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# Sixth Annual 340B Coalition Winter Conference

## Co-Hosted by Apexus/340B Prime Vendor Program

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February 1-3, 2010 • Hyatt Regency San Francisco • San Francisco, CA

### AGENDA

**MONDAY, FEBRUARY 1, 2010**

9:00 am – 12:00 pm    Exhibit Set up  
(Grand A)

12:00 – 5:00 pm        Early Registration – Exhibits Open  
(Grand Foyer)  
(Grand A)

1:30 pm                 Pre-Conference Workshop (Two Options)<sup>1</sup>

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

(ACPE 0085-9999-10-003-L04 P and T)

1:30 pm  
(Grand B)  
(ACPE 3 Hours)

**340B Basics – Introduction to the 340B Drug Pricing Program**

This session is designed for representatives of 340B providers and programs, pharmaceutical manufacturers, wholesalers, state Medicaid agencies and other 340B stakeholder groups who are new to the 340B 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, inventory management standards, contract pharmacy guidelines, and compliance issues, especially with respect to diversion and Medicaid billing.

**Mary Ellen England**, Director of Education and Marketing, Apexus/PVP

**Paul Shank**, Consultant Coordinator, Pharmacy Services Support Center

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

3:00 pm  
(Grand A)

**Refreshment and Networking Break**

3:30 pm  
(Grand B)

**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.

**Mike Casida**, Regional Sales Manager/National Accounts, Morris & Dickson, Co. LLC

**Clarissa Crain**, Director of Government Contract and Health Care Law Compliance,  
Compliance Implementation Services

**Susan Edmondson**, Pharmacy Coordinator, Lifelong Medical Care

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<sup>1</sup> Please note there is an additional cost to attend the pre-conference workshop and you must register for it.

## **Option 2 – Patient Assistance Programs: Current and Future**

**(ACPE 0085-9999-10-004-L04 P and T)**

**1:30 pm**  
**(Grand C)**  
**(ACPE 3 Hours)**

### **Patient Assistance Programs**

As a result of the economic downturn, more uninsured and vulnerable populations are relying on safety net pharmacies and pharmaceutical manufacturer patient assistance programs (PAPs) to access prescription drugs. This first session examines current activities, successes and challenges of PAP programs, both those aimed at individual patients and those “institutional” patient assistance programs operating in some hospitals and clinics. Our speakers will discuss innovative efforts by safety net providers and pharmaceutical companies to address unmet pharmaceutical care needs and will highlight opportunities to maximize pharmaceutical savings and bring in much needed revenue. We will also provide an overview of a landmark HHS Office of Inspector General guidance that gives the green light to a further expansion of institutional PAPs. There will be time allotted for questions and discussion at the end of each session.

**Kathryn Duke, Health Care Consultant (Moderator)**

**Elaine Levy, System Director of Pharmacy, Sharp Healthcare**

**Christopher Palombo, Project Manager, Access Leadership, Ascension Health**

**Tamara Vogel, Practice Manager, The Hemophilia Center at OHSU**

**3:00 pm**  
**(Grand A)**

### **Refreshment and Networking Break**

**3:30 pm**  
**(Grand C)**

### **Health Care Reform and its Impact on Patient Assistance Programs**

Federal health care reform legislation, if enacted, is expected to include new assistance during Medicare Part D’s “doughnut hole” (coverage gap), so that patients will pay less for brand name drugs. This second session will examine whether there will still be manufacturer patient assistance programs if health care reform takes effect, and if so, how those programs are likely to be structured. Specific topics will include whether PAPs will focus more on underinsured than uninsured patients, whether there will be more emphasis on co-pay assistance than on directly providing pharmaceuticals, and what states might be doing to create or revise programs to reduce medication costs for some people.

**John Doster, Executive Vice President and Managing Director, The Franklin Group, inVentiv Health**

**Kathryn Duke, Health Care Consultant (Moderator)**

**Dana Kuhn, President/Founder, Patient Services, Inc. (PSI)**

**Sharon Levine, Associate Executive Director, The Permanente Medical Group, Kaiser Permanente**

**Elisabeth Normand, Director of Pharmacy Services, Saban Free Clinic, Managing Partner, Safety Net Audit Professionals**

**5:00 pm**

**Adjourn**

**6:00 – 8:30 pm**  
**(Garden Room)**

**Welcome Reception and Dinner for Hospitals, SNHPA Corporate Partners and PVP Suppliers<sup>2</sup>**

Other attendees can enjoy a night on the town.

***Commencement of Main Conference***  
**(ACPE 0085-9999-10-005-L04 P and T)**

## **TUESDAY, FEBRUARY 2, 2010**

**7:00 am**  
**(Grand Foyer)**  
**(Grand A)**

**Registration and Continental Breakfast**

**Exhibits Open**

**8:00 am**  
**(Grand BC)**

**Opening Remarks**

**Representatives from the Conference Hosts and Industry Leaders**

<sup>2</sup> Please note that this session is limited to hospitals, SNHPA corporate partners and Apexus/PVP suppliers. There is an additional cost to attend and registration is required.

8:15 am  
(ACPE 1 Hour)

### **Federal Health Care Reform: Where Do We Go Next?**

Our knowledgeable panel will discuss the current status of the federal health care reform effort, and where the legislation may be headed. Panelists will explore the non-340B elements of the respective health care bills that would have the most impact on 340B stakeholders. They will discuss why health reform is stalled and whether it can be resurrected before the November elections.

**Chris Burch**, Executive Director, National Association of Public Hospitals and Health Systems

**Michael McCaughan**, Editor-in-Chief, The Pink Sheet and RPM Report

**Roger Schwartz**, Associate Vice President and Legal Counsel, National Association of Community Health Centers (Moderator)

9:15 am  
(ACPE 1 Hour)

### **Health Care Reform at the State and Local Level**

Our panel of experts on health care reform at the state and local level will examine some of the more far-reaching efforts and whether they're succeeding in providing access for vulnerable populations to affordable healthcare. We will also explore what type of impact these reforms have had on the financial health of 340B providers. Finally, the panelists will look at whether these programs could serve as models for elsewhere in the nation.

**Tangerine Brigham**, Deputy Director of Health, Director of Healthy San Francisco, San Francisco Department of Public Health

**Richard Cauchi**, Program Director, Health Program, National Conference of State Legislatures

**Allen Meyer**, Vice President of Programs, San Francisco Community Clinic Consortium

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

10:15 am  
(Grand A)

### **Exhibitor Forum, Refreshment Break, and Networking Opportunity**

10:45 am  
(Grand BC)  
(ACPE 1 Hour)

### **340B Reform: What it Would Mean for You and What's Next on the Horizon?**

Major reforms to the 340B program have never been so close to passage, but final enactment remains in doubt. Panelists will review the key elements of the pending 340B reform bill and how it would impact 340B stakeholders including providers, industry and the government. They will touch upon some of the more controversial measures and provide their thoughts on where we go from here.

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

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

**Donna Yesner**, Partner, McKenna Long & Aldridge (Counsel to The Coalition for Government Procurement)

11:45 am  
(ACPE 1 Hour)

### **Federal Government Update**

Get an update from HRSA's two 340B federal contractors – the Pharmacy Services Support Center (PSSC) and Apexus/340B Prime Vendor Program (PVP) – on various initiatives. In addition, find out the status of pending HRSA guidelines that could expand the contract pharmacy program and definition of 340B eligible patients. There will also be an update on how enrollment of children's hospitals is proceeding. You will also learn about the latest details on HRSA's clinical pharmacy initiative to identify and disseminate "best practice" models for improving patient safety.

**Chris Hatwig**, Vice President, Apexus/340B Prime Vendor Program

**Lisa Scholz**, Senior Director, Pharmacy Services Support Center

12:45 pm  
(Atrium)

### **Luncheon and Networking Opportunity**

2:00 pm  
(Grand BC)  
(ACPE 1.25 Hours)

### **New Opportunities with Contract Pharmacies**

Even before HRSA's long-anticipated multiple contract pharmacy guidelines are finalized, the agency announced a new policy allowing patients of a covered entity with multiple sites to receive their 340B drugs at any of the in-house or contract pharmacies associated with those sites. This new policy and the multiple contract pharmacy guidelines will provide greater flexibility to 340B covered entities in meeting their patients' needs. A panel of experts will explore what is permitted under the new policy and what may be permitted under the proposed guidelines. What will be the optimal approach to

setting up pharmacy access for patients? How have Alternative Methods Demonstration Projects (AMDPs) utilizing multiple contract pharmacies been able to optimize use of a multiple contract pharmacy structure? Panelists also will discuss the possible role of pharmacy benefit managers in coordinating prescription drug benefits dispensed by multiple pharmacies.

**Anthony Lesser, Pharmacy Inventory Manager, Harris County Hospital District**  
**Sharon Kotabe, Pharmacy Director, San Francisco Department of Public Health,**  
**Assistant Dean, USCF School of Pharmacy**  
**Lisa Scholz, Senior Director, Pharmacy Services Support Center (Moderator)**

3:15 pm  
(Grand A)

### Exhibitor Forum, Refreshment Break, and Networking Opportunity

4:00 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.]**

(Bayview Room)  
(ACPE 1.25 Hours)

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

- Numerous provisions in health care reform have specific hospital implications, which we will address
- Where do we go from here on 340B reform?
- Maximizing pharmaceutical savings: a case study

**Donald Davies, Pharmacy Government Programs Coordinator, Clarian Health Partners, Inc.**

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

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

(Grand BC)  
(ACPE 1.25 Hours)

#### B. Pharmaceutical Manufacturers

- The latest legal update on emerging issues
- What to expect or not with healthcare reform
- Update on 340B identifier in chargeback requests
- Pricing transparency

**Marcus Farbstein, Director, Federal Accounts, Genentech, Inc.**

**Chris Hatwig, Vice President, Apexus/340B Prime Vendor Program**

(Seacliff AB)  
(ACPE 1.25 Hours)

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

- State/health center arrangements on sharing 340B savings vs. states seeking rebates
- State prohibitions on centers carving out Medicaid patients from 340B
- Issues regarding health centers contracting with Medicare Part D plans
- Optimizing 340B at health centers--best practices

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

**David Quackenbush, Chief Executive Officer, Central Valley Health Network**

**Roger Schwartz, Associate Vice President and Legal Counsel, National Association of Community Health Centers**

(Seacliff C)  
(ACPE 1.25 Hours)

#### D. Hemophilia Treatment Centers

- Healthcare reform with 41 Republican Senators
- Alliance/Apexus collaboration
- Update on Third party payers
- Strategies on selling the comprehensive care model

**Joseph Pugliese, President, Hemophilia Alliance, Inc.**

**Sean Singh, Vice President, Hemophilia Alliance, Inc.**

5:15 pm

Adjourn

5:30 – 6:45 pm  
(Grand A)

Reception and Networking Opportunity for All Attendees

**WEDNESDAY, FEBRUARY 3, 2010**

7:00 am  
(Grand Foyer)  
(Grand A)

Continental Breakfast  
Exhibits Open

8:15 am  
(Grand BC)  
(ACPE 1.25 Hours)

**Trends and Developments in Medicaid and Medicare Reimbursement & Billing**

340B providers are under increased scrutiny by both federal and state governments over how they bill Medicaid and Medicare. Panelists will discuss how to best balance the fiscal health of safety net providers and the Medicaid and Medicare programs. There will be an update on on-going HHS Inspector General's studies of both Medicaid and Medicare Part B reimbursement and the possible implications of the study findings for 340B providers and industry. Panelists will discuss how the new California law prohibiting providers from carving out 340B for their Medicaid patients is impacting program participants. You will also learn about innovative efforts by many states to allow for "win win" arrangements for Medicaid and providers. In addition, there'll be a review of the SNHPA settlement with CMS on the NDC reporting regulations, what that settlement means for providers and state Medicaid programs in making the reporting requirement less burdensome and permitting providers to bill at other than actual acquisition cost for physician-administered drugs.

Brian Chase, Assistant General Counsel, AIDS Healthcare Foundation  
Debra Demers, Consultant, 340B Pharmacy Operations  
Michael Glomb, Partner, Feldesman, Tucker, Leifer, Fidel (Counsel to National Association of Community Health Centers)  
Stuart Gordon, Director of Legal and Regulatory Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

9:30 am  
(Grand A)

Networking and Refreshment Break - Exhibits Open

*The remaining sessions have been organized into separate tracks to meet the varying interests of conference attendees. Track One sessions 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, that 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. Track Three sessions are designed to be small roundtable discussions primarily focused on the other two track's topics. These sessions will allow for a more intimate discussion with panel experts and allow for more questions and answers. These sessions will be limited to 50 attendees each; first come, first served.*

10:00 am  
(Bayview Room)  
(ACPE 1.25 Hours)

**Track One – Operationalizing 340B**  
**How to Enroll in 340B**

If you are interested in enrolling your facility or health program into 340B, learn more about how to get this accomplished efficiently and accurately. Potential hurdles to implementation also will be discussed, as will be the details of the children's hospital guidelines' implementation process and the progress of children's hospitals in getting enrolled. Also learn about what new entities might qualify under the proposed reform legislation.

Paul Shank, Consultant Coordinator, Pharmacy Services Support Center  
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access

(Grand BC)  
(ACPE 1.25 Hours)

**Track Two – 340B Policy and Compliance**  
**Preparation for Expansion of 340B Market: Manufacturers' Perspective**

This session will focus on how pharmaceutical manufacturers should prepare for the possible expansion of the 340B market. As new covered entities come into the program and the program is extended to the inpatient setting, the pharmaceutical industry will need to react to the changes. In addition, there are numerous enforcement measures in

340B reform legislation that would require beefed up compliance. What compliance challenges will they, and the new covered entities seeking discounts face? Would the product demands of the 340B community create challenges to manufacturer supply? Would the changes impact the availability and types of patient assistance programs?

**Marcus Farbstein, Director, Federal Accounts, Genentech, Inc.**

**Perry Knight, Associate, Sidley Austin LLP**

**Edith Marshall, Counsel, Arnold & Porter LLP**

### **Track Three – Roundtables (Limit 50 attendees per session)**

#### **Concurrent Sessions (2 Choices)**

*(Seacliff C)*  
*(ACPE 1.25 Hours)*

#### **(1) Navigating the 340B Prime Vendor Program**

Apexus/340B Prime Vendor will discuss different opportunities for maximizing the value of the PVP program. Providers will learn how to identify and take advantage of resources – from PVP directly and from PVP suppliers – to ensure that your organization is not missing any opportunities to lower its costs and improve outcomes under the program.

**John Barnes, Portfolio Executive, Apexus/340B Prime Vendor Program**

**Mary Ellen England, Director Education and Marketing, Apexus/340B Prime Vendor Program**

*(Seacliff D)*  
*(ACPE 1.25 Hours)*

#### **(2) How to Set Up a Contract Pharmacy**

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 roundtable is designed to help covered entities and their pharmacy partners identify and perform the necessary tasks for operationalizing a contract pharmacy arrangement.

**Gary Horne, Director of Pharmacy, San Mateo Medical Center**

**Danielle Mathers, Communications Manager, Pharmacy Services Support Center**

**Lisa Scholz, Senior Director, Pharmacy Services Support Center**

**11:15 am**  
*(Bayview Room)*  
*(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 roundtable 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 to help attendees identify and understand a “best practices” approach for their institutions.

**Rosie Jadidian, Director of Pharmacy, Northeast Valley Health Corporation, Managing Partner, Safety Net Audit Professionals**

**Andrew Wilson, Managing Consultant, Pharmacy Optimization, McKesson Health Systems**

**Doug Wong, Vice President, Pharmacy Services, Pharmacy Healthcare Solutions**

*(Grand BC)*  
*(ACPE 1.25 Hours)*

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

#### **Pricing Changes Under Health Care Reform & Their Implications for 340B**

Health reform includes significant changes in price calculations that would have a major impact on the 340B and Medicaid rebate programs. Legislation includes a major increase in the discounts that manufacturers would be required to offer Medicaid and 340B participants. In addition, a key component of the rebate and 340B discount calculation, “average manufacturer price” would be redefined to exclude many non-retail costs. This session will examine how these changes are likely to impact 340B stakeholders. Panelists also will review the potential expansion of Medicaid rebates to managed care and whether that expansion would affect 340B providers and other 340B stakeholders.

Finally, panelists will discuss how the recent litigation settlement forcing a redefinition of AWP will likely impact pharmacy providers generally and 340B pharmacy providers specifically.

**Stuart Gordon, Director of Legal and Regulatory Affairs, Safety Net Hospitals for  
Pharmaceutical Access (Moderator)**

**Edith Marshall, Counsel, Arnold & Porter LLP**

**Tom Renshaw, Vice President of Pharmacy, ESI**

### **Track Three – Roundtables (Limit 50 attendees per session)**

#### **Concurrent Sessions (2 Choices)**

*(Seacliff C)*  
*(ACPE 1.25 Hours)*

##### **(1) Optimizing 340B**

Program participants will discuss various opportunities for maximizing the value of the 340B program. Providers will learn about different purchasing and dispensing strategies designed to improve both access and affordability of medications for underserved populations. Hear from experts on how to identify and take advantage of resources to ensure that your organization is not missing any opportunities to lower its costs under the program.

**Petra Fippen, Manager of Inventory Control, Pharmacy Department, Wishard Health Services**

**Jason Hardaway, Senior Director, Contract Pharmacy Programs, Wellpartner, Inc.**

*(Seacliff D)*  
*(ACPE 1.25 Hours)*

##### **(2) California Medicaid Carve-Out Prohibition**

This roundtable will focus on California's new budget-cutting prohibition against covered entities carving their Medicaid drugs from the 340B program, and how that has impacted covered entities in the Golden State. Representatives from California 340B hospitals will discuss their efforts to avoid having to bill at actual acquisition cost and what Medi-Cal's actions could portend for Medicaid programs in other states. The roundtable will offer insight into how other states have worked with 340B covered entities to find shared savings arrangements. Covered entities from other states are invited to attend and offer their own thoughts on possible solutions to the California issue.

**Clara Evans, Director, Public Policy and Fiscal Advocacy, Catholic Healthcare West**

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

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

12:30 pm

Conference Adjourns



Comprehensive Pharmacy Services, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. In order to receive credit, all participants must sign in daily at the conference and then complete an online CE request form answering the appropriate post-test questions. Credit statements will be sent via e-mail approximately eight weeks following the program. Statements for those unable to receive e-mail will be mailed.