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# Third Annual 340B Coalition Winter Conference

## Major Changes on the Horizon for the 340B Drug Discount Program

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February 26–28, 2007  
Hilton Salt Lake City Center  
Salt Lake City, Utah

### AGENDA

#### MONDAY, FEBRUARY 26, 2007

9:00 am - 12:00 pm            Exhibit Set up  
12:00-5:00 pm                Early Registration  
1:30 pm                         Exhibits Open 1:30 – 5:15 pm  
                                      Pre-Conference Workshop (Two Options)\*

#### Option 1 - An Introduction to the Federal 340B Drug Pricing Program for Covered Entities

1:30 pm

(Grand Ballroom C)  
(085-999-07-001-L03) (3.5 hrs)

#### **Introduction to the 340B Drug Pricing Program**

This session is designed for hospitals, community health centers, state and local governments, hemophilia treatment centers, HIV/AIDS providers and other safety net institutions that are eligible to participate in the 340B program. It will teach the basics of the 340B drug discount program for covered entity representatives who are new to the program or need a refresher course. You will receive an overview of the program covering such topics as 340B eligibility and enrollment procedures, manufacturer discount requirements, anti-diversion standards, Medicaid billing restrictions and the 340B contract pharmacy guidelines.

William von Oehsen, President, Safety Net Hospitals for Pharmaceutical Access  
(Formerly Public Hospital Pharmacy Coalition)

Freda Mitchem, Director of Systems Development and Policy Administration, National  
Association of Community Health Centers

Zandra Glenn, Program Development Consultant, HRSA Pharmacy Services Support  
Center

Derek Robertson, Executive Director, Hemophilia Alliance

2:45 pm

#### **Refreshment and Networking Break**

3:15 – 4:30 pm

#### **Best Practices for 340B Participants: Tips from Experienced Colleagues**

Representatives of the 340B provider community will expand upon the themes introduced in the first session and discuss the nuts and bolts of implementing the 340B program. Panelists will provide practical advice on how to use and comply with the program, especially with respect to anti-diversion, Medicaid billing, contract pharmacies and inventory management. Covered entity representatives will provide perspectives on how to maximize the benefits of the program while complying with 340B requirements.

Jim Jorgenson, Director of Pharmacy, University of Utah Health Sciences Center

Bill von Oehsen, President, Safety Net Hospitals for Pharmaceutical Access (Formerly  
Public Hospital Pharmacy Coalition) (Moderator)

Steve Zielinski, Director of Pharmacy, Crusader Clinic

Katherine Kneer, President and CEO, Planned Parenthood Affiliates of California

4:30 – 5:15 pm

#### **Question and Answer Session**

This session will give the audience an opportunity to ask more questions of our panel of experts. Questions may be posed in person or by written comment. The focus will be on the practicalities of participating in the 340B program.

## **Option 2 - An Introduction to the Federal 340B Drug Discount Program for Industry**

**1:30 pm**  
*(Grand Ballroom AB)*  
**(085-999-07002-L03) (3.5 hrs)**

### **Introduction to the 340B Drug Discount Program**

This session is designed to teach the basics of the 340B program for industry representatives who are new to the program or need a refresher course. It will focus on topics that are specifically relevant to industry participants: how to calculate 340B ceiling prices; the relationship between 340B, AMP and best price; nominal price arrangements; identifying 340B providers and the subset of their drugs subject to 340B pricing; protecting against the Medicaid rebate/340B duplicate discount problems; and monitoring covered entity compliance to avoid diversion and overutilization. Attendees will receive up-to-date information reflecting recent changes under the Deficit Reduction Act of 2005. The emphasis in this session is on program requirements and enforcement.

**Karen Biancalana, Associate Director, Pricing and Reimbursement, Amylin Pharmaceuticals, Inc. (Conference Team Leader)**

**Harry Hagel, Senior Director, Pharmacy Services Support Center**  
**T. Reed Stephens, Partner, McDermott Will & Emery (Moderator)**

**2:45 pm**

### **Refreshment and Networking Break**

**3:15 – 4:15 pm**

### **Hear from Pharmaceutical Industry Experts on 340B Compliance**

Experts on manufacturer 340B compliance will expand upon the themes introduced in the first session and discuss strategies for complying with 340B requirements. Panelists will provide practical advice on calculating 340B prices, how to address 340B price adjustments, coordinating CMS reporting requirements under the Medicaid rebate and 340B programs, ensuring that 340B discounts are only extended to eligible entities for eligible drugs, clarifying the scope of drugs subject to 340B pricing, and protecting against potential Medicaid rebate/340B duplicate discounts, diversion, Medicaid best price problems and other risks.

**T. Reed Stephens, Partner, McDermott Will & Emery (Moderator)**

**Steve Young, Managing Director, Huron Group**

**Allison Pugsley, Associate, Hogan and Hartson**

**David Chan, Manager of Pharmaceutical Advisory Services Practices, KPMG**

**4:15 – 5:15 pm**

### **Question and Answer Session**

This expanded question-and-answer session is offered to give the audience an opportunity to ask more questions of our panel of experts. Questions may be posed in person or by written comment.

**5:15 pm**

### **Conclusion**

**5:30-7:30**  
*(Topaz Room)*

### **Networking Reception for FQHCs\*\***

**6:30-8:30 pm**  
*(Alpine Ballroom)*

### **Dinner Workshop for Hospitals \*\*\***

Other attendees can enjoy a night on the town.

\* Please note there is an additional cost to attend the pre-conference workshop and you must register for it.

\*\* Please note that this reception is limited to community health centers and other invited guests only. This reception is being hosted by the Association for Utah Community Health and the National Association of Community Health Centers.

\*\*\* Please note that this session is limited to hospitals and SNHPA corporate partners. There is an additional cost to attend and registration is required.

## TUESDAY, FEBRUARY 27, 2007

**7:00-8:00 am**  
(Grand Ballroom Foyer)

### Registration and Continental Breakfast

Exhibits Open 7:00 am - 5:00 pm

**8:00-8:30 am**  
(Grand Ballroom)

### Welcome and Introductory Remarks

Marc Babitz, Director of the Division of Health Systems Improvement, Utah  
Department of Health

Karen Biancalana, Associate Director of Pricing and Reimbursement, Amylin  
Pharmaceuticals, Inc.

Freda Mitchem, Director of Systems Development and Policy Administration,  
National Association of Community Health Centers

Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical  
Access (Formerly Public Hospital Pharmacy Coalition)

Derek Robertson, Executive Director, Hemophilia Alliance

Bill von Oehsen, President and General Counsel, Safety Net Hospitals for  
Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition)

**8:30-10:00 am**  
(085-999-07-003-L04) (1.5 hrs)

### Impact of Deficit Reduction Act on 340B Program

This session will focus on implementation of the DRA of 2005 by the Centers for Medicare and Medicaid Services (CMS) with respect to calculation of average manufacturer price (AMP), expansion of the Medicaid drug rebate program, changes to nominal price regulation, extension of 340B pricing to children's hospitals, and other drug pricing provisions. CMS recently issued a notice addressing each of these issues. While proposed changes to AMP may increase 340B ceiling prices, the Health Resources and Services Administration (HRSA) and the 340B covered entity community are advocating an interpretation that would preserve current pricing levels for the 340B program by requiring manufacturers to calculate AMP using pre-DRA methodologies. The 340B community is also anxious about how CMS plans to implement a DRA provision expanding the Medicaid rebate program to physician-administered drugs. If CMS expands the program to 340B drugs administered in covered entity clinics, it will (1) expose manufacturers to a risk of providing 340B discounts and Medicaid rebates on the same drugs, and/or (2) force covered entities to pass their 340B savings on such drugs to state Medicaid agencies. Another area of concern relates to CMS' proposal not to expand the list of safety net providers that would be eligible for nominal price protection. Finally, children's hospitals are still waiting for HRSA guidelines describing eligibility and enrollment procedures. These and other DRA-related developments will be discussed in detail during this session.

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net  
Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy  
Coalition)

Steve Young, Managing Director, Huron Group

Amy Gutierrez, Pharmacy Director, Los Angeles County Department of Health  
Services

**10:00-10:30 am**  
(Grand Ballroom Foyer)

### Break - Exhibits Open

**10:30 am-12:00 pm**  
(Grand Ballroom)  
(085-999-07-004-L04) (1.5 hrs)

### Changes to 340B Patient Definition and Anti-Diversion Requirements

HRSA has just proposed new guidelines clarifying the 340B definition of patient. These proposed guidelines would fundamentally change how covered entities purchase and dispense 340B drugs. Issues to be covered include: (1) an analysis of the proposed guidelines and how they will affect different covered entity groups, manufacturers, and distributors; (2) eligibility under the new guidelines of different patient populations, including employees, nursing home residents, home health patients, prisoners, etc.; (3) implications for covered entity partnerships with jails, health departments, and Medicaid programs; (4) technical guidance on inventory management, stock replacement, patient verification, and audit preparation; (5) the future of new

and existing 340B case management, disease management, and telemedicine models; and (6) impact on alternative method demonstration projects. Presenters will provide guidance on how covered entities, manufacturers and distributors can adjust their operations to accommodate these changes to minimize compliance risks without compromising program benefits.

**Bradford Lang, Public Health Analyst, Office of Pharmacy Affairs**  
**Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition)**  
**Michael Glomb, Partner, Feldesman, Tucker, Leifer, Fidell, Inc. (Counsel to National Association of Community Health Centers)**  
**Derek Robertson, Executive Director, Hemophilia Alliance**  
**Allison Pugsley, Associate, Hogan and Hartson**

12:00-1:30 pm

### Luncheon and Networking Opportunity

1:30-3:00 pm

### Concurrent Stakeholder Breakout Sessions

(085-999-07-005-L04) (1.5 hrs)

Conference attendees are invited to participate in separate breakout sessions for each 340B stakeholder group. Each group will focus on the issues raised during the morning sessions that have the most significant impact on members of that group. **[PLEASE NOTE: THESE SESSIONS ARE LIMITED TO THE RESPECTIVE COVERED ENTITY OR INDUSTRY GROUPS AND THEIR REPRESENTATIVES.]**

(Grand Ballroom C)

#### A. DSH Hospitals

**Chris Hatwig, Senior Director, 340B Prime Vendor Program**  
**Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition)**  
**Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition)**

(Grand Ballroom A)

#### B. Pharmaceutical Manufacturers

**T. Reed Stephens, Partner, McDermott Will and Emery, LLP (Moderator)**  
**Steve Young, Managing Director, Huron Group**  
**David Chan, Manager of Pharmaceutical Advisory Services Practice, KPMG**

(Grand Ballroom B)

#### C. Community Health Centers, Health Departments, Family Planning Clinics, and Other Non-Hospital Providers

**Freda Mitchem, Director of Systems Development and Policy Administration, National Association of Community Health Centers**  
**Dana Thomas, Associate Director, Regulatory Affairs, National Association of Community Health Centers**  
**Chris Hatwig, Senior Director, 340B Prime Vendor Program**  
**James Donnelly, Pharmacy Services Director, Hudson Headwaters Network**

(Seminar Theater)

#### D. Hemophilia Treatment Centers

**Derek Robertson, Executive Director, Hemophilia Alliance**

3:00-3:30 pm

### Break - Exhibits Open

3:30-5:00 pm

### Concurrent Stakeholder Breakout Sessions (Continued)

(085-999-07-006-L04) (1.5 hrs)

(Grand Ballroom C)

#### A. DSH Hospitals

**Bill Wood, Director, Infusion Services & 340B Programs, University of Utah Health Sciences Center**  
**Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition) (Moderator)**  
**Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition)**

(Grand Ballroom A)

#### B. Pharmaceutical Manufacturers

**Steve Young, Managing Director, Huron Group (Moderator)**  
**Chris Hatwig, Senior Director, 340B Prime Vendor Program**

(Grand Ballroom B)

- C. Community Health Centers, Health Departments, and Other Non-Hospital Providers

**Freda Mitchem, Director of Systems Development and Policy Administration, National Association of Community Health Centers**  
**Dana Thomas, Associate Director, Regulatory Affairs, NACHC**  
**James Donnelly, Pharmacy Services Director, Hudson Headwaters Network**

(Seminar Theater)

- D. Family Planning Clinics  
**Katherine Kneer, President and CEO, Planned Parenthood Affiliates of California**

5:15-6:30 pm  
(Grand Ballroom Foyer)

**Reception and Networking Opportunity**

**WEDNESDAY, February 28, 2007**

7:30-8:30 am

**Continental Breakfast**

8:30-10:00 am  
(Grand Ballroom)  
(085-999-07-007-L04) (1.5 hrs)

**Changes to Contract Pharmacy Requirements: Opportunities and Integrity Issues**

HRSA's recently published a notice proposing changes to the 340B contract pharmacy program. Among the proposed changes is the ability of covered entities to contract with multiple pharmacies and to supplement in-house pharmacy services with outsourced pharmacy arrangements. This session will examine the potential impact of these changes on covered entities, manufacturers, wholesalers, community pharmacies, and patients. Special emphasis will be given to the increased resources that covered entities will need to support multi-pharmacy networks, especially in the areas of inventory management, billing, data analysis and compliance. Presentations will reflect the perspectives of the government, covered entities and retail pharmacies.

**Bradford Lang, Public Health Analyst, Office of Pharmacy Affairs**  
**Harry Hagel, Senior Director, HRSA Pharmacy Services Support Center (Moderator)**  
**Sharon Kotabe, Hospital Associate Administrator, Pharmaceutical Services, Community Health Network of San Francisco**  
**Bette Vierra, Executive Director, Association for Utah Community Health**  
**Blair Woolf, Pharmacy Director, Smith's Food and Drug**  
**Julie Meents, Regional Manager, Longs Drug Stores, Inc.**

10:00-10:30 am  
(Grand Ballroom Foyer)

**Break - Exhibits Open**

10:30 am-12:00 pm  
(085-999-07-008) (1.5 hrs)

**Concurrent Topic-Oriented Breakout Sessions**

Rather than dividing attendees into their stakeholder groups, these breakout sessions will be organized based on topic areas that will likely affect more than one group.

(Topaz Room)

- A. Further Discussion of Calculation of Average Manufacturer Price for 340B Program

**Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition) (Moderator)**  
**David Chan, Manager of Pharmaceutical Advisory Services Practice, KPMG**  
**Karen Biancalana, Associate Director of Pricing and Reimbursement, Amylin**

(Grand Ballroom A)

- B. Further Discussion on Patient Definition Changes and Their Anticipated Impact on Inventory Management and Pharmacy Counter Practices

**Bill von Oehsen, President, Safety Net Hospitals for Pharmaceutical Access (Formerly Public Hospital Pharmacy Coalition) (Moderator)**

- (Grand Ballroom B) C. The "Nuts and Bolts" of Developing a Contract Pharmacy Arrangement  
**Harry Hagel**, Senior Director, HRSA Pharmacy Services Support Center
- (Salon 2) D. Medicare Part D Update and Interface with 340B Program  
**Doug Miller**, Vice President and Chief of Pharmacy, Grady Health System  
(Moderator)  
**Steve Zielinski**, Director of Pharmacy, Crusader Clinic
- (Grand Ballroom C) E. Status Report on Manufacturer Patient Assistance Programs  
**Jim Martin**, Director, PAP and Reimbursement Services, Amgen  
**Susan Edmondson**, Pharmacy Program Manager, Lifelong Medical Care  
**Diana Bond**, Pharmacy Director, UMC Southern Nevada

12:00 pm

Conference Adjourns



Comprehensive Pharmacy Services, Inc. is accredited by the Accreditation Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. Pharmacists are eligible to receive a maximum of 1.25 CEUs (12.5 contact hours) (ACPE Number 085-999-07-xxx-L04, where xxx represents the individual session). In order to receive credit, each pharmacist must sign in daily and must complete the request for credit form and the program evaluation. All completed forms must be turned in at the registration desk at the conclusion of the conference. PLEASE NOTE: Forms mailed in after the conclusion of the conference will not be accepted for continuing education credit.