
Medicare Rx and Patient Assistance Programs: Key Issues for 340B Stakeholders

February 27 – March 1, 2006
Hyatt Regency Phoenix
Phoenix, Arizona

AGENDA

MONDAY, FEBRUARY 27, 2006

9:00 am - 12:00 pm (The Atrium)	Exhibit Set up
12:00-5:00 pm (Regency Ballroom Foyer)	Early Registration
1:30 pm (The Atrium)	Exhibits Open 1:30 – 5:00 pm
	Pre-Conference Workshop (Two Options)*

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

1:30 pm
(Regency Ballroom C)
(0.3 CEU-002-L04)

Introduction to the 340B Drug Pricing Program

This session is designed to teach the basics of the 340B drug discount program for those who are new to the 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, anti-diversion standards, Medicaid billing restrictions and the 340B contract pharmacy guidelines. Panelists will provide practical advice on how to use and comply with the program, especially with respect to anti-diversion, Medicaid billing, contract pharmacies and how to track inpatient versus outpatient drugs.

Jennifer Davis, Senior Pharmacy Manager, Pharmacy Services Support Center
Claire Holloway, Counsel, Public Hospital Pharmacy Coalition
**Freda Mitchem, Director of Systems Development and Policy Administration,
National Association of Community Health Centers**
Derek Robertson, Counsel, Hemophilia Alliance, Inc.

Moderator: Bill von Oehsen, General Counsel, Public Hospital Pharmacy Coalition

2:45 pm

Refreshment and Networking Break

3:15 – 4:30 pm

Comments from the 340B Community, Manufacturers and Wholesalers

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.

James Donnelly, Director of Pharmacy, Hudson Headwaters Health Network
Marcus Farbstein, Government Accounts Manager, Genentech, Inc.
Dale James, National Account Manager, McKesson
Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center

Moderator: Bill von Oehsen, General Counsel, Public Hospital Pharmacy Coalition

4:30 – 5:00 pm

Question and Answer Session

This expanded question-and-answer session is offered to give the audience an opportunity to ask more questions of our panel of experts. Questions may be posed in person or by written comment. The focus will be on the practicalities of participating in the 340B program.

Option 2 - A Detailed Introduction to Pharmaceutical Manufacturer Patient Assistance Programs

1:30 pm
(Regency Ballroom D)
(0.3 CEU-003-L04)

Patient Assistance Programs 101

As the number of uninsured patients continues to grow, safety net providers are becoming increasingly reliant on manufacturers' patient assistance programs (PAPs). These programs offer free or low cost pharmaceuticals to low-income uninsured patients. Experts on patient assistance programs will provide background on PAPs including various models of assistance, eligibility standards, and how the application process works. The experts will also explore what role PAPs will play in the new Medicare Part D environment.

Lois Bugos, Program Support Assistant, University of Colorado Hospital
Petra Fippen, Manager Inventory Control, Wishard Health Services
Sandra Leal, President, Association of Clinicians for the Underserved, Clinical Pharmacy Supervisor, El Rio Community Health Center
Pamela Powell, Patient Assistance Coordinator, Wishard Health Services
Bill Shearer, Managing Partner, The Franklin Group, Inc.

Moderator: Kathryn Duke, Program Director, Medicine for People in Need

2:45 pm

Refreshment and Networking Break

3:15 – 4:15 pm

Patient Assistance Programs and Compliance Issues

The roll-out of Medicare Part D has created considerable confusion about the legal limits applicable to manufacturer PAPs. This session will review the legal issues affecting PAPs as a backdrop for Tuesday's expert panel discussion on "PAPs in the New Medicare Environment." Among the legal issues to be addressed are the application of anti-kickback and civil monetary penalty laws to PAPs; continued viability of traditional PAPs for the uninsured; compliance guidelines for safety net providers participating in institutional PAPs; and the use of "inside" and "outside" the Part D benefit models for filling the gaps in Medicare Part D coverage.

Joseph Metro, Partner, Reed Smith

Moderator: Mark Fitzgerald, Principal, Powers Pyles Sutter & Verville, PC

4:15 – 5:00 pm

Question and Answer Session

This expanded question-and-answer session is offered to give the audience an opportunity to ask more questions of our panel of experts. Questions may be posed in person or by written comment.

5:00 pm

Conclusion

6:30-8:30 pm
(Regency Ballroom AB)

Dinner Workshop for DSH Hospitals **

Other attendees can enjoy a night on the town.

TUESDAY, FEBRUARY 28, 2006

7:00-8:00 am
(Regency Ballroom Foyer)
(The Atrium)

Registration and Continental Breakfast

Exhibits Open 7:00 am - 5:00 pm

8:00-8:15 am
(Regency Ballroom CD)

Welcome and Introductory Remarks

Phil King, Account Director 340B Contract, GlaxoSmithKline
Freda Mitchem, Director of Systems Development and Policy Administration, National Association of Community Health Centers
Ted Slafsky, Executive Director, Public Hospital Pharmacy Coalition
Bill von Oehsen, General Counsel, Public Hospital Pharmacy Coalition

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

** Please note that this session is limited to DSH hospitals. There is an additional cost to attend and registration is required.

8:15-9:30 am
(0.1 CEU-004-L04)

Medicare Part D Implementation and the Future of Patient Assistance Programs: Overview and Status Update

Topics to be covered include overview of Part D benefit design, timetable, dual-eligibles and auto-enrollment, "extra help" subsidies for non-dual-eligible low-income beneficiaries, Part D versus Part B coverage, and status of Part D implementation and enrollment. We will also cover what role PAPs will play in this new environment.

John Doster, Vice President and Managing Director of Patient Services, The Franklin Group, Inc.

Michael Sullivan, Health Insurance Specialist, Centers for Medicare & Medicaid Services

Patricia White, Administrator, West Virginia Health Right

Moderator: Perry Knight, Legal and Regulatory Affairs Director, Public Hospital Pharmacy Coalition

9:30 -10:45 am
(0.1 CEU-005-L04)

Network Participation and Contracting Issues

This session is designed to help 340B pharmacies, Part D plans and other 340B stakeholders with contracting issues. It will address contracting strategies, manufacturer double discount issue, preferred pharmacies, closed pharmacies, formulary considerations, prime vendor role, pricing strategies, etc.

Chris Hatwig, Senior Director, 340B Prime Vendor Program

Scott Hughes, Vice President, MemberHealth, Inc., Community Care Rx Card

Roger Schwartz, Legislative Counsel, National Association of Community Health Centers

Moderator: Freda Mitchem, Director of Systems Development and Policy Administration, National Association of Community Health Centers

10:45-11:15 am
(The Atrium)

Break - Exhibits Open

11:15 am-12:30 pm
(Regency Ballroom CD)
(0.1 CEU-006-L04)

Patient Education and Outreach

Panelists will discuss Part D anti-steering requirements, how to draw the line between steering and education, analysis of CMS' marketing guidelines, co-branding pros and cons, dual-eligible strategies, and concerns over privacy and anti-kickback protection.

Andrea Maresca, Associate Director, Medicare/Medicaid Regulatory Policy, National Association of Community Health Centers

Jim Pavletich, Public Affairs Officer, U.S. Social Security Administration

Moderator: Adam Greene, Attorney, Powers Pyles Sutter & Verville, PC

12:30-1:45 pm
(Regency Ballroom AB)

Luncheon and Networking Opportunity

2:00-3:15 pm
(Regency Ballroom CD)
(0.1 CEU-007-L04)

Part D at the Pharmacy Counter

This session will provide practical advice in addressing issues such as the unenrolled Medicare patient, how to query a beneficiary's enrollment status, record retention procedures, TrOOP reporting, waiving co-pays, and medication therapy management.

RoseMarie Babbitt, Associate Director Pharmacy Services, Government Reimbursement and Logistical Support, Parkland Health and Hospital System

Vanessa Duran, Senior Policy Analyst, Division of Drug Plan Policy, Medicare Plan Policy Group, Centers for Medicare and Medicaid Services

Kirk Vital, Pharmacy Director, Gulf Coast Health Center

Moderator: Perry Knight, Legal and Regulatory Affairs Director, Public Hospital Pharmacy Coalition

3:15-3:45 pm
(The Atrium)

Break - Exhibits Open

3:45-5:00 pm
(Regency Ballroom CD)
(0.1 CEU-008-L04)

Patient Assistance Programs in the New Medicare Environment

This presentation will focus on recent OIG guidance, the future of PAPs for Medicare and non-Medicare patients, counting PAP assistance towards TrOOP, the impact of MMA on institutional PAPs, and future roles for foundation-based PAPs and coalition model PAPs.

Larry Atkins, Senior Director of Public Policy and Reimbursement, Schering-Plough

Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General

Moderator: Mark Fitzgerald, Principal, Powers Pyles Sutter & Verville, PC

5:30-7:00 pm
(The Atrium)

Reception and Networking Opportunity

WEDNESDAY, MARCH 1, 2006

7:00-8:00 am
(The Atrium)

Continental Breakfast

8:00-9:15 am
(Regency Ballroom CD)
(0.1 CEU-010-L04)

340B Update

Learn about the latest activities of the Office of Pharmacy Affairs and the 340B prime vendor program, especially with respect to Part D implementation. Also learn about the latest 340B legislative developments from 340B experts.

Jim Mitchell, Director, Office of Pharmacy Affairs, U.S. Department of Health and Human Services

Diane Goyette, Senior Director, Pharmacy Services Support Center

Chris Hatwig, Senior Director, 340B Prime Vendor Program

Moderator: Ted Slafsky, Executive Director, Public Hospital Pharmacy Coalition

9:15-10:30 am
(0.1 CEU-009-L04)

Next on the Medicare Part D and PAP Horizon

Medicare Part D issues to be addressed include anti-fraud provisions, late enrollment penalties, renegotiating contract terms, facilitated enrollment of "extra help" beneficiaries, and possible legislative changes. PAP issues to be addressed include institutional PAPs, foundation-model PAPs, coalition model PAPs, and SPAP wrap-around coverage.

Scott Haenni, Senior Director, Legal Affairs and Corporate Compliance, Lash Group

Karmen Hanson, Senior Policy Specialist, National Conference of State Legislatures

Moderator: Bill von Oehsen, General Counsel, Public Hospital Pharmacy Coalition

10:30-11:00 am

Break - Exhibits Open

11:00 am-12:30 pm

Concurrent Sessions

Attendees have an opportunity to learn from and network with colleagues within their own stakeholder 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 OR INDUSTRY GROUPS AND THEIR REPRESENTATIVES.]**

(Regency Ballroom CD)
(0.1 CEU-011-L04)

A. DSH Hospitals

This session will focus on DSH specific Part D and PAP issues. Share experiences with other hospital pharmacies and learn from experts. Topics to be covered will include how to maximize use of PAPs in inpatient setting, Part

D vs. Part B coverage issues, and co-branding and other options for partnering with Part D plans.

Jennifer Davis, Senior Pharmacy Manager, Pharmacy Services Support Center

Jacqueline Encalade, Lead Pharmacist, Regional Medical Center

Perry Knight, Legal and Regulatory Affairs Director, Public Hospital Pharmacy Coalition

Moderator: Claire Holloway, Counsel, Public Hospital Pharmacy Coalition

**(Cowboy Artists Room)
(0.1 CEU-012-L04)**

B. Pharmaceutical Industry

This session will focus on industry specific Part D and PAP issues. Speakers on this panel represent a variety of organizations offering independent foundation model PAPs and work closely with manufacturers to evaluate and structure PAPs to meet a company's individual needs. Learn how to integrate a foundation model program into your existing PAP portfolio, and discover other PAP and Part D service options available for manufacturers.

Scott Haenni, Senior Director, Legal Affairs and Corporate Compliance, Lash Group

Dana Kuhn, President and Founder, Patient Services, Inc.

Moderator: John Doster, Vice President and Managing Director of Patient Services, The Franklin Group, Inc.

**(Ellis Room)
(0.1 CEU-013-L04)**

C. Federally Qualified Health Centers, Community Clinics and Other Non-Hospital Providers

This session will provide a forum for discussion and interchange among Federally Qualified Health Centers regarding their experiences with implementation of Medicare Part D and the 340B Drug Pricing Program. The discussion will identify obstacles to participation in Part D by centers and their patients, policy issues that need to be addressed, and training and technical assistance needed. Centers will be encouraged to share their experiences, problems, and solutions. Technical assistance resource persons will be available to respond and facilitate the discussion.

Andrea Maresca, Associate Director, Medicare/Medicaid Regulatory Affairs, National Association of Community Health Centers

Roger Schwartz, Legislative Counsel, National Association of Community Health Centers

Moderator: Freda Mitchem, Director of Systems Development and Policy Administration, National Association of Community Health Centers

**(Remington AB)
(0.1 CEU-014-L04)**

D. Hemophilia Treatment Centers

This interactive session will be designed to generate discussion on challenges facing HTC's in the 340B Program. From the operational challenges of working with payers to the grant requirements of reporting program income, this will be an opportunity to hear innovative strategies and share experiences that will be useful to centers when they return home. The session will also address any questions participants may have about the conference program.

Moderator: Derek Robertson, Counsel, Hemophilia Alliance, Inc.

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. Pharmacists are eligible to receive a maximum of 1.1 CEUs (11.0 contact hours) (ACPE Number 085-999-06-xxx-L04, where xxx represents the individual session). In order to receive credit, each pharmacist must sign in daily and 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.