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# *Tenth Anniversary 340B Coalition Conference*

on Improving Access to Pharmaceutical Care and Ensuring  
Compliance with Federal and State Laws

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July 17-19, 2006  
Omni Shoreham Hotel  
Washington, DC

## AGENDA

### SUNDAY, JULY 16, 2006

- 2:00 – 6:00 pm            Exhibitor Set Up  
(Ambassador Ballroom)
- 4:00 – 6:00 pm            Early Registration  
(West Registration)
- 5:30 – 8:30 pm            Welcome Reception and Dinner for DSH Hospitals\*  
(Palladian Room)

### MONDAY, JULY 17, 2006

- 7:00 am                    Registration and Exhibits Open 7:00 am – 5:15 pm  
(West Registration)  
(Ambassador Ballroom) Pre-Conference Workshop (Two Options)\*\*

#### Option 1 - A Detailed Introduction to the Federal 340B Drug Pricing Program

7:00 am                    Continental Breakfast (Workshop Attendees Only)  
(Ambassador Ballroom)

8:30 am                    A Detailed Introduction to the Federal 340B Drug Pricing Program  
(Palladian Room)

This session will provide an introduction to the 340B Drug Pricing Program and will include a review of the guidelines that govern the rights and obligations of 340B providers, manufacturers, wholesalers and state Medicaid agencies. Among the topics to be addressed are: definition of patient, covered outpatient drugs, contract pharmacies, inventory management, distribution procedures, 340B prime vendor program, pricing requirements, and compliance issues, especially with respect to diversion and Medicaid billing.

Ann Ferrero, Public Health Analyst, Office of Pharmacy Affairs

Harry Hagel, Senior Director, Pharmacy Services Support Center

Chris Hatwig, Senior Director, 340B Prime Vendor Program

Moderator: Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition

10:00 am                    Networking and Refreshment Break  
(Ambassador Ballroom)

10:30 am                    Session Continues

John Armitstead, Director of Pharmacy, University of Kentucky Hospital

Larry Pederson, Pharmacy Director, Family Medical and Dental Center

Donna Yesner, Partner, McKenna Long & Aldridge

Moderator: Claire Holloway Licastro, Attorney, Powers Pyles Sutter & Verville, PC and Counsel to Public Hospital Pharmacy Coalition

12:00 pm                    Networking Lunch (Workshop Attendees Only)  
(Blue Room)

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\* Please note this event is for DSH hospitals only. There is no additional cost to attend the event, but registration is required.

\*\* Please note there is an additional cost to attend the pre-conference workshop and registration is required.

## **Option 2 - A Detailed Introduction to Pharmaceutical Manufacturer Patient Assistance Programs**

**7:00 am**                    **Continental Breakfast (Workshop Attendees Only)**  
*(Ambassador Ballroom)*

**8:30 am**                    **A Detailed Introduction to Pharmaceutical Manufacturer Patient Assistance Programs**  
*(Diplomat Room)*

This session will provide an introduction to pharmaceutical manufacturers' Patient Assistance Programs (PAPs) which provide free or low cost drugs to low-income, uninsured people. The panel will outline the various elements of PAPs including eligibility requirements, dispensing processes, and auditing provisions. The panel will also summarize recent PAP guidance from the Department of Health and Human Services' Office of the Inspector General and will outline the basics of anti-kickback and beneficiary inducement laws. Panelists will discuss how hospitals and health centers have successfully integrated PAPs into their pharmacy care models and innovative programs offered by manufacturers.

**Tracy Foster**, Vice President and Chief Operating Officer, Lash Group  
**Debbie Nowlin**, Assistant Director of Pharmacy Services, Columbus Regional Healthcare System-The Medical Center

**Steven Zielinski**, Director of Pharmacy, Crusader Clinic

Moderator: **Kathryn Duke**, Program Director, Medicine for People in Need

**10:00 am**                    **Networking and Refreshment Break**  
*(Ambassador Ballroom)*

**10:30 am**                    **Session Continues**

**James Beckner**, Executive Director, Rx Partnership

**Anna Spencer**, Partner, Sidley Austin LLP

Moderator: **Mark Fitzgerald**, Principal, Powers Pyles Sutter & Verville, PC

**12:00 pm**                    **Networking Lunch (Workshop Attendees Only)**  
*(Blue Room)*

### *Commencement of Main Conference*

**1:00 pm**                    **Opening Remarks from 340B Coalition Hosts and Conference Leaders**  
*(Regency Ballroom)*

**Marcus Farbstein**, Director, Government Affairs, Genentech

**Freda Mitchem**, Senior Advisor, National Association of Community Health Centers

**Murray Penner**, Deputy Executive Director of Domestic Programs, National Alliance of State and Territorial AIDS Directors

**Derek Robertson**, General Counsel, Hemophilia Alliance, Inc.

**Bill von Oehsen**, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition

**1:30 pm**                    **Federal Government Update**

- Database management
- Covered entity certification and recertification
- Price verification activities
- Enforcement of anti-diversion and other compliance measures
- Collaboration with Pharmacy Services Support Center (PSSC) and 340B Prime Vendor Program

**Dennis Williams**, Deputy Administrator, Health Resources and Services Administration

**Jim Mitchell**, Director, Office of Pharmacy Affairs

**Harry Hagel**, Senior Director, Pharmacy Services Support Center

**Chris Hatwig**, Senior Director, 340B Prime Vendor Program

**3:15 pm**                    **Networking and Refreshment Break**  
*(Ambassador Ballroom)*

3:45 pm

## **Breakout Session for Various 340B Stakeholders**

Attendees have an opportunity to learn from and network with colleagues within their own industry or covered entity or government group. These breakout sessions are structured to foster open dialogue about the issues that matter most to each group.

**[PLEASE NOTE: THESE SESSIONS ARE LIMITED TO THE RESPECTIVE COVERED ENTITY, INDUSTRY OR GOVERNMENT GROUPS AND THEIR REPRESENTATIVES. FOR EXAMPLE, DSH HOSPITALS SHOULD NOT ATTEND THE PHARMACEUTICAL MANUFACTURER'S SESSION AND VICE VERSA.]**

*(Palladian Room)*

### **Disproportionate Share Hospitals**

- 340B Patient Definition
- Medicare Part D Status Report

**Scott Hughes, Vice President, Member Health, Inc**

**Claire Holloway Licastro, Attorney, Powers Pyles Sutter & Verville, PC and Counsel to Public Hospital Pharmacy Coalition**

**Edith Marshall, Special Counsel and Director of Legal Affairs, Public Hospital Pharmacy Coalition**

**Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition**

*(Diplomat Room)*

### **Pharmaceutical Industry**

- Measures to Increase Transparency in 340B Pricing
- Efforts to Ensure 340B Program Integrity

**Marcus Farbstein, Director, Government Affairs, Genentech**

**Chris Hatwig, Senior Director, 340B Prime Vendor Program**

**Jim Mitchell, Director, Office of Pharmacy Affairs**

*(Empire Room)*

### **Community Health Centers**

This breakout discussion session will provide an opportunity for health centers and their pharmacy partners to identify issues of concern to them, exchange information with each other, and identify potential solutions. The discussion will have a facilitator and resource persons familiar with 340B, pharmacy management, contracted pharmacy arrangements, and Medicare Part D who will respond to questions. Participants also will be encouraged to respond to questions and concerns and share information based on their own experiences.

**Freda Mitchem, Senior Advisor, National Association of Community Health Centers**

**Larry Pederson, Pharmacy Director, Family Medical and Dental Center**

**Roger Schwartz, Legislative Counsel, National Association of Community Health Centers**

**Carl Taylor, Pharmacy Director, Piedmont Health Services & Clinical Assistant Professor, Division of Pharmacotherapy, University of North Carolina**

*(Executive Room)*

### **State and Local Government**

**Karmen Hanson, Senior Policy Specialist, National Conference of State Legislatures**

**Andrea Maresca, Policy Associate, National Association of State Medicaid Directors**

**Tim Morley, Program Manager, Drug Utilization Review Board, Utah Medicaid**

**Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition**

**Bill Wood, Director of 340B Programs, University of Utah Health Sciences Center**

*(Cabinet Room)*

### **Hemophilia Treatment Centers**

Hear the latest developments in the 340B Program and how they will impact HTC's. Be a part of a discussion on just how HTC's are utilizing innovative strategies to stay competitive in a rapidly changing environment.

**Derek Robertson, General Counsel, Hemophilia Alliance, Inc.**

(Senate Room)

### **HIV/AIDS Clinics, ADAPs, and AIDS Service Providers**

- ADAPs, PAPs, and Part D
- How to determine the correct 340B price
- Identifying your wholesaler
- New HIV medications in the pipeline and their impact on costs

**Beth Crutsinger-Perry**, Program Manager, Care & Treatment Programs,  
National Alliance of State & Territorial AIDS Directors

**Murray Penner**, Deputy Executive Director of Domestic Programs, National  
Alliance of State and Territorial AIDS Directors

(Forum Room)

### **Family Planning Clinics**

Join other conference attendees from Planned Parenthood and family planning health center locations and organizations. Let's talk about how the 340B program has worked for you, share contact information, discuss your business needs and work through any questions you may have.

**John Barnes**, Senior Product Manager, 340B Prime Vendor Program

**Marilyn Keefe**, Vice President for Public Policy, National Family Planning &  
Reproductive Health Association

**Sue Speth**, Director of National Contracts, Planned Parenthood Federation of  
America, Inc.

**Emily Stewart**, Regulatory and Policy Analyst, Planned Parenthood Federation  
of America, Inc.

(Congressional Room)

### **Children's Hospitals**

- Update on HRSA efforts to implement participation of children's hospitals in 340B
- Guidance on qualifying and applying for 340B program
- 340B start-up tasks and challenges

**Ann Langley**, Senior Counsel for Public Policy, National Association of  
Children's Hospitals

**John Van Eeckhout**, Vice President, Clinical Services, Child Health  
Corporation of America

**Peters Willson**, Vice President for Public Policy, National Association of  
Children's Hospitals

5:15 pm

Conclusion

5:30 – 6:30 pm

Reception and Networking Opportunity

(Ambassador Ballroom and Bird Cage Walk)

## **TUESDAY, JULY 18, 2006**

7:00 am

Continental Breakfast – Exhibits Open

(Ambassador Ballroom)

8:00 am

340B Achievement Awards

(Regency Ballroom)

Presented to:

Senator Charles Grassley\*

Senator Edward Kennedy\*

Kathy Kovarcik, Office of Pharmacy Affairs

\*The awards for the Senators will be accepted by staff members

8:45 am

Legislative Update

- Update from Congressional staff and 340B experts
- Outlook for 2006 legislative activities
- Pending 340B legislation
- Medicare Part D, Deficit Reduction Act, Medicaid "best price" and other drug pricing issues

**Bruce Lesley**, Senior Health Policy Advisor, Office of U.S. Senator Jeff Bingaman  
**Rodney Whitlock**, Health Policy Advisor, Chairman Charles Grassley, U.S. Senate  
Finance Committee

Moderator: **Jonni McCrann**, Manager of Government Relations, Public Hospital  
Pharmacy Coalition

9:45 am                      **Networking and Refreshment Break**  
(Ambassador Ballroom)

10:15 am                      **Breakout Sessions (2 choices)**

(Palladian Room)

**(1) Future of Patient Assistance Programs**

- Various new models
- What programs pass legal muster?
- Key compliance issues
- Congressional efforts on PAPs

Dara Corrigan, Partner, Arnold & Porter LLP

Colette Desmarais, Health Policy Advisor, U.S. Senate Finance Committee

Mark Fitzgerald, Principal, Powers Pyles Sutter & Verville, PC

(Regency Ballroom)

**(2) Contract Pharmacies and Partnership Models**

- Update on 340B contract pharmacy program
- Multiple versus single contract pharmacy arrangements
- Recent alternative method demonstration projects
- New pharmacies guidelines allowing multiple contract pharmacies
- Partnerships with Medicaid, state and local government, etc.

Elaine Carroll, Patient Services Administrator, City of Austin Community  
Care Services Department

Jeff Lewis, President, Heinz Family Philanthropies

Moderator: Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC  
and General Counsel to Public Hospital Pharmacy  
Coalition

11:15 am                      **Breakout Sessions (2 choices)**

(Regency Ballroom)

**(1) Distribution Chain Issues**

- Wholesaler rights and responsibilities
- Role of specialty pharmacies in 340B program
- IVIG and other drug shortage problems
- Prime Vendor distribution arrangements

Marcus Farbstein, Director, Government Affairs, Genentech

Jerry Holmberg, Senior Advisor for Blood Policy, Advisory Committee on  
Blood Safety and Availability, U.S. Department of Health and Human  
Services

Thomas Schleis, Medical Affairs Manager, Octapharma

Patrick Schmidt, President and CEO, FFF Enterprises

Moderators: Chris Hatwig, Senior Director, 340B Prime Vendor Program  
Edith Marshall, Special Counsel and Director of Legal Affairs,  
Public Hospital Pharmacy Coalition

(Palladian Room)

**(2) Medicaid Billing**

- Impact of Medicaid rebate program expansion to include physician-administered drugs
- Protecting against duplicate discounts
- Enhanced dispensing fee arrangements
- Working with state Medicaid agencies

James Hardy, Deputy Secretary of Medical Assistance Programs,  
Pennsylvania Department of Public Welfare

Craig Rodenhizer, President, The Rodenhizer Group

Roger Schwartz, Legislative Counsel, National Association of Community  
Health Centers

Moderator: Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC  
and General Counsel to Public Hospital Pharmacy  
Coalition

12:30 pm                      **Lunch and Networking Opportunity**  
(Blue Room and Blue Room Prefunction)

**1:30 pm**  
*(Regency Ballroom)*

### **Federal Government Investigations and Recommendations**

- Presentation by OIG about October 2005 report on the 340B program and forthcoming report assessing pricing problems
- HRSA and CMS response to recommendations
- Presentation on recent report about AIDS Drug Assistance Programs (ADAPs) and 340B pricing

**Marcia Crosse, Director, Health Care, Government Accountability Office**

**Madeline Francescatti, Program Analyst, Office of Inspector General**

**Jim Mitchell, Director, Office of Pharmacy Affairs**

**Murray Penner, Deputy Executive Director of Domestic Programs, National Alliance of State and Territorial AIDS Directors**

**Moderator: Edith Marshall, Special Counsel and Director of Legal Affairs, Public Hospital Pharmacy Coalition**

**2:45 pm**

### **Impact of the Deficit Reduction Act of 2005 on the 340B Program**

- Disclosure of average manufacturer price (AMP)
- Clinic-administered drugs and 340B duplicate discount risks
- Nominal pricing changes
- Drug payment reform
- 340B participation by children's hospitals

**Deirdre Duzor, Director, Medicaid Pharmacy Program, Centers for Medicare & Medicaid Services**

**Bill von Oehsen, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition**

**Moderator: Freda Mitchem, Senior Advisor, National Association of Community Health Centers**

**3:45 pm**  
*(Ambassador Ballroom)*

### **Networking and Refreshment Break**

**4:15 pm**

### **Topic Oriented Breakout Sessions (5 choices)**

These breakout sessions focus on the value that 340B and patient assistance programs bring to different patient populations. Participants can choose from among a variety of sessions that focus on how 340B providers, state and local government and/or the private sector are expanding access to needy patient populations through innovation and collaboration.

*(Diplomat Room)*

#### **(1) Innovative Use of PAPs to Expand Access**

- Systems and software to better handle individual PAP applications
- Creating and maximizing use of replenishment, "institutional PAP" programs
- Statewide models for nonprofit provider-pharmaceutical manufacturer partnerships

**Larry Atkins, Senior Director of Public Policy & Reimbursement, Schering Plough**

**Bill Shearer, President, The Franklin Group**

**Ken Trogdon, Executive Director, Communicare**

**Moderator: Kathryn Duke, Program Director, Medicine for People in Need**

*(Regency Ballroom)*

#### **(2) Optimizing Use of 340B**

- Full implementation using split billing software
- Helping community health centers, family planning clinics and other non-hospital providers in extending 340B to all settings
- Working with the Prime Vendor program and your wholesaler to maximize value

**Patrick Barnes, Pharmacy Manager, Shands Jacksonville Medical Center**

**Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center**

**Carl Taylor, Pharmacy Director, Piedmont Health Services**

**Moderator: Chris Hatwig, Senior Director, 340B Prime Vendor Program**

*(Executive Room)*                    **(3) Maximizing 340B in Rural Communities to Expand Access and Improve Care**

- Identify new strategies that go beyond using samples and patient assistance programs (PAPs)
- Benefits of tele-pharmacy
- Economies of scale in building networks with other safety net providers

**Bill Adrian**, President, Pharmacy Group Practice Associates  
**Michael Holmes**, Chief Executive Officer, Cook Area Health Services

Moderator: **Claire Holloway Licastro**, Attorney, Powers Pyles Sutter & Verville, PC and Counsel to Public Hospital Pharmacy Coalition

*(Palladian Room)*                    **(4) Clinical Pharmacy Success Stories and New Opportunities in Medication Therapy Management**

- Learn how MTM improves outcomes
- Case studies on developing MTM programs that work
- Working with physicians, nurses and other caregivers in building a successful MTM team

**Sarita Doshi**, Director of Pharmacy Clinical Programs, Whitman-Walker Clinic

**Melinda Joyce**, Director of Pharmacy, The Medical Center at Bowling Green

Moderator: **Lori Bickel**, Director of Policy, Pharmacy Services Support Center

*(Congressional Room)*                    **(5) Expanding Access to Care Through Public/Private Collaboration**

- Partnering with government, local businesses, media and others in the community to expand pharmacy access
- Fundraising strategies in the private sector
- How to maximize 340B and PAPs within the community

**JoAnn Pearson Knox**, Executive Director, Campbell Hoffman Foundation  
**Linda Pepper**, President and Chief Executive Officer, Pepper Consulting Services

Moderator: **Harry Hagel**, Senior Director, Pharmacy Services Support Center

**5:30 – 6:30 pm**                    **Reception and Networking Opportunity**  
*(Ambassador Ballroom and Bird Cage Walk)*

**WEDNESDAY, JULY 19, 2006**

**7:00 am**                                **Continental Breakfast – Exhibits Open**  
*(Ambassador Ballroom)*

**8:00 am**                                **Breakout Sessions (2 choices)**

*(Regency Ballroom)*                    **(1) 340B/Medicaid Pricing Investigations and Dispute Resolution Models**

- Federal and state investigations
- Innovative resolutions to pricing disputes
- 340B lawsuits against manufacturers

**Alice Valder Curran**, Partner, Hogan & Hartson  
**Jim Mitchell**, Director, Office of Pharmacy Affairs  
**Mary Riordan**, Senior Counsel, Office of Counsel to the Inspector General  
Moderator: **Edith Marshall**, Special Counsel and Director of Legal Affairs, Public Hospital Pharmacy Coalition

*(Palladian Room)*

## **(2) Medicare Part D Status Report**

- Pharmacy contracting challenges and solutions
- Any willing pharmacy provisions
- TrOOP issues and coverage gap challenges
- Formulary management

**Frank McCree**, Director of Outpatient Pharmacy Services, Carolinas Healthcare System

**David Schwartz**, Professional Health Staff, U.S. Senate Finance Committee

**Roger Schwartz**, Legislative Counsel, National Association of Community Health Centers

Moderator: **Freda Mitchem**, Senior Advisor, National Association of Community Health Centers

9:15 am

*(Regency Ballroom)*

## **Patient Definition, Prescription Drug Marketing Act and Diversion**

- Investigations into allegations of provider drug diversion (U.S. v. Rudolph)
- Relationship between 340B anti-diversion provision and PDMA
- HRSA patient definition proposed clarifications
- Covered entity and industry reaction to proposed changes

**Michael Glomb**, Partner, Feldesman, Tucker, Leifer, Fidell LLP

**Derek Robertson**, General Counsel, Hemophilia Alliance, Inc.

**Joy Sturm**, Partner, Hogan & Hartson

Moderator: **Bill von Oehsen**, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition

10:30 am

*(Ambassador Ballroom)*

## **Networking and Refreshment Break**

11:00 am

*(Regency Ballroom)*

## **Ask the Experts**

Experts representing various stakeholder groups are available to take questions on any issue raised over the course of the conference. Questions may be asked in person or by written comment.

**Alice Valder Curran**, Partner, Hogan & Hartson

**Jim Mitchell**, Director, Office of Pharmacy Affairs

**Freda Mitchem**, Senior Advisor, National Association of Community Health Centers

**Derek Robertson**, General Counsel, Hemophilia Alliance, Inc.

**Bill von Oehsen**, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition

12:15 pm

## **Breakout Sessions for Various 340B Stakeholders\***

**[PLEASE NOTE: THESE SESSIONS ARE LIMITED TO THE RESPECTIVE COVERED ENTITY, INDUSTRY OR GOVERNMENT GROUPS AND THEIR REPRESENTATIVES. FOR EXAMPLE, DSH HOSPITALS SHOULD NOT ATTEND THE PHARMACEUTICAL MANUFACTURER'S SESSION AND VICE VERSA. BOX LUNCH WILL BE SERVED.]**

*(Regency Ballroom)*

## **Disproportionate Share Hospitals**

- Further discussion of key issues from conference
- Enrolling new DSH clinics in the 340B program

**Claire Holloway Licastro**, Attorney, Powers Pyles Sutter & Verville, PC and Counsel to Public Hospital Pharmacy Coalition

**Edith Marshall**, Special Counsel and Director of Legal Affairs, Public Hospital Pharmacy Coalition

**Bill von Oehsen**, Principal, Powers Pyles Sutter & Verville, PC and General Counsel to Public Hospital Pharmacy Coalition

*(Diplomat Room)*

## **Pharmaceutical Industry**

- Further discussion of key issues from conference

**Alice Valder Curran**, Partner, Hogan & Hartson

**Marcus Farbstein**, Director, Government Affairs, Genentech

(Palladian Room)

**Community Health Centers**

This breakout session will provide a further opportunity for health centers and retail pharmacists that are interested in developing or already have contracted pharmacy arrangements utilizing the 340B program to get together to further share information and experiences. Facilitators and resource persons will be available for the discussion.

**Harry Hagel, Senior Director, Pharmacy Services Support Center**

**Moderator: Freda Mitchem, Senior Advisor, National Association of Community Health Centers**

(Executive Room)

**Hemophilia Treatment Centers**

It's open mic! If you have an interest in hemophilia and 340B Programs, this is the session to get your questions answered. Raise questions about the day's program and discuss issues of concern from your perspective of the 340B Program with the experts in the field.

**Derek Robertson, General Counsel, Hemophilia Alliance, Inc.**

1:15 pm

**Conference Adjourns**

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**Please Note:** Continuing Education credits will be available for pharmacists.



The American Society of Health-System Pharmacists (ASHP) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The **main conference** is approved for **14.5 hours (1.45 CEUs)** of continuing education credit under the ACPE Universal Program Number: 204-999-06-029-L04. The **pre-conference workshop** is approved for **3.0 hours (0.30 CEUs)** of continuing education credit under the ACPE Universal Program Number: 204-999-06-028-L04.

Participants must complete the CE Request form before they leave the conference to earn CE credit. ASHP will mail validated Statements of CE credit within four to six weeks after the conference.