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# Fourth Annual 340B Coalition Winter Conference

## Update on Key Compliance and Operational Issues

### Co-Hosted by the 340B Prime Vendor Program

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January 30 - February 1, 2008  
Westin Long Beach  
Long Beach, CA

#### AGENDA

**WEDNESDAY, JANUARY 30, 2008**

9:00 am – 5:00 pm      Exhibit Set up  
(Centennial Foyer)

12:00 – 5:00 pm      Early Registration  
(Escalator Foyer)

1:30 pm                  Pre-Conference Workshop (Two Options)\*  
(ACPE 085-999-08-001-L03)

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

1:30 pm  
(Centennial Salon A)  
(ACPE 3.5 Hours)

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

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.

Christopher Hatwig, Senior Director, 340B Prime Vendor Program

Freda Mitchem, Associate Vice President, Policy and Programs, National Association of Community Health Centers

Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

2:45 pm  
(Centennial Foyer)

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

3:15 pm  
(Centennial Salon A)

#### **Session Continues**

In order for the 340B program to function properly, each party in the pharmaceutical supply chain must adjust to a unique set of requirements and procedures. Representatives of the 340B provider community and the manufacturer and wholesaler industries will expand upon the themes introduced in the first session and discuss implementation of the 340B program from their respective viewpoints.

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center

Tim Nugent, Managing Director, Huron Consulting Group

Larry Pederson, Pharmacist Consultant, National Association of Community Health Centers

Larry Stepp, Vice President of National Accounts, AmerisourceBergen Corporation

4:30 pm

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

## **Option 2 – New Developments in Patient Assistance Programs**

**1:30 pm**  
**(Centennial Salon B)**  
**(ACPE 3.5 Hours)**

### **New Developments in Patient Assistance Programs**

This session will describe the different models available to safety net providers in accessing 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 PAP guidance from the Department of Health and Human Services' Office of the Inspector General (OIG) 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.

**Kathryn Duke, Consultant, The 340B Coalition (Moderator)**

**Michael Glomb, Partner, Feldesman Tucker Leifer Fidell LLP; Counsel to National Association of Community Health Centers**

**Jennifer McGovern, Manager, Institutional Patient Assistance Programs, AstraZeneca LP**

**Kate Romanow, Attorney, Powers Pyles Sutter & Verville PC; Counsel to Safety Net Hospitals for Pharmaceutical Access**

**2:45 pm**  
**(Centennial Foyer)**

### **Refreshment and Networking Break**

**3:15 pm**  
**(Centennial Salon B)**

### **Session Continues**

The roll-out of Medicare Part D has created considerable confusion about the limits applicable to manufacturer PAPs. This session will update attendees on the latest developments affecting utilization of PAPs. Among the issues to be addressed are recent OIG advisory opinions analyzing application of anti-kickback and civil monetary penalty laws to PAPs; continued viability of traditional PAPs for the uninsured; preparing for and responding to manufacturer audits; and the use of "inside" and "outside" the Part D benefit models for filling the gaps in Medicare Part D coverage.

**Lois Bugos, Program Support Assistant, University of Colorado Hospital Department of Pharmacy**

**Tony Felix, Pharmacy Director, El Rio Neighborhood Health Center**

**Bill Shearer, Corporate Vice President, InVentor, inVentiv Health, Inc.**

**4:30 pm**

### **Question and Answer Session**

**5:00 pm**

### **Conclusion**

**5:30 – 8:30 pm**  
**(Centennial Salon D)**

### **Welcome Reception and Dinner for Hospitals\*\***

Other attendees can enjoy a night on the town.

***Commencement of Main Conference***  
**(ACPE 085-999-002-L04)**

***Note that the main conference agenda has been organized into two separate tracks to meet the varying interests of conference attendees. Track One presentations are designed for covered entities and other parties that are interested in learning about how to operationalize the 340B program. Track Two sessions will appeal to the broader community of 340B stakeholders, including the pharmaceutical industry, who might be more interested in hearing about (1) recent developments involving 340B policy and compliance and (2) expert analysis of such developments. Although attendees will likely be drawn to all of the presentations organized under one track or the other, they are free to attend any Track One or Track Two session that interests them.***

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

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

## THURSDAY, JANUARY 31, 2008

- 7:00 am**  
*(Centennial Foyer)*                      **Registration and Continental Breakfast**  
**Exhibits Open**
- 8:15 am**  
*(Centennial Salon A&B)*                      **Opening Remarks**  
**Kevin Gorospe, Chief, Medi-Cal Pharmacy Policy Branch, California Department of Health Care Services**  
**Representatives from the Conference Hosts**
- 8:30 am**  
*(ACPE 1 Hour)*                      **Federal Government Update**  
Get updates on several 340B activities including the status of pending HRSA proposals to change the definition of 340B eligible patients, to expand the contract pharmacy program and to enroll children's hospitals into the program. Also hear about a new federal clinical pharmacy initiative to identify and disseminate "best practice" models of how clinical pharmacy programs can improve patient safety. Speakers will include senior executives from HRSA's two 340B federal contractors – the Pharmacy Services Support Center (PSSC) and the 340B Prime Vendor Program (PVP). The PSSC will also provide an update on its technical assistance activities, and the PVP will address its latest success in negotiating sub-ceiling prices and its work with industry in establishing a pilot program for verifying 340B price calculations and increasing pricing transparency.  
**Harry Hagel, Senior Vice President, Government and Professional Affairs, American Pharmacists Association; Senior Director, HRSA Pharmacy Services Support Center**  
**Christopher Hatwig, Senior Director, 340B Prime Vendor Program**
- 9:30 am**  
*(ACPE 1 Hour)*                      **Legislative Update**  
Hear from a representative who is on the frontlines of lobbying on federal bills that would have a dramatic impact on both the scope and enforcement of the 340B program. For example, pending legislation would clarify the 340B eligibility of children's hospitals and would add to the program new types of health care facilities. These bills would also extend 340B to inpatient drugs and tighten oversight. At the same time, 340B providers are seeking support in opposing HRSA's proposed changes to the definition of patient and implementation of NDC reporting requirements for physician-administered drugs within the Medicaid program. These and other 340B-related legislative matters will be discussed. In addition, you will hear the latest information from the chain drug store industry on retail pharmacists' efforts to block Medicaid pharmacy cuts as well as tackle other matters impacting pharmacists including legislation to extend federal discounts for TRICARE patients in the retail setting.  
**Stuart Gordon, Director of Policies and Programs, National Association of Chain Drug Stores**  
**Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Moderator)**
- 10:30 am**  
*(Centennial Foyer)*                      **Networking and Refreshment Break - Exhibits Open**
- 11:00 am**  
*(Centennial Salon A)*  
*(ACPE 1.25 Hours)*                      **Track One – Operationalizing 340B**  
**Contract Pharmacies: Planning and Pre-Implementation Challenges**  
HRSA launched the contract pharmacy program in 1996 in response to concerns that eligible entities were unable to benefit from the program because they lacked and could not afford to build their own in-house pharmacies. Since then, the number of contract pharmacies participating in the 340B program has grown significantly. This session will focus on the pros and cons of establishing a contract pharmacy arrangement, how to develop an implementation plan, and whether the covered entity should explore other options such as physician dispensing or investing in an in-house pharmacy. It will also discuss the proposed HRSA guidelines to allow the use of multiple contract pharmacies.

Harry Hagel, Senior Vice President, Government and Professional Affairs, American Pharmacists Association; Senior Director, HRSA Pharmacy Services Support Center (Moderator)

Gary Horne, Director of Pharmacy, San Mateo Medical Center

Peter Tyczkowski, University of Connecticut School of Pharmacy; HRSA Pharmacy Services Support Center Consultant

## Track Two – 340B Policy and Compliance

*(Centennial Salon B)  
(ACPE 1.25 Hours)*

### Federal and State Implementation of New NDC Reporting Requirements

Congress created the Medicaid rebate program in 1990 and, two years later, created the 340B program. Overlap of these two programs creates multiple risks – risks that manufacturers will be asked to give 340B discounts and Medicaid rebates on the same drugs, risks that states will have to pay more for outpatient drugs by losing access to manufacturer rebates, and risks to covered entities by reducing what they can bill and receive from Medicaid for covered outpatient drugs. The triangular relationship between manufacturers, states and covered entities requires each party to do its part in protecting the other two from undue harm. This session will feature a panel of state Medicaid officials who will discuss state implementation of a provision in the Deficit Reduction Act of 2005 (DRA) requiring the reporting of NDC information so that states can collect rebates from manufacturers on physician-administered drugs. Special attention will be given to the impact of new NDC reporting procedures on providers and manufacturers participating in the 340B program.

Kevin Gorospe, Chief, Medi-Cal Pharmacy Policy Branch, California Department of Health Care Services

Tim Morley, Drug Utilization Review Program Manager, Utah Department of Health

Alan Shugart, Health Insurance Specialist, Center for Medicaid and State Operations

Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

12:15 pm

*(Salon Terrace A/Ocean Terrace)*

## Luncheon and Networking Opportunity

1:30 pm

*(Centennial Salon A)  
(ACPE 1.25 Hours)*

## Track One – Operationalizing 340B

### Operationalizing a Contract Pharmacy Arrangement

When a covered entity establishes a contract pharmacy arrangement, both the covered entity and the pharmacy should be prepared to meet several requirements as soon as the arrangement goes into effect. Compliance with 340B anti-diversion and Medicaid billing standards, for example, may entail significant changes in how the parties purchase medications, manage their price files, track drug utilization and bill third party payers. These changes, in turn, may impact wholesaler relationships, staffing needs, information system demands, and billing procedures. This session is designed to help covered entities and their pharmacy partners identify and perform the necessary tasks for operationalizing a contract pharmacy arrangement. Both covered entities and contract pharmacies will share their experiences and advice.

Harry Hagel, Senior Vice President, Government and Professional Affairs, American Pharmacists Association; Senior Director, HRSA Pharmacy Services Support Center (Moderator)

Richard Jajeh, Co-Owner, Anchor Pharmacy, Contract Pharmacy for San Mateo Medical Center Satellite Clinics

Peter Tyczkowski, University of Connecticut School of Pharmacy; HRSA Pharmacy Services Support Center Consultant

## Track Two – 340B Policy and Compliance

*(Centennial Salon B)  
(ACPE 1.25 Hours)*

### Other Stakeholder Perspectives on New NDC Reporting Requirements

The panel of state Medicaid regulators from the prior Track Two session is joined by representatives of various 340B stakeholder groups, including covered entities and the pharmaceutical industry, who will respond to the prior presentations regarding state implementation of the DRA.

John Grubbs, Director of Pharmacy, University of California Davis Medical Center

Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Constance Wilkinson, Partner, Epstein Becker & Green

**Discussants:**

**Kevin Gorospe**, Chief, Medi-Cal Pharmacy Policy Branch, California Department of Health Care Services

**Tim Morley**, Drug Utilization Review Program Manager, Utah Department of Health

**Alan Shugart**, Health Insurance Specialist, Center for Medicaid and State Operations

2:45 pm  
(Centennial Foyer)

**Networking and Refreshment Break - Exhibits Open**

3:15 pm

**Concurrent Stakeholder Breakout Sessions**

Conference attendees are invited to participate in separate breakout sessions for each 340B stakeholder group. **[PLEASE NOTE: THESE SESSIONS ARE LIMITED TO THE RESPECTIVE COVERED ENTITY OR INDUSTRY GROUPS AND THEIR REPRESENTATIVES. FOR INSTANCE, HOSPITALS SHOULD NOT ATTEND THE MANUFACTURER SESSION AND VICE VERSA.]**

(Centennial Salon A)  
(ACPE 2 Hours)

**A. DSH and Children's Hospitals**

This breakout session will be divided into two parts. The first part will involve a presentation by SNHPA staff about what DSH and children's hospitals should be doing to: (1) Support legislation that would improve the integrity of the 340B program and extend the program to inpatient drugs and new hospital groups; (2) Address efforts within the Medicaid program to require hospitals to report NDCs on clinic-administered drugs and change how such drugs are billed if purchased through 340B; (3) Oppose HRSA's proposed guidance that would narrow the patient populations eligible to receive 340B drugs from covered entities. The second half of the session will feature a few DSH representatives who will briefly discuss how their institutions are responding to these opportunities and challenges.

**Diana Bond**, Director, Pharmaceutical Services, University Medical Center of Southern Nevada

**Myron Lewis**, Director, Pharmacy Operations, R. E. Thomason Hospital

**Ted Slafsky**, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Moderator)

**Bill von Oehsen**, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access

(Centennial Salon B)  
(ACPE 2 Hours)

**B. Pharmaceutical Manufacturers**

This session will focus on: (1) Impact on 340B pricing resulting from CMS final AMP rule; (2) Update on the AMP lawsuit by NACDS; (3) "Old" AMP versus "New" AMP; (4) Manufacturers role in maintaining program integrity. There will also be an opportunity for manufacturers to raise other issues and concerns.

**Ben Martin**, Senior Associate, Epstein Becker & Green

**Edward McAdam Sr.**, Contract Administration Director, Daiichi Sankyo (Moderator)

**Meghan Davis**, Manager, Pharmaceuticals and Health Plans Practice, Huron Consulting Group

(Centennial Salon C)  
(ACPE 2 Hours)

**C. Community Health Centers**

This session will focus on: (1) establishing charges and discounts for drugs to comply with statute and regulations, avoid legal risks, and maximize value to the center and its patients; and (2) complying with fraud and abuse training requirements. Participants will also be able to raise other issues of concern to them and share experiences as a group.

**Michael Glomb**, Partner, Feldesman Tucker Leifer Fidell LLP (Counsel to National Association of Community Health Centers)

**Freda Mitchem**, Associate Vice President, Policy and Programs, National Association of Community Health Centers (Moderator)

**Larry Pederson**, Pharmacist Consultant, National Association of Community Health Centers

(Centennial Salon D)  
(ACPE 2 Hours)

**D. Health Departments, Family Planning Clinics, and Other Non-Hospital Providers**

Participants will choose and informally discuss topics such as (1) Proposed guidelines on 340B patient definition; (2) Study of Title X grantees' knowledge and use of 340B and prime vendor; (3) Nominal drug pricing.

Charles Thomas, State Pharmacy Director, Alabama Department of Public Health (Co-Moderator)

Emily Stewart, Regulatory and Policy Analyst, Planned Parenthood Federation of America (Co-Moderator)

(Tokyo Room)  
(ACPE 2 Hours)

**E. Hemophilia Treatment Centers**

Derek Robertson, Executive Director, Hemophilia Alliance (Moderator)

5:15 – 6:30 pm  
(Centennial Foyer)

**Reception and Networking Opportunity for All Attendees**

**FRIDAY, FEBRUARY 1, 2008**

7:00 am  
(Centennial Foyer)

**Continental Breakfast**

**Exhibits Open**

8:30 am  
(Centennial Salon A)  
(ACPE 1.25 Hours)

**Track One – Operationalizing 340B**

**Inventory Management**

Whether a covered entity chooses to establish a contract pharmacy arrangement or not, 340B participation typically involves unique drug purchasing and inventory management systems which, in turn, may require infrastructure changes such as investment in new staff, split-billing software programs and other information system technologies. This session will focus on practical solutions to the challenges of implementing a compliant stock replacement system, maintaining virtual inventories, developing effective tracking systems, and meeting 340B anti-diversion requirements. Covered entity representatives will describe their implementation models in an effort to help attendees identify and understand a “best practices” approach for their institutions.

Dale Adams, Vice President of Medical Services, Long Beach Memorial and Miller Children's Hospitals (Moderator)

Kevin Kyle, Pharmacy Buyer, Long Beach Memorial and Miller Children's Hospitals

Jerry Sveum, Consultant, HRSA Pharmacy Services Support Center; Longtime Independent Pharmacy Owner

Doug Wong, Senior Executive Consultant, Pharmacy Healthcare Solutions (Moderator)

**Track Two – 340B Policy and Compliance**

(Centennial Salon B)  
(ACPE 1.25 Hours)

**Changes to AMP and Best Price: Impact on 340B Pricing**

This session will focus on calculating average manufacturer price (AMP) and Medicaid “best price” in accordance with the DRA and how these DRA-related changes will affect 340B ceiling prices. CMS's final regulation addressing these issues will be analyzed in detail. OPA has struggled with whether AMP changes under the DRA, especially the exclusion of prompt pay discounts, should apply to 340B ceiling price calculations. The 340B covered entity community advocates an interpretation that would preserve current pricing levels for the 340B program by requiring manufacturers to calculate AMP using pre-DRA methodologies. Both manufacturer and covered entity perspectives will be provided during this session, with an emphasis on compliance.

Christopher Hatwig, Senior Director, 340B Prime Vendor Program

Edward McAdam Sr., Contract Administration Director, Daiichi Sankyo

Steve Schondelmeyer, Director, PRIME Institute, University of Minnesota College of Pharmacy

Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

9:45 am  
(Centennial Foyer)

**Networking and Refreshment Break - Exhibits Open**

10:15 am

**Track One – Operationalizing 340B**

**(Centennial Salon A)  
(ACPE 1.25 Hours)**

### **Preventing Drug Diversion**

The 340B statute prohibits covered entities from selling or otherwise transferring 340B-discounted drugs to anyone other than the entity's own patients. HRSA guidelines specify that, in order for an individual to be considered an eligible patient, (1) the covered entity must maintain a record of healthcare services for the individual, (2) the individual must receive services from a professional who is employed by, under contract with or in other arrangements with the entity such that responsibility for care for the individual remains with the entity, and (3) the individual receives services within the scope of the covered entity's federal grant. Representatives from different covered entities discuss how these standards apply to contract pharmacy customers and other 340B provider patient groups. The focus of this session will be on the systems developed by covered entities to protect against diversion.

**Tony Felix, Pharmacy Director, El Rio Neighborhood Health Center**  
**Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center**  
**Freda Mitchem, Associate Vice President, Policy and Programs, National Association of Community Health Centers (Moderator)**  
**Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access**

### **Track Two – 340B Policy and Compliance**

**(Centennial Salon B)  
(ACPE 1.25 Hours)**

### **Nominal Price Contracting in a Post-DRA Era**

The DRA narrowed the exclusion of nominal prices from "best price" calculations such that some very low drug prices paid by safety net providers qualify for the exclusion while others do not. 340B providers still qualify for nominal pricing under the DRA but the larger health systems in which they operate generally do not. As a result, manufacturers have restructured and even terminated some of their nominal price contracts in an effort to avoid increasing their Medicaid rebate and 340B discount obligations by setting a new best price. The impact of these contract changes on safety net providers will be explored with a special emphasis on how contracting is being handled for systems comprised of both 340B and non-340B entities. Also discussed will be the advocacy efforts by some safety net provider groups to expand the list of provider types eligible for nominal pricing.

**Amy Gutierrez, Director of Pharmacy Affairs, Los Angeles County DHS Pharmacy Services**  
**Ronald Hartmann, Vice President, Pharmacy Division, MedAssets Supply Chain Systems (Moderator)**  
**Emily Stewart, Regulatory and Policy Analyst, Planned Parenthood Federation of America**

**11:30 am  
(Centennial Salon A&B)**

### **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.

**Edward McAdam Sr., Contract Administration Director, Daiichi Sankyo**  
**Freda Mitchem, Associate Vice President, Policy and Programs, National Association of Community Health Centers**  
**Larry Pederson, Pharmacist Consultant, National Association of Community Health Centers**  
**Derek Robertson, Executive Director, Hemophilia Alliance**  
**Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)**

**12:15 pm**

### **Conference Adjourns**



Comprehensive Pharmacy Services, Inc. is accredited by the Accreditation Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. In order to receive credit, each pharmacist 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.