
13th Annual 340B Coalition Conference

on Improving Access to Pharmaceutical Care and Ensuring
Compliance with Federal and State Laws

Co-hosted by Apexus/340B Prime Vendor Program

July 13-15, 2009 • Omni Shoreham Hotel • Washington, DC

AGENDA

SUNDAY, JULY 12, 2009

1:00 – 5:00 pm Exhibitor Set Up
(Ambassador Ballroom)

3:00 – 5:00 pm Early Registration
(West Registration)

6:00 – 8:30 pm Welcome Reception and Dinner for Hospitals, SNHPA Corporate Partners and
(Palladian Room) PVP Suppliers*

MONDAY, JULY 13, 2009

7:00 am Registration and Exhibits Open 7:00 am – 5:15 pm
(West Registration)
(Ambassador Ballroom) Pre-Conference Workshop (Two Options) **
(ACPE 085-999-09-051-L03-P and T)

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

7:00 am Continental Breakfast (Workshop Attendees Only)
(Ambassador Ballroom)

8:30 am 340B Basics – Introduction to the Federal 340B Drug Pricing Program
(Palladian Room)
(ACPE 2.75 Hours) 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, PharmTA Coordinator and Consultant, 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

10:00 am Networking and Refreshment Break
(Ambassador Ballroom)

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 implementation of the 340B program from their respective viewpoints.

Chris Roberson, Director of Pharmacy Operations, Indiana Hemophilia and Thrombosis Center
Debbe Saez, Senior Compliance Manager, Compliance Implementation Services
Larry Stepp, Vice President, National Accounts, AmerisourceBergen Drug Corporation
Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc. and Consultant, Pharmacy Services Support Center

11:45 am Networking Lunch (WORKSHOP ATTENDEES AND EXHIBITORS ONLY)
(Blue Room)

* 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.

** Please note there is an additional cost to attend the pre-conference workshop and registration is required.

Option 2 - Recent Developments in Patient Assistance Programs

7:00 am Continental Breakfast (Workshop Attendees Only)
(Ambassador Ballroom)

8:30 am Recent Developments in Patient Assistance Programs
(Diplomat Room)
(ACPE 2.75 Hours)

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 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. You will also learn about the latest compliance initiatives required to utilize these program. There will be time allotted for questions and discussion at the end of each session.

Brenda Dane, Executive Director, West Virginia Rx

Arlene Rufalo, Director of Auditing, Corporate Compliance, inVentiv Health Commercial Services

Ann Schulte, Director of Account Management, HealthBridge

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

10:00 am Networking and Refreshment Break
(Ambassador Ballroom)

10:30 am Session Continues

Rita Baskett, Pharmacy Supervisor, Carolinas HealthCare System

Robert Brown, Pharmacy Director, CommUnity Care of Central Texas

Patricia Dominic, Chief Executive Officer, Hemophilia of Georgia

Kathryn Duke, Health Care Consultant (Moderator)

11:45 am Networking Lunch (WORKSHOP ATTENDEES AND EXHIBITORS ONLY)
(Blue Room)

Commencement of Main Conference
(ACPE 085-999-09-053-L04 P and T)

1:00 pm Opening Remarks from Conference Hosts and HRSA Administrator Dr. Mary
(Regency Ballroom) **Wakefield**

1:30 pm Awards Ceremony

Sharley Chen, Former Public Health Advisor, Office of Pharmacy Affairs

Derek Robertson, Former Executive Director and Founder, Hemophilia Alliance

1:45 pm Federal Government Update: Presentations by OPA, PVP and PSSC
(ACPE 1 Hour)

New leadership in the White House and the Health Resources and Services Administration (HRSA), coupled with recent funding appropriated by Congress, has already led to changes in how the 340B program is being administered by the Office of Pharmacy Affairs (OPA). 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. In addition, OPA will describe its efforts to improve its online database of 340B participants and will 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. Also presenting will be representatives of two HRSA contractors – Apexus and the American Pharmacists Association – who will provide an update on the Prime Vendor Program and the Pharmacy Services Support Center, respectively.

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

Jim Mitchell, Director, Office of Pharmacy Affairs

Lisa Scholz, Senior Director, Pharmacy Services Support Center

2:45 pm Networking and Refreshment Break
(Ambassador Ballroom)

3:15 pm
(Regency Ballroom)
(ACPE 1 Hour)

Legislative Update: 340B Reform Legislation, Medicaid Rebate Changes, Expansion of Nominal Pricing Law, etc.

Now that comprehensive health reform is being seriously debated in Washington, the chances of major changes to the 340B and Medicaid rebate program have increased significantly. Topics to be covered include:

- 340B reform legislation including expansion of program to hospital inpatient setting and new entities including rural and children's hospitals;
- Future of Medicaid rebate program including increased discounts and expansion to Medicaid managed care plans;
- Expansion of nominal pricing opportunities;
- How health reform will impact providers and pharmaceutical industry

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

4:15 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 to 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 to discuss the latest 340B issues specifically affecting health centers. We will also have an update on the latest developments on health reform so that we can all then discuss what role we would like to see for the health centers and their pharmacies as these reform efforts take shape.

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

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

(Senate Room)
(ACPE 1 Hour)

Family Planning Clinics

- Restoration of nominal drug pricing for family planning clinics
- Update on status of patient definition guidelines
- 340B expansion legislation
- IOM Report on the Title X program
- New Title X Program Instruction on the clinical delivery of services

Amy Yenyo, Assistant Director, Planned Parenthood Federation of America

(Forum Room)
(ACPE 1 Hour)

Hemophilia Treatment Centers

- Patient Definition
- Multiple Contract Pharmacies – How to benefit
- Strategies for contracting with payors

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

(Cabinet Room)
(ACPE 1 Hour)

HIV/AIDS Clinics, ADAPs, and AIDS Service Providers

This session will provide a national update on AIDS Drug Assistance Programs (ADAPs) as well as detail some significant concerns for the programs' future. Particular time will be set aside for specific 340B program questions from all HIV related providers.

Lanny Cross, Consultant, National Alliance of State & Territorial AIDS Directors
Beth Crustinger-Perry, Associate Director, Care & Treatment Programs, National Alliance of State & Territorial AIDS Directors

(Regency Ballroom)
(ACPE 1 Hour)

Hospitals (DSH and Children's Hospitals)

This session will include a presentation by former a Federal Trade Commission policy director on opportunities for addressing pharmaceutical product scarcity

through the antitrust process. In addition, will share the results of a Medicaid billing survey and provide an update on legislative issues. The session will conclude with a question and answer session.

David Balto, Senior Fellow, Center for American Progress and Counselor, Law Offices of David A. Balto

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

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

(Palladian Room)
(ACPE 1 Hour)

Pharmaceutical Industry

- Current efforts to expand the 340B program
- How will healthcare reform impact the program
- Update on the status of the proposed rules
- OIG Q&A
- Legal update

Marcus Farbstein, Director, Government Affairs, Genentech (Industry Team Leader)

(Council 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 save on prescription drug and medical costs.

Shana Phares, Pharmaceutical Advocate, Office of the Governor, State of West Virginia (State and Local Government Team Leader)

5:15 pm

Adjourn

5:30 – 6:45 pm

Reception and Networking Opportunity

(Ambassador Ballroom)

TUESDAY, JULY 14, 2009

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 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.

7:15 am

Continental Breakfast – Exhibits Open

(Ambassador Ballroom)

8:30 am

Track One – Operationalizing 340B

(Regency Ballroom)
(ACPE 1.25 Hours)

Inventory Management and Preventing Diversion

The complexities of 340B inventory management extend beyond split billing software and contract pharmacy arrangements. This session reviews current technology and software to support compliant inventory management practice and provides guidance for the policies and resources required to maintain 340B compliance while maximizing 340B savings.

- Stock Replacement/NDC Substitution
- Split-billing
- Virtual inventories
- Recordkeeping
- Retroactive processing of credits/rebills

Robert Butcher, Director of Pharmacy Services, Access Health West Virginia

John Foss, Vice President of Support Services, Memorial Health System

Lisa Scholz, Senior Director, Pharmacy Services Support Center

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 Choices)

*(Palladian Room)
(ACPE 1.25 Hours)*

(1) Partnerships with States and Local Governments

State and local governments are increasingly reaching out to covered entities to expand access to a range of services, including pharmacy services, for indigent patients, prisoners, mental health patients, residents of long-term care facilities and other government-funded populations. Because these partnerships expand access to care and lower drug costs for vulnerable patients, their potential role in health reform is increasingly being studied by policy makers. Different partnership models will be presented, with special attention given to compliance with anti-diversion standards. Our expert panel will also discuss the different options available for delivering 340B medications to target populations through in-house pharmacies and/or contract arrangements with retail pharmacy networks, central fill facilities and mail order pharmacies.

Jeffrey Lewis, President, Heinz Family Philanthropies

Lori Hunt, Clinical Director, Coordinated Care Network

Shana Phares, Pharmaceutical Advocate, Office of the Governor, State of West Virginia

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

*(Diplomat Room)
(ACPE 1.25 Hours)*

(2) Medicare Part D

With the Medicare Part D program in its fourth year of operation, new challenges have arisen to confront 340B providers interested in participating, while older issues continue to daunt. In this session, speakers will review new low-income beneficiary subsidy rules, address how to prepare for increasing scrutiny by federal and state compliance investigators, and suggest ways to combat Part D plan efforts to reduce reimbursement rates for 340B providers. Speakers will also discuss the possibility that health reform could eliminate the prohibition against government price negotiation or require that manufacturers pay rebates for drugs used by dual eligibles, and what those changes could mean for 340B providers.

RoseMarie Babbitt, Director of Corporate Compliance, Parkland Health & Hospital System, and Consultant, Pharmacy Services Support Center

Michael Bukach, Vice President, Pharmacy Operations, MemberHealth, Inc.

Adam Falk, Partner, Feldesman Tucker Leifer Fidell LLP (Counsel to NACHC)

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

Cheri Arnott Parlamen, Associate Commissioner, Social Security Administration

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 waiting for implementation of pending guidelines which will specify applicable 340B qualification and enrollment procedures. Among the topics that will be addressed are: what hospitals should be doing in preparation for eventual enrollment, the impact of pending 340B reform legislation, and how hospitals can maximize current use of the 340B program based on their status as HRSA grantees or sub-grantees.

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

Brad Lang, Public Health Analyst, Office of Pharmacy Affairs

**Jim Kaufman, Vice President of Public Policy, National Association of Children's
Hospitals and Related Institutions**

**Steve Pate, Manager, Outpatient Pharmacy Services, St. Jude's Children's
Research Hospital**

**John VanEckhout, Vice President, Clinical Services, Child Health Corporation of
America**

*(Congressional Room)
(ACPE 1.25 Hours)*

(2) 340B Opportunities for Rural Health Providers

With new leadership in both the White House and HRSA, the federal government is looking for ways to support rural health providers and the patient populations they serve. Among the strategies being explored is facilitating broader use of the 340B program by providing technical assistance to rural participants and encouraging

innovation in telepharmacy and contract pharmacy arrangements. At the same time, Congress is considering expanding the 340B program to several new categories of rural hospitals as part of its health reform efforts. These and other 340B opportunities for rural providers will be discussed.

Paul Crowther, Pharmacy Director, Central Virginia Health Services, Inc.
Jim Mitchell, Director, Office of Pharmacy Affairs
Tom Morris, Associate Administrator, Office of Rural Health Policy, HRSA
**Rob Recklaus, Director of Government Relations, Safety Net Hospitals for
Pharmaceutical Access (Facilitator)**

9:45 am **Exhibitor Forum, Refreshment Break, and Networking Opportunity**
(Ambassador Ballroom)

10:45 am **Track One – Operationalizing 340B**
Optimizing Pharmacy Savings and Value
(Regency Ballroom)
(ACPE 1.25 Hours)

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. Topics to be covered include:

- Getting the most out of the prime vendor program
- Formulary management tools
- Patient assistance program maximization
- Medicare Part D success stories
- Other helpful resources

Burnis Breland, Director of Pharmacy and Clinical Research, The Medical Center/Columbus Regional Healthcare System
Chris Hatwig, Vice President, Alexis/340B Prime Vendor Program (Moderator)
Nadra Havican, Pharmacy Manager, Family Health Center Pharmacy

Track Two – 340B Policy and Compliance
Concurrent Sessions (2 Choices)

(Diplomat Room)
(ACPE 1.25 Hours)

(1) HIT and 340B Pharmacy Opportunities and Compliance Issues

With passage of the economic stimulus law, Congress has focused on health implementation technology as a means to cut health care costs, creating grant, loan, and provider incentive programs to implement electronic medical records (EMR) and e-prescribing technologies within Medicaid and Medicare. How will implementation of EMR and greater use of e-prescribing impact 340B providers? Will greater access to electronic medical records make determining patient eligibility easier or will eligibility determinations be frustrated by public concerns about patient privacy and new regulations governing breaches of personal health information?

John Foss, Vice President of Support Services, Memorial Health System
**Stuart Gordon, Director of Legal and Regulatory Affairs, Safety Net Hospitals for
Pharmaceutical Access (Moderator)**
**Michael Lardiere, Director, Health Information Technology, National Association
of Community Health Centers**

(Palladian Room)
(ACPE 1.25 Hours)

(2) 340B Pricing Changes

Whether intentional or not, Congress changed how 340B ceiling prices are calculated when it redefined average manufacturer price (AMP) and Medicaid “best price” under the Deficit Reduction Act of 2005 (DRA). Covered entities have reason to believe that, with respect to future price calculations, more changes are in store. 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. The DRA also narrowed the exclusion of nominal prices from “best price” calculations such that some very low drug prices paid by safety net providers qualify for the exclusion while others do not. Congress revisited the nominal price issue earlier this year and decided to add two new categories of safety net providers – family planning clinics and student health centers – to the list of entities eligible for nominal price protection. Will CMS exercise its own authority and extend best price exemptions to other safety net purchasers? Both manufacturer and covered entity perspectives will be provided during this session, with an emphasis on compliance.

- Proposed increase in Medicaid rebate percentage and impact on 340B

- Average Manufacturer Price (AMP) changes and lawsuit
- Future of nominal pricing
- Restated Unit Rebate Amounts (URAs) and 340B ceiling prices

Ben Martin, Associate, Epstein Becker & Green

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

Amy Yenyo, Assistant Director, Planned Parenthood Federation of America

Track Three – Roundtables (Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

(Congressional Room)
(ACPE 1.25 Hours)

(1) Inventory Management

Robert Butcher, Director of Pharmacy Services, Access Health West Virginia

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

Robert Scholz, Vice President, McKesson Pharmacy Optimization

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

Doug Wong, Senior Executive Consultant, Pharmacy Healthcare Solutions

(Executive Room)
(ACPE 1.25 Hours)

(2) 340B Partnerships with State and Local Government

As state and local governments continue to face bleak revenue forecasts and shrinking budgets, the opportunities for covered entities to partner with government are greater than ever. Collaborative projects range from providing drug benefits to employees, inmates and special populations to full medical homes with chronic disease components and capitated rates. Learn how to approach state and local governments and present the value of 340B.

Lori Hunt, Clinical Director, Coordinated Care Network

Shana Phares, Pharmaceutical Advocate, State of West Virginia

12:00 pm
(Blue Room)

Networking Lunch

1:30 pm

Track One – Operationalizing 340B

(Regency Ballroom)
(ACPE 1.25 Hours)

Contract Pharmacies

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

- Negotiating contract terms
- “Ship to/bill to” arrangements
- Inventory management
- Billing and collection functions

Barbara Brice, PharmTA Coordinator and Consultant, Pharmacy Services Support Center

Steve Petersen, Director of Pharmacy, Avera McKennan Hospital & University Health Center

Katheryne Richardson, Senior Quality and Compliance Specialist, Pharmacy Services Support Center (Moderator)

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

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 Choices)

(Diplomat Room)
(ACPE 1.25 Hours)

(1) Patient Safety Collaborative

Patient Safety and Clinical Pharmacy Services Collaborative – Why you should join this breakthrough effort!

- Overview and assessment of progress to date
- Team enrollment for PSPC 2.0 – the second wave
- The PSPC experience from high performing teams

Tracy Cole, Director of Pharmacy, Holyoke Health Center
Denise Geolot, Director, Center for Quality, Health Resources and Services Administration
Zandra Glenn, Pharmacy Services Support Center Patient Safety Consultant (Moderator)
Jim Mitchell, Director, Office of Pharmacy Affairs
Susan Wolf Nelson, Pharmacy Director, Family HealthCare Pharmacy, North Dakota State University
Commander Krista Pedley, Program Management Officer, Office of Pharmacy Affairs

(Palladian Room)
(ACPE 1.25 Hours)

(2) NDC Reporting/Physician-Administered Drugs

This session will feature a panel of experts who will provide an update on state-level implementation of the Deficit Reduction Act of 2005 national drug code (NDC) reporting mandate that was designed to enable states to collect manufacturer rebates on physician-administered drugs. Attendees will also be updated on the status of the litigation challenging CMS' decision to extend the NDC reporting requirement to drugs administered in hospital outpatient clinics. Panelists also will discuss joint manufacturer-provider advocacy efforts focused on educating state Medicaid programs on how they might implement the reporting mandate in a flexible manner that is less burdensome for 340B hospitals.

- Status of state implementation
- Update on hospital exemption litigation
- What should hospitals be doing?
- What should manufacturers be doing?

Larry Gondelman, Principal, Powers Pyles Sutter & Verville
Stuart Gordon, Director of Legal and Regulatory Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)
Deborah Williams, Director, Public Policy, Baxter Healthcare Corporation

Track Three – Roundtables (Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

(Congressional Room)
(ACPE 1.25 Hours)

(1) Prime Vendor Program (hosted by Apexus)

Mary Ellen England, Director of Marketing, Apexus/340B Prime Vendor Program
Chris Hatwig, Vice President, Apexus/340B Prime Vendor Program
Tom Renshaw, Director, Apexus/340B Prime Vendor Program

(Executive Room)
(ACPE 1.25 Hours)

(2) Inventory Management

Robert Butcher, Director of Pharmacy Services, Access Health West Virginia
Lisa Scholz, Senior Director, Pharmacy Services Support Center (Facilitator)
Robert Scholz, Vice President, McKesson Pharmacy Optimization
Andrew Wilson, Director, Pharmacy and Educational Services, Safety Net Hospitals for Pharmaceutical Access (Facilitator)
Doug Wong, Senior Executive Consultant, Pharmacy Healthcare Solutions

2:45 pm
(Ambassador Ballroom)

Exhibitor Forum, Refreshment Break, and Networking Opportunity

3:45 pm
(Regency Ballroom)
(ACPE 1.25 Hours)

Track One – Operationalizing 340B

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.

Joseph Pugliese, President, Hemophilia Alliance

Katheryne Richardson, Senior Quality and Compliance Specialist
Pharmacy Services Support Center (Moderator)

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

Nathan Thompson, Director of Outpatient Pharmacy, Johns Hopkins Hospital

Track Two – 340B Policy and Compliance

Concurrent Sessions (2 choices)

*(Diplomat Room)
(ACPE 1.25 Hours)*

(1) Emergency Preparedness

Whether one examines our nation's response to 9/11, Hurricanes Katrina and Rita, flooding in Iowa and now the H1N1 flu, the role of safety net providers in meeting the pharmacy needs of disaster victims cannot be overlooked. HRSA policies accelerating enrollment of 340B-eligible entities and relaxing patient definition standards have helped hospitals, health centers, hemophilia treatment centers, and other safety net providers stretch their dollars during these times of crisis. But what about stockpiling 340B drugs? Can covered entities stretch their homeland security funds by buying emergency drugs through the 340B program in advance of the emergency? And how have drug manufacturers adapted their patient assistance programs and helped coordinate drug distribution activities to protect displaced families and afflicted patients from losing access to needed medications? Our panel of speakers will share their experiences and suggestions in trying to answer these and related issues.

Tim Brent, Executive Director, Indiana Hemophilia & Thrombosis Center, Inc.

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center and
Clinical Pharmacist, Disaster Medical Assistance Team CA-2, Public Health
Service Emergency Response Team (Moderator)

Mollie Melbourne, Director of Emergency Management, National Association of
Community Health Centers

Jim Mitchell, Director, Office of Pharmacy Affairs

*(Palladian Room)
(ACPE 1.25 Hours)*

(2) Specialty Pharmacies/Distributors

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 for a growing number of Americans, 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 often appear to preclude purchasing drugs at 340B 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.

David Chen, Director, Pharmacy Practice Sections, American Society of Health-
System Pharmacists

Bruce Kutinsky, Senior Vice President Business Development and Strategic
Relations, Walgreens Specialty Pharmacy

Mike McPherson, Federal Account Manager, Government Affairs, Genentech, Inc.

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

Track Three – Roundtables (Limit 50 attendees per session)

Concurrent Sessions (2 Choices)

*(Congressional Room)
(ACPE 1.25 Hours)*

(1) Contract Pharmacies

Barbara Brice, PharmTA Coordinator and Consultant, Pharmacy Services
Support Center (Facilitator)

Michael Glomb, Counsel, National Association of Community Health Centers

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

Phil Trunnell, Senior Account Executive, eRx Network, LLC

(Executive Room)
(ACPE 1.25 Hours)

(2) Patient Safety

Denise Geolot, Director, Center for Quality, Health Resources and Services Administration

Zandra Glenn, Patient Safety Consultant, Pharmacy Services Support Center

Commander Krista Pedley, Program Management Officer, Office of Pharmacy Affairs

5:00 pm

Adjourn / Free Evening

WEDNESDAY, JULY 15, 2009

7:15 am

(Ambassador Ballroom)

Continental Breakfast – Exhibits Open

8:30 am

(Regency Ballroom)
(ACPE .75 Hours)

Keynote Speakers: Hon. Jo Ann Emerson, Hon. Bobby Rush and Hon. Bart Stupak, Members of the U.S. House of Representatives

Policymakers are struggling to come up with ways to cover the cost of an ambitious health reform agenda to insure all Americans and provide access to affordable pharmaceutical care. Expansion of the 340B and Medicaid rebate programs are among the options that Congress and the Administration are seriously considering to address the cost of reform and rising drug costs. This expansion includes promoting partnerships between 340B entities and state and local government. The pharmaceutical industry, while supportive of the goal of expanding health insurance coverage, is concerned about government's role in regulating drug pricing.

9:15 am

(ACPE .5 Hours)

Keynote Speaker: Dan Mendelson, President, Avalere Health (former high level Clinton Administration health care official)

9:45 am

(Ambassador Ballroom)

Networking and Refreshment Break

10:00 am

(Regency Ballroom)
(ACPE .75 Hours)

Panel Discussion: Impact of Health Reform on 340B Program

Dr. Claude Earl Fox, Director of Florida Public Health Institute, Former HRSA Administrator and member of Obama's HHS Transition Team

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

Donna Yesner, Partner, McKenna Long & Aldridge

10:45 am

(Regency Ballroom)
(ACPE 1.25 Hours)

Concurrent Session (2 Choices)

Increased Scrutiny of Medicaid Billing Practices and 340B Overcharges

Both covered entities and drug manufacturers find their 340B compliance status being scrutinized by federal and state authorities. The federal government and State Medicaid are increasing their focus on covered entity billing practices to protect against overpaying for 340B drugs. Federal investigators are about to launch a study to determine whether 340B providers are billing Medicaid properly and some states have initiated recoupment efforts and regular audit programs. Manufacturers, likewise, are being scrutinized under the 340B program. More companies continue to be compelled to issue refunds to covered entities as part of broader settlement agreements with Medicaid 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.

Perry Knight, Associate, Sidley Austin LLP

Marilyn May, Assistant United States Attorney, Health Care Fraud Coordinator, U.S. Attorney's Office, Eastern District of Pennsylvania

Ann Maxwell, Regional Inspector General, Office of Evaluation and Inspections, U.S. Department of Health and Human Services

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

Roundtable (Limit 50 attendees)

(Executive Room)
(ACPE 1.25 Hours)

Alternative Methods Demonstrations Projects (AMDPs)

Until and unless current HRSA guidance is amended, covered entities need federal approval before they can establish multiple contract pharmacy arrangements, supplement in-house pharmacy services with contract pharmacies and/or use 340B to fill prescriptions for patients of different covered entities. To obtain such approval,

providers must submit a proposal for establishing an alternative methods demonstration project (ADMP). This roundtable will be facilitated by an OPA representative who oversees the review of AMDP submissions.

Bhavani Pattabiraman, Public Health Analyst, Office of Pharmacy Affairs

12:00 pm
(Regency Ballroom)

Ask the Experts: Representatives of OPA, PVP, PSSC, Drug Industry, SNHPA, NACHC, Hemophilia Alliance, etc.

12:45 pm

Conference Adjourns



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