
Fifth Annual 340B Coalition Winter Conference

Co-Hosted by Apexus/340B Prime Vendor Program

February 2-4, 2009 • Hyatt Regency La Jolla • San Diego, CA

AGENDA

MONDAY, FEBRUARY 2, 2009

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

12:00 – 5:00 pm Early Registration – Exhibits Open
(Aventine Foyer C)
(Pavilion)

1:30 pm Pre-Conference Workshop (Two Options)¹

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

(ACPE 085-999-09-001-L04P and 085-999-09-001-L04T)

1:30 pm
(Aventine AB)
(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.

Barbara Brice, Pharmacy Technical Assistance Program Coordinator, Pharmacy Services Support Center

Tom Renshaw, Director, Apexus/340B Prime Vendor Program

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

3:00 pm
(Pavilion)

Refreshment and Networking Break

3:30 pm
(Aventine AB)

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.

Karen Biancalana, Associate Director, Pricing & Reimbursement, Amylin Pharmaceuticals, Inc.

Chris Roberson, Director of Pharmacy Operations, Indiana Hemophilia and Thrombosis Center

Scott Summers, Vice President, Safety Net Solutions, Cardinal Health

Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.

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

Option 2 – Patient Assistance Programs and Medicare Part D

(ACPE 085-999-09-002-L04P and 085-999-09-002-L04T)

1:30 pm
(Aventine 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. There will be time allotted for questions and discussion at the end of each session.

Christian Clymer, Senior Director, Affordability and Access, PhRMA

Susan Edmondson, Pharmacy Program Manager, Lifelong Medical Health Centers

Jennifer McGovern, Director, AstraZeneca Patient Assistance Programs

**Gary McWilliams, Executive Vice President, Chief Ambulatory Services Officer,
University Health System San Antonio**

**Andrew Wilson, Director of Pharmacy and Educational Services, Safety Net Hospitals for
Pharmaceutical Access (Moderator)**

Cecilia Wu, Clinical Pharmacist, QueensCare Family Clinics

3:00 pm
(Pavilion)

Refreshment and Networking Break

3:30 pm
(Aventine C)

Medicare Part D Challenges and Solutions

As Part D begins its fourth year of coverage, there are accomplishments to celebrate and new implementation challenges. Speakers will address implications of drug plan design and premium changes from one year to the next, increased rate of generic drug dispensing, and billing operations, with special attention to Part D's low income subsidies. Other issues that will be covered include strategies for assisting patients whose prescriptions are not covered under the “donut hole,” declining reimbursement by Part D health plans, and opportunities to capture much needed revenue.

Todd Crosslin, Vice President Pharmacy Services, ESI Network

Dana Darger, Director of Pharmacy, Rapid City Regional Hospital

Kathryn Duke, 340B and Patient Assistance Program Consultant (Moderator)

Susan Edmondson, Pharmacy Program Manager, Lifelong Medical Health Centers

Lucy Saldaña, Chief Pharmacist, Region IX, Centers for Medicare & Medicaid Services

5:00 pm

Adjourn

6:30 – 8:30 pm
(Portofino AB)

Welcome Reception and Dinner for Hospitals, SNHPA Corporate Partners and PVP Suppliers²

Other attendees can enjoy a night on the town.

Commencement of Main Conference
(ACPE 085-999-09-003-L04P and 085-999-09-003-L04T)

TUESDAY, FEBRUARY 3, 2009

7:00 am
(Aventine Foyer C
Pavilion)

Registration and Continental Breakfast

Exhibits Open

8:15 am
(Aventine ABCG)

Opening Remarks

Representatives from the Conference Hosts and Industry Leaders

² 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.

8:30 am
(ACPE 1.25 Hours)

Federal Government Update

HRSA's Office of Pharmacy Affairs (OPA) will provide updates on several 340B-related activities, including the status of proposed guidelines that would change the definition of 340B-eligible patients, expand the contract pharmacy program and allow enrollment of children's hospitals into the program. OPA will also provide the latest details on its clinical pharmacy initiative to identify and disseminate "best practice" models of how clinical pharmacy programs can improve patient safety. Other speakers will include senior executives from HRSA's two 340B federal contractors – the Pharmacy Services Support Center (PSSC) and Apexus/340B Prime Vendor Program (PVP).

Christopher Hatwig, Vice President, Apexus/340B Prime Vendor Program
Jimmy Mitchell, Director, Office of Pharmacy Affairs
Lisa Scholz, Senior Director, HRSA Pharmacy Services Support Center

9:45 am
(ACPE 1 Hour)

Legislative Update

It is no secret that Democratic leaders in Congress want to open up the Medicare Part D law in 2009 and make significant programmatic changes, including giving the federal government more control over regulating and/or negotiating drug prices. At the same time, legislation that would make significant changes to the 340B program has been introduced and is expected to be addressed. Other pharmaceutical pricing matters that are likely to appear on Congress' agenda in 2009 include drug reimportation and expansion of the Medicaid drug rebate program to managed care drugs and the dual-eligibles. Against this backdrop, the 340B and Medicaid rebate programs are ripe for legislative reform. This panel will focus on what 340B stakeholders can expect from Congress in 2009.

Michael McCaughan, Editor in Chief, The Pink Sheet and RPM Report
Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access
(Moderator)

10:45 am
(Pavilion)

Exhibitor Forum, Refreshment Break, and Networking Opportunity

11:30 am
(Aventine ABCG)
(ACPE 1 Hour)

Health Reform, Drug Pricing, and 340B Under the Obama Administration

Mr. Obama's presidency catapults a wide range of health reform issues onto the national agenda, e.g., reducing health disparities and the number of uninsured in the U.S., improving the transparency of health care costs and covering care management of patients suffering from multiple chronic conditions. Our panel of Washington insiders will analyze both the role and future of the 340B program within these broader policy initiatives. Among the issues that will be addressed is the pressing need to fund the administration of the 340B program. Although Congress can choose to appropriate funds to HRSA specifically earmarked for 340B program administration, lawmakers may be more interested in establishing a user fee arrangement similar to the one currently used for the federal vaccine compensation program.

Roger Schwartz, Associate Vice President, Policy and Programs Division, National Association of Community Health Centers
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access
Marcus Farbstein, Director, Government Affairs, Genentech, Inc.

12:30 pm
(Aventine DEF/Palm Court)

Luncheon and Networking Opportunity

1:45 pm
(Aventine G)
(ACPE 1.25 Hours)

Concurrent Session – Option 1

340B Reimbursement Under the Hospital Outpatient Prospective Payment System (HOPPS)

Medicare Part B covers a wide range of self-administered and physician-administered drugs that must be discounted when sold to 340B providers. This session will focus on the unique issues arising out of the interaction between the Part B and 340B programs, especially with respect to a recent proposal by CMS that average sales price (ASP) reimbursement be reduced for disproportionate share hospitals participating in the 340B program. Practical solutions to Part B billing and reimbursement challenges will be explored.

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

Katie Leblanc, Director of Revenue Services, Catholic Healthcare West
Greg White, Senior Director, Health Policy and Reimbursement, Johnson & Johnson

Concurrent Session – Option 2

(Aventine ABC)
(ACPE 1.25 Hours)

Status of 340B Federal Register Notices

In 2007, HRSA issued three proposed notices that, if implemented, would introduce far-reaching changes to the 340B program. One would narrow the patient populations eligible to receive 340B drugs. Another would expand the contract pharmacy program to allow multiple contract pharmacy arrangements. The third would specify the procedures necessary for children's hospitals to qualify and apply for 340B participation. The fate of these three proposals – whether they will be finalized and published in 2009 and whether stakeholders can expect significant changes to them – will be debated by our expert panelists.

Michael Glomb, Counsel, National Association of Community Health Centers
Lisa Scholz, Senior Director, Pharmacy Services Support Center
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

3:00 pm
(Pavilion)

Exhibitor Forum, Refreshment Break, and Networking Opportunity

3:45 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.]**

(Aventine ABC)
(ACPE 1 Hour)

A. DSH and Children's Hospitals

- Update on pricing investigations and refund opportunities
- Latest news from Washington, D.C. on key legislative and regulatory matters

Virginia Gibson, Assistant U.S. Attorney, Chief Civil Division, Eastern District of Pennsylvania

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

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

(Aventine G)
(ACPE 1 Hour)

B. Pharmaceutical Manufacturers

Ed McAdam, Senior Director, Contracting, Pricing and Analytics, Daiichi Sankyo, Inc. (Moderator)

Marcus Farbstein, Director, Government Affairs, Genentech, Inc.

Miree Lee, Pricing & Contracts Consultant, M. Lee Consulting, LLC

(Mykonos AB)
(ACPE 1 Hour)

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

- Competing in the current economic situation (e.g., \$4 RX at Wal-Mart) – what is appropriate and legal?
- How to ensure compliance?
- IRS statute – certification process for pharmacies related to Health Savings Accounts. How does this apply to CHC's?
- Fraud and abuse training for Medicare
- Medicare D and private insurers – how to deal with third parties?

Michael Glomb, Counsel, National Association of Community Health Centers
Roger Schwartz, Associate Vice President, Policy and Programs Division, National Association of Community Health Centers, Inc.

Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.

(Athenia A)
(ACPE 1 Hour)

D. Hemophilia Treatment Centers

Joseph Pugliese, President, Hemophilia Alliance, Inc.
Sean Singh, Vice President, Hemophilia Alliance, Inc.

5:00 pm

Adjourn

5:15 – 6:30 pm
(Pavilion)

Reception and Networking Opportunity for All Attendees

WEDNESDAY, FEBRUARY 4, 2009

7:00 am
(Aventine Foyer C
(Pavilion)

Continental Breakfast

Exhibits Open

8:15 am
(Aventine ABCG)
(ACPE 1.25 Hours)

Enforcement and Investigations Relating to Overcharging and Other 340B Violations

Both covered entities and drug manufacturers find their 340B compliance status being scrutinized by federal and state authorities. Covered entities are increasingly being asked to explain their use of the 340B program and why such uses comply with 340B patient definition standards. State Medicaid agencies, in the meantime, are keeping a watchful eye over covered entity billing practices to protect against overpaying for 340B drugs. Some states have initiated recoupment efforts and regular audit programs. Manufacturers, likewise, are being scrutinized under the 340B program. Some companies have been compelled to issue refunds to covered entities as part of broader settlement agreements with the Medicaid program for alleged overcharges arising out of best price errors or questionable marketing practices. A panel of government enforcement officials and lawyers representing industry and covered entities will discuss these 340B-related compliance trends and offer their insights into future enforcement activities.

Madeline Carpinelli, Research Fellow, PRIME Institute (Former lead HHS OIG investigator on 340B program)

Virginia Gibson, Assistant U.S. Attorney, Chief Civil Division, Eastern District of Pennsylvania

John Shakow, Partner, King & Spalding LLP

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

9:30 am
(Pavilion)

Networking and Refreshment Break - Exhibits Open

Note: 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

Track One – Operationalizing 340B

(Aventine ABC)
(ACPE 1.25 Hours)

Optimizing 340B

Program participants will discuss different 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 – Prime Vendor, PSSC, wholesalers, vendors, consultants and advocacy groups – to ensure that your organization is not missing any opportunities to lower its costs under the program.

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center
Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.
Andrew Wilson, Director of Pharmacy and Educational Services, Safety Net Hospitals
for Pharmaceutical Access

Track Two – 340B Policy and Compliance

(Aventine G)
(ACPE 1.25 Hours)

NDC Reporting

This session will feature a panel of experts who will provide an update on state implementation of a provision in the Deficit Reduction Act of 2005 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. Attendees will be updated on pending litigation challenging CMS' decision to extend NDC reporting requirements to hospitals.

Kevin Gorospe, Chief, Pharmacy Policy Unit, Medi-Cal Pharmacy Benefits Division
Katie Leblanc, Director of Revenue Services, Catholic Healthcare West
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for
Pharmaceutical Access (Moderator)

Track Three – Roundtables

(Delphi AB)
(ACPE 1.25 Hours)

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.

Walt Priest, Executive Director, Family Health Network Central New York
Barbara Brice, Pharmacy Technical Assistance Program Coordinator, Pharmacy
Services Support Center

(Athenia AB)
(ACPE 1.25 Hours)

Prime Vendor Program

Apexus/340B Prime Vendor will discuss different opportunities for maximizing the value of the 340B program by enrolling in 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 under the program.

Mary Ellen England, Director of Marketing, Apexus/Prime Vendor Program
Tom Renshaw, Director, Apexus/Prime Vendor Program

11:15 am

Track One – Operationalizing 340B

(Aventine G)
(ACPE 1.25 Hours)

Multiple Contract Pharmacies

This session will focus on the operational challenges faced by covered entities interested in implementing multiple contract pharmacy arrangements. The contractual and inventory management responsibilities that must be assumed by covered entities to set up a single contract pharmacy arrangement will be multiplied if the entity wants to contract with multiple pharmacies. How should providers manage their network of contract pharmacies? Can some of these functions be outsourced to third parties? What patient verification and tracking systems need to be adopted for compliance purposes? These and other operational issues will be addressed by our panel of experts.

Barbara Brice, Pharmacy Technical Assistance Program Coordinator, Pharmacy
Services Support Center
Jason Hardaway, Senior Director, Contract Pharmacy Programs, Wellpartner, Inc.
(Moderator)
Walt Priest, Executive Director, Family Health Network Central New York

Track Two – 340B Policy and Compliance

(Aventine ABC)
(ACPE 1.25 Hours)

Average Manufacturer Price Changes and Impact on 340B Program

This session will focus on calculating average manufacturer price (AMP) in accordance with the Deficit Reduction Act (DRA) and how DRA-related changes to AMP will affect 340B ceiling prices. CMS's final regulation redefining AMP has been successfully challenged in court by retail pharmacies raising the possibility that AMP will have to be redefined again causing further changes to 340B ceiling price calculations. OPA has struggled with whether AMP changes under the DRA should apply to 340B. 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 current methodologies. Both manufacturer and covered entity perspectives will be provided during this session, with an emphasis on compliance.

Madeline Carpinelli, Research Fellow, PRIME Institute (Former lead HHS OIG investigator on 340B program)

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

John Shakow, Partner, King & Spalding LLP

Track Three – Roundtables

(Athenia AB)
(ACPE 1.25 Hours)

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 in an effort to help attendees identify and understand a “best practices” approach for their institutions.

Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.

Robert Scholz, Vice President, McKesson Pharmacy Optimization

Andrew Wilson, Director of Pharmacy and Educational Services, Safety Net Hospitals for Pharmaceutical Access

(Delphi AB)
(ACPE 1.25 Hours)

Billing Medicaid

When Congress enacted the 340B statute, it recognized that it was placing manufacturers at risk of giving two discounts on the same drug – an upfront discount to the pharmacy under 340B and a rebate to Medicaid under the Medicaid drug rebate program. Congress directed HHS to develop procedures for protecting manufacturers from the duplicate discount problem which has altered the traditional billing and payment relationships between covered entities and state Medicaid agencies. This roundtable showcases different methodologies that covered entities have employed to bill Medicaid properly. It also highlights how manufacturers can be exposed to duplicate discounts if either states or covered entities fail to follow applicable requirements.

Kevin Gorospe, Chief, Pharmacy Policy Unit, Medi-Cal Pharmacy Benefits Division

Roger Schwartz, Associate Vice President, Policy and Programs Division, National Association of Community Health Centers, Inc.

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 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.