Learn the do's and don'ts of government pricing and develop necessary controls to bill medicaid.

Prerequisites: None

Save the Date: October 24 – 26, 2001

The 3rd Annual National Congress on the Future of Genomics, Biotechnology & Pharmaceuticals in Medical Care

Grand Hyatt Hotel, Washington, DC
www.PharmaCongress.com

Sunday, June 10th

Special Pre-Conference Symposia on Privacy

Privacy has become a key issue for lawmakers, regulators, class action lawyers and patients/customers alike. To protect against the possibility of significant reputational harm and financial liability, pharmaceutical and medical product companies need to take affirmative steps to comply with the wave of new rules and increasing regulatory scrutiny that is sweeping the industry.

1:00 - 5:00 pm **Three Sessions on Privacy for the Pharmaceutical Industry**

1:00 - 2:15 pm **The Impact of HIPAA's Privacy Requirements**
Alan S. Goldberg, Esq., *Partner, Goulston & Storrs, PC*

2:15 - 3:30 pm **Other Privacy Issues: EU Safe Harbor, State Laws and Class Actions**
Andrea Kahn-Kothmann, Esq., *Partner, Reed Smith, LLP*
Kerry Kearney, Esq., *Partner, Reed Smith, LLP*

3:30 - 3:45 pm **BREAK**

3:45 - 5:00 pm **How to Build an Effective Privacy Program**
Brent Saunders, JD, MBA, *Director, PricewaterhouseCoopers and Founder, Privacy Officers Association*
Oliver M. Johnson, II, Esq., *Chief Privacy Officer, Merck & Co., Inc.*

Monday, June 11th

8:00 am **WELCOME AND INTRODUCTION**

8:00 am **The OIG's Enforcement Initiatives in the Pharmaceutical Industry**
Lewis Morris, Esq., *Assistant Inspector General for Legal Affairs, Office of the Inspector General, US Department of Health and Human Services*

8:30 am **State Enforcement Initiatives in the Pharmaceutical Industry**
David Waterbury, Esq., *Senior Counsel, Washington State Attorney General's Office, Medicaid Fraud Control Unit*

9:00 am **A Federal Prosecutor's Perspective on the Pharmaceutical Industry**
James Sheehan, Esq., *Assistant United States Attorney, United States Attorney's Office, Eastern District of Pennsylvania*

9:30 am **Insights into the Department of Justice's Initiatives**
Michael K. Loucks, Esq., *Health Care Fraud Chief, United States Attorney's Office, District of Massachusetts*

10:00 am **FDA Enforcement Activities**
Arvin P. Shroff, Ph.D., *Arvin Shroff Associates and Former Deputy Director, Office of Enforcement, Food and Drug Administration*

10:30 am **Regulator Roundtable**
Lewis Morris, David Waterbury, James Sheehan, Michael K. Loucks and Arvin P. Shroff
Moderator: Michael Kendall, Esq., *Partner, McDermott, Will & Emery*

11:00 - 11:15 am **TRANSITION BREAK**

11:15am - 12:30 pm — CONCURRENT SESSIONS 1

101. Compliance Strategies under PDMA for Samples Management
Arjun Rajaratnam, Esq., *Compliance Officer, Global Pharmaceuticals, GlaxoSmithKline*

102. How to Conduct an Internal Investigation
Robert S. Litt, Esq., *Partner, Arnold & Porter and Former Deputy Assistant Attorney General, U.S. Department of Justice and Principal Associate Deputy Attorney General*
Mark D. Pollack, Esq., *Partner, Jenner & Block*

103. Issues and Compliance Strategies Related to Medicaid Pricing
Carolyn McElroy, Esq., *Mintz Levin Cohn Ferris Glovsky & Popeo and Former Director of the Medicaid Fraud Control Unit for the State of Maryland*

104. A Primer on Fraud and Abuse
Robert Fabrikant, Esq., *Partner, Sidley & Austin*

12:30 - 2:30 pm — **LUNCH AND PRESENTATIONS**

12:45 - 1:45 pm — **Perspectives on Health Care Fraud**
Professor Malcolm K. Sparrow, Ph.D., *Lecturer in Public Policy, John F. Kennedy School of Government, Harvard University*

1:45 - 2:30 pm — **Compliance Roundtable**
Arjun Rajaratnam, Esq., *Compliance Officer, Global Pharmaceuticals, GlaxoSmithKline*
Douglas M. Lankler, Esq., *Corporate Counsel, Compliance, Pfizer Inc*
Charles M. Brock, Esq., *Chief Ethics and Compliance Officer, Abbott Laboratories*
Roger W. Louis, Esq, *Chief Compliance Officer, Genzyme Corporation*

2:30 - 2:45 pm — **TRANSITION BREAK**

2:45 - 3:45 pm — CONCURRENT SESSIONS 2

201. Pharmaceutical Sales and Marketing Compliance
Anthony Farino, *Partner, PricewaterhouseCoopers*
Joseph W. Metro, Esq., *Partner, Reed Smith, LLP*

202. Compliance 101: Implementing an Effective Compliance Plan
Michael B. McCulley, Esq., *Assistant General Counsel, Johnson & Johnson*
Deborah A. Randall, Esq., *Member Health Group, Arent Fox Kintner Plotkin & Kahn, PLLC*

203. Compliance with FDA Labeling and Advertising Requirements
Richard J. Kenny, Jr., Esq., *Assistant General Counsel, AstraZeneca Pharmaceuticals, LP*
Peter S. Reichertz, Esq., *Partner, Arent Fox Kintner Plotkin & Kahn, PLLC*

204. Strategic Defenses to Pharmaceutical Investigations
Michael Kendall, Esq., *Partner, McDermott, Will & Emery*
Katherine A. Lauer, Esq., *Partner, Latham & Watkins*

3:45 - 4:00 pm — **TRANSITION BREAK**

4:00 - 5:00 pm — **Congressional Review of Pharmaceutical Marketing Practices**
Congressman John Shadegg (R-Ariz.), *United States Congress (invited)*

5:00 pm — **ADJOURNMENT AND NETWORKING RECEPTION**

Tuesday, June 12th

8:00 — **WELCOME**

8:00 - 9:15 am — **Lessons from Health Care Compliance**
John Markus, Esq., *Senior Vice President, Fresenius Medical Care North America*
Anthony O. Boswell, Esq., *Corporate Compliance Officer and Corporate Counsel, Laidlaw, Inc.*
Vickie McCormick , Esq., *Integrity Officer, UnitedHealth Group*
Moderator: Roy Snell, *Chief Executive Officer, Health Care Compliance Association*

9:15 - 9:30 am — **TRANSITION BREAK**

9:30 - 10:30 am

CONCURRENT SESSIONS 3

301. Compliance Strategies for Clinical Trials
Michele Russell-Einhorn, J.D., *Director, PricewaterhouseCoopers*
Leslie A. Platt, Esq., *Principal & Leader, Health Sciences Research Compliance Group, Ernst & Young, LLP*

302. The Global Impact of the Internet on the Pharmaceutical Industry
Keith Korenchuk, Esq., *Partner, DavisWrightTremaine and Chairperson for the Global Alliance for eCommerce Law*

303. Developing an Effective Compliance Training Program
Victoria Wesseler, *President, Ethics & Compliance Strategies*

304. Government Contracting Compliance
James P. Gallatin, Jr., Esq., *Partner, Reed Smith, LLP*
Robert M. Jenkins, III, Esq., *Partner, Mayer Brown & Platt*

10:30 - 11:00 am — **TRANSITION BREAK**

11:00 am - 12:00 pm

CONCURRENT SESSIONS 4

401. Compliance 202: Assessing the Effectiveness of your Compliance Program
Steven S. Diamond, Esq., *Partner, Arnold & Porter*
Paul J. Silver, *Director, Health Sciences Litigation Advisory Services, Ernst & Young, LLP*

402. Negotiating and Living Under a Corporate Integrity Agreement
Brent Saunders, J.D., M.B.A., *Director, PricewaterhouseCoopers and Founder, Privacy Officers Association*
Paul E. Kalb, J.D., M.D., *Partner, Sidley & Austin*

403. Responding to a Governmental Investigation: Record Retention, Search Warrants and Subpoenas, Grand Jury Representations and Settlement Strategies
Peter Crane Anderson, Esq., *Partner, Davis Wright Tremaine and Former Assistant United States Attorney*
Richard L. Cys, Esq., *Partner, Davis Wright Tremaine and Former Assistant United States Attorney*
David V. Marshall, Esq., *Partner, Davis Wright Tremaine and Former Assistant United States Attorney*
Charles P. Murdter, Esq., *Of Counsel, Davis Wright Tremaine and Former Trial Attorney, Department of Justice*

404. GxP Compliance for Computerized Systems
David L. Stone, *General Manager Validation Services, Glemser Technologies Corporation*

12:00 - 3:00 pm — **LUNCHEON AND PRESENTATIONS**

12:30 - 1:30 pm — **The Government's Use of Technology in Fraud and Abuse Control**
Richard P. Kusserow, *President, Strategic Management Systems, Inc. and Former Inspector General, Department of Health and Human Services*

1:30 - 3:00 pm — **Qui Tam Panel**
Mark A. Kleiman, Esq., *Partner, Mark Allen Kleiman*
Stephen L. Meagher, Esq., *Partner, Phillip & Cohen*
Zachary Bentley, *President, Venacare*
Moderator: Paul E. Kalb, J.D., M.D., *Partner, Sidley & Austin*

3:00 - 3:30 pm **TRANSITION BREAK**

3:30 - 4:30 pm

CONCURRENT SESSIONS 5

501. A Program for Compliance with 21 CFR Part 11
Patrick D. Roche, *Senior Manager, Global Risk Management Solutions, PricewaterhouseCoopers*
Robert L. Steinmeier, *Corporate 21 CFR Part II Program Director, Abbott Laboratories*

502. Building a Privacy Program
Stephen W. Bernstein, Esq., *Partner, McDermott, Will & Emery*
Roger W. Louis, Esq., *Chief Compliance Officer, Genzyme Corporation*

503. Conducting Compliance Risk Assessments: Issues & Strategies
Mary E. Riordan, Esq., *Senior Counsel, Office of Counsel to the Inspector General, HHS-OIG*
Ted Acosta, Esq., *Senior Manager, Litigation Advisory Services, Ernst & Young, LLP*

504. Public Sector Pharmaceutical Pricing Issues: VA, DOD, PHS and Medicaid
Frank M. Rapoport, Esq., *Partner, McKenna & Cuneo and Past Chairman, American Bar Association, Health Care Contracting Committee*

4:30 pm **CONFERENCE ADJOURNS**

Continuing Education Credits: Total credit hours include pre-conference

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Medical Education Collaborative and Health Care Conference Administrators, LLC. Medical Education Collaborative (MEC), a nonprofit education organization, is accredited by the ACCME to provide continuing medical education for physicians and takes responsibility for the content, quality and scientific integrity of this CME activity.

Medical Education Collaborative designates this educational activity for a maximum of 18.5 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Medical Education Collaborative, Inc. is approved by the American Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Medical Education Collaborative, Inc. has assigned 18.5 contact hours/1.85 CEUs of continuing pharmaceutical education credit. ACPE provider number: 815-999-01-021-L03

Participants will be required to sign in daily and complete an evaluation form for credit. Registration fee includes certificate, which will be mailed within six weeks after the meeting.

CNA (Nursing Credit) - This educational activity for 22.2 contact hours is provided by Medical Education Collaborative. Medical Education Collaborative is approved as a provider of continuing education in nursing by the Colorado Nurses Association, which is accredited as an approver of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation. Provider approved by the California BRN Provider Number CEP-12990 for 22.2 contact hours. Florida BN Provider Number: FBN-2773

ACHE - Medical Education Collaborative is authorized to award 18.5 hours of pre-approved Category II (non-ACHE) continuing education credit for this program toward advancement or re-certification in the American College of Healthcare Executives. Participants in this program wishing to have the continuing education hours applied toward Category II credit should list their attendance when applying for advancement or re-certification in ACHE.

ABA MCLE - Required sponsor documentation has been forwarded to and credit requested from most MCLE states with general requirements for all lawyers. We have requested a total of 18.5 CLE hours from most MCLE states. Lawyers seeking credit in Pennsylvania must pay fees of $1.50 per credit hour directly to the PA CLE Board. Medical Education Collaborative pays applicable fees in other states where the sponsor is required to do so, and in states where a late fee may become applicable. Please be aware that each state has its own rules regulations, including its definition of CLE; therefore, certain programs may not receive credit in some states. For information on approved credit hours for your state, please contact Medical Education Collaborative at (303) 278-1900 ext. 151 starting two to three weeks prior to the program date.

NASBA - Registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be addressed to the National Registry of CPE Sponsors, 150 Fourth Avenue North, Nashville, TN, 37219-2417. Telephone: 615-880-4200.

A maximum of 22 credits based on a 50-minute hour will be granted. Recommended experience level for this course is intermediate to advanced.

ACMPE – This program may qualify for continuing education credit in the American College of Medical Practice Executives (ACMPE). To apply for ACMPE credit, submit a generic credit hour form with a copy of the brochure. Forms will be available on-site.

HCCB - This program has been approved for 19 HCCB continuing education credits for compliance certification.

AHIMA - This program is pending approval of 18 CE credits for use in fulfilling the continuing education requirements of the American Health Information Management Association (AHIMA).

REGULATORY & COMPLIANCE SUMMIT

HOTEL ACCOMMODATIONS

Special rates of $179 (plus tax) per single per night, and $204 (plus tax) per double per night, have been arranged for the Second Annual Pharmaceutical Industry Regulatory & Compliance Summit. **There are a limited number of rooms available at the special rate.** Please make your reservations directly with the hotel and mention the Second Annual Pharmaceutical Industry Regulatory & Compliance Summit to receive the reduced rate. Reservations will be accepted until May 19, 2001. After that cut-off date, reservations will be accepted on a space-available basis only.
Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Reservations: 800-233-1234

AIRLINE TRAVEL

Get there for less! HCCA has selected Stellar Access, Inc. (SAI) as the official travel agency for this meeting. Call 1-800-929-4242 and ask for Group #551 to receive the following discounts or the lowest available fares on any other carrier:

American Airlines and US Airways: Save 5-10% on the lowest applicable fares. Applicable zone fares may apply. All rules and restrictions apply. Travel between June 5–17, 2001.

Call SAI: 1-800-929-4242, ask for Group # 551
Website: www.stellaraccess.com
NOTE: First time users must register and refer to Group # 551

- Lowest available fares on any airline
- Completely secure environment
- Book online! Pay NO transaction fee.
- $10 transaction fee will be applied to all tickets purchased via phone

Outside US & Canada, call 619-232-4298/fax 619-232-6497
Reservation Hours: M-F 6:30am – 5:00pm Pacific Time

If you call direct or use your own agency, refer to these codes:

American Airlines	1-800-433-1790	File# 13761
US Airways	1-877-874-7687	GF# 56651791

FAX OR MAIL REGISTRATION

Fax: 215-545-8107

Email: conference.office@hcca-info.org

No registrations will be accepted by phone.

Make payment by check (to Health Care Conference Administrators, LLC), MasterCard, Visa or American Express. A $20 fee will be charged on any returned checks. Purchase orders must be paid by the conference date or payments will be required by the individual on site.

Groups: Have registration and credit card information for each person. List all group members on FAX cover sheet.

CANCELLATIONS/SUBSTITUTIONS: Registration fees are not refundable, but are transferrable to a person in the same company. Please contact the Conference Office at 1-800-546-3750.

ASSOCIATION MEMBERSHIP OPTION: For an additional $50 you may join the Health Care Compliance Association with a trial membership for four months.

❑ Yes, add $50 to my registration, I would like to become a member of HCCA.

REGISTRATION FORM

❑ To May 22 (Early Bird) $995
❑ After May 22 $1,095

Subtract discount if applicable:
❑ HCCA Member $100
❑ Group Discount (two or more from same company) $100

To join HCCA for one year, add to your NON-MEMBER registration:
❑ HCCA Membership Option $50

TOTAL PAYMENT $

Please type or print

First Name Last Name

Degrees Title

ACHE Credentials: ❑ CHE ❑ FACHE

Place of Employment

❑ Work Address or ❑ Home Address (List only preferred mailing address)

Address

City State Zip

Daytime Phone ( ) Fax ( )

Years in Compliance Position

Areas of Most Interest/Compliance Focus

❑ Special Disability Needs

First name as it will appear on your badge

Group discount available when two or more register from same organization. Save $100 on second and all other registrations.

FOR FURTHER INFORMATION

Call 1-800-546-3750, Monday-Friday, 9AM – 5PM Eastern Time

REGISTER TODAY!

Fax: 215-545-8107
Or mail this form with correct tuition fee (U.S. funds) to:
Conference Office, 1211 Locust Street, Philadelphia, PA 19107

PAYMENT TERMS

Please enclose payment with your registration and return it to the conference registrar at the above address, or fax your credit card payment to 215-545-8107. No registrations will be accepted by phone.

❑ Check/money order enclosed
(checks payable to Health Care Conference Administrators, LLC)
❑ American Express ❑ Visa ❑ MasterCard

Account No.

Name of Cardholder

Signature Exp. Date /

TAX DEDUCTIBILITY

Expenses of training, including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession, may be tax deductible. Consult your tax advisor.
Federal Tax ID: 91-1892021.

Conference Office
1211 Locust Street
Philadelphia, PA 19107

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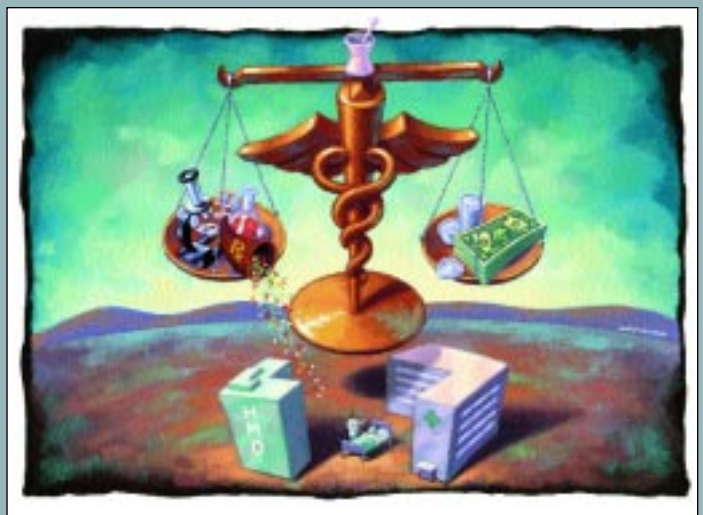

Continuing Education Credits Available: ACCME, ACPE, AHIMA, CNA, ACHE, ABA MCLE, NASBA, ACMPE, HCCB