The Nation's Largest Cross-Functional Rebate Summit Offers:

- ✓ CMS on Implementation Strategies for DRA Compliance
- ✓ HHS and OIG on Lessons Learned from Current Litigations
- ✓ Updated Information by NACDS detailing the AMP Litigation
- ✓ Organized Dispute Resolution Meetings Facilitated by CMS

13th Annual Summit on the

MDRP

Medicaid Drug Rebate Program

& Other Public Sector Reimbursement Programs

September 15-17, 2008 • Marriott Downtown Magnificent Mile • Chicago, IL

CMS OPERATIONS PANEL
DRA Implementation Advice From CMS

- Tamara Bruce, *Technical Director* **CMS DRUG REBATE OPERATIONS** (Invited)
- Diane Dunstan, *Lead RO DRP and Drug Rebate Analyst, Denver Regional Office,* **CMS** (Invited)
- Dusty Kerhart, *Senior Analyst, Drug Rebate Operations,* **CMS** (Invited)
- Dona Coffman, *Technical Director, Division of Information Analysis and Technical Assistance,* **CMS,** (Invited)

OIG and USDOJ on CIAs

Lessons Learned from the Merck Settlement Agreement and Corporate Integrity Agreements

- Mary E. Riordan, Esq. *Senior Counsel, Office of Counsel to the Inspector General,* **OIG HHS** (Invited)
- Viveca Parker *Assistant United States Attorney* **UNITED STATES DEPARTMENT OF JUSTICE, USDOJ** (Invited)

KEYNOTE ADDRESS

Innovations in Health Care: What's Next?

Tommy Thompson
Former Secretary, **HEALTH AND HUMAN SERVICES** *(2001-2005)*

FEATURED SESSIONS

Detailed Update for the AMP Litigation and AMP Legislation from NACDS
Don L. Bell, II
Senior Vice President and General Counsel, **NATIONAL ASSOCIATION OF CHAIN DRUG STORES**

New Civil and Criminal Enforcement Activities to Ensure Compliance
- Julie Brill, *Assistant Attorney General,* **STATE OF VERMONT**
- Terry Glavin, *Assistant Attorneys General, Medicaid Fraud Bureau,* **ILLINOIS ATTORNEY GENERAL'S OFFICE**
- Jim Kole, *Assistant Attorney General, Consumer Protection Division,* **ILLINOIS ATTORNEY GENERAL'S OFFICE**

Updates for the 340B Program and the DRA
Jimmy R. Mitchell, RPh, MPH, MS, *Director*
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)
HEALTHCARE SYSTEMS BUREAU (HSB)
OFFICE OF PHARMACY AFFAIRS (OPA)

TRICARE: Retail Pharmacy Program Status Update
Lt. Col. Travis Watson, MS, *Deputy Director*
DOD PHARMACY PROGRAMS

Three Pre-Conference In-Depth Workshop Choices

Full Day Symposium

Operational Clarification & Improvement for Compliance with Deficit Reduction Act

- Process Improvement for DRA Implementation
- Clear Guidance for Correct Calculations
- Class of Trade Designation
- Bundling and Smoothing Clarification
- Are All Reasonable Assumptions Created Equal?
- DRA Impact on 340B

Half Day Technical Workshops

AM MDRP 101-Connecting Products, Pharmacy, Policy and Operations

PM State Medicaid Leadership Forum

Track Choices

TRACK A: Medicaid Rebate Operations for Manufacturers

TRACK B: 340B and Other Public Sector Reimbursement Programs

TRACK C: Specific State Program Initiatives and Requirements

TRACK D: Compliance with State and Federal Regulations

MORE NEW HOT TOPICS!

- Optimize Your Limited Resources to Comply with Time Consuming New Regulations
- Process Improvement Lessons Learned in Implementing Changes for Complying with the DRA
- How to Operationalize the Struggle of Collecting NDCs for J-codes
- Current Legal Issues with NDCs and Physician Administered Drugs and Extended Rebates in Hospital Outpatient Setting
- 340B Pricing Structure Clarification as a Result of the Deficit Reduction Act
- Dual Eligibles – What Happened To Them After Medicare Part D?
- The Future of Medicaid Budget Problems

STATES THAT PARTICIPATED IN 2007

Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Missouri, New York, N. Carolina, Ohio, Oklahoma, Rhode Island, Texas, Utah, Wyoming

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www.medicaiddrugrebates.com

13th Annual Summit on the

Medicaid Drug Rebate Program

MDRP

Dear Government Contracting Professional,

Today, Medicaid is the largest government health care program in combined federal and state spending and is costing close to $259 billion. Manufacturers are devoting more internal resources to adapt to new MDRP processes and incurring increased costs due to pending litigations and compliance requirements. The emerging budget shortfalls are prompting the States to reassess their Medicaid programs. Innovation needs to happen. How will legislators and presidential candidates influence reforms? How will these changes affect Medicaid, Medicare and your role?

KEYNOTE PRESENTATION

Future of US Healthcare, Medicare and Medicaid Innovations in Health Care: What's Next?

Tommy Thompson, *Former Secretary,* **HEALTH AND HUMAN SERVICES**

Recent Litigations and Corporate Integrity Agreements

With a top down approach, the 13th Annual Summit on the MDRP offers you highly anticipated CMS keynote panel, HHS and USDOJ explanation of current litigations and corporate integrity agreements and presentations and four concurrent tracks for more specific learning opportunities to help you navigate the upcoming changes.

Lessons Learned from the Merck Settlement Agreement and the Corporate Integrity Agreement

Mary E. Riordan, Esq., *Senior Counsel, Office of Counsel to the Inspector General,* **OIG HHS** (invited)

Viveca Parker, *Assistant United States Attorney,* **UNITED STATES DEPARTMENT OF JUSTICE, USDOJ** (invited)

Detailed Update for the AMP Litigation and AMP Legislation

Don L. Bell, II, *Senior Vice President and General Counsel,* **NATIONAL ASSOCIATION OF CHAIN DRUG STORES**

DRA PROCESS IMPLEMENTATION ANSWERS

The cost for implementation and degree of complexity of the DRA on MDRP have caused significant rebate program challenges. There are open DRA requirement questions for the MDRP that are left for interpretation which create legal and financial exposure. The DRA's impact on manufacturers, states, and pharmacies continues to bring frustration to an industry striving to maximize beneficiary care, control costs and ensure compliance. The CMS operations panel is your opportunity to ask your burning questions to CMS, anonymously.

Operational Clarification for CMS Monthly and Quarterly Reporting and Dispute Activity Answers

Tamara Bruce, *Technical Director,* **CMS DRUG REBATE OPERATIONS** (invited)

Dusty Kerhart, *Senior Analyst,* **CMS DRUG REBATE OPERATIONS** ((invited)

Samone Angel, *Senior Analyst,* **CMS DRUG REBATE OPERATIONS** (invited)

Dona Coffman, *Technical Director, Division of Information Analysis and Technical Assistance,* **CMS** (invited)

DRA Questions Answered! Why This is a Can't Miss Summit!

- With increase in drug rebate audits, can you risk not educating yourself on all the current drug rebate changes?
- Do you need to keep your senior management aware of the critical importance of making sure these calculations are accurate and compliant?
- Learn the questions you need to ask to ensure you are doing everything correctly
- Everyone has open DRA questions, find out what you don't know and what you need to know.

The 2008 Summit provides specific answers to your most pressing questions from state and federal compliance and enforcement officials to understand the effect of the DRA impacting the 340B program. Additional conference highlights include:

COMPLIANCE & ENFORCEMENT

Ensure Your Company's' Compliance with Current Civil and Criminal Enforcement Activities

Julie Brill, *Assistant Attorney General,* **STATE OF VERMONT**

Terry Glavin, *Assistant Attorneys General, Medicaid Fraud Bureau,* **ILLINOIS ATTORNEY GENERAL'S OFFICE**

Jim Kole, *Assistant Attorney General, Consumer Protection Division,* **ILLINOIS ATTORNEY GENERAL'S OFFICE**

VA, DOD, & 340B PROGRAM UPDATES

Updates for the 340B Program: New Information on Price Reporting, Membership Management and Cross Walking

Jimmy R. Mitchell, RPh, MPH, MS, *Director*
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)
HEALTHCARE SYSTEMS BUREAU (HSB)
OFFICE OF PHARMACY AFFAIRS (OPA)

TRICARE: Retail Pharmacy Program Status Update

Lt. Col. Travis Watson, MS, *Deputy Director,* **DOD PHARMACY PROGRAMS**

CMS-Moderated Dispute Resolution Service
September 15, 2008 8:30am- 12:00pm

Optimize your travel time and take advantage of the presence of CMS to moderate state/manufacturer disputes.

Dispute Resolution meetings are facilitated by:

Tamara Bruce, *Central Office DRP Coordinator,* **CMS**

Diane Dunstan, *Lead Regional Office DRP Coordinator,* **CMS**

visit *www.medicaiddrugrebates.com* to sign up!

PRE-SUMMIT FULL DAY SYMPOSIUM

DEFICIT REDUCTION ACT Final Rule Compliance: Understand how to implement the changes to the MDRP Processes.

HALF-DAY WORKSHOP CHOICES

MEDICAID 101: Back by popular demand for professionals new to the area of the Medicaid Drug Rebate Program, need a refresher course, or would just like to strengthen fundamental knowledge to connect Products, Pharmacy, Policy and Operations.

STATE MEDICAID PROFESSIONALS: This forum is dedicated to the current challenges of State Medicaid Professionals to improve processes and learn new compliance techniques under the DRA. Learn from this technical and instructional workshop detailing what state officials need to know to do their job in a DRA environment.

TRACK CHOICES

TRACK A: Medicaid Rebate Operations for Manufacturers

TRACK B: 340B and Other Public Sector Reimbursement Programs

TRACK C: Specific State Program Initiatives and Requirements

TRACK D: Compliance with State and Federal Regulations

Based on your feedback, we have added new process improvement case studies and deliver more panel discussions to help alleviate the most frustrating aspects of your position in the Rebate program. This is your opportunity to have access to the outstanding speaking faculty including key pharmaceutical manufacturers, States, attorneys, experienced consultants, government agency representatives, enforcement agencies and legislative and policy groups. With your continued interest and the presentations on new solutions to your day-to-day compliance challenges, our conference remains unmatched by any other.

Sincerely,

Anne Reel
Event Director
13th Annual Summit on the MDRP
AReel@iirusa.com

Edward J McAdams
Director, Contract Administration,
DAIICHI SANKYO PHARMA

UP TO 16.5 CPE AND 14 ACPE CREDITS AVAILABLE

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Pre-Conference Symposium 09/15/08= 6

Half Day Morning Workshop 09/15/08= 3

Half Day Afternoon Workshop 09/15/08=3.5

Main Summit Day 1 09/16/08= 5.5

Main Summit Day 2 09/17/08= 4.5

Maximum amount of CPE credits a delegate may receive is 16.5

PTi international is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmaceutical education. Participants will receive a maximum of 14 hours (1.4 CEUs) of continuing education credit for full participation in the (3) day training. ACPE #326-999-07-195-L04-P.

Initial release: 09/15/2008

Pre-Conference Symposium 09/15/08= 5

Half Day Morning Workshop 09/15/08= 2.5

Half Day Afternoon Workshop 09/15/08=3

Main Summit Day 1 09/16/08= 4.75

Main Summit Day 2 09/17/08= 3.75

Maximum number of ACPE credit a delegate may receive = 14

Event-at-a-Glance

Monday, September 15, 2008

Full Day Symposium

B1: Final DRA Rule Compliance

8:15 *Symposium Registration*

9:00 **Chairpersons' Welcome**
Pamela Vaal, Consultant, formerly Manager Medicaid, ELI LILLY & COMPANY

9:15-12:00 **Today's MDRP and DRA Landscape: Operational Clarification for Ensuring Compliance**

10:30 – 11:00 *Refreshment and Networking Break in Exhibit Hall*

12:00 -1:15 *Networking Luncheon*

1:15 **Are All Reasonable Assumptions Created Equal?**

2:15 OPEN SESSION

3:15 *30 minute Afternoon Refreshment Break*

3:45 **How to Discussion: Manufacturers Answer the Most Frustrating DRA Process and Compliance Questions**

5:00 *Symposium concludes*

Morning Workshops		Afternoon Workshops	
8:15	*Registration and Morning Coffee*	1:00	*Workshop Registration*
9:00-12:00	**B2: Medicaid Drug Rebate Program Fundamentals - Building the Unity Between Products, Pharmacy, Policy and Operations** Dispute Resolution Meetings	1:30–5:00	**B3- State Medicaid Leadership Forum** This Unique Forum is Dedicated to the Current Challenges of State Medicaid Directors to Improve Processes and Learn New Compliance Techniques under the DRA
9:00-12:00	**CMS Facilitation available from:** Diane Dunstan, CMS Lead Regional Office DRP Coordinator, Cindy Bergin and Tamara Bruce, CMS Central Office DRP Coordinators	3:00	*30 Minute Afternoon Refreshment Break*
12:00	*Luncheon for Morning Workshop Delegates and Presenters*	4:00–5:00	*Pre registration for Main conference*

Tuesday, September 16, 2008

7:30 *Registration and Morning Coffee*

8:15 **Chairperson Welcome & Industry Introduction**
Edward J McAdam, Director, Contract Administration, DAIICHII SANKYO PHARMA

8:30 **Future of US healthcare, Medicare and Medicaid Innovations in Health Care: What's Next?**
Tommy Thompson, Former Secretary of Health and Human Services (2001-2005)

9:15 **Operations and Dispute Q & A**
Tamara Bruce, Technical Director, CMS DRUG REBATE OPERATIONS
Diane Dunstan, CMS Lead RO DRP and Drug Rebate Analyst, DENVER REGIONAL OFFICE
Dusty Kerhart, CMS Senior Analyst, DRUG REBATE OPERATIONS
Samone Angel, CMS Senior Analyst, DRUG REBATE OPERATIONS

10:15–10:45 *Refreshment and Networking Break in Exhibit Hall*

10:45 **Lessons Learned from the Merck Settlement Agreement and the Corporate Integrity Agreement**
Moderator: Mitchell J. Lazris, Partner, HOGAN & HARTSON
Mary E. Riordan, Esq., Senior Counsel, Office of Counsel to the Inspector General, HEALTH AND HUMAN SERVICES (invited)
Viveca Parker, Assistant United States Attorney, UNITED STATES DEPARTMENT OF JUSTICE, USDOJ (invited)

11:45 **Ensure Your Company's Compliance with Current Civil and Criminal Enforcement Activities**
Julie Brill, Assistant Attorney General, STATE OF VERMONT
Terry Glavin, Assistant Attorneys General, Medicaid Fraud Bureau, ILLINOIS ATTORNEY GENERAL'S OFFICE
Jim Kole, Assistant Attorney General, Consumer Protection Division, ILLINOIS ATTORNEY GENERAL'S OFFICE

12:30 *Networking Luncheon*

1:30 **Afternoon Tracks Begin** Following lunch, the summit divides into four afternoon tracks. You are welcome to attend any session in any track of your choice.

	Track A **MDRP 101 Medicaid Rebate Operations for Manufacturers** **Chairperson:** **William Baxter, former Director, Rebate Management, JOHNSON & JOHNSON HEALTH CARE SYSTEMS**	**Track B:** **340B and Other Public Sector Reimbursement Programs** **Chairperson:** **Mary Kay Owens R.Ph C.Ph President, SOUTHEASTERN CONSULTANTS**	**Track C:** **Specific State Program Initiatives and Requirements** **Chairperson:** **Laurie Squartsoff, Director of Professional Affairs, PROFESSIONAL PROVIDER SERVICES**	**Track D:** **Compliance with State and Federal Regulations** **Chairperson:** **John Bliss, Manager, Contract Management, GRACEWAY PHARMACEUTICALS**
1:30	**Medicaid Payment Process Improvement to Avoid Pitfalls and Duplicate Discounts** ELI LILLY & COMPANY	**Updates for the 340B Program: New Information on Price Reporting, Membership Management and Cross Walking** U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) HEALTHCARE SYSTEMS BUREAU (HSB) OFFICE OF PHARMACY AFFAIRS (OPA)	**How to Operationalize the Struggle of Collecting NDCs for J-codes** EDS NORTH CAROLINA MEDICAID STATE OF MONTANA GEORGIA DEPT OF COMMUNITY HEALTH	**Strategic Management of the Government as a Customer** COMPLIANCE IMPLEMENTATION SERVICES
2:15	**Training and Staffing** **Strategies to Utilize your Limited Resources to Comply with Time Consuming New Regulations** DAIICHII SANKYO PHARMA GRACEWAY PHARMACEUTICALS	**Interactive Tour to Get the Most from the Pharmacy Affairs Database** OFFICE OF PHARMACY AFFAIRS	**Current Legal Issues with NDCs and Physician Administered Drugs and Extended Rebates in Hospital Outpatient Setting** SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS	**Class of Trade at the Margin: Identifying and Operationalizing in the Gray Area** PRICEWATERHOUSECOOPERS
3:00- 3:30	*Afternoon Refreshment Break in Exhibit Hall*			
3:30	**Process Improvement Lessons Learned in Implementing Changes for Complying with the DRA** JOHNSON & JOHNSON CONSUMER COMPANIES ORTHO-MCNEIL JANSSEN PHARMACEUTICALSERVICES ABRAXIS PHARMACEUTICAL PRODUCTS	**340B Pricing Structure Updates as a Result of the Deficit Reduction Act** 340B Prime Vendor Program/HPPI SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS	**Hot Topics for States Open Round Table** FEDERAL FUNDS INFORMATION FOR STATES EDS NORTH CAROLINA MEDICAID	**Improve Compliance, Minimize Revenue Loss and Improves Overall Operational Efficiency** I-MANY
4:15	**Auditing and Monitoring Practices and Procedures for Manufacturers** JOHNSON AND JOHNSON BIOGEN IDEC	**Session Continues** **340B Pricing Structure Updates as a Result of the Deficit Reduction Act**	**Implementation of Simplified Medicare Part D Supplement for SPAPs in Missouri Rx Program** MISSOURI RX PLAN	**Optimizing Profitability and Maintaining Compliance with Managed Care Rebates** IMS CONSULTING, CONTRACTING, and COMPLIANCE
5:00-6:00	*Conclusion of Tuesday. Please join us for a reception* 			

Wednesday, September 18, 2008

8:00 *Morning Coffee*

8:30 **Chairpersons Recap of Day One**
Edward J McAdam, Director, Contract Administration, DAIICHII SANKYO PHARMA

8:45 **Detailed Update for the AMP Litigation and AMP Legislation**
Don L. Bell, II, Senior Vice President and General Counsel, NATIONAL ASSOCIATION OF CHAIN DRUG STORES

9:15 **How Private Part litigations Effect the Industry and Manufacturer Behavior**
Constance A. Wilkinson, Member of the Firm, EPSTEIN BECKER AND GREEN
Benjamin S. Martin, Senior Associate, EPSTEIN BECKER AND GREEN

10:00-10:30 *Networking and Refreshment Break*

10:30 **Renewed Focus on Coordination of Care in Medicaid to Achieve Cost Savings and State Budget Goals**
Mary Kay Owens R.Ph C.Ph President, SOUTHEASTERN CONSULTANTS

11:15 **Understanding State HCP Spend Reporting Requirements**
Cynthia Hwang, Pharmaceutical Advisory Services Practice, KPMG

11:45 **Current Hot Topics in Medicaid and Other Public Sector Reimbursement Programs**
Alice Valder Curran, Partner, HOGAN & HARTSON
Mary Kay Owens RPh CPh President, SOUTHEASTERN CONSULTANTS

12:30 *Luncheon*

	Track A: **Medicaid Rebate Operations for Manufacturers** **Chairperson:** **William Baxter, Former Director, Rebate Management, JOHNSON & JOHNSON HEALTH CARE SYSTEMS**	**Track B:** **340B and Other Public Sector Reimbursement Programs** **Chairperson:** **Mary Kay Owens R.Ph C.Ph President SOUTHEASTERN CONSULTANTS**	**Track C:** **Specific State Program Initiatives and Requirements** **Chairperson:** **Laurie Squartsoff, Director of Professional Affairs PROFESSIONAL PROVIDER SERVICES**	**Track D:** **Compliance with State and Federal Regulations** **Chairperson:** **John Bliss, Manager, Contract Management GRACEWAY PHARMACEUTICALS**
1:30	**Best Practices and Lessons Learned for Successful Dispute Resolution** AMGEN JOHNSON & JOHNSON MORTON GROVE PHARMACEUTICALS PROFESSIONAL PROVIDER SERVICES	**Dual Eligibles – What Happened To Them After Medicare Part D?** UNIVERSITY OF ILLINOIS AT CHICAGO COLLEGE OF PHARMACY	**Cost Saving Strategies for State Medicaid Professionals** PROFESSIONAL PROVIDER SERVICES	**OPEN SESSION**
2:15	**Session Continues** **Best Practices and Lessons Learned for Successful Dispute Resolution**	**TRICARE Retail Pharmacy Program Status Update** DOD PHARMACY PROGRAMS	The Changing Landscape of Pharmacy Reimbursement FIRST DATABANK	**CIS PANEL DISCUSSION**
3:00	*Conference Concludes*			

B1

Full Day Symposium
Operational and Legal Clarification for DRA & MDRP Compliance

Updated

8:15 *Symposium Registration and Morning Coffee*

9:00 **Symposium Chairperson's Welcome**
Pamela Vaal, *Consultant, formerly Manager Medicaid,* **ELI LILLY & COMPANY**

9:15 **Legal and Operational Perspective on Current AMP & BP Calculation Issues**
The DRA Final Rule provided clarity in many areas but failed to clarify others, necessitated extensive changes and introduced extensive new issues. Subsequent litigation, published Q&A's and general industry developments have added additional uncertainties and complications. This extended session will review some of the original AMP and BP calculation challenges presented by the Final Rule and then focus on identifying and exploring some of the most current and problematic AMP and BP calculation issues from both a legal and operational perspective.
The speakers address the most current issues at the time of the conference which may include matters such as:
- Bundling/discount reallocation
- Eligible transaction type identification in areas such as service fees, returns and coupons/PAPs
- Estimating through 12 month rolling averages
- Processing problematic transaction types such as PBM discounts and payment in product
- Discount stacking for BP
- BP calculation for authorized generics
- Base AMP restatements
- Documentation

Richard Zimmerer, *Partner, Advisory Services,* **KPMG**
Alice Valder Curran, *Partner,* **HOGAN & HARTSON LLP**

10:30-11:00 *Morning Networking Break*

12:00 *Networking Luncheon*

1:15 **Are All Reasonable Assumptions Created Equal?**
This session explores manufacturers' authorization to make "reasonable assumptions" used in performing their price calculations. Understand the "scope" of this authority – to what types of issues does it apply? What it means for an assumption to be "reasonable" and who should be involved in its formulation.
Constance A. Wilkinson, *Member of the Firm,* **EPSTEIN BECKER AND GREEN**
Benjamin S. Martin, *Associate,* **EPSTEIN BECKER AND GREEN**

2:15 **OPEN SESSION**

3:15 *30-Minute Networking Break*

3:45 **"How to" Discussion: Manufacturers Answer the Most Frustrating DRA Process and Compliance Questions**
This panel discusses current industry best practices and risk-reduction strategies in the evolving and ever more complicated pharmaceutical price reporting area Clarify reporting requirements and learn to streamline processes to minimize the additional resource strain.

Ensure Compliance
- Update from DRA fraud, waste, and abuse provisions
- What the AMP data means to avoid potential for confusion and frustration
- How to handle products that were released previously but were not sold until recently? How do you provide previous AMPS when there is none?
- Restating previous quarters- when the final rule is published can we restate using that methodology?
- How to measure fair market value of services under the bona fide service fee exemption rule?
- How labelers implementation of rules has worked out for assuring accurate and timely reporting
- Recent changes to the program and make sure my company is dealing with them appropriately
- What analysis do people perform on their numbers to ensure that they are correct?
- How to report and process the rebates for the different programs

Process Improvement
- How to improve documenting procedures and SOP's
- What are the resources to track changes?
- Strategies to resolve the challenge of the volume of reporting requirements (from data elements 4 times a year to monthly reporting and 4 data elements 4 times a year
- How will certification work in relation to a web based reporting system?
- How is small pharma operating vs. big pharma ?
- Better Management strategies of DRA system changes
- Strategies for automating DRA rules into a GP system

Clarify Calculation Methodology
- Can different methodologies be used for Monthly and Quarterly since true-ups are used with Quarterly Calculation?
- Will BP provisions require matching PBM rebates, coupons and other discounts to originating sales?
- How to handle false positives and negatives with the monthly AMP?
- Learn what to do about prompt pay in the base AMP and PHS AMP

Panelists:
Paula Grist, Senior Director, *Sales Operations,* **MORTON GROVE PHARMACEUTICALS**
Steven C. Benz, Esq., *Legal Counsel,* **ELI LILLY AND COMPANY**
Edward J McAdam, *Director, Contract Administration,* **DAIICHII SANKYO PHARMA**
Jay McKinley, *Director, Contract Operations Government,* **CEPHALON**

5:00 *Symposium Concludes*

ADDED BENEFIT FOR SUMMIT ATTENDEES!

Dispute Resolution Meetings

8:30- 12:00 CMS Facilitation available from: Diane Dunstan, CMS Lead Regional Office DRP Coordinator & Cindy Bergin and Tamara Bruce, CMS Central Office DRP Coordinators

For the fifth year running, IIR's Summit on the MDRP offers a morning opportunity for dispute resolution between states and manufacturers, moderated and facilitated where needed by dispute resolution professionals from CMS. Sign up for 30-minute private sessions that enable you to address outstanding issues or, if you have no disputes, take this opportunity for face-to-face communication with your state or manufacturer counterpart.

Meetings will be scheduled on a first come, first serve basis, so the quicker you respond, the earlier time slot you can fill.

If you choose to have CMS facilitate your meeting a representative can take notes for you that will be given to you at the conclusion of the meeting. CMS will also note action plans, time frames for follow up, etc.

Please visit www.medicaiddrugrebates.com and follow the dispute resolution tabs to request meetings with attending states or manufacturers. If you need technical assistance please contact: Anne Reel, Program Director areel@iirusa.com or 919-676-0306.

Are you New to the MDRP?

Join us for the pre conference Fundamentals workshop to learn how a product begins and is maintained in the Medicaid drug program. Learn who the "players" are from the manufacturer, state and pricing compendia. Understand how they are connected and can work together to successfully report on products. During the main conference Track A in the afternoon details the fundamentals of the process of payments, contracting and dispute resolution all under the new DRA guidelines.

B2 Half Day Morning Workshop

Medicaid Drug Rebate Program Fundamentals - Building the Unity Between Products, Pharmacy, Policy and Operations

8:15 *Registration and Morning Coffee*

9:00 *Workshop Begins*

10:30 *30-Minute Refreshment Break*

12:00 *Workshop Concludes;*
Luncheon for Workshop Leaders and Participants

The Medicaid Drug Rebate Program can be a complicated endeavor to any pharmaceutical manufacturer. It is a program that works best when all components are properly "connected" in the drug delivery industry. How one goes about making this connection and why it is so important is the topic of this workshop, also known as the Medicaid Drug Rebate Program 101.

Whether your new to the area of the Medicaid Drug Rebate Program, need a refresher course, or would just like to increase your knowledge, this workshop is your answer. Come and network and build your knowledge about Medicaid rebates and the drug delivery industry. This is one of the rare workshops offered that allows participants the opportunity to experience trainers from a manufacturer, a state Medicaid, and the pricing compendia. The focus is on pharmaceutical manufacturers and the basic understanding of how a product begins, grows and is maintained in the Medicaid Rebate Program. Emphasis is placed on understanding all the "players" in the industry and the crucial component of understanding a product.

As we move toward supplemental programs being introduced, it is essential that we not forget about the basics and the importance in making the necessary connections to be most successful in the reporting of products within the Medicaid Drug Rebate Program. Failure to report correctly will have a profound effect on many other programs introduced and can impact the reimbursement of your products.

Pharmaceutical Manufacturer:

- Review a brief history of OBRA '90 and '93 legislation
- Introduce and understand a product in the industry (internally and externally)
- Understand Medicaid rebate roles and responsibilities within a pharmaceutical manufacturer
- Review the processing of rebates as it currently exists
- Understand the role of the pharmacy and identifying players in the drug delivery industry
- Learn how to reduce disputes
- Balance timelines and maximize internal efficiencies
- Obtain lessons learned

State Medicaid:

- Gain an understanding of how a state places a product in their system
- Learn about formularies and how are policies created
- Learn how are rebate invoices are generated and how disputes are handled
- Receive important processing hints to a pharmaceutical manufacturer: What works, what doesn't work…when you send a rebate check where does it go?
- Explore future improvements and /or challenges in the rebate arena

NCPDP:

Learn how to partner and understand how the NCPDP can achieve data uniformity and reliability through standardization in the Medicaid Drug Rebate Program. Connect through standardization, a common language and understanding by all associated within the healthcare delivery industry. Gain a better understanding of:

- NDC numbers
- Products: Sold versus dispensed
- NCPDP Workgroup #2 Product Identification (Quic Form) available

Who Should Attend:

This workshop is designed for all professionals in the Pharmaceutical, Biotechnology, industries as well as state government officials who are involved with:

- Medicaid Rebate Manager, Directors, Analysts, Associates
- Government Contracts, Operations and Public Policy
- General Chief Counsel/Legal
- Compliance Officers
- Pharmacy Advisors
- Accounting/Finance
- IT / IS

Workshop Leaders:

Linda L. Schock, *Associate Director,* **CV THERAPEUTICS**
Kay Morgan, *Vice President, Drug Product Pricing,* **GOLD STANDARD**
Heather Murphy, *Manager, Pharmacy Contracts and Rebates, Medicaid/CHIP Program Operations,* **TEXAS HEALTH & HUMAN SERVICES COMMISSION** (invited)

B3 Half Day Afternoon Workshop

State Medicaid Leadership Forum

12:30 *Afternoon Workshop Registration*

11:15 *Workshop Begins*

3:15 *30-Minute Refreshment Break*

5:00 *Workshop Concludes*

This Unique Forum is Dedicated to the Current Challenges of State Medicaid Directors to Improve Processes and Learn New Compliance Techniques under the DRA

Learn from technical and instructional workshop detailing what state officials need to know to do their job in a DRA environment. Technical process improvement lessons including how to handle the new pricing methodology. A panel of the big states discuss how they are implementing the program including trying to convert old J-code claims. Discover new strategies that other states utilize to improve our own processes, including:

- Overcoming J-code billing issues
- How to provide good data to manufacturers to support claims
- Improving data consistency
- Uncover how other states are preparing for NDC capture

Who Should Attend:

This forum is designed specifically for State Medicaid Rebate Directors and Specialist

Forum Leaders:

Cindy LaClair, *Kansas Drug Rebate Specialist,* **EDS KANSAS**
Karen Kluczykowski, RPh, *Director Pharmacy Benefits Management,* **EDS KANSAS**
Jerry Dubberly, *Pharmacy Director,* **GEORGIA DEPT OF COMMUNITY HEALTH**

7:30 *Registration and Morning Coffee*

8:15 **Chairperson Welcome & Industry Introduction**
Edward J McAdams, *Director, Contract Administration,* **DAIICHI SANKYO PHARMA**

Future of US Healthcare

8:30 **Future of US Healthcare, Medicare and Medicaid Innovations in Health Care: What's Next?**

KEYNOTE

During this eye opening presentation, Tommy Thompson reveals his thoughts on the future of health care. Focused on issues relevant to your audience, he navigates the murky waters of today's complicated issues. The following are just a few of the subject areas most often requested: Medicare and Welfare Reform, the Pharmaceutical Debate, the FDA Approval Process, Future Cures and Treatments, General Nutrition, Child Health & Immunization and the Cost of Staying Healthy.

Medicare Policy Reform

Not one to shy away from a difficult challenge, he is the architect of the most important health policy initiative in decades – the Medicare Modernization Act. During this presentation he unfolds the complexities of the Medicare discussion.

Tommy Thompson, *Former Secretary,* **HEALTH AND HUMAN SERVICES (2001-2005)**

CMS Keynote Panel Session

9:15 **CMS Operational Clarification and Dispute Q & A**

CMS Medicaid Operations has had an extremely challenging workload due to DRA implementation activities and is now happy to provide an update on their activities as well as a dispute update, and then will be available for general operations questions & answers. This session will provide information on the new DRA monthly reporting requirement as well as new quarterly reporting issues, and DDR, the new reporting mechanism for both monthly and quarterly data. Hear detailed explanation of the agency's internal process for reviewing and processing recalculation requests. Bring your specific questions to ask the expert CMS panel!

Tamara Bruce, *Technical Director,* **CMS DRUG REBATE OPERATIONS** (Invited)

Diane Dunstan, *Lead RO DRP and Drug Rebate Analyst,* **DENVER REGIONAL OFFICE CMS** (Invited)

Dusty Kerhart, *Senior Analyst, Drug Rebate Operations,* **CMS** (Invited)

Dona Coffman, *Technical Director, Division of Information Analysis and Technical Assistance,* **CMS** (Invited)

10:15 *30-Minute Morning Networking and Refreshment Break*

TRACK	A **A Medicaid Rebate Operations for Manufacturers** **Chairperson:** William Baxter, *Former Director, Rebate Management,* **JOHNSON & JOHNSON HEALTH CARE SYSTEMS**	B **340B and Other Public Sector Reimbursement Programs** **Chairperson:** Mary Kay Owens R.Ph C.Ph, *President* **SOUTHEASTERN CONSULTANTS**
1:30	**Medicaid Payment Process Improvement to Avoid Pitfalls and Duplicate Discounts** NEW Hear the fundamentals of Medicaid payment processing and learn overcome common challenges facing manufacturers today. How do manufacturers handle MDRP payments in the SAP world? Review the process flow for Medicaid payments. Identify and handle the double dipping due to TriCare and Medicare. Understand the impact of the major risks have on rebates pad and utilization. Learn to identify and handle these major pitfalls: • Unit of Measure • Incorrect NDC reporting • Units vs reimbursed $ • Medicaid as secondary insurance • Double dipping • Generic substitution • Adjustments to prior quarter Pamela Vaal, *Consultant, Former Manager Medicaid,* **ELI LILLY & COMPANY**	**Updates for the 340B Program: New Information on Price Reporting, Membership Management and Cross Walking** NEW • New information about the OIG recommendations • Updates for pricing reporting • Membership management in the OPA database • Introduction to the pilot program • Updates for Cross walking the 340B id number with the NPI Number • DRA Impact on AMP for 340B Program • DRA impact and 340B additional reporting requirements • Change of DRA and final rule PHS Children's hospital Jimmy R. Mitchell, RPh, MPH, MS, *Director* **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)** **HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)** **HEALTHCARE SYSTEMS BUREAU (HSB)** **OFFICE OF PHARMACY AFFAIRS (OPA)**
2:15	**Training and Staffing** **Strategies to Utilize your Limited Resources to Comply with Time Consuming New Regulations** NEW Are you struggling to perform the additional calculations and analyze the data with your limited resources? How do you handle staff turnover in this complicated GP area? How are the other pharmaceutical companies training their employees to meet these requirements? This session discuss the strategies for appropriately staffing to pay invoices and complying with time consuming new regulations with limited resources (headcount & capital $$). Hear how to improve analytical capabilities for both staff and computer software. John Bliss, Manager, *Contract Management,* **GRACEWAY PHARMACEUTICALS** Edward J McAdam, *Director, Contract Administration,* **DAIICHII SANKYO PHARMA**	**Interactive Tour to Get the Most from the Pharmacy Affairs Database** The OPA database is the primary means for drug manufacturers and wholesalers to determine the eligibility status of customers who wish to purchase drugs under the 340B Drug Pricing Program. The OPA database provides the most current information OPA has on participating entities, contracted pharmacy arrangements, and drug manufacturers. Our speaker presents: • Learn to access and Utilize the Pharmacy Affairs Database • How to access the 340B database - an interactive primer • The Medicaid Exclusion File • How to request a change in the manufacturer record • Opportunities for feedback and input Sharley L. Chen, *Public Health Advisor,* **OFFICE OF PHARMACY AFFAIRS**
3:00	*30-Minute Afternoon Networking Break*	
3:30	**Process Improvement Lessons Learned in Implementing Changes for Complying with the DRA** NEW The short timelines, cost for implementation and degree of complexity of the DRA changes causes significant rebate program challenges. The DRA requirements for the MDRP are not specifically defined in law or regulation which can create legal and financial exposure based upon interpretation. The DRA's impact on manufacturers continues to bring frustration to your daily job. Hear industry rebate professionals have implemented new processes for the MDRP from the DRA. Discuss the information the CMS presented earlier in the day and ask specific questions help you when you return to the office. **Panelists:** Barbara Winget, *Manager, Contracts & Medicaid,* **JOHNSON & JOHNSON CONSUMER COMPANIES** Michael Hepburn, *Controller, Government Contract Compliance,* **ORTHO-MCNEIL JANSSEN PHARMACEUTICALSERVICES** Marijo Bustos, *Government Business Analyst, Contract Marketing,* **APP PHARMACEUTICALS**	**340B Pricing Structure Updates as a Result of the Deficit Reduction Act** Hear how the DRA has impacted the 340B program, including answers AMP and URA Calculation for 340B. • How companies are coping with the PHS-340B requirements on AMP calculations vs. the newly implemented DRA requirements • AMP and its use in PHS calculations – Should you use old or new calculation methodology? • PHS AMP methodology as it differs from Medicaid AMP methodology and the implications **Other 340B pricing questions:** • What is the 340B Ceiling Price and how is it calculated? • What is a 340B selling price? • How do parties (OPA, wholesalers, covered entities) get pricing information? • What happens if I sell products at 340B prices to organizations that are not 340B participants? Christopher A. Hatwig, *Senior Director,* **340B PRIME VENDOR PROGRAM/HPPI** William Von Oehsen, *President,* **SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS**
4:15	**Panel Discussion** **Auditing and Monitoring Practices and Procedures for Manufacturers** Are you concerned with bringing your company's internal audit group up to speed on current MDRP issues? Do you have current procedure in place to ensure complete auditing & monitoring your internal program? Take part in this session to discuss current auditing practices for DRA and the internal controls necessary for sufficient analytical and compliance tools. Strategies for creating and maintaining valid policy and procedure documents Lorraine Moccio, *Director of Government Pricing Analytics,* **JOHNSON AND JOHNSON** Lisa Kiniklis, *Senior Manager, Government Pricing & Reporting,* **BIOGEN IDEC**	**Session Continues** **340B Pricing Structure Updates as a Result of the Deficit Reduction Act**
5:00	*Day One Concludes*	5:00-6:00 *Networking reception in the Exhibit Hall*

Recent Litigations and Corporate Integrity Agreements

10:45 **Lessons Learned from the Merck Settlement Agreement and the Corporate Integrity Agreement**

KEYNOTE PANEL

Hot Topics

Learn from the civil settlement that resolves claims under the False Claims Act occurring from discounts and prices that Merck offered to hospitals as incentives for purchasing certain Merck drugs. Merck offered large discounts for certain drugs in exchange for the hospital's achieving and maintaining a pre-set volume of purchases of certain Merck drugs. Merck did not report these prices to the Medicaid program. Hear more about the five-year Corporate Integrity Agreement, that the Office of Counsel for the HHS Inspector General and Merck have entered into, which builds on a compliance program to ensure that such improper conduct does not occur in the future.

Moderator:
Mitchell J. Lazris, *Partner,* **HOGAN & HARTSON**

Mary E. Riordan, Esq., *Senior Counsel, Office of Counsel to the Inspector General,* **HEALTH AND HUMAN SERVICES** (invited)
Viveca Parker, *Assistant United States Attorney,* **UNITED STATES DEPARTMENT OF JUSTICE, USDOJ** (invited)

State and Federal Enforcement

11:45 **Ensure Your Company's Compliance with Current Civil and Criminal Enforcement Activities**

Updated

This enforcement panel provides new lessons learned from recent case experiences with civil and criminal investigations. Use this information to keep you company compliant during discussion specifically addressing:

- Hear what enforcement officials examine in their assessment of a specific action, is meant to defraud?
- Areas of concern from state Attorney General perspective
- State Attorney General consumer protection enforcement actions
- Clarification of how PBM pricing issues fit into criminal law
- New DRA Vulnerabilities

Julie Brill, *Assistant Attorney General,* **STATE OF VERMONT**
Terry Glavin, *Assistant Attorneys General, Medicaid Fraud Bureau* **ILLINOIS ATTORNEY GENERAL'S OFFICE**
Jim Kole, *Assistant Attorney General, Consumer Protection Division,* **ILLINOIS ATTORNEY GENERAL'S OFFICE**

12:30 *Networking Luncheon*

1:30 **Afternoon Tracks Begin**

Following lunch, the summit divides into four afternoon tracks. You are welcome to attend any session in any track of your choice

TRACK	C **Specific State Program Initiatives and Requirements** **Chairperson:** Laurie Squartsoff, *Director of Professional Affairs* **PROFESSIONAL PROVIDER SERVICES**	D **Compliance with State and Federal Regulations** **This track is not ACPE-accredited.* **Chairperson:** John Bliss, Manager, Contract Management **GRACEWAY PHARMACEUTICALS**
1:30	**How to Operationalize the Struggle of Collecting NDCs for J-codes** NEW PANEL • State implementation of the J-code provision of the DRA • Overcome the challenges brought by errors in NDC reporting • Are State ready for NDC capture • Overcome the struggle for implementation of physician training on billing codes • Discuss ongoing drug rebate issues including J-Code processes • Technical discussion for J-code Billing from the state perspective • How to keep track of administrative requirements of each state contract (pricing requirements, obtaining eligible participate #s, obtaining formulary position information, membership changes to NMPI, TOPS, etc. **Panelist:** Sharon Greeson, *Pharmacy Program Manager,* **EDS NORTH CAROLINA MEDICAID** Betty Devaney, *Coordinator, Drug Rebate,* **STATE OF MONTANA** Jerry Dubberly, *Pharmacy Director,* **GEORGIA DEPT OF COMMUNITY HEALTH**	**Strategic Management of the Government as a Customer** As the battle for the White House continues to heat up, the pharmaceutical industry awaits the November election with apprehension. Either of the major party candidates, if elected, will work to implement varying degrees of health care reform that could directly impact the statutory Government Programs as we know them today. Couple this with the growing number of patients gaining access to pharmaceuticals through Government Programs and it becomes clear that the evolution and growth of the Government as a customer is just beginning. This session explores the growing need for pharmaceutical manufacturers to shift from an operational and administrative view to a concerted effort towards strategic management of the Government Business. Christopher Cobourn, *Government Program, Practice Lead,* **COMPLIANCE IMPLEMENTATION SERVICES** Clarissa Crain, *Senior Compliance Specialist,* **COMPLIANCE IMPLEMENTATION SERVICES**
2:15	**Current Legal Issues with NDCs and Physician Administered Drugs and Extended Rebates in Hospital Outpatient Setting** NEW • Requirement of NDC information for manufacturers to pay rebates on J code drugs. • Are hospitals exempt from physician administered drug- are they rebate able? • How to handle changing claims payment system to capture the NDCs • Hear status of the retroactive claim reimbursement for physician administered drugs William Von Oehsen, *President,* **SAFETY NET HOSPITALS FOR PHARMACEUTICAL ACCESS**	**Class of Trade at the Margin: Identifying and Operationalizing in the Gray Area** The MDRP statute and related guidance attempt to characterize many common means of distribution of pharmaceutical and biotechnology products for purposes of AMP and Best Price eligibility, but leave many questions unanswered. Now that you've pulled back the curtain and have attempted to make the gray more black and white, how do you operationalize the decision in your company's system in a manner that allows contracting flexibility and ensures government price reporting compliance. This presentation addresses the classification and MDRP treatment of undefined and non-standard distribution channels, provide practical advice for operationalizing the decisions and present a common approach against which attendees can measure their own companies' practices. Erinn Hutchinson, *Director,* **PRICEWATERHOUSECOOPERS LLP** Katherine Buckley, *Manager,* **PRICEWATERHOUSECOOPERS LLP** John Shakow, *Partner,* **KING & SPALDING LLP**
3:00	*30-Minute Afternoon Networking Break*	
3:30	**Hot Topics for States Open Round Table** NEW ROUND TABLE Join the working round table session where states and manufacturers can brainstorm to work through current issues to bounce ideas off of each other in an effort to make the rebate process easier for all and friendlier to patients. Session topics are not limited to: • Discuss billing provider number in database pay each county or state • NPU- National Provider Identity Number • Strategies for handling the new invoice format, especially for crossovers • Strategies to handle to transition to Electron Health Records and E-prescribing in terms of prices in database and State Medicaid want to get on state Medicaid. • DRA implementation of new FULs and what to use for reimbursement Vic Miller, *Senior Fellow for Intergovernmental Finance,* **FEDERAL FUNDS INFORMATION FOR STATES** Sharon Greeson, *Pharmacy Program Manager,* **EDS NORTH CAROLINA MEDICAID**	**Improve Compliance, Minimize Revenue Loss and Improves Overall Operational Efficiency** NEW Medicaid claims processing is long and labor-intensive consuming considerable resources for most life sciences manufacturers, and the risks of error are substantial—fines are increasing and the number of firms triggering fines is rising. New state programs are here and on the horizon, burying life sciences companies in a sea of claims-processing complexity and risk. Maintain compliance with federal, state and supplemental government-mandated programs, such as the guidelines and processes set forth by the Centers for Medicare & Medicaid Services (CMS). Automate the management and clerical tasks of the Medicaid Drug Rebate Law, processes invoices, calculates rebates per unit (RPU) and creates payments while providing efficiency, accuracy, reporting and auditing capability. Paul Pettengill, *Director of Strategy, Life Sciences,* **I-MANY**
4:15	**Session Continues** **Hot Topics for States Open Round Table**	**Optimizing Profitability and Maintaining Compliance with Managed Care Rebates** Managed Care Rebates: Adjudicating, Challenging, Disputing - Optimize profitability through your agreements and maintain compliance. Understand and identify eligible and in-eligible components for your government reporting. • Managed Care • Mail Order • Medicare Part D • Tricare • Medicaid Phil Coburn, *Principal,* **IMS MANAGED MARKETS SERVICES** Terri Bernacchi, RPh, MBA, IHS, **A UNIT OF IMS**
5:00	*Day One Concludes*	5:00-6:00 *Networking reception in the Exhibit Hall*

8:00 *Registration and Morning Coffee*

8:15 **Chairperson Recap of Day One**
Edward J McAdams, *Director, Contract Administration,* **DAIICHI SANKYO PHARMA**

8:30 **Detailed Update for the AMP Litigation and AMP Legislation**
- Relevant provisions of the DRA and their impact on pharmacies
- Provisions of the AMP rule that concern pharmacies
- Principal arguments asserted by pharmacies in our lawsuit
- Impact of the preliminary injunction on manufacturers and pharmacies
- Effect of CMS's new definition of "multiple source drugs" on the AMP litigation and the Medicaid program
- How long should the injunction last? Next steps and timing in the lawsuit
- New AMP legislation: The best long-term solution for CMS, manufacturers and pharmacies

Don L. Bell, II, *Senior Vice President and General Counsel,* **NATIONAL ASSOCIATION OF CHAIN DRUG STORES**

9:15 **How Private Part litigations Effect the Industry and Manufacturer Behavior**

Hot Topics

Take part in the session that examines current private party litigation and its effects on the industry, including the AWP/WAC litigation, the pharmacy AMP litigation, the First Databank litigation, and more. Learn how private party (non-qui tam) litigation helps shape manufacturers' behavior. Using specific examples, understand key takeaway lessons from each litigation, for example, the "mega-spread" concept under the AWP litigation

Constance A. Wilkinson, *Member of the Firm,* **EPSTEIN BECKER AND GREEN**
Benjamin S. Martin, *Senior Associate,* **EPSTEIN BECKER AND GREEN**

10:00 *30-Minute Morning Networking and Refreshment Break*

TRACK	A — Medicaid Rebate Operations for Manufacturers **Chairperson:** William Baxter, *Former Director,* Rebate Management, **JOHNSON & JOHNSON HEALTH CARE SYSTEMS**	B — 340B and Other Public Sector Reimbursement Programs **Chairperson:** Mary Kay Owens R.Ph C.Ph, *President* **SOUTHEASTERN CONSULTANTS**
1:30	**Best Practices and Lessons Learned for Successful Dispute Resolution** Experts come together with vast experiences on handling disputes. They share best practices make recommendations for resolving both new and long-standing disputes. More specifically, the panel addresses: • Optimizing your communication strategy with states when challenging a claim • What qualifies as a valid dispute and what does not • Defining a dispute: When is a dispute, a dispute? • Leading a positive discussion, knowing that both parties want to be accountable for their responsibilities • Verification that disputed units match • Checking with the state to see if they accept claims from 3rd parties, or if the state will provide the claims • How have corporate mergers and acquisitions have affected the dispute resolution process • Strategies for resolving old disputes • Proactively preparing proposals to the state • Ensuring proper documentation and audit trail to support the final resolution • Learn to settle long-standing disputes and comply with the 12-quarter limit on interest where states and manufacturers can turn when a dispute cannot be resolved Peggy Watson-Meinke, *Manager, Contracts & Pricing, Medicaid Drug Rebate Program,* **AMGEN** Kris Flynn, *Medicaid Analyst,* **MORTON GROVE PHARMACEUTICALS** Vince Powell, *Director of Pharmaceutical Operations,* **PROFESSIONAL PROVIDER SERVICES** *former Technical Director Medicaid Drug Rebate,* **CMS** William Baxter, *Former Director, Rebate Management,* **JOHNSON & JOHNSON HEALTH CARE SYSTEMS**	**Dual Eligibles – What Happened To Them After Medicare Part D?** NEW This case study describes prescription drug utilization and expenditures for a longitudinal sample of dual eligible beneficiaries in Illinois before and after implementation of Medicare Part D. The University of Illinois Medical Center at Chicago (UIMCC) and the UIC College of Pharmacy (UIC-COP) operates seven outpatient clinic pharmacies, including one 340B pharmacy in a federally qualified health center. The study sample is from a longitudinal database of over 2,000 pharmacy customers for whom Medicare Part D paid for all or some of their prescriptions in 2006 or 2007. Pre-Medicare Part D data are available for Part D customers for whom Illinois Medicaid paid for their prescriptions prior to 2006, also known as dual eligibles. This talk will describe overall trends in prescription drug utilization, expenditures, and patient cost sharing for dual eligibles before and after implementation of Part D. JoAnn Stubbings, RPh, MHCA, *Manager, Research and Public Policy, Ambulatory Care Pharmacy Department,* **UNIVERSITY OF ILLINOIS MEDICAL CENTER AT CHICAGO** *Clinical Assistant Professor, Department of Pharmacy Practice, Center for Pharmacoeconomic Research,* **UNIVERSITY OF ILLINOIS AT CHICAGO COLLEGE OF PHARMACY**
2:15	**Session Continues** **Best Practices and Lessons Learned for Successful Dispute Resolution**	**TRICARE Retail Pharmacy Program Status Update** This session presents an overview of the DoD pharmacy benefit and its most recent objectives. It also offers information on "voluntary rebates" for the retail pharmacy network, aimed at achieving federal pricing for the retail segment. Hear an update on the DoD Uniform Formulary as a management tool. • Best practices TRICARE treatment in GP calculations • Details surrounding DoD's second attempt at TriCare Retail Pharmacy • Country of Origin issues that affect Trade Agreements Act compliance for VA and DoD Contracts • Enactment of Sec. 03 of the National Defense Authorization Act which applies provisions of the Veterans Health Care Act included in manufacturer agreements to the TRRx program Lt. Col. Travis Watson, MS, *Deputy Director,* **DOD PHARMACY PROGRAMS**
3:00	*Conference Concludes, See You Next Year!*	

Distinguished Members of the 13th Annual Advisory Board

- William Baxter, *former Director, Medicaid Market & Rebate Management,* **JOHNSON & JOHNSON HEALTH CARE**
- Marijo Bustos, *Government Business Analyst, Contract Marketing,* **APP PHARMACEUTICALS**
- Lori Greene, Director, *OIG Compliance,* **STIEFEL LABORATORIES INC**
- Sharon H Greeson, *Pharmacy Program Manager,* **EDS NORTH CAROLINA MEDICAID**
- Pamela Vaal, *Consultant, Formerly* **ELI LILLY & COMPANY**
- Edward J McAdam, *Director, Contract Administration,* **DAIICHII SANKYO PHARMA**
- Heather Murphy, *Manager, Pharmacy Contracts and Rebates, Medicaid/CHIP Program Operations,* **TEXAS HEALTH & HUMAN SERVICES COMMISSION**
- Mary Kay Owens, *President,* **SOUTHEASTERN CONSULTANTS, INC.**
- Linda L. Schock, *Associate Director,* **CV THERAPEUTICS**
- Tom Simonson, *Manager, Drug Rebate Program,* **OKLAHOMA HEALTH CARE AUTHORITY**
- Peggy Watson-Meinke, *Manager, Contracts & Pricing, Medicaid Drug Rebate Program* **AMGEN**

10:30 **Renewed Focus on Coordination of Care in Medicaid to Achieve Cost Savings and State Budget Goals**

- Overview of service utilization and care patterns indicative of uncoordinated care
- Strategies to address uncoordinated care and cost inefficiencies in the system
- Designing and implementing provider centric care models and new reimbursement models
- How to achieve provider and payor buy-in for care coordination
- Role of technology in care coordination programs
- Budget implications for public programs at state and federal levels

Mary Kay Owens R.Ph C.Ph, *President,* **SOUTHEASTERN CONSULTANTS**

11:15 **Understanding State HCP Spend Reporting Requirements**

Numerous states have passed or are in the process of passing legislation requiring the reporting of and/or limitations on various categories of health care professional (HCP) spend. Meeting the unique requirements of each state is an enormously complicated exercise for most pharmaceutical manufacturers since the relevant data may reside with multiple departments across the organization or third-party vendors, and is not easily aggregated. Although not a government pricing issue, there are significant parallels between this and government pricing matters in terms of the challenges, resources, scope, and potential impact of non-compliance. In this session, we will explain some of the requirements, major challenges, nexus with government pricing, and how you as government practitioners may be able to add value to your organization.

Cynthia Hwang, *Pharmaceutical Advisory Services,* **KPMG**

11:45 **Current Hot Topics in Medicaid and Other Public Sector Reimbursement Programs**

Government programs are changing so rapidly that we decided to carve out time in the program to address the most current issues that will arise after this brochure prints. Please visit our website for the most current listing of the hot topics as they arise.

Alice Valder Curran, *Partner,* **HOGAN & HARTSON**
Mary Kay Owens RPh CPh, *President,* **SOUTHEASTERN CONSULTANTS**

12:30 *Networking Luncheon*

1:30 **Afternoon Tracks Begin**

Following lunch, the Summit divides into four afternoon tracks. You are welcome to attend any session in any track of your choice.

TRACK	C	D
	Specific State Program Initiatives and Requirements **Chairperson:** Laurie Squartsoff, *Director of Professional Affairs* **PROFESSIONAL PROVIDER SERVICES**	**Compliance with State and Federal Regulations** **This track is not ACPE-accredited.* **Chairperson:** John Bliss, Manager, Contract Management **GRACEWAY PHARMACEUTICALS**
1:30	**Panel Discussion** **Cost Saving Strategies for State Medicaid Professionals** This session is an in-depth look at cost saving strategies used in Medicaid programs for States. Hear case reports and updates for health care industry, including innovative ways to reduce health care costs associated with chronic conditions Laurie Squartsoff, *Director of Professional Affairs,* **PROFESSIONAL PROVIDER SERVICES** Vince Powell, *Director of Pharmaceutical Operations,* **PROFESSIONAL PROVIDER SERVICES** *former Technical Director Medicaid Drug Rebate,* **CMS**	 Please visit the www.medicaiddrugrebates.com for updated session information
2:15	**New! Hot Topics for States** **The Changing Landscape of Pharmacy Reimbursement** The panel discusses the changing landscape of pharmacy reimbursement processes. Hear the history of the methodology, the present and the changing future of pharmacy reimbursement is discussed. The panel reveals current areas of concern to the industry, what changes may be on the horizon and what might we do to improve current processes. Take advantage of this opportunity to ask your specific questions. State Implications for Using Medicaid Data to Set Reimbursement Amounts for Pharmacies • Will states use AMP-M as a reimbursement tool? • more information on pharmacy pricing policy **Panelist:** Thomas R Bizzaro, *Vice President,* **FIRST DATABANK**	**CIS Panel Discussion** Please see website for more information
3:00	*Conference Concludes, See You Next Year!*	

Do You Want to Reach the Audience at This Event?

The **13th Annual Summit on the Medicaid Drug Rebate Program** offers you an excellent opportunity to showcase your product in front of key decision-makers.

Morning and afternoon breaks are carefully designed to ensure maximum networking opportunities, and all the exhibits are strategically positioned to ensure excellent traffic. Maximize your marketing dollars by exhibiting at the Summit, or increase your exposure even further by sponsoring a cocktail reception, luncheon or breakfast.

To learn more about sponsorship opportunities, please call Business Development Manager, Sarah Scarry at (646) 895-7472 E-mail at sscarry@iirusa.com To learn more about exhibiting, please call Business Development Manager, David Borrok at (646) 895-7485; E-mail at dborrok@iirusa.com

ABOUT THE SUMMIT SPONSORS

Gold Sponsors

KPMG's multidisciplinary professionals help life sciences companies to minimize compliance risk and maximize opportunities in areas such as:

- Government Pricing including DRA, Systems/SOPs, Class of Trade/Membership, and Recalculations
- Commercial Contracting including Rebate Analysis and Wholesaler Compliance
- Compliance with State Market-Spend Reporting, Cost-Based Grants & Contracts, and CIAs
- Strategic Data Analysis and other Business Support

I-Many (NASDAQ:IMNY) delivers advanced enterprise contract management solution for managing corporate commitments. I-many comprehensive solutions have enabled more than 280 customers worldwide to manage contracts and obligations to payment and collections, allowing them to ensure transaction compliance, increase revenues and maximize ROI. With 22 of the top 25 pharmaceutical companies as customers, I-many's life science solution suites automate all aspects of commercial and government contract processes including rebate and incentives management, collections and deductions, compliance monitoring, pricing optimization, and analytics. The results are optimized contract development process and higher contract revenues.

Associate Sponsors

Compliance Implementation Services, LLC (CIS), located in Media, Pennsylvania, is a consulting firm specializing in establishing a Culture of Compliance for pharmaceutical companies. We evaluate, promote, and execute effective compliance programs by evaluating an organization's compliance policies, procedures, and systems. CIS prioritizes areas of risk and creates short-term and long-term remediation and monitoring plans. Our goal is to provide an efficient and affordable means of compliance and risk management that is scalable to companies' needs and priorities.

Epstein Becker & Green EBG has been at the forefront of health care law for more than 30 years, taking the lead in understanding, interpreting and shaping laws and regulations that affect every institution involved in the health care industry. We have the critical mass of knowledge needed to help them deal effectively with legal issues small and large – from day-to-day decisions to core business strategies. Our experience in all aspects of health care and life sciences assures legal advice and solutions that are grounded in a thorough understanding of the challenges facing health care organizations.

Hogan & Hartson with more than 1,100 lawyers practicing in 22 offices worldwide, Hogan & Hartson works seamlessly across multiple practices and offices to provide our clients with exceptional service and creative advice. Our health practice is grounded in an in-depth understanding of the industry's relationship with the U.S. federal government. Most of our health lawyers have had experience in government, industry, or both. Our clients range from start-ups to multi-national enterprises and come from every part of the health sector. Because of the breadth of our practice, we bring multiple perspectives to the analysis of policy issues, business transactions, government investigations, and regulatory counseling. We act as regulatory lawyers, strategic advisors, lobbyists, litigators, and dealmakers. More at www.hhlaw.com.

IMS Managed Markets Services provides a range of services for the life sciences industry. These specialized areas include management consulting capabilities such as managed markets strategy, contracting, pricing and planning, and assistance with rebate claims validation and optimizing contracting performance. IMS is recognized as the leader in providing services across the contracting continuum.

Price Waterhouse Coopers PricewaterhouseCoopers, a global leader in serving the pharmaceutical and life sciences industry, has extensive experience in working with companies on industry-specific strategic, operational and financial issues. Our services include assurance, tax and advisory services. Our advisory practice works with clients to address a broad range of performance and process improvement, compliance and risk management challenges in the areas of R&D, manufacturing, and sales and marketing. For more information, visit our website at www.pwc.com/pharma.

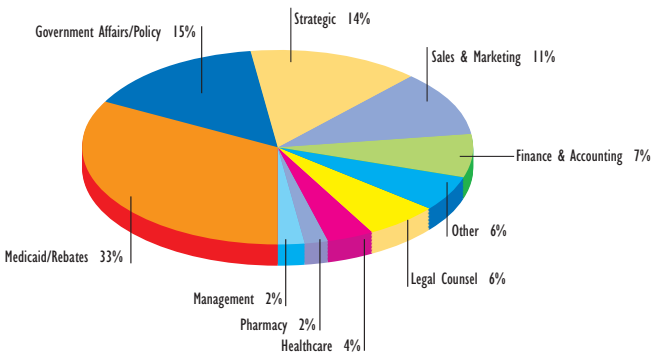
MEDIA PARTNER

The Monitor is the definitive source for the latest news on the Public Health Service 340B drug discount program and related developments in the federal drug discount arena. **The Monitor's** Washington, D.C.-based staff has the inside scoop on 340B, a program that affects over 12,000 health care providers and over 700 pharmaceutical manufacturers. From new developments in the regulatory front to the latest news from Capitol Hill, you can count on **The Monitor** as your guide to the 340B program. **The Monitor** will also track the latest developments in drug pricing litigation impacting 340B and the Medicaid drug rebate programs

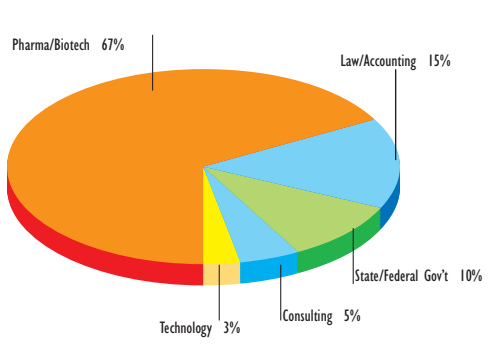
EXHIBITOR

WHO YOU CAN EXPECT TO MEET:

By Job Function:



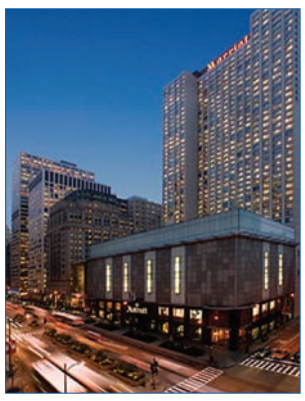
By Industry:



This Summit is also of special interest to:

- Consultants specializing in Medicaid/Health Care
- Attorneys to the Pharmaceutical Industry
- Data Analysts
- IT consultants
- Accounting Firms
- Insurance Companies and Hospitals

ABOUT THE VENUE:



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The Institute for International Research is proud to donate a portion of the Summit proceeds to help support the Jimmy V Foundation for cancer research.

Administrative Details

FIVE WAYS TO REGISTER

CALL:
(888) 670-8200 U.S. or
(941) 951-7885 Intl.

FAX:
(941) 365-2507

MAIL:
Registration form to:
IIR NY, PO Box 3685,
Boston, MA 02241-3685

E-MAIL:
Register@iirusa.com

WEB:
www.medicaiddrugrebates.com

Your Full Registration Includes:

- Choice of pre-summit symposium or workshops
- Keynote presentations
- Plenary as well as concurrent tracks
- Exhibit hall access
- Interactive panel discussions
- Networking reception
- Plated luncheons
- Networking refreshment breaks
- Private area for dispute resolution meetings

SUMMIT FEES: Including summit documentation, luncheons, refreshments and receptions, your investment for attending the **13th Annual Summit on the Medicaid Drug Rebate Program** is:

	Register By 5/30/2008	Register By 7/4/08	Register By 8/1/2008	Register By 8/29/208	Register After 8/29/08
Conference Only	$2095	$2195	$2295	$2395	$2495
Conference Plus 1-Half Day Workshop	$2295	$2395	$2495	$2595	$2695
Conference Plus 2-Half Day Workshops or 1-Full Day Symposium	$2495	$2595	$2695	$2795	$2895

The Academic rate is 30% off the registration price. Full-time Federal and State government employee rate: $295 (*Other group discounts do not apply.)

GROUP DISCOUNTS AVAILABLE: Please contact Aloycia Bellillie at (646) 895- 7410 for details. No two discounts can be combined.

Payment is due within 30 days of registering. If registering within 30 days of event, payment is due immediately. You may pay by check, VISA, MasterCard, Diner's Club, American Express or Discover. Please make all checks payable to the "Institute for International Research, Inc." and write the name of the delegate(s) and our reference number **P1358** on the face of the check. If payment has not been received prior to registration the morning of the conference a credit card hold will be required.

DATES: September 15-17, 2008
VENUE: **Chicago Marriott Downtown Magnificent Mile**
540 North Michigan Avenue,
Chicago, Illinois 60611 USA
Telephone: 1-312-836-0100*

Book Early! Hotel Will Sell Out

*This # is for general hotel information only. The hotel will not accept individual call-ins for hotel room reservations at IIR's group rate.

HOTEL ACCOMMODATIONS: A block of rooms will be held for a limited period of time at the Chicago Marriott Downtown Magnificent Mile. All hotel bookings should be made through The Global Executive's Internet booking site. Please visit www.globalexec.com/iir to make your reservation. If you do not have web access, or need additional assistance, please call The Global Executive at 800-516-4265 or 203-431-8950 or send them an email at conf@globalexec.com. The hotel will not accept individual calls for room reservations at the IIR negotiated rate.

DRESS CODE: Casual and comfortable attire is suggested. We recommend bringing a sweater, as the conference room may be cool.

CANCELLATIONS: Should you be unable to attend for any reason, please inform us IN WRITING 10 days prior to the start of the conference and a credit voucher for the full amount will be issued. If you prefer, a full refund, less a $395 non-refundable deposit will be issued. No refunds or credits will be given for cancellations received on or after 10 days prior to the conference.

Substitutions of enrolled delegates may be made at any time. Please indicate upon registration whether you are eligible for a discount. No two discounts can be combined. If for any reason, IIR decides to cancel this event, we are not responsible for covering airfare, hotel or other costs incurred by event registrants. Program content is subject to change without notice.

All speakers and topics listed are confirmed as of press time. When substitutions must be made due to speaker cancellations, IIR makes every effort to find a replacement of equal caliber to present the scheduled topic.

Press permission must be obtained prior to the event and is dependent upon speakers' approval. The press may not quote speakers or delegates unless they have obtained their approval in writing.

Any disabled individual desiring an auxiliary aid for this event should notify IIR at least 3 weeks prior to the event in writing or by faxing to (212) 661-6045.

Press permission must be obtained prior to the event and is dependent upon the speakers' approval. The press may not quote speakers or delegates unless they have obtained their approval in writing. Press passes do not include admittance to pre-Summit workshops.

COMPLAINT RESOLUTION POLICY: For more information regarding administrative policies such as complaint and refund, please contact our offices at (888) 670-8200 or (941) 951-7885.

SUMMIT DOCUMENTATION ORDER: If you are unable to attend the program, or would simply like to order additional sets of documentation for your colleagues, they are available for $395 per set, including taxes, postage and shipping in the US. The Documentation is a compilation of the speaker handouts including overheads, power point presentations, articles and charts. Please fill out the order form on the back of the brochure. The documentation is available two weeks after the Summit takes place. CREDIT CARD PAYMENTS ONLY.

13th Annual Summit on the Medicaid Drug Rebate Program & Other Public Sector Reimbursement Programs Registration Form

❑ Conference Only (P1358C)

❑ Conference Plus One Half Day Workshop

❑ B2 ❑ B3

❑ Conference Plus Two Half Days Workshops or Full Day Symposium

❑ B1 **or** ❑ B2 and B3

❑ I qualify for the State/Federal Employee rate

❑ I would like to order ___ set(s) of documentation

❑ Payment Enclosed

❑ Please charge my credit card:

❑ Visa ❑ MasterCard ❑ American Express ❑ Diners Club ❑ Discover

Card Number

Signature Exp. Date

❑ I cannot attend, but please keep me informed of future events.

EXHIBITION/SPONSORSHIPS:

Please send me more information on how to: ❑ Exhibit ❑ Sponsorship

INCORRECT MAILING INFORMATION: If you are receiving multiple mailings, have updated information or would like to be removed from our database, please contact us at 212-661-3876 ext 3211, or fax this brochure to 419-781-6036. Please keep in mind that amendments can take up to six weeks.

P1358

❑ Yes, please register the following individual(s)

❑ I prefer to receive a CD with speaker presentations at the conference

❑ I prefer to receive a documentation book with speaker presentations at the conference

1.Name

Title Dept.

2. Name

Title Dept.

3. Name

Title Dept.

Approving Manager

CompanyAddress Mail Stop

City State Zip

Telephone ( ) Fax ( )

E-Mail:

ATTENTION MAILROOM: If undeliverable to addressee, please forward this important announcement to your Director of Medicaid/Government Contracts.

❑ Yes, keep me informed about future events via fax

Signature

❑ Yes, keep me informed about future events via email

Signature

13th Annual Summit on the
Medicaid Drug Rebate Program
MDRP

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CMS OPERATIONS PANEL
DRA Implementation Advice From CMS

- Tamara Bruce, *Technical Director* **CMS DRUG REBATE OPERATIONS** (Invited)
- Diane Dunstan, *Lead RO DRP and Drug Rebate Analyst, Denver Regional Office,* **CMS** (Invited)
- Dusty Kerhart, *Senior Analyst, Drug Rebate Operations,* **CMS** (Invited)
- Dona Coffman, *Technical Director, Division of Information Analysis and Technical Assistance,* **CMS,** (Invited)

OIG and USDOJ on CIAs
Lessons Learned from the Merck Settlement Agreement and Corporate Integrity Agreements

- Mary E. Riordan, Esq. *Senior Counsel, Office of Counsel to the Inspector General,* **OIG HHS** (Invited)
- Viveca Parker *Assistant United States Attorney* **UNITED STATES DEPARTMENT OF JUSTICE, USDOJ** (Invited)

KEYNOTE ADDRESS
Innovations in Health Care: What's Next?

Tommy Thompson
Former Secretary, **HEALTH AND HUMAN SERVICES** *(2001-2005)*

STATES THAT PARTICIPATED IN 2007

Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Missouri, New York, N. Carolina, Ohio, Oklahoma, Rhode Island, Texas, Utah, Wyoming

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