
11th Annual 340B Coalition Conference

on Improving Access to Pharmaceutical Care and Ensuring
Compliance with Federal and State Laws
Co-hosted by the 340B Prime Vendor Program

July 23 – 25, 2007
Marriott Wardman Hotel
Washington, DC

AGENDA

SUNDAY, JULY 22, 2007

- 2:00 – 6:00 pm Exhibitor Set Up
(Exhibit Hall C)
- 4:00 – 6:00 pm Early Registration
(Convention Registration 2)
- 5:30 – 8:30 pm Welcome Reception and Dinner for DSH Hospitals*
(Salon 2)

MONDAY, JULY 23, 2007

- 7:00 am Registration and Exhibits Open 7:00 am – 5:15 pm
(Convention Registration 2)
(Exhibit Hall C)

Pre-Conference Workshop (Two Options)**
(CE 085-999-07-011-L03)

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

7:00 am
(Exhibit Hall C)

Continental Breakfast (Workshop Attendees Only)

8:45 am
(Salon 2)
(CE 3.25 Hours)

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

This session is designed to teach the basics of the 340B program for those who are new to the program or need a refresher course. A HRSA representative will provide a tour of the government's website on the 340B program. The government's technical assistance contractor, the Pharmacy Services Support Center (PSSC), will provide an overview of the program covering such topics as 340B eligibility and enrollment procedures, manufacturer discount requirements, and the 340B contract pharmacy guidelines. A hospital representative will provide his perspective on anti-diversion standards, Medicaid billing restrictions, and inventory management.

Sharley Chen, Public Health Analyst, Office of Pharmacy Affairs

Harry Hagel, Senior Director, Pharmacy Services Support Center

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

10:00 am
(Exhibit Hall C)

Networking and Refreshment Break

10:30 am
(Salon 2)

Session Continues – 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. Panelists will provide practical advice on how to use and comply with the

* Please note this event is only for DSH hospitals and corporate partners of Safety Net Hospitals for Pharmaceutical Access. Registration is required.

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

program, especially with respect to anti-diversion, and Medicaid billing. The 340B Prime Vendor Program will present on the role of the prime vendor in negotiating better prices and arranging distribution and other value-added services.

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

Chris Hatwig, Senior Director, 340B Prime Vendor Program

Dale James, Senior National Account Manager, McKesson

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

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

12:00 pm
(Exhibit Hall C)

Networking Lunch (WORKSHOP ATTENDEES ONLY)

Option 2 – Interface Between Medicaid and 340B Programs: Policy and Compliance Issues

7:00 am
(Exhibit Hall C)

Continental Breakfast (Workshop Attendees Only)

8:45 am
(Salon 3)
(CE 3.25 Hours)

Interface Between Medicaid and 340B Programs: Policy and Compliance Issues

Congress created the Medicaid rebate program in 1990 and, two years later, created the 340B program. This session will offer an in-depth look at the interface between these two drug discount programs and how compliance with these programs is intricately linked. Overlap of these two programs creates multiple risks – risks that manufacturers will be asked to give 340B discounts and Medicaid rebates on the same drugs, risks that states will have to pay more for outpatient drugs by losing access to manufacturer rebates, and risks to covered entities by reducing what they can bill and receive from Medicaid for covered outpatient drugs. The triangular relationship between manufacturers, states and covered entities requires each party to do its part in protecting the other two from undue harm. This first session will feature a panel of state and federal officials who will discuss the 340B related roles and responsibilities of Medicaid program officials and the interaction of the statutory authorities under the two programs, including their responsibility to take action against covered entities and/or manufacturers for incidents of non-compliance. A topic addressed in this session will be state implementation of a provision in the Deficit Reduction Act of 2005 (DRA) expanding the Medicaid rebate program to physician-administered drugs and implications of this DRA provision for the 340B program.

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Nancy Schiff, Policy Analyst, Office of Clinical Affairs, University of Massachusetts Medical School

James Stansel, Deputy General Counsel, Office of the Secretary, U.S. Department of Health and Human Services

Amy Williams-Phelps, Pharmacist Investigator, North Carolina Medicaid

10:00 am
(Exhibit Hall C)

Networking and Refreshment Break

10:30 am
(Salon 3)

Session Continues

The second session will continue to address key issues raised in the first session, but from the perspective of manufacturers, covered entities and the Office of Pharmacy Affairs. Among the topics to be discussed are: detecting and avoiding duplicate discounts, billing Medicaid properly for covered outpatient drugs, preparing for expansion of the Medicaid rebate program under the DRA, and dispute resolution.

Burnis Breland, Director of Pharmacy and Clinical Research, The Medical Center/Columbus Regional Healthcare System

Sharley Chen, Public Health Analyst, Office of Pharmacy Affairs

Michael Glomb, Partner, Feldesman Tucker Leifer Fidell LLP (General Counsel to NACHC)

Donna Yesner, Partner, McKenna, Long & Aldridge

12:00 pm
(Exhibit Hall C)

Networking Lunch (WORKSHOP ATTENDEES ONLY)

Commencement of Main Conference
(CE 085-999-012-L04)

1:00 pm
(Salons 2 & 3)

Opening Remarks from 340B Coalition Hosts, 340B Prime Vendor and Industry Conference Leader

1:30 pm
(CE 1.25 Hours)

Federal Government Update

November will mark the 15 year anniversary of the 340B program. Both the Health Resources and Services Administration (HRSA) and the Office of Pharmacy Affairs (OPA) have been busy over the past year with important 340B initiatives: proposing significant changes to the definition of a 340B eligible patient and the contract pharmacy program; proposing guidelines that would allow children's hospitals into the program; adjusting to changes in how 340B prices are calculated as a result of the Deficit Reduction Act of 2005 (DRA); and working with industry in developing a pilot program for verifying 340B price calculations. You will hear from OPA and the two HRSA contractors that are vital to operation of the 340B program – the Prime Vendor Program and the Pharmacy Services Support Center (PSSC).

Harry Hagel, Senior Director, Pharmacy Services Support Center
Chris Hatwig, Senior Director, 340B Prime Vendor Program
Jim Mitchell, Director, Office of Pharmacy Affairs

2:45 pm
(CE 1 Hour)

Legislative Update

2007 promises to be an active year for 340B legislation. Growing demand for access to 340B discounts has motivated Congress to consider 340B legislation that would add new safety net provider groups to the program. Legislation introduced in the House and Senate would add, for example, critical access hospitals, rural referral centers and sole community hospitals. The legislation would also extend the 340B program to inpatient drugs and tighten federal oversight of the program to prevent diversion, overcharges and other potential violations that threaten program integrity. Hear from key Congressional staff and 340B Coalition representatives who are on the frontlines of monitoring and lobbying on these legislative issues.

Meredith Brown, Legislative Assistant, Senator John Thune
Craig Kennedy, Associate Vice President, Federal and State Affairs, National Association of Community Health Centers
Jonni McCrann, Director of Government Relations, Safety Net Hospitals for Pharmaceutical Access
Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Moderator)

3:45 pm
(Exhibit Hall C)

Networking and Refreshment Break

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, DSH HOSPITALS SHOULD NOT ATTEND THE PHARMACEUTICAL MANUFACTURER'S SESSION AND VICE VERSA.]

(Salon 2)
(CE 1 Hour)

Disproportionate Share Hospitals

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access
Ted Slafsky, Executive Director, Safety Net Hospitals for Pharmaceutical Access (Moderator)
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access

(Salon 3)
(CE 1 Hour)

Pharmaceutical Industry

Marcus Farbstein, Director of Government Affairs, Genentech, Inc. (Moderator)
Donna Yesner, Partner, McKenna Long & Aldridge

(Virginia Suite)
(CE 1 Hour)

Community Health Centers

Update on Medicaid Part D and Other Key Issues Impacting Community Health Centers

This breakout session will include: 1) a brief presentation of health center experiences with the Medicare Part D Program, including outstanding issues, followed by group discussion 2) a brief presentation on the issue of establishing charges and discounts appropriately for prescription drugs consistent with 340B, PHS Act 330, Part D, and fraud and abuse guidelines and policies. Some health centers are inadvertently encountering problems resulting from the way in which they structure their charges and discounts. Presentations will be followed by a group discussion.

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

Jackie Leifer, Senior Partner, Feldesman Tucker Leifer Fidell LLP (General Counsel to NACHC)

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

(Delaware A)
(CE 1 Hour)

State and Local Government

Debra Demers, Center for Health Law and Economics, University of Massachusetts Medical School (Moderator)

Nancy Schiff, Policy Analyst, Office of Clinical Affairs, University of Massachusetts Medical School

Dale Stafford, Director of Pharmacy, Truman Medical Center East

(Delaware B)
(CE 1 Hour)

Hemophilia Treatment Centers

Hear how the latest 340B developments, including patient definition, will impact 340B factor distribution programs. Meet with federal officials from MCHB and OPA overseeing Hemophilia Treatment Centers in the 340B Program. Discuss various grant reporting requirements.

Derek Robertson, Executive Director, Hemophilia Alliance (Moderator)

(Park Tower Suite 8219)
(CE 1 Hour)

HIV/AIDS Clinics, ADAPs, and AIDS Service Providers

Beth Crutsinger-Perry, Program Manager of Care and Treatment Programs, National Alliance of State and Territorial AIDS Directors (Moderator)

(Park Tower Suite 8222)
(CE 1 Hour)

Family Planning Clinics

Jennifer Lockwood-Shabat, Director of Public Policy, National Family Planning and Reproductive Health Association

Sue Speth, Director of National Contracts, Planned Parenthood Federation of America, Inc.

Emily Stewart, Regulatory and Policy Analyst, Planned Parenthood Federation of America, Inc. (Moderator)

(Salon 2)
(CE 1 Hour)

Children's Hospitals (Children's hospitals are invited to attend the breakout session for DSH hospitals. A special breakout session for children's hospitals is scheduled for Wednesday at 8:00 am)

5:15 pm

Conclusion

5:30 – 6:45 pm
(Exhibit Hall C)

Reception and Networking Opportunity

Note that the remainder of the conference agenda has been organized into two separate tracks to meet the varying interests of conference attendees. Track One presentations 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.

TUESDAY, JULY 24, 2007

7:00 am
(Exhibit Hall C)

Continental Breakfast – Exhibits Open

8:30 am
(Salon 3)
(CE 1.5 Hours)

Track One – Operationalizing 340B **Setting Up Your 340B Purchasing Program**

When a covered entity enrolls in the 340B drug discount program, it should be prepared to meet several requirements as soon as its enrollment status goes into effect. Compliance with 340B anti-diversion and Medicaid billing standards, for example, may entail significant changes in how the covered entity purchases medications, manages its price files, tracks drug utilization and bills third party payers. These changes, in turn, may require the 340B provider to restructure its relationship with its wholesaler, hire or redeploy covered entity staff, modify and/or expand its information systems, develop new policies and procedures, and work with its finance team to implement changes to its billing and reimbursement programs. Some of these changes should be instituted as soon as the provider is eligible to place 340B orders and others should be completed within the first three months of participation. This session is designed to help covered entities identify and perform the initial tasks necessary to operationalize the providers' 340B programs.

Scott Summers, Vice President of HealthSystems, Cardinal Health
Carl Taylor, Director of Pharmacy Services, Piedmont Health Services, Inc.
Doug Wong, Senior Executive Consultant, Pharmacy Healthcare Solutions
(Moderator)

Track Two – 340B Policy and Compliance

(Salon 2)
(CE 1.5 Hours)

How to Prepare for 340B Changes on the Horizon

In January, HRSA issued two proposed policies that, if implemented, would make sweeping changes to the 340B drug discount program. These proposed changes could significantly narrow the patient populations eligible to receive discounted drugs from 340B providers and expand the number of pharmacies with which covered entities may contract to dispense 340B medications. HRSA also just published a third proposed guidance implementing a year-old provision in the DRA intending to add freestanding high-Medicaid children's hospitals to the 340B program. Attendees will learn about these pending changes, what covered entities and industry are doing to shape or block their implementation and what your organizations should be doing now to prepare for them.

Michael Glomb, Partner, Feldesman Tucker Leifer Fidell LLP (General Counsel to NACHC)
Jim Mitchell, Director, Office of Pharmacy Affairs
Larri Short, Partner, Arent Fox LLP
Bill von Oehsen, President and General Counsel, Safety Net Hospitals for Pharmaceutical Access (Moderator)

10:00 am
(Exhibit Hall C)

Networking and Refreshment Break

10:30 am
(Salon 3)
(CE 1.5 Hours)

Track One – Operationalizing 340B

Inventory Management

340B participation requires covered entities to adopt unique drug purchasing and inventory management systems which, in turn, may require infrastructure changes such as investment in new staff, split-billing software programs and other information system technologies. This session will focus on practical solutions to the challenges of implementing a compliant stock replacement system, maintaining virtual inventories, developing effective tracking systems, and meeting 340B anti-diversion requirements. Covered entity representatives will describe their implementation models in an effort to help attendees identify and understand a "best practices" approach for their institutions.

Donald Davies, Pharmacy Value Analyst, Clarian Health Partners
James Donnelly, Pharmacy Services Director, Hudson Headwaters Health Network
David Jones, Pharmacy Director, Northern Hospital of Surry County
Andrew Wilson, Health and Science Senior Manager, Ernst & Young LLC
(Moderator)

Track Two – 340B Policy and Compliance

340B Consequences of Medicaid and Medicare Reforms

With passage of the DRA in 2005 and the Medicare Modernization Act (MMA) in 2003, Congress has made significant changes to the Medicaid and Medicare programs that threaten to raise costs and/or lower revenue for safety net pharmacies. Some of these reforms – such as expansion of the Medicaid rebate program to clinic-administered drugs under the DRA and establishment of the Medicare Part D program under the MMA – may require covered entities to pass some or all of their 340B savings to the government. Other provisions within the DRA and MMA reduce payment rates for drugs under Medicaid and Medicare Part B, respectively. These changes complicate an already complex landscape of 340B billing and reimbursement standards that vary depending on the payer, the setting and whether drug is self-administered or physician-administered. Our panel of experts will discuss and analyze these DRA and MMA related changes to the 340B program.

Deirdre Duzor, Director, Medicaid Pharmacy Program, Centers for Medicare and Medicaid Services

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

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

John Shakow, Counsel, King & Spalding LLC

*(Salon 2)
(CE 1.5 Hours)*

12:00 pm

Networking Lunch

1:30 pm

Track One – Operationalizing 340B

Optimizing the Benefits of the 340B Program

Program participants will discuss different opportunities for maximizing the value of the program. Providers will learn about different purchasing and dispensing strategies designed to improve both access and affordability of medications for underserved populations. Hear from experts on how to identify and take advantage of resources – Prime Vendor, PSSC, wholesalers, vendors, consultants and advocacy groups – to ensure that your organization is not missing any opportunities to lower its costs under the program.

Chris Hatwig, Senior Director, 340B Prime Vendor Program (Moderator)

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

William Wood, Director of 340B Programs/Government Relations, University HealthCare, Department of Pharmacy Services

Steve Zielinski, Pharmacist, Lawndale Christian Community Health Center

*(Salon 2)
(CE 1.5 Hours)*

Track Two – 340B Policy and Compliance

Breakout Sessions (2 choices)

(1) Pharmaceutical Manufacturer Patient Assistance Programs

This session will describe the different models available to safety net providers in accessing pharmaceutical manufacturers' Patient Assistance Programs (PAPs) which provide free or low cost drugs to low-income, uninsured people. The panel will outline the various elements of PAPs including eligibility requirements, dispensing processes, and auditing provisions. The panel will also summarize PAP guidance from the Department of Health and Human Services' Office of the Inspector General (OIG) and will outline the basics of anti-kickback and beneficiary inducement laws. Panelists will discuss how hospitals and health centers have successfully integrated PAPs into their pharmacy care models and innovative programs offered by manufacturers.

Tom Behan, Customer Programs Leader, AstraZeneca

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

Kathryn Saenz Duke, Director, Medicine for People in Need (Moderator)

Mark Fitzgerald, Principal, Powers Pyles Sutter & Verville PC

Rita Baskett, Supervisor/Project Coordinator, Pharmacy Administration, Carolinas Healthcare System

*(Virginia Suite)
(CE 1.5 Hours)*

(Salon 3)
(CE 1.5 Hours)

(2) Calculating AMP, “Best Price” and 340B Ceiling Prices in a Post-DRA Era

This session will delve into the details of calculating average manufacturer price (AMP) and Medicaid “best price” in accordance with the DRA and how these DRA-related changes will affect 340B ceiling prices. A CMS final regulation addressing these issues has just been finalized. OPA has struggled with whether AMP changes under the DRA, in particular the exclusion of prompt pay discounts, should apply to 340B ceiling price calculations. The 340B covered entity community, meanwhile, has advocated an interpretation that would better preserve current pricing levels for the 340B program by requiring manufacturers to calculate AMP using pre-DRA methodologies in connection with prompt pay discounts. 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. As a result, manufacturers have terminated some of their nominal price contracts with providers in an effort to avoid increasing their Medicaid rebate and 340B discount obligations by setting a new best price. Both manufacturer and covered entity perspectives will be provided during this session, with an emphasis on compliance.

Alice Valder Curran, Partner, Hogan & Hartson

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Timothy Nugent, Managing Director, Huron Group

3:00 pm
(Exhibit Hall C)

Networking and Refreshment Break

3:30 pm

Plenary Breakout Sessions for Both Tracks One and Two (3 choices)

Track One and Track Two have been combined to cover three critical subject areas that are relevant to both covered entity representatives interested in 340B operational issues and the broader attendee group interested in 340B policy and compliance issues. Registrants should choose one of the following three plenary breakout sessions to attend.

(Virginia Suite)
(CE 1.5 Hours)

(1) Distribution Chain Issues – Shortages, Allocations and the Increasing Impact of Specialty Pharmacies

340B providers have expressed concerns that, although a manufacturer may have a contract with the government to extend 340B pricing for its drugs, some of the company’s drugs are not available for purchase under the program. In recent years, there has been a “shortage” of certain drugs available for 340B purchase, and providers have sometimes been put in a position where their 340B status can actually be a disadvantage to obtaining drugs through the most economical means. Some attribute this problem to the allocation methods used to distribute products in high demand. Others cite the increasing use of specialty pharmacies and their uncertain status under the 340B program. Panelists representing different perspectives on the problem will discuss why and how these “shortages” occur in the 340B market even when drugs are readily available in the private, commercial market. Specific access problems associated with intravenous immune globulin (IVIG) will be discussed in light of recent federal studies focusing on the IVIG market.

Ayesha Berlind, Senior Economist, Eastern Research Group, Inc. (HHS Contractor for IVIG Study)

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

Derek Robertson, Executive Director, Hemophilia Alliance

Anna Spencer, Partner, Sidley Austin LLP

(Salon 2)
(CE 1.5 Hours)

(2) Proposed Changes to Patient Definition and Anti-Diversion Requirements

In January, HRSA proposed new guidelines clarifying the 340B definition of patient. These proposed guidelines could fundamentally change how covered entities purchase and dispense 340B drugs. Issues to be covered include: (1) an analysis of the proposed guidelines and how they will affect different covered entity groups, manufacturers, and distributors; (2) eligibility under the

new guidelines of different patient populations, including employees, nursing home residents, home health patients, prisoners, etc.; and (3) implications for covered entity partnerships with state and local governments. Presenters will provide guidance on how covered entities, manufacturers and distributors can address these changes to minimize compliance risks without compromising program benefits. Also covered will be some of the advocacy initiatives that 340B provider groups are pursuing to modify the government's proposed changes.

Michael Glomb, Partner, Feldesman Tucker Leifer Fidell LLP (General Counsel to NACHC)

Bradford Lang, Public Health Analyst, Office of Pharmacy Affairs

Joy Sturm, Partner, Hogan & Hartson

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

*(Salon 3)
(CE 1.5 Hours)*

(3) Partnerships, Demonstration Projects and Pharmacy Delivery Options

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. These partnerships expand access to care and lower drugs costs for vulnerable patients. Different partnership models will be presented, including examples requiring demonstration approval by HRSA. Special attention will be given to compliance with anti-diversion standards and the different options available for delivering 340B medications to the target population through in-house pharmacies and/or contract arrangements with retail pharmacy networks, central fill facilities and mail order pharmacies.

John Allen, Assistant VP and COO, Community Health Services and Correctional Managed Care, UTMB at Galveston

Karen Enright, COO, Greater New Bedford Community Health Center, Inc.

Karmen Hanson, Program Principal, Pharmaceuticals and Cancer Issues, National Conference of State Legislatures (Moderator)

Andrew Lowe, Director of Pharmacy, Arrowhead Regional Medical Center

5:00 pm

Conclusion

5:15 – 6:30 pm
(Exhibit Hall C)

Reception and Networking Opportunity

WEDNESDAY, JULY 25, 2007

7:00 am
(Exhibit Hall C)

Continental Breakfast – Exhibits Open

8:00 am

Track One – Operationalizing 340B

*(Salon 3)
(CE 1.5 Hours)*

Contract Pharmacy Arrangements: How, When, Whether and the Future

HRSA launched the contract pharmacy program in 1996 in response to concerns that eligible entities were unable to benefit from the program because they lacked and could not afford to build their own in-house pharmacies. Since then, the number of contract pharmacies participating in the 340B program has grown significantly. This session will focus on how to establish a contract pharmacy relationship, when it makes sense to develop such an arrangement, and whether the covered entity should explore other options such as physician dispensing or investing in an in-house pharmacy. It will also discuss the proposed HRSA guidelines to allow the use of multiple contract pharmacies.

Fred Grasser, Senior Implementation Manager, Coordinated Care Network

Harry Hagel, Senior Director, Pharmacy Services Support Center (Moderator)

Jason Hardaway, Senior Director of 340B Programs, Wellpartner, Inc.

Track Two – 340B Policy and Compliance

Breakout Sessions (3 Choices)

(Salon 2)
(CE 1.5 Hours)

(1) 340B Under the Microscope – Increased Scrutiny and Enforcement Activity

In the wake of multiple OIG reports and recently-introduced federal legislation focusing on the need to improve 340B program integrity, both covered entities and drug manufacturers find their compliance status being scrutinized by federal and state authorities. Covered entities are increasingly being asked by OPA to explain their use of the 340B program and why such uses comply with 340B patient definition standards. Although such inquiries are informal in nature, at least one investigation led federal prosecutors to bring a criminal action against a physician for alleged diversion of 340B-discounted oncology drugs. State Medicaid agencies, in the meantime, are keeping a watchful eye over covered entity billing practices to protect against overpaying for 340B drugs. Some states have initiated recoupment efforts and regular audit programs. Manufacturers, likewise, are being scrutinized under the 340B program. As both government regulators and covered entities develop more sophisticated pricing analysis systems, manufacturers are increasingly being asked to verify that their 340B prices are not inflated. Some companies have been compelled to issue refunds to covered entities as part of broader settlement agreements with the Medicaid program for alleged overcharges arising out of best price errors. 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.

Edith Marshall, Special Counsel and Director of Legal Affairs, Safety Net Hospitals for Pharmaceutical Access (Moderator)

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

Leah Terrell, Pharmacy Review Pharmacist, Program Integrity, North Carolina Medicaid

Eugene Thirolf, Managing Director, Office of Consumer Litigation, U.S. Department of Justice

(Virginia Suite)
(CE 1.5 Hours)

(2) Medicare Part D – Contracting Issues and Counting TrOOP

The Medicare prescription drug program went into effect a year-and-a-half ago and many of the early implementation problems have been resolved. Safety net pharmacies are still struggling, however, with identifying when cost-sharing waivers may count towards true-out-of-pocket (TrOOP) expenses and with Part D contracting issues, especially in the areas of reimbursement and formulary compliance. This session will review relevant Part D laws and policies, and will feature speakers who will describe their experience and provide practical advice on both serving Part D patients and complying with Part D requirements. It will also provide the latest information on how prescription drug plans are offering and paying for medication therapy management and how they are reimbursing for 340B-discounted drugs.

RoseMarie Babbitt, Associate Director of Pharmacy, Parkland Health & Hospital System

Michael Bukach, Vice President of Network Management, MemberHealth
Vanessa Duran, Technical Advisor/Senior Policy Analyst, Centers for Medicare and Medicaid Services

Dana Thomas, Associate Director of Regulatory Affairs, National Association of Community Health Centers

Courtney Yohe, Policy and Advocacy Analyst, Safety Net Hospitals for Pharmaceutical Access (Moderator)

(Delaware Suite)
(CE 1.5 Hours)

(3) Update on 340B Eligibility of Children's Hospitals

Congress included a provision in the Deficit Reduction Act of 2005 intending to add freestanding high-Medicaid children's hospitals to the 340B program. After more than a year long wait, HRSA has just released a proposed notice describing how children's hospitals can qualify for and enroll in the 340B program. This special breakout session for children's hospitals will provide an

update on the implementation process for children's hospitals. It will also offer guidance on what hospitals can do now to prepare for the future, including how to negotiate and execute indigent care contracts with state or local government in order to meet 340B eligibility standards and other issues. Attendees will have an opportunity to engage in a question-and-answer session with speakers.

Jim Mitchell, Director, Office of Pharmacy Affairs

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

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

Peters D. Willson, Vice President for Public Policy, National Association of Children's Hospitals

9:30 am
(Salons 2 & 3)
(CE 1 Hour)

Ask the Experts

Experts representing various stakeholder groups are available to take questions on any issue raised over the course of the conference. Questions may be asked in person or by written comment.

10:30 am
(Exhibit Hall C)

Networking and Refreshment Break

11:00 am

Breakout Sessions for Various 340B Stakeholders*

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

(Salon 2)
(CE 1 Hour)

Disproportionate Share Hospitals

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

(Salon 3)
(CE 1 Hour)

Pharmaceutical Industry

Marcus Farbstein, Director of Government Affairs, Genentech, Inc. (Moderator)

Chris Hatwig, Senior Director, 340B Prime Vendor Program

(Virginia Suite)
(CE 1 Hour)

Community Health Centers

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

(Delaware B)
(CE 1 Hour)

Hemophilia Treatment Centers

Derek Robertson, Executive Director, Hemophilia Alliance

(Park Tower Suite 8219)
(CE 1 Hour)

HIV/AIDS Clinics, ADAPs, and AIDS Service Providers

Beth Crutsinger-Perry, Program Manager of Care and Treatment Programs, National Alliance of State and Territorial AIDS Directors (Moderator)

12:15 pm

Conference Adjourns



Comprehensive Pharmacy Services, Inc. is accredited by the Accreditation Council on Pharmaceutical Education as a provider of continuing pharmaceutical education. In order to receive credit, each pharmacist must complete the request for credit form and the program evaluation. All completed forms must be turned in at the registration desk at the conclusion of the conference. PLEASE NOTE: Forms mailed in after the conclusion of the conference will not be accepted for continuing education credit.