
14th Annual 340B Coalition Conference

Co-Hosted by Apexus/340B Prime Vendor Program

July 19-21, 2010 • Omni Shoreham Hotel • Washington, DC

AGENDA

SUNDAY, JULY 18, 2010

- 1:00 – 5:00 pm Exhibitor Set Up
(Exhibit Hall)
- 3:00 – 5:00 pm Early Registration
(West Registration)
- 6:00 – 8:30 pm Welcome Reception and Dinner for Hospitals, SNHPA Corporate Partners and PVP Suppliers¹
(Palladian Room)

MONDAY, JULY 19, 2010

- 7:00 am Registration and Exhibits Open 7:00 am – 5:15 pm
Pre-Conference Workshop (Two Options)²
(ACPE# 0085-9999-10-021-L03)

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

7:00 am
(Exhibit Hall)

Continental Breakfast (Workshop Attendees Only)

8:30 am
(Palladian Room)
(ACPE 2.75 Hours)

340B Basics – Introduction to the Federal 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.

Jae Choi, Program Manager, Office of Pharmacy Affairs

Mary Ellen England, Director of Marketing, Apexus/340B Prime Vendor Program

Paul Shank, Consultant Coordinator, Pharmacy Services Support Center

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

10:00 am
(Exhibit Hall)

Networking and Refreshment Break

10:30 am

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 enrollment and implementation of the 340B program from their respective viewpoints.

Janell Claudy, Pharmacy Manager, Family Health Pharmacy

Dale James, Senior National Account Manager, McKesson Health Systems Support Services

Chris Roberson, Director of Compliance and Community Programs, Indiana Hemophilia & Thrombosis Center

Debbe Saez, Senior Compliance Manager, Compliance Implementation Services

11:45 am
(Exhibit Hall)

Networking Lunch (WORKSHOP ATTENDEES ONLY)

¹ Please note this event is only for hospitals, corporate partners of Safety Net Hospitals for Pharmaceutical Access and 340B Prime Vendor Program suppliers. Registration is required.

² Please note there is an additional cost to attend the pre-conference workshop and Monday's lunch and you must register for it.

Option 2 – Patient Assistance Programs: Current and Future

7:00 am
(Exhibit Hall)

Continental Breakfast (Workshop Attendees Only)

8:30 am
(Diplomat Room)
(ACPE 2.75 Hours)

Recent Developments in 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 session examines current activities, successes and challenges of PAP programs, both those aimed at individual patients and those “institutional” patient assistance programs operating in hospitals, health centers 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.

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

Merrill Thomas, Chief Executive Officer, Providence Community Health Centers

Koula Tsahas, Director of Pharmacy, St. Catherine Hospital

Janet Walton, Deputy Program Director, RxAssist (Moderator)

10:00 am
(Exhibit Hall)

Networking and Refreshment Break

10:30 am

The Future of PAPS: Where Do We Go from Here?

During this portion of the session, we will discuss the short- and long-term impact of healthcare reform on the future of PAPS, especially whether the drug discounts agreed to by pharmaceutical companies to fill the Medicare Part D “doughnut hole” will lead to a decline of PAPS. In addition, we will provide an update on efforts by advocacy organizations and providers to educate manufacturers about the increasing burden to comply with audit requests.

- How to address increased audit requirements
- Future of bulk replacement and institutional patient assistance programs
- Trends in patient assistance including co-pay assistance programs

Mark Fitzgerald, Principal, Powers Pyles Sutter & Verville PC

Ken Trogdon, Chief Executive Officer, Welvista

Janet Walton, Deputy Program Director, RxAssist (Moderator)

Nathan White, Executive Director, Reimbursement Services, inVentiv Patient Outcomes

11:45 am
(Exhibit Hall)

Networking Lunch (WORKSHOP ATTENDEES ONLY)

Commencement of Main Conference
(ACPE# 0085-9999-10-022-L04)

1:00 pm
(Regency Ballroom)

Opening Remarks from Conference Hosts and HRSA Administrator Dr. Mary Wakefield

1:30 pm

Lifetime Achievement Awards Ceremony

Jim Mitchell, Director, Office of Pharmacy Affairs

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

2:00 pm
(ACPE 1 Hour)

Federal Government Update: Presentations by OPA, PVP and PSSC

The Office of Pharmacy Affairs and its federal contractors face many new responsibilities as a result of the 340B expansion included in health reform and recently published guidelines on contract pharmacies and children’s hospitals. This comes at a time that OPA is about to undergo a change in leadership for the first time in over a decade. You will hear updates on implementation of the 340B reform law from the enrollment process for new covered entities to the new compliance provisions that will affect providers and industry. You will also get the latest details on its clinical pharmacy initiative to identify and disseminate “best practice” models of how clinical pharmacy programs can improve outcomes and patient safety. Also presenting are representatives from HRSA’s two 340B

federal contractors – the Pharmacy Services Support Center (PSSC) and Apexus/340B Prime Vendor Program (PVP) – on various initiatives.

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

3:00 pm
(Exhibit Hall)

Networking and Refreshment Break

3:30 pm
(Regency Ballroom
(ACPE 1 Hour)

Legislative Update

Congress just enacted the most dramatic changes to the 340B program since the program's inception. And already, lawmakers are considering more changes including expanding 340B to the inpatient setting. Not only will there be a significant increase in the number and categories of entities participating in the 340B program, there are new compliance requirements that will affect every 340B stakeholder from the smallest health center to the largest drug companies in the country. Learn more about the new 340B law and get an inside look on how the final legislation came to fruition and what is on the horizon.

- What were the most controversial aspects of the 340B reform debate?
- What are the new requirements for covered entities and industry?
- What is going to happen to 340B prices?
- What is the orphan drug exemption?
- What happens next to efforts to extend 340B pricing to the inpatient setting?
- What else is on the 340B legislative agenda?
- What does the GAO study mean for the 340B program?
- How about Medicaid billing?

Alice Valder Curran, Partner, Hogan and Lovell
Roger Schwartz, Associate Vice President, National Association of Community Health Centers
Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

4:30 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 for each group.

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

(Diplomat Room)
(ACPE 1 Hour)

Community Health Centers

Join us at this session to discuss the latest 340B issues specifically affecting health centers. This is an opportunity to raise any issues that may be affecting your health centers or ask questions on the latest developments in the Accountable Care Act, the new health reform law.

Roger Schwartz, Associate Vice President, National Association of Community Health Centers
Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc., Consultant, Pharmacy Services Support Center

(Council Room)
(ACPE 1 Hour)

Family Planning Clinics

- 340B Coalition Work: Update on meetings with (and outreach to) HRSA, CMS re: patient definition, Medicaid billing, nominal pricing
- Title X: Update on new DASPA, program strategic planning
- FDA: Update on status of ELLA application/advisory hearing
- Health Care Reform: Review of 340B provisions in legislation

Amy Yenko, Assistant Director, Government Relations, Planned Parenthood

(Forum Room)
(ACPE 1 Hour)

Hemophilia Treatment Centers

- Expanding the 340B program: Pros and Cons
- Healthcare Reform on 340B Programs
- Medicaid Rebate Calculations on PHS Pricing
- Utilizing Multiple Contract Pharmacy to your benefit

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

(Senate Room)
(ACPE 1 Hour)

HIV/AIDS Clinics, ADAPs, and AIDS Service Providers

Beth Crutsinger-Perry, Associate Director, Care and Treatment Team, National Alliance of State & Territorial AIDS Directors
Robert Styron, Controller, The Pharmacy at CARES

(Regency Room)
(ACPE 1 Hour)

Hospitals (DSH, Rural, Children's and Cancer Hospitals)

- Credit/Rebill Developments
- Refund Process under Health Reform
- Contract Pharmacy Outreach and Opportunities
- Next Steps on Nominal Pricing?
- Role of 340B Hospitals in Specialty Pharmacy Area

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

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

Walt Woods, Director of Ambulatory Operations, Vanderbilt University Medical Center

Tony Zappa, Chief Information Officer and Director, Specialty/Infusion Operations, Fairview Pharmacy Services

(Palladian Room)
(ACPE 1 Hour)

Pharmaceutical Industry

- Should there be a materiality standard for ceiling price corrections and credits?
- The mechanics of the ceiling price true-up and credit process
- The scope and implementation of the orphan drug exception
- Reclassification of GPO sales to 340B sales- seeking more efficient approaches between the covered entity, wholesaler and manufacturer
- Potential impact on 340B price from AMP changes in October
- Outpatient purchases under the 340B program for "inpatient" type drugs- having a policy to process and manage them

Chris Cobourn, Vice President, Regulatory Compliance, Compliance Implementation Services

Alice Valder Curran, Partner, Hogan and Lovell

Donna Yesner, Partner, McKenna Long & Aldridge LLP

(Cabinet Room)
(ACPE 1 Hour)

State and Local Government

This workshop provides an opportunity for state and local government officials to exchange ideas and share experiences in using the 340B program to expand access and save on costs with respect to prescription drugs for government supported patient populations

Hunt Blair, Deputy Commissioner, Vermont Department of Health Access

Elisabeth Doyle, Associate, Power Pyles Sutter & Verville

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center

(Congressional A)
(ACPE 1 Hour)

340B Contract Pharmacies (New in 2010!) (Chain, Independent & Mail Order Pharmacies and Related Vendors)

This breakout provides an opportunity to engage with fellow contract pharmacies to exchange ideas and share information on maintaining a contract pharmacy relationship with a 340B covered entity. Learn from fellow colleagues how they implemented various models to improve medication access to the community; share ideas on improving patient outcomes through medication therapy management and other clinical programs; offer solutions for improving contract pharmacy relationships as the future of the 340B program grows.

5:45 – 7:00 pm Reception and Networking Opportunity
(Exhibit Hall)

TUESDAY, JULY 20, 2010

Note: Tuesday's sessions have been organized into three 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 may 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 facilitate small roundtable discussions primarily focused on the other two tracks' topics. These sessions, which are limited to 50 attendees each (first come, first served), will allow for more dialogue and questions-and-answers with our panel of experts. Finally, for the first time, we are offering even smaller group discussion sessions that are limited to registrants within a particular stakeholder group (hospitals, health centers, etc.) and moderated by a single expert within that group. The small group discussions are limited to 10 attendees per session and are not open to other stakeholder groups. Pre-registration was required for these sessions prior to the meeting. But you can check the registration desk to see if there are any openings.

7:15 am Continental Breakfast – Exhibits Open
(Exhibit Hall)

8:30 am
(Regency Ballroom)
(ACPE 1.25 Hours)

Track One – Operationalizing 340B
Inventory Management and Preventing Diversion

Covered entities participating in the 340B program must establish inventory management systems that will protect against the risk of drug diversion and duplicate discounts. For hospitals, inventory controls must also ensure that covered outpatient drugs are not purchased through a group purchasing arrangement. Community health centers and other 340B entities have their own unique challenges as well. Finding suitable information technology solutions to these compliance needs can be challenging, especially for providers that operate one or more contract pharmacy arrangements or are required to keep separate inventories because they serve both 340B and non-340B patients or they participate in institutional patient assistance programs. This session reviews current technology and split billing software options to support compliant inventory management practices. Our speakers will also provide guidance on how to maintain 340B compliance while maximizing 340B savings.

- Various technology solutions and approaches
- Stock replacement/NDC substitution
- Split-billing
- Virtual inventories
- Recordkeeping

Rita Baskett, Director of Pharmacy and Educational Services, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Anthony Lesser, Pharmacy Inventory Manager, Harris County Hospital District, Consultant, Pharmacy Services Support Center

Andrew Maurer, Director, Macro Helix

Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc., Consultant, Pharmacy Services Support Center

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 Choices)

(Diplomat Ballroom)
(ACPE 1.25 Hours)

(1) Specialty Pharmacies

The past decade has witnessed a sharp increase in both the number of specialty pharmacies and the variety of specialty pharmaceuticals available in the U.S. drug

market. Although this trend may offer new treatment options and improve health care outcomes, both the short-term and long-term impact on 340B providers is uncertain. Specialty pharmacy practice presents unique challenges for 340B covered entities, as manufacturer business arrangements and FDA risk maps and agreements make it difficult to purchase drugs at 304B prices. This session examines the structure of the specialty pharmacy market, manufacturer and wholesaler business arrangements and options for 340B providers to consider when providing specialty pharmacy services and pharmaceuticals to their patients.

- What is the difference between a specialty pharmacy and a restricted drug delivery system?
- What challenges are there to accessing 340B prices and what options are available to address this matter?
- What are the short-term and long-term implications for 340B?
- Does the FDA REMS program unduly restrict access to newer prescription drugs by limiting distribution to specialty pharmacies (and not retail or hospital pharmacies)?

Edward Dillon, President, Community Specialty Pharmacy Network
Clay Keene, Director, Business Development, CVS Caremark Specialty Pharmacy

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

Tony Zappa, Chief Information Officer and Director, Specialty/Infusion Operations, Fairview Pharmacy Services

(Palladian Ballroom)
(ACPE 1.25 Hours)

(2) Medicare Part D

The Medicare Part D program continues to provide an important source of prescription drug coverage and reimbursement for safety net providers and their patients, although declining payment rates for 340B drugs makes Part D contracting a challenge. With the passage of health care reform, major changes are in store for the Medicare Part D program. Part D beneficiaries can expect to receive immediate relief from having to pay full price for drugs in the coverage “donut hole” and, by 2020, the Part D coverage gap could be closed completely. Speakers will discuss what the closing of the donut hole means for 340B stakeholders and how to prepare for these changes. Panelists will also discuss ways to continue to operate in the Part D market at a time of reduced reimbursement by health plans.

- What changes are in store for the Part D program?
- What will the closing of the donut hole mean to providers and industry?
- Tips on how to continue to operate in Part D market at a time of reduced reimbursement by health plans
- How to challenge unfavorable Part D contracts
- Do multiple contract pharmacy guidelines offer new opportunities for Part D revenue?
- Part D and AIDS Drug Assistance Programs (ADAPs)

Michael Bukach, Senior Vice President, Pharmacy Network and Clinical Operations, Universal American

Adam Falk, Partner, Feldesman, Tucker, Leifer, Fidel (Counsel to National Association of Community Health Centers)

Gary Horne, Director of Pharmacy, San Mateo Medical Center (Moderator)

Track Three – Roundtables

(Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

(Executive Room)
(ACPE 1.25 Hours)

(1) Children’s Hospitals

This roundtable is designed for children’s hospitals that are enrolled in the 340B program or are still thinking of applying. Among the topics that will be discussed are: qualifying and enrolling in 340B, addressing the new prohibition against purchasing orphan drugs at 340B prices, advocacy opportunities for accessing inpatient DSH pricing, complying with Medicaid billing and payment policies applicable to 340B drugs, and accessing nominal pricing contracts. Children’s hospitals can propose additional topics during the session.

Liz Parry, Assistant Director, Policy Analysis and Implementation, National Association of Children's Hospitals
Steve Pate, Manager, Outpatient Pharmacy Services, St. Jude Children's Research Hospital
Eddie Read, Vice President, Finance, Driscoll Children's Hospital
Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Facilitator)
John VanEckhout, Vice President, Clinical Services, Child Health Corporation of America

(Congressional A)
(ACPE 1.25 Hours)

(2) 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, Director of Contract Services, Apexus/340B Prime Vendor Program

Small Group Discussions

(Limit 10 attendees per session; limited to stakeholder groups only; pre-registration required)

(Senate Room)
(ACPE 1.25 Hours)

(1) Community Health Center 340B Expert

Paul Crowther, Pharmacy Director, Central Virginia Health Services, Inc.

(Council Room)
(ACPE 1.25 Hours)

(2) Drug Pricing Calculations Expert (for Pharmaceutical Manufacturers)

Ed McAdam, Senior Director, Contracting, Pricing and Analytics, Daiichi Sankyo

Debbe Saez, Senior Compliance Manager, Compliance Implementation Services

9:45 am
(Exhibit Room)

Exhibitor Forum, Refreshment Break, and Networking Opportunity

10:45 am
(Palladian Room)
(ACPE 1.25 Hours)

Track One – Operationalizing 340B

Optimizing Pharmacy Savings and Value

During this economic downturn, pharmacy departments are under increased pressure to reduce costs and find new sources of revenue. This session will showcase success stories from various 340B covered entities that are maximizing savings opportunities and taking proactive steps to weather the recession. Providers will learn about different purchasing and contracting strategies designed to improve both access and affordability of medications for underserved populations. Topics to be covered include:

- Formulary management tools
- Getting the most out of the prime vendor program and other 340B resources
- Patient assistance program maximization
- Medicare Part D success stories

Rita Baskett, Director of Pharmacy and Educational Services, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Tony Felix, Pharmacy Director, El Rio Health Center

Steve Petersen, Director of Pharmacy, Avera McKennan Hospital

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 Choices)

(Diplomat Room)
(ACPE 1.25 Hours)

(1) Interface Between Electronic Medical Records, e-Prescribing, PAPs & 340B

The 2009 American Recovery and Reinvestment Act (ARRA) established federal payments for hospitals and non-hospital providers that adopt electronic medical record (EMR) programs, but the “all or nothing” standards set by CMS for adoption of health technology may make it difficult for providers to access these payments. Congress has asked CMS to modify its standards, but will it? The use of electronic medical records should make it easier for pharmacies to identify customers who qualify as 340B patients or who qualify for manufacturer patient assistance programs (PAPs), but can those records be made available to contract pharmacies? Will manufacturers be permitted to

access EMRs when auditing PAP compliance? Will e-prescribing systems qualify for the federal payments?

- How do covered entities implement electronic medical records (EMR) and e-prescribing technologies?
- How will implementation affect 340B providers?
- How can EMR & e-prescribing help PAP participation?

Sachin Jain, Special Assistant to the National Coordinator, Office of the National Coordinator for Health Information Technology

Sabrina Allen, Pharmacy Manager, Terry Reilly Health Services

Greg Doggett, Associate Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Michael Rigas, Chief Clinical Officer, KabaFusion, former Associate Chief Innovation Officer, Pharmaceutical Care and Chief Clinical Officer, Geisinger Health System

**(Regency Ballroom)
(ACPE 1.25 Hours)**

(2) 340B Pricing Changes

340B price calculations will likely experience dramatic changes as a result of national health reform legislation. For example, a drug's average manufacturer price (AMP) – which serves as the benchmark for 340B discounts – has been redefined to reflect more closely pricing in the retail class of trade. Although this change is likely to drive up 340B prices, it should be more than offset by two other changes under health reform, namely, a steep increase in the minimum rebate percentage and tighter pricing controls over reformulations of existing drugs. At the same time, the recent settlement of landmark average wholesale price (AWP) litigation has resulted in a change to the markup used in determining AWP-based Medicaid pharmacy reimbursement. Experts will discuss how these changes will affect 340B providers, manufacturers, and the state Medicaid programs. Stricter 340B refund requirements, including when manufacturers “true up” their AMP and best price submissions, will also be covered.

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

John Shakow, Partner, King & Spalding

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

Track Three – Roundtables

(Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

**(Ambassador Ballroom)
(ACPE 1.25 Hours)**

(1) Inventory Management

This roundtable is designed for attendees interested in participating in an interactive small group discussion about the complexities and challenges of 340B inventory management. Learn about various inventory management solutions from companies specializing in this area.

Anthony Lesser, Pharmacy Inventory Manager, Harris County Hospital District, Consultant, Pharmacy Services Support Center

Andrew Maurer, Director, Macro Helix

Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc., Consultant, Pharmacy Services Support Center (Facilitator)

Representatives from various I.T. vendors

**(Congressional A)
(ACPE 1.25 Hours)**

(2) Enrollment Process for Newly Eligible Hospitals

The health reform law expands 340B eligibility to free-standing children's hospitals, free-standing cancer hospitals and critical access hospitals, while also easing the eligibility requirements for sole community hospitals and rural referral centers. If you are interested in qualifying and enrolling your facility into 340B, our expert faculty will provide valuable guidance and share lessons learned.

Elisabeth Doyle, Associate, Power Pyles Sutter & Verville (Facilitator)

Lisa Scholz, Senior Director, Pharmacy Services Support Center

Jeff Spade, Executive Director, North Carolina Rural Health Center

Barbara Straub Williams, Principal, Powers Pyles Sutter & Verville, PC

Small Group Discussions

(Limit 10 attendees per session; limited to stakeholder groups only; pre-registration required)

(Senate Room)
(ACPE 1.25 Hours)

(1) Hospital 340B Expert
Ellen Williams, Pharmacy Director, Mission Hospitals

(Council Room)
(ACPE 1.25 Hours)

(2) Hemophilia Treatment Center 340B Expert: Strategies for Success
Joseph Pugliese, President, Hemophilia Alliance

12:00 pm
(Exhibit Hall)

Networking Lunch

1:30 pm
(Regency Ballroom)
(ACPE 1.25 Hours)

Track One – Operationalizing 340B

Multiple Contract Pharmacies

The recently published federal guidelines allowing covered entities to establish an unlimited number of contract pharmacy arrangements could significantly expand the reach of the 340B program. For the first time, patients of safety net providers will be able to access 340B drugs from their local neighborhood pharmacies, thereby avoiding the transportation challenges of filling prescriptions at the hospitals, health centers or other 340B providers where they originally received their care. Not only will the new multiple contract pharmacy program improve access to affordable medications, it will augment an important revenue source for safety net institutions. However, before launching a multiple contract pharmacy program, covered entities should be prepared to meet increased compliance standards, including the performance of annual independent audits. A panel of experts will explore what is permitted under the final guidelines and will analyze the risks and benefits associated with implementing multiple contract pharmacy arrangements. Panelists will also discuss compliance with 340B anti-diversion and Medicaid billing standards.

- The dos and don'ts of setting up contract pharmacies
- What role will chains and independent pharmacies play?
- What role will pharmacy benefit managers (PBMs) play?
- Will existing 340B contract pharmacy arrangements need to be amended to comply with the new guidelines?

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

Karl Meehan, Director, Pharmacy Services, Walgreen Co.

Holly Russo, Vice President, Hospitals and Health Systems, Chief Clinical Officer, CaptureRx

Lisa Scholz, Senior Director, Pharmacy Services Support Center (Moderator)

Michael Sullivan, Director, Government Programs and Policy, Wellpartner

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 Choices)

(Palladian Room)
(ACPE 1.25 Hours)

(1) Credit & Rebill/340B Reclassification Process

It is not uncommon for covered entities to discover instances in which non-340B drugs purchased in the past should have been bought through the 340B program and 340B drugs should have been purchased outside the program. To rectify these errors, covered entities often rely on wholesaler credit and rebill procedures to reverse these non-compliant transactions and repurchase the drugs under the proper account. Pharmaceutical manufacturers and federal regulators, however, have recently expressed concern over the credit and rebill process, leaving the future of this practice in doubt. Concerns about possible overutilization of credit and rebill transactions and the lack of transparency for drug suppliers have motivated both OPA and PVP to issue informal policies recommending limited use of this mechanism. Our panelists will explore the following topics during this session:

- What is credit and rebill?
- Why is it an important option for some covered entities and are there any alternatives?
- How transparent is the process to manufacturers?
- What are the manufacturer and wholesaler perspectives on this issue?

Chris Cobourn, Vice President, Regulatory Compliance, Compliance Implementation Services

Keith Hanchey, Managing Director, Navigant Consulting, Inc.

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

**Dale James, Senior National Account Manager, McKesson Health Systems
Support Services**

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

**(Diplomat Room)
(ACPE 1.25 Hours)**

(2) Billing Medicaid for Physician-Administered Drugs

By July, it will be nine months since CMS and 340B hospitals settled a lawsuit regarding whether hospitals are required under federal law to submit NDC information and change their Medicaid billing practices for drugs administered in clinic settings. As a result of the settlement, CMS issued a policy clarification to each Medicaid agency recognizing a state's right to exempt hospitals from NDC reporting and Medicaid billing changes under certain circumstances. Some states are now adopting or considering new policies to take advantage of this recently-recognized flexibility by protecting 340B hospitals from onerous billing and payment policies. Other states, like California, not only require NDC reporting, they require 340B providers to pass their entire discounts through to the Medicaid program by billing at actual acquisition cost. In the meantime, many covered entities are confused about applicable billing and payment requirements for both their 340B and non-340B drugs. This session will attempt to dissect and analyze the complexities surrounding billing Medicaid for physician administered drugs.

- How are states implementing CMS' transmittal acknowledging that states have the authority to exempt all or a subset of hospital clinic-administered drugs from NDC reporting?
- How are hospitals adapting to NDC reporting requirements and other billing changes?
- What are some of the different approaches that states and hospitals are taking to create a "win-win" for the parties?
- What state policies are causing the greatest burden for covered entities?

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

**Marijo Bustos, Senior Government Business Analyst, APP
Pharmaceuticals, LLC**

Elisabeth Doyle, Associate, Power Pyles Sutter & Verville (Moderator)

**Kevin Gorospe, Principal, Health Management Associates, Former Chief,
Pharmacy Policy Unit, Medi-Cal Pharmacy Benefits Division**

**Derrick Grant, Health Planner, Division of Policy and Performance,
MaineCare**

Track Three – Roundtables

(Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

**(Ambassador Ballroom)
(ACPE 1.25 Hours)**

(1) Inventory Management

This roundtable is designed for attendees interested in an interactive small group discussion about the complexities and challenges of 340B inventory management. Learn about various inventory management solutions from companies specializing in this area.

**Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.,
Consultant, Pharmacy Services Support Center**

**Andrew Wilson, Managing Consultant, Pharmacy Optimization, McKesson Health
Systems (Facilitator)**

Representatives from various I.T. vendors

**(Congressional A)
(ACPE 1.25 Hours)**

(2) Patient Safety Collaborative

Learn about HRSA's patient safety and clinical pharmacy services collaborative and lessons learned from safety net provider participants.

**Zandra Glenn, Patient Safety Senior Consultant, Pharmacy Services Support Center
(Facilitator)**

Linda Kwon, Public Health Analyst, Office of Pharmacy Affairs

Eric Lai, Public Health Analyst, Office of Pharmacy Affairs

Small Group Discussions

(Limit 10 attendees per session; limited to stakeholder groups only; pre-registration required)

*(Senate Room)
(ACPE 1.25 Hours)*

(1) Hospital 340B Expert

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center

*(Council Room)
(ACPE 1.25 Hours)*

(2) Community Health Center 340B Expert

Paul Crowther, Pharmacy Director, Central Virginia Health Services, Inc.

2:45 pm
(Exhibit Hall)

Exhibitor Forum, Refreshment Break, and Networking Opportunity

3:45 pm

Track One – Operationalizing 340B

Concurrent Sessions (2 Choices)

*(Regency Ballroom)
(ACPE 1.25 Hours)*

(1) Third Party Billing

When Congress enacted the 340B law, 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 session showcases different methodologies, including the Medicaid carve-out option that covered entities have employed to bill Medicaid properly. The duplicate discount problem arises in other areas than Medicaid, including in Medicare Part D and with commercial payers, because the payment of rebates by manufacturers for preferred formulary status is a common business practice. Manufacturers are responding by increasingly scaling back their rebate arrangements when 340B drugs are involved. To offset the loss of rebates, payers are trying to ratchet down their reimbursement rates to 340B pharmacies, intensifying rate negotiations and raising questions as to who should benefit from 340B discounts. Our panel of experts will share their experience and advice on third party billing of 340B drugs. They will also discuss the problems that have arisen involving TRICARE's contracting decisions.

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

Joe Pugliese, President, Hemophilia Alliance Inc.

Gary Reiss, Chief Operating Officer, SUNRx, LLC

*(Diplomat Room)
(ACPE 1.25 Hours)*

(2) Patient Safety Collaborative

The Patient Safety and Clinical Pharmacy Services Collaborative is a breakthrough effort to improve the quality of health care across America by integrating evidence-based clinical pharmacy services into the care and management of patients with chronic diseases. It is a way to spread leading evidence-based practices to multidisciplinary, expanded care teams of community-based health care providers, including pharmacists, who serve patients with chronic conditions.

- Why you should join this breakthrough effort!
- Who are the participants?
- What lessons have been learned?
- Where does the Collaborative go next as it approaches its third year?
- The PSpC experience from high performing teams

Tracey Cole, Pharmacy Director, Holyoke Health Center

Zandra Glenn, Patient Safety Senior Consultant, Pharmacy Services Support Center (Moderator)

Linda Kwon, Public Health Analyst, Office of Pharmacy Affairs

Eric Lai, Public Health Analyst, Office of Pharmacy Affairs

Kim Seigler, Director of Pharmacy, Great Brook Valley Health Center

Track Two – 340B Policy and Compliance

*(Palladian Room)
(ACPE 1.25 Hours)*

Orphan Drugs and 340B

The final health care reform legislation contained a highly controversial last-minute surprise. The entities newly covered under health care reform –children’s hospitals, free-standing cancer hospitals, and rural hospitals – are to be denied access to 340B prices on close to 350 “orphan drugs,” many of which are high-cost oncology drugs or specialty drugs developed for pediatric indications. The exclusion means these entities could end up paying more for orphan drugs than they did prior to their admission into 340B. In addition, it is unclear whether the orphan drug exclusion applies only for the indication for which the drug was designated for orphan status, or for all purposes. Representatives from hospital advocacy organizations and orphan drug makers will provide their unique perspectives on the new law and its potential impact. HRSA will also offer more details about their implementation plans.

Michael Bonck, Pharmacy Manager, St. Joseph Medical Center
Marcus Farbstein, Director, Federal Accounts, Genentech, Inc.
Brad Lang, Public Health Analyst, Office of Pharmacy Affairs
**Rob Recklaus, Director of Government Relations, Safety Net Hospitals for
Pharmaceutical Access (Moderator)**
**John VanEckhout, Vice President, Clinical Services, Child Health Corporation of
America**
Eric Zimmerman, Counsel, Rural Referral Center/Sole Community Hospital Coalition

Track Three – Roundtables

(Limit 50 attendees per session)

Concurrent Sessions (3 Choices)

(Congressional A)
(ACPE 1.25 Hours)

(1) Multiple Contract Pharmacies for Covered Entities

This roundtable will allow covered entity representatives to discuss and analyze new opportunities and compliance challenges associated with implementing multiple contract pharmacy arrangements.

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

(Executive Room)
(ACPE 1.25 Hours)

(2) Multiple Contract Pharmacies for Chain, Independent and Other Pharmacy Businesses

Pharmacies that are interested in contracting with 340B providers or are already participating in contract pharmacy arrangements are invited to this roundtable. Our facilitator will lead a discussion focused on key business and compliance issues from the contract pharmacy perspective.

Lisa Scholz, Senior Director, Pharmacy Services Support Center

(Ambassador Ballroom)
(ACPE 1.25 Hours)

(3) Optimizing 340B

Attendees will have an opportunity to interact with the roundtable facilitators, as well as with each other, as they drill down deeper into the various strategies employed and challenges encountered when trying to maximize the benefits of the 340B program while complying with program requirements.

**Rita Baskett, Director of Pharmacy and Educational Services, Safety Net Hospitals
for Pharmaceutical Access (Facilitator)**

Tony Felix, Pharmacy Director, El Rio Health Center

Steve Petersen, Director of Pharmacy, Avera McKennan

Small Group Discussions

(Limit 10 attendees per session; limited to stakeholder groups only; pre-registration required)

(Senate Room)
(ACPE 1.25 Hours)

(1) Hospital 340B Expert

**Burnis Breland, Director of Pharmacy, The Medical Center/Columbus Regional
Healthcare System**

(Council Room)
(ACPE 1.25 Hours)

(2) Community Health Center 340B Expert

**Susan Sumrell, Assistant Director, Regulatory Affairs, National Association of
Community Health Centers**

5:00 pm

Adjourn / Free Evening

WEDNESDAY, JULY 21, 2010

7:15 am
(Exhibit Hall) **Continental Breakfast – Exhibits Open**

8:30 am
(Regency Ballroom)
(ACPE 1 Hour) **An Insider's Look at Health Reform - A Conversation With:**
Howard Dean, M.D., Senior Strategic Advisor, McKenna Long & Aldridge LLP, Former Governor of Vermont, U.S. Presidential Candidate and Head of the Democratic National Committee
Susan Dentzer, Editor-in-Chief, *Health Affairs*, Health Care Analyst for *PBS* and *NPR*

9:30 am
(ACPE 1.25 Hours) **The Non-340B Elements of Health Reform: Why They Matter To You**
While the 340B provisions in the new health reform law will create the most significant changes to the program since its inception, there are many other parts of the legislation that will also have a major effect on 340B stakeholders. Learn more about:

- When will the uninsured begin to be covered and what will happen to reimbursement?
- What kinds of funding and grant opportunities are available to hospitals, health centers and other covered entities?
- What are the implications of care coordination and provider accountability for the safety net?
- What is comparative effectiveness and what will it mean to stakeholders?
- How will new taxes on the drug industry be implemented?
- What is the future of Medicaid and pharmacy reimbursement?
- What role will medication therapy management play?

Shawn Gremminger, Assistant Vice President for Advocacy, National Association of Public Hospitals and Health Systems

Joe Hill, Director, Federal Legislative Affairs, American Society of Health-System Pharmacists

Michael McCaughan, Editor, *The RPM Report: Regulation, Policy, Market Access*

Roger Schwartz, Associate Vice President, National Association of Community Health Centers

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

10:45 am
(Exhibit Hall) **Networking and Refreshment Break**

11:00 am
(Palladian Room)
(ACPE 1.25 Hours) **Track One – Operationalizing 340B**
340B & Medical Homes

Health care reform requires the HHS Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, inter-professional teams that include pharmacists. These teams would be expected to assist patient-centered medical home providers in providing care to patients, particularly those with multiple chronic conditions.

- What is a medical home interdisciplinary team and how will a 340B provider be able to get involved?
- Can a hospital, community health center or other 340B provider qualify as a medical home and will that qualify its patients for 340B?
- Could the involvement of accountable care organizations (ACOs) in pediatric care complicate the 340B relationship?

Zandra Glenn, Patient Safety Senior Consultant, Pharmacy Services Support Center (Moderator)

Joe Hill, Director, Federal Legislative Affairs, American Society of Health-System Pharmacists

Kyle Peters, Clinical Pharmacist, Siouxland Community Health Center

Sari Siegel Spieler, Assistant Vice President for Research, National Association of Public Hospitals and Health Systems

Track Two-340B Policy and Compliance

**(Regency Ballroom)
(ACPE 1.25 Hours)**

Integrity, Compliance & Sanctions

The 340B provisions in health care reform confer greater oversight and enforcement authority to the Office of Pharmacy Affairs and other federal agencies charged with administering the 340B program. Accordingly, both covered entities and manufacturers need to prepare for a new environment of compliance and integrity in which, for the first time, civil money penalties may be imposed on non-compliant parties. The agency also will be expected to verify and post 340B ceiling prices and implement a formalized dispute resolution procedure. At the same time, Medicaid fraud enforcement agencies are focusing increasingly on how 340B covered entities are billing Medicaid programs. Learn about these current and future enforcement activities and get a timetable for when stakeholders can expect the new integrity measures to be implemented. Panelists will also discuss recent developments in Medicaid billing oversight, rules and regulations.

- Key integrity components of the new 340B law
- Update on the HHS Office of Inspector General study on 340B providers' Medicaid billing practices
- Recent investigations and recoupment efforts by states
- Where is the Department of Justice headed next on drug overcharges?
- How should providers and manufacturers prepare for increased 340B enforcement and oversight?
- How can publication of ceiling prices be restricted to covered entities?
- What will annual recertification mean for covered entities?

Brad Lang, Public Health Analyst, Office of Pharmacy Affairs

Reed Stephens, Partner, McDermott Will & Emery LLP

Gerald Sullivan, Assistant U.S. Attorney, Eastern District of Pennsylvania

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

Track Three – Roundtables

(Limit 50 attendees per session)

**(Diplomat Room)
(ACPE 1.25 Hours)**

Breakout Session for Rural Hospitals

This session is designed to address the unique needs and challenges that rural hospitals face in providing medical and pharmaceutical care. You will get an update on various health care policy matters affecting rural providers. In addition, we will address the specific requirements that rural hospitals must meet for 340B eligibility.

Elisabeth Doyle, Associate, Power Pyles Sutter & Verville

Maggie Elehwany, Vice President, Government Affairs and Policy, National Rural Health Association

Alison Renner, Government Affairs and Policies Staff Assistant, National Rural Health Association

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

Jeff Spade, Executive Director, North Carolina Rural Health Center

12:15 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.