Medicaid Drug Rebate Program

September 20th – September 22nd
The Palmer House, Chicago, IL

Final Agenda

Pre-Conference Day: Tuesday, September 20th, 2016

A: Full Day Symposia **Fundamentals of Government Pricing Programs** *Understanding the Fundamentals of MDRP & Other Key Government Programs & How It Relates to Different Critical Aspects of the Business*	
8:00-8:55	Registration & Morning Coffee
8:55	*Chairpersons Opening Remarks* Miree Lee, Principal, **M. Lee Consulting LLC**
9:00	**Part I** **General Overview of the Medicaid Drug Rebate Program: History, Core Elements, and Manufacturer Requirements** **Part II** **Understand How to Calculate Critical Price Types Such as AMP, URA, Best Price, Base Line AMP** This session will cover everything MDRP; Past, Present & Future and is applicable to veterans and beginners alike providing the context for current processes and challenges industry professionals are facing. Attendees will get a timeline and overview of how the Medicaid Drug Rebate program has evolved including milestone changes over the years. At the conclusion of this session, attendees will understand what the calculations are, how they are made, and answer any questions related to their completion. In addition, this session seeks to clear any confusion you might have and will walk you through the rationale behind the importance, methodologies and approaches you can use to calculate and recalculate the AMP, BP and Medicaid Unit Rebate Amount. If the AMP and/or BP confuse you, this is the session that will clear up that confusion. Questions to be addressed: • What is AMP and BP? • What are they used for? • Why are they important? • How do you calculate them and are there different methodologies? • When are recalculations necessary? Miree Lee, Principal, **M. Lee Consulting LLC**
9:45	**Understanding the Drug Delivery Industry;**

	Government Programs can be a complicated and highly visible endeavor to any pharmaceutical manufacturer. These programs work best when all components are properly "connected" in the drug delivery industry. This connection begins with a pharmaceutical product in and or entering the market. Step out from within the Pharmaceutical Manufacturing *walls* and experience how products move through the drug delivery industry and how this can prove beneficial in reducing future disputes and gaining a better understanding of your rebate liability. This session is intended to provide insight into: • Ensure compliance in the knowledge of Pharmaceutical Products in the drug delivery industry • Evaluate the different Government Programs, Medicaid & Medicare and a products (unit of measurement) and the importance of a **billing unit** • Understand the role and importance of the National Council of Prescription Drug Programs (NCPDP) and the *Billing Unit Standard.* • Recognize the role of the Pricing Compendia and their importance in Government Programs Linda L. Schock, Director, Government Programs & Price Reporting, **Jazz Pharmaceuticals, Inc.** Kay Morgan, Vice President Drug Product Data and Industry Standards, **Elsevier/Gold Standard**
10:30	*Morning Networking Break*
11:00	**MDRP Operations: A Timeline From Contracting to Claims** Learn about the various types of MDRP contracting, including how Medicaid Supplemental and SPAP contracts differ from FFS and MCO Medicaid, Medicaid Expansion, and waiver programs, as well as the expectations from states for each program. Follow a guide to the flow of MDRP Operations from bids to contracts to claims, gaining best practice advice from each segment. Participants will receive an overview on how states and consortiums conduct their Medicaid Supplemental bids, what information is required to submit bids, and how to verify the contract once a bid is successful. The AMP Final Rule is also bringing changes to MDRP Operations – learn what to expect in the next year. • Receive an overview of the various programs and requirements, learn best practices and understand how to protect your company's interests with the bids, contracts, and claims. • Learn how to investigate new program solicitations or invoices for unfamiliar programs. • Learn about the Medicaid Supplemental timelines, acronyms, bid types and calculations. • Determine how to investigate disputes in supplemental RPUs. Josephine Hawkins, Senior Contract Specialist, **AstraZeneca**
11:45	**Overview of the 340B Drug Discount Program and Pricing Calculations** This session will focus on the 340B program as it impacts hospitals. There will be an overview of the program, and discussion of current research and legislative and regulatory developments. • Benefits and obligations of the 340B program as applied to hospitals • Overview of research relating to hospitals' role in the 340B program • Discussion of potential impact of legislative and regulatory developments, such as HRSA's mega-guidance proposal Maureen Testoni, Senior Vice President, General Counsel, **340B Health**
12:30	*Networking Lunch for Summit Participants*
1:30	**Overview of the FSS Contract and Requirements for Manufacturers**

	Just because we're at the 21st annual MDRP, it doesn't mean we can forget about everything else! This is especially true because participation in the FSS for covered drugs is required if you want to participate in Medicaid. During this "Get Back to 101" session, we will begin with an overview of the Veterans Healthcare Act. We will take a ride down memory lane looking at a bit of history. Then we will dive into the nuts and bolts of being a government contractor, the similarities and differences between FSS and other government customers, and, of course, solicitations and calculations. Our tour guide has scheduled the following stops, which you won't want to miss! • Where it all began • Negotiating and administering your contract • Did we mention something about calculations? This discussion will include, among other things, a look at the differences in the various pricing calculations • Compliance considerations – how to remain a compliant government contractor Kristin Hicks, Associate, **Arnold & Porter**
2:30	**Medicare Part B and ASP Pricing Calculations** Put down the AMP Final Rule and join this discussion on Medicare Part B and the ASP calculations. We can't forget the importance of ASP in the world of government price reporting. We will discuss: • What is Medicare Part D and why do we care? • History of ASP and its importance to the industry • Calculating ASP • Proposed Changes to the Part D Payment Model Cynthia B. Bass, Associate General Counsel, **Sanofi**
3:00	*Afternoon Refreshments Break*
3:30	**Wrap Up: Key Takeaways and Critical Points on the Different Programs** Miree Lee, Principal, **M. Lee Consulting LLC**
4:15	*Close of Symposia*
4:15	*Grand Opening Reception in the MDRP Hall*

B: Full Day Symposia **Gross-To-Net Finance, Accounting & Accruals Symposia**	
8:00 -8:55	Registration & Morning Coffee
8:55	*Chairpersons Opening Remarks*
9:00	**Calculating & Forecasting** The management of gross-to-net continues to be challenging given the diverse array of line items and individual transactions that impact it. In addition, industry dynamics such as the introduction of new legislation, new channels of distribution, and more complex contract structures will continue to present ongoing operational challenges. Because of these dynamics, one of the most challenging areas for accurate gross-to-net management is commercial managed care forecasting and accruals. However, despite these challenges, there is a great opportunity to integrate gross-to-net management with Pricing & Contracting strategies for competitive advantage. • Part D Coverage Gap Liability

	• Reducing Revenue Leakage • Chargeback Reserve Estimates & Methodology Richard L. Burcham, CEO, **BPI Technologies**
9:45	**Working with an Automated System and Its Impact on GTN** As GTN continues to grow in importance, it has become a priority to establish a platform in which we can construct and manipulate our forecasts in a timely manner. With multiple moving pieces, the need for a completely integrated system has proven essential in being able to react to scenario analyses in short time frames and under the highest levels of scrutiny. Multiple vendors are now attempting to create solutions but the end-all solution is truly unique to your company's needs. The lifecycle position of your products, the markets and therapeutic classes they compete in all will play in to what your system looks like and how it operates.
10:30	*Morning Networking Break*
11:15	**Modeling Price Increases and the effects on Customer Segments** Pharmaceutical manufacturer finance managers face tremendous pressure to understand the sales activity impact on inventory levels and customer agreements, to ensure the validity and accuracy of incentive payments and to accrue for all future liabilities in a timely manner all the while monitoring the company's customer and product profitability. • Utilization of automation to improve the accuracy of Financial Accruals and GTN calculations • Gaining visibility into chargebacks, incentives and product wins / losses to fuel financial forecasts and drive demand planning • Developing models to drive customer and product profitability • Leveraging systems to increase operational accuracy and efficiency Jennifer English, Director Contracts & Pricing, **Acorda Therapeutics**
12:00	**Modeling Price Increases and the Effects on Customers by Segment** Pharmaceutical manufacturer finance managers face tremendous pressure to understand the sales activity impact on inventory levels and customer agreements, to ensure the validity and accuracy of incentive payments and to accrue for all future liabilities in a timely manner all the while monitoring the company's customer and product profitability. • Utilization of automation to improve the accuracy of Financial Accruals and GTN calculations • Gaining visibility into chargebacks, incentives and product wins / losses to fuel financial forecasts and drive demand planning • Developing models to drive customer and product profitability • Leveraging systems to increase operational accuracy and efficiency <u>Moderator</u> Marijo G. Bustos, Manager, Chargebacks, **Fresenius Kabi USA, LLC** <u>Panelists</u> Jeffrey R. Miller CPA, Director, Revenue Accounting & Contract Administration, **Impax Laboratories** David Buckley, Contract Operations Mgr, Contract Management and Operations, **GSK**
12:30	*Networking Lunch for Summit Participants*
1:30	**Benchmark GTN Processes, Systems and Methodology Best Practices** The management of Gross-to-Net continues to be challenging given the diverse array of line items and individual transactions that impact it. In addition, industry dynamics such as the

	introduction of new legislation, new channels of distribution and more complex contract structures will continue to present ongoing operational challenges. Because of these dynamics, one of the most challenging areas for accurate Gross-to-Net management is commercial managed care forecasting and accruals. Implementing a streamlined process that eliminates inefficiencies, mitigates risk and has appropriate controls is imperative. Jeffrey R. Miller CPA, Director, Revenue Accounting & Contract Administration, **Impax Laboratories**
2:15	**GTN Issues and Concerns in M&A Deal Execution** • Identifying the organizational stake-holders and what they should be able to contribute to the process • Prioritizing internal training for the GTN process including critical process drivers • Big Picture corporate strategy and overall organizational direction as a process driver
3:00	*Afternoon Refreshments Break*
3:30	**Interdepartmental & Cross-Functional Collaborating Between GP & GTN** The need to create a cross functional operating team between all the various stakeholders of strategies, contracting, operations, finance and execution. Ensuring regulatory compliance, financial completeness, pre-deal analytics, overall business impact not only to commercial business but government segments as well. Ensuring that negotiations will not put the business as risk from a compliance or financial perspective. Understanding how the actual execution of a strategy could have unintended consequences to your government reporting requirements and to the financials of the business. Understanding the implications across all various business segments, Commercial, Medicaid, VA, PHS. Key take away: • Learn the various teams that are negotiating and operationalizing contracts • Partner with your Finance Team to ensure comprehensive analysis of all downstream impacts • Understand not only the intended strategy but the way it will be executed Brian McCartney, Director Government Pricing & Reporting, **AstraZeneca** Odalys Caprisecca, Senior Director, Pricing & Government Reporting, **AstraZeneca**
4:15	*Close of Symposia*
4:15	*Grand Opening Reception in the MDRP Hall*

C: Full Day Symposia **The AMP Rule Symposia : Application, Implementation and Impact of the Final Rule**	
8:00 -8:55	Registration & Breakfast & Morning Coffee
8:55	*Chairpersons Opening Remarks* Joe Birdsall, SVP Financial Services, **Dohmen Life Science Services**
9:15 **Panel Discussion**	**Deconstructing the AMP Final Rule: A Step by Step Analysis of the Key Implications of the Final Rule** The AMP Rule is finally here and we are faced with a myriad of issues and operational complications. From line extensions to 5i drugs to the retail class of trade, manufacturers

	will need new processes and new partnerships throughout their organizations. Identify what new data is required, where to get it and what controls need to be put in place to establish a consistent process to stay compliant with the regulation. Additionally, the new Rule will require GP professionals to provide early stage input to decisions related to new drug formulations and distribution channels that can have significant downstream financial implications on Medicaid rebates. Key topics will include: • Defining the retail community pharmacy class of trade and what's included. Where is specialty pharmacy? • Identifying line extensions and the key data sources • Identifying 5i drugs and the key data sources for measuring retail community pharmacy sales • Should you include authorized generic sales in the AMP calculation • Which contracts are bundled sales arrangements and how are discounts allocated – contingent verse non-contingent <u>Moderator</u> Matt Fornataro, Senior Associate, **Arnold & Porter** <u>Panelists</u> Frank Prybeck, Director, Government Pricing & Contract Administration, **Celgene Corporation** Josh O Harra, Assistant General Counsel, **Eli Lilly** Kave Niksefat, Executive Director, **Amgen**
10:30	*Morning Networking Break*
11:00	**Identification & Alternate Rebate Formula for Line Extensions** To implement new Alternative Rebate Formula, you need not only understand how the new formula works, but also be able to identify the products to which it applies. In this session you will learn how to apply the formula as well as the key issues relating to the identification of line extensions and their related original products. Chris Schott, Counsel, **Hogan Lovells US LLP**
11:45	**5 i AMP: Eligibility, Calculations & Implications** Congress recognized that some drugs are not sold primarily through RCPs, and for those drugs, additional sales can be included in calculations. The Rule uses a two part test: • Is the drug a 5i drug? if so, • Is it generally dispensed through the RCP? Regarding what "generally" means, the proposed rule uses a 90/10 rule. This means that each month or quarter, manufacturers must determine for each 5i drug, the percentage of sales to RCPs. If > 90% of sales of a 5i drug are dispensed through non-RCP channels, then the drug can be considered "Not Generally Dispensed" and the AMP calculation must include both RCP and specific non-RCP customer transactions. A particular concern here is what to do if a 5i drug varies by month or quarter between being generally dispensed and not generally dispensed through RCPs John Shakow, Partner, **King & Spalding**
12:30	*Networking Lunch for Summit Participants*
1:30	**Bundling**

	One of the bigger implications of AMP is a re-definition of what constitutes a 'bundled sale'. This is crucial for manufacturers for the purposes of allocating the value of discounts across all the products in the bundled arrangement to determine the products' AMPs. This session will shed light on the implications of this diversion from the initial definition, and how to manage and calculate value of discounts based on precedent. Topics include: • How the definition of a bundled sale changed from the initial guidance in the DRA versus the proposed AMP rule. • The different types of bundled sales arrangements prevalent in the industry and how they can be identified. • What guidance exists to determine how to allocate bundled discounts? • The operational challenges of managing bundled sales arrangements. • What steps should be considered when developing allocation methodologies and documentation of reasonable assumptions?
2:15	**Impact of the Final Rule on COT** A manufacturer should ensure that the foundational elements of their product master and COT are in place, both for historical calculations as well as laying the foundation for the Final Rule methodology. A GP Product Master clarifies the treatment of each product in each of the Statutory Pricing Calculations, as well as the many required product attributes. Most systems don't currently capture all of the components of what we call a GP Product Master, and it is often a process that needs to be developed and maintained. A COT review ensures that the COT assignments in your Customer Master are accurate and you can ensure the appropriate treatment of customer data in your calculations. Jesse Mendelsohn, Senior Director, Global Customer Success, **Model N** Dhirendra Jena, Associate Director, **Model N**
3:00	*Afternoon Refreshments Break*
3:30	**Service Fees: Bona Fide or Constructive Price Concessions?** Proper treatment of service fees in government pricing has never been so important, or under such scrutiny by enforcers and qui tam relators. Manufacturers are required to undertake and contemporaneously document analyses of service fees paid to entities in the chain of distribution of or payment for drugs, and to make determinations about whether each fee (or part of a fee) is to be included in, or excluded from government price points. While the various qualitative assessments manufacturers must undertake can generally be achieved in-house and through discussions with counsel, determination of the Fair Market Value of the services may require more rigorous outside help. The tests for determining inclusion/exclusion of service fees, including recent regulatory/sub-regulatory changes in the rules governing this increasingly complicated process, will be addressed in this session. Additional topics will include: • The CMS/VA methodology divide • The scope of services that can be considered bona fide • Bifurcating service fees • Litigation risk • Management of FMV evaluations • Policies and procedures/documentation Kathleen Petersen, Counsel, **Hogan Lovells US LLP**

4:15	*Close of Symposia*
4:15	*Grand Opening Reception in the MDRP Hall*

D: Full Day Symposia **340B Guidance Symposia for Pharmaceutical Manufacturers: Fundamentals, Operations & Compliance**	
8:00 – 8:55	Registration & Morning Coffee
8:55	*Chairpersons Opening Remarks* **Hogan Lovells**
9:00	**Addressing Key Areas covered Within the 340B Guidance** • Extent to which patients of covered entities are eligible for 340B drugs • Hospital eligibility including criteria for hospitals' off-site facilities • Use of multiple contract pharmacies **HRSA, OPA Guidance** • Patient Definition • Contract Pharmacy • Limited Distribution Plans • CE Eligibility and Recertification Dennis Kim, Director of Government Programs**, Dohmen Life Sciences** Mike Benedict, VP, **Apexus**
9:45	**HRSA, OPA 2016 Rulemaking** The Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA) has finally begun implementing the program integrity provisions added to the 340B statute by the Affordable Care Act. These include requirements for OPA to: develop and publish "precisely defined standards and methodology for the calculation of ceiling prices"; impose manufacturer civil monetary penalties for "knowingly and intentionally" overcharging covered entities; and establish and implement an administrative dispute resolution process. The agency also is moving towards "[t]he development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers." This session will explore the potential manufacturer impact of the following agency policies: • 340B ceiling price calculation, reporting requirements, and website • Manufacturer civil monetary penalties (CMP) • Administrative dispute resolution (ADR) Kristin Viswanathan, Director, Health Policy & Research, **Biotechnology Innovation Organization (BIO)**
10:30	*Morning Networking Break*
11:00	**Manufacturer 340B Ceiling Price Reporting** As the 340B program continues to try to stretch scarce Federal resources as far as possible, its' expansion has included more Covered Entities eligible to purchase covered outpatient drugs at significantly reduced prices. With each change in legislature, it has added layers of complexity to the governance and compliance of the program for both Manufacturers and Covered Entities. This session will take a look into the history of the program, current regulations and the challenges they present for Manufacturers. The Agenda will include:

	• 340B Program Background
	• Eligible Entities and Drugs
	• Requirements of Covered Entity and Manufacturer
	• 340B Ceiling Price Calculations
	• Challenges for Manufacturers
	  o GPO Prohibition
	  o Orphan Drug Ruling
	• Impact of Inflationary Penalty of Generic Products on PHS prices
	• Impact of Mega-Rule
	• HRSA/OPA Audit results
	
	Elizabeth M. Wicyk-McGovern, Senior Analyst, Government Reporting, Price Factor Calculations, **Hospira, a Pfizer Company**

11:45	**340B and Apexus Update**
	The recent focus on 340B program compliance has prompted manufacturers to take actions to ensure their own compliance with pricing as well as the compliant practices of entities. This session will present key compliance information and current hot topics raised by covered entities and manufacturers through the Apexus Answers national call center. The 340B Prime Vendor, managed by Apexus provides critical services and resources to support compliance of both manufacturers and entities. This session will outline the role of the prime vendor and explain how manufacturers can benefit from this essential program. Topics include:
	1. An update on recent 340B hot topics:
	  a. New orphan drug contracting option available through Apexus/PVP
	  b. Medicaid duplicate discount challenges for manufacturers and current marketplace approaches to Medicaid duplicate discount prevention
	  c. Recent policies impacting 340B from CMS (Medicaid and Medicare reimbursement)
	  d. Product availability and limited distribution
	  e. Covered entity corrective action and manufacturer repayment process
	2. Examples of tools and resources available to manufacturers supporting integrity and compliance
	  a. Manufacturer refund service and support of manufacturers' compliance
	  b. Entity Self-Report of Non-compliance Tool
	  c. Educational programs supporting 340B program integrity and manufacturers' compliance
	
	Christopher Hatwig, MS, RPh, FASHP, President, **Apexus**
	Jason Atlas, RPh, MBA, Manager, 340B Compliance and Support, **Apexus**

12:30	*Networking Lunch for Summit Participants*
1:30	**Getting it Right: 340B Policy & Procedure Compliance Checklist** One of the more turbulent areas in government programs space has been the 340B program, as compliance of both manufacturers and entities has been scrutinized. This session presents key compliance information as well as actions manufacturers can take to bolster the integrity of their operations. • Learn updates on recent 340B hot topics including GPO prohibition, orphan drugs, HRSA audit corrective action plans and manufacturer repayment processes

	• Evaluate challenges to the 340B and Medicaid interface • Discover tools and resources available to manufacturers
2:15	**Insights on Medicaid Billing, Reimbursement, Duplicate Discounts, Managed Care and Fee for Service** • CMS guidance • State Medicaid Perspective / Case Study • Dispensing and Claims Adjudication • Inventory Replenishment and Split billing Software • Contract Pharmacy Jeremy Docken, Founder & General Manager, **Kalderos**
3:00	*Afternoon Refreshments Break*
3:30 Panel Discussion	**340B Hot Topics** • Is there a policy on who (state or manufacturer) is responsible for recovering 340B duplicate discounts • CMS should publish States policy and scrubbing process on CMS site similar to Medicaid Covered Outpatient Prescription Drug Reimbursement Information by State • AMP Rule and language regarding Best Price exclusion prices under the 340B program and what happens to sub-ceiling prices? <u>Moderator</u> Marcy Imada, Principal, **Deloitte** <u>Panelists</u> Kathleen Dynan Black, Director Government Strategy, **Pfizer Inc.** Jonathan Connell, Senior Counsel**, Bristol-Myers Squibb**
4:15	*Close of Symposia*
4:15	*Grand Opening Reception in the MDRP Hall*

E: Half Day Symposia **Generic Drug Manufacturers Symposia**	
8:00 – 8:55	Registration & Morning Coffee
8:55	*Chairpersons Opening Remarks* Robert La Porte, Dir Government Reporting & Compliance, **West-Ward Pharma**
9:00 Panel Discussion	**Generics Manufacturers Perspective** • What areas do you need to be looking at • What areas do not concern you • Compliance & changing landscape • CPI Penalty for Generics 2017 – smoothing and commercial contract strategy. What are you doing to prepare? • Inclusion of Territories for 2017 • COT Considerations • Implications of the Final Rule on Generic Manufacturers <u>Moderator</u> Robert La Porte, Dir Government Reporting & Compliance, **West-Ward Pharma** <u>Panelists</u>

	Paula Martins, Director, Government Pricing, **Valeant Pharmaceuticals** Paula J. Grist, Director, Government Reporting, **Pfizer** Terry Pierce, Sr. Manager, Government Reporting, **Mylan**
10:30	*Morning Networking Break*
11:00	**Consideration Checklist: Mergers & Acquisitions** As indicated by increases of mergers and acquisitions over the past few years, the pharmaceutical industry is going through a transformation and redefinition. As more pharmaceutical manufacturers embark on such activities within a changing regulatory landscape, due diligence is generally performed to ensure legal, financial and strategic considerations are taken into account, especially when it comes to matters pertaining to government pricing. Topics will include: • Where and when does the GP team need to be involved? • How to communicate with your executive team on your requirements? • What is the final checklist you need for success? Sanjida F. Chowdhury, Senior Director, Financial Government Compliance, **Fresenius Kabi USA**
11:30 Panel Discussion	**Strategies for Managing the Portfolio and Doing Calculations when Dealing with Generics and Authorized Generics at the Same Company** Generics don't go out and negotiate with formularies. If they have a hundred NDCs, they have to pull out any branded generics and treat them differently. This becomes very complicated for companies who are new to rebate programs. Now Generic manufacturers have to play both sides of the coin — branded and generic. But unlike branded companies, they don't have the same resources and are struggling to learn BP and its implications on Medicaid RPU calculations. FSS/FCP for a 42-2A drugs — branded, the Medicare Coverage Gap Discount program (Donut Hole), and Prescription Drug Fee participation. Session topics include: • Identifying key issues from policy and operational perspectives when entering into an authorized generic arrangement • Nuances of AGs with pricing calculations for the primary and secondary manufacturer • Methodology considerations when calculating government price types • Other types of quasi-AG arrangements (e.g. NDA holder is marketing the original brand and secondary product) <u>Moderator</u> Robert La Porte, Dir Government Reporting & Compliance, **West-Ward Pharma** <u>Panelists</u> Andrea Johnson, V.P Sales Operations, **Alvogen Inc.** Terry Pierce, Sr. Manager, Government Reporting, **Mylan**
12:30	*Close of Symposia*

F: Half Day Symposia **Pharmaceutical VA Contracting and Compliance Summit**	
1:25	*Chairpersons Opening Remarks* Allison Pugsley, Counsel, **Hogan Lovells US LLP**
1:30	**The Ins and Outs of a VA Audit: Comprehensive Overview of the Review Process**

	This session will explain the key players at VA that are involved in establishing the FCPs and each of their respective roles. Briefly explain the annual process of establishing FCPs and also the process for correcting and restating the NFAMPS and FCPs. Special focus will be on the OIG role in the restatement process. Mark Myers, Director, Healthcare Resources Division, Office of Contract Review, Office of Inspector General, **US Department of Veterans Affairs**
2:15	**Understand and Navigate the Challenges of the FSS Small Business Contracting Plan** Provide a better understanding of how to complete the FSS Small Business Subcontracting Plan. How departments within your organization fulfill these goals and how to better work with them to compile the information needed. This session will also address specifics surrounding the goals and the review process, internal and external. • Understanding the FSS Small Business Subcontracting Plan, its components, the goals and the different small business categories that may or may not affect your business. • Unmet goals – addressing or justifying when your proposed goals are less than your actual percentage achievement goals or when you are proposing goals that are lower than the VA suggested goals • Review process – Ensuring that your plan answers all necessary questions according to the way your organization does business. Also provide a picture of the VA Review Process Stephen E. Ruscus, Partner, **Morgan Lewis**
3:00	*Afternoon Refreshments Break*
3:30 Panel Discussion	**Prepare for Contract Renegotiations** This session will provide you with a broad perspective on the Overview of contract negotiations Some companies are currently in the five-year contract negotiation period, and many companies are approaching this cycle. The contract negotiation could be a complex and time consuming process that involves many departments in the company and additional internal/external resources. For many companies, pre-award audit is an important part of the process. The result of the negotiation will set base prices and tracking ratios for the FSS contract for next five years and have a big impact on the company's sales and bottom line. In addition to the 5 year negotiation of all products, every time a new product is added, a mini contract negotiation also takes place. We will look into the process, challenges and strategies of the contract negotiation. Panelist will provide different perspectives from brand and generic manufacturers. You will walk away with insights on: • Overview of contract negotiations with VA • Key points to consider when negotiating • Challenges during the negotiation with VA • Communications with VA and internal resources • What do you need to know about your product and strategy • How to determine fair and reasonable price • The importance and impact of the tracking customer <u>Moderator</u> Allison Pugsley, Counsel, **Hogan Lovells US LLP** <u>Panelists</u>

	Paula Martins, Director, Government Pricing, **Valeant Pharmaceuticals** Cathy Zhang, Associate Director, Government Pricing and Medicaid, Corporate Ethics and Compliance, Finance, **Eisai Inc.**
4:15	*Close of Symposia*
4:15	*Grand Opening Reception in the MDRP Hall*

G: Half Day Town Hall **Best Practice & Policy Ideas: An open dialogue between Manufacturers and States** Symposia participants have the option of submitting additional questions via the MDRP website leading up to the summit. In addition, Town Hall discussions are not limited to discussions and questions submitted prior to the summit, the aim of this town hall is to facilitate open conversation acting as a platform for improving collaboration between manufacturers and state rebate vendors minimizing process and operational frustrations and best practice when dealing with state drug rebate policies	
8:00-8:50	Registration & Morning Coffee
8:55	*Chairpersons Opening Remarks* Rich Holsapple, Pharmacy Services Manager, **HP Enterprise Services (Oregon)**
9:00	**<u>Questions to be Discussed</u>** • What kind of validation do you do on your CLD and how do you decide when to dispute? What information do you look for from State's? • What do you see from individual states that you would consider to be a "best practice" that other states should consider adopting? • How do you process State invoices? • What determines which disputes are addressed first? Do the people States work with have the authority to make resolution decisions? • What are the rules for putting a termination on a drug? Why does it get terminated retroactively?
10:30	*Morning Networking Break*
	• What is your process for reporting term dates and URA information to CMS? • What are your termination date procedures when drug has been recalled from the market? • What are your thoughts on disputing quarters or getting retro invoices for quarters > 2 years old? • How do manufacturers decide that a drug meets the definition on a "covered out-patient drug" and gets reported on the DDR? Specifically OTC products? • How is the unit of measure determined? Why don't they match what CMS has for a UOM? • What is your biggest frustration with State drug rebate policies? <u>Faculty Members</u> Kathleen Dynan Black, Director Government Strategy, **Pfizer Inc** Brooke Goobic, Director, Pricing & Contract Administration, **Vertex Pharmaceuticals** Dara Horcasitas, Pharmacy Support & Drug Rebate Supervisor, UNO Medicaid Support Contract, **La Department of Health & Hospitals** Mandy Hunter, Pharmacy Services Manager, **HP Enterprise Services (Delaware)**

	Cemeria M. Ehis, Pharmacy Rebate Analyst, **Alabama** John Curless, Department of Health, Division of Medicaid and Health Financing, **Bureau of Coverage and Reimbursement Policy (Utah)** Cindy LeClair, Pharmacy Services Manager, **HP Enterprise Services (Kansas)**
12:30	*Close of Symposia*

1:30 – 4:15	**Dispute Resolution Meetings** **States Participating** 1. Dara Horcasitas, Pharmacy Support & Drug Rebate Supervisor, UNO Medicaid Support Contract, La Department of Health & Hospitals **(Louisiana)** 2. Mandy Hunter, Pharmacy Services Manager, HP Enterprise Services **(Delaware)** 3. Cemeria M. Ehis, Pharmacy Rebate Analyst, **Alabama** **4.** John Curless, Department of Health, Division of Medicaid and Health Financing, Bureau of Coverage and Reimbursement Policy **(Utah)** **5.** Cindy LeClair, Pharmacy Services Manager, HP Enterprise Services **(Kansas)** 6. Beth Slamowitz, PharmD, Pharmacy Services Manager, NV MMIS **(Nevada)** **7.** Participant TBD, Molina Healthcare (**West Virginia)** **8.** Participant TBD, (**Florida)** 9. Rich Holsapple, Pharmacy Services Manager, HP Enterprise Services **(Oregon)** 10. Patricia Bartolotta, Drug Rebate Coordinator, HP Enterprise Services **(Connecticut)** 11. Participant TBD, Catamaran **(Virginia)** 12. Participant TBD, Catamaran (**Nevada)** 13. Participant TBD, Catamaran **(Indiana)** 14. Maury Anderson, Director, Rebate Operations, Felicia DiPaolo, Supervisor, Rebate Operations, Magellan (**Alaska, Arizona, Arkansas, Idaho, Kentucky, Michigan, New Hampshire, North Carolina, South Carolina, and Tennessee**)
4:15	**Grand Opening Reception in the MDRP Hall**

<u>Main Conference Day One: Wednesday, September 21st, 2016</u>

7:15	*Registration and Morning Coffee*
8:15	*Chairpersons Opening Remarks* Edward McAdam, Vice President, Sales Administration, Pricing and Contract Solutions, **Fresenius Medical Care North America**
8:30	**Opening Keynote Address** **A Conversation with Scott Gottlieb: Health Care Policy Winds in an Election Year: Payment Reform, Data Sharing, and Patient Access**

	Scott Gottlieb, Resident Fellow, **American Enterprise Institute**, Former, Deputy Commissioner for Medical and Scientific Affairs, **Food and Drug Administration (FDA)**, Former, Senior Adviser, **Centers for Medicare and Medicaid Services (CMS)** <u>About Dr. Gottlieb</u> Scott Gottlieb is a physician and Resident Fellow at the American Enterprise Institute. A leading expert in health policy, Dr. Gottlieb's work focuses on providing insights into the economic and technological forces driving the transformation of healthcare. From 2005-2007, Dr. Gottlieb served as FDA Deputy Commissioner for Medical and Scientific Affairs and before that, from 2003-2004, as a senior advisor to the FDA Commissioner and as the FDA's Director of Medical Policy Development. He left FDA in the spring of 2004 to work on implementation of the new Medicare Drug Benefit as a Senior Adviser to the Administrator of the Centers for Medicare and Medicaid Services (CMS). Dr. Gottlieb's articles appear regularly in leading publications, including The Wall Street Journal, New York Times, and USA Today.
9:15	CMS UPDATE **Update on the Final Regulation Implementation** John Coster, Director, Division of Pharmacy, **CMS**
10:15	**HRSA 340B Update** The recent focus on 340B Program Compliance has prompted manufacturers to take actions to ensure their own compliance with pricing as well as the compliant practices of entities. This session will present key compliance information (updates regarding HRSA clarifications to policy, audit findings of entities), as well as actions manufacturers can take to bolster the integrity of their operations. CDR Krista M. Pedley, Director, Office of Pharmacy Affairs, **Health Resources and Services Administration (HRSA)** Michelle Herzog, Deputy Director, Office of Pharmacy Affairs**, Health Resources and Services Administration (HRSA)**
11:00	*Morning Networking & Exhibit Break*
11:45	**The AMP Final Rule: Operationalizing for MDRP** Knowing the policy and operational updates from the regulatory bodies like CMS and OPA is only the first step in the operations process. This session discusses how to put the government updates into practice at your company and details those hottest topics in the industry and how you need to prepare for them Alice Valder Curran, Regional Managing Partner, **Hogan Lovells US LLP**
12:30	**The Evolution of Payer Power 2006-2015** • Part D, Exclusionary Formularies and the New Mental Model of Access • Pharmacy Deductibles, Patient Savings Programs and the Manufacturers Burden • The Impact on U.S. Gross to Net for Major Manufacturers • Scenarios for Pricing and Contracting 2016-2025 or "Buckle your seatbelts, it is about to get bumpy" Mason Tenaglia, Vice President, Payer & Managed Care Insights**, IMS Health**
1:00	**GP Insights** Chris Coburn, Managing Director, **Huron Consulting**

1:30	*Seated Networking Lunch & Announcement of the MDRP Lifetime Achievement Award Winner*

Concurrent Sessions Begin – Choose one track or move freely between sessions of your choice

Track One: All Things Government Programs – Price Calculation, Chargebacks, Reimbursement & Contracting Strategy	
2:30	**Spillover Effects Between Government Pricing, Commercial Business & Contracting Strategies** • Discuss healthcare reforms impact on contracting & emerging contracting practices • Evaluate the impact of government pricing changes on commercial accounts • Reevaluate and restructure rebate and discount agreements Michael Kurland, VP Market Access, **Dohmen Life Sciences**
3:15	*Afternoon Refreshments Break*
3:45	**MDRP Expansion to Puerto Rico in Crisis: The Manufacturer Perspective** John Shakow, Partner, **King & Spalding**
4:30	**Retail Community Pharmacies: Identification And Impact Of The Final Rule** Under the final AMP rule, manufacturers face challenges identifying sales of drugs distributed to Retail Community Pharmacies (RCPs) for inclusion in AMP calculations. Pharmacies face challenges with dramatically altered reimbursement for brands, generics and dispensing fees. This session will explore how the final rule is expected to impact sales and pharmacies' relationships with manufacturers, wholesalers, payors and others. • Exclusion of sales to specialty, home health and home infusion pharmacies • Prompt pay discounts for chain drug warehouses • Assessing "nationwide availability" of drugs under the AMP rule • Inclusion of sales in US territories • Impact of move to cost-based reimbursement • Pharmacy AMP litigation Don Bell, Senior Vice President & General Counsel**, National Association of Chain Drug Stores (NACDS)**
5:15	*Summit Concludes*
5:15	*MDRP Main Day One Cocktail Reception*

Track Two: Regulatory Impact of Changes on Legal & Compliance	
2:30	**Ensure Compliance with Government Program Mandates and Develop Strategies to Streamline Pricing and Reporting** • Discuss strategies to calculate best price and ensure prompt and accurate reporting • Update calculations based on the AMP Final Rule • Leverage an integrated approach for reporting requirements • Provide proof of compliance with detailed audit trails
3:15	*Afternoon Refreshments Break*
3:45	**Top Price Reporting Related Enforcement Risks in an Era of Regulatory Change and Pricing Scrutiny**

	This session will discuss current enforcement trends, cases, and compliance issues and their relationship to regulatory changes and the increasing focus on the price of pharmaceutical products. Topics covered will include: • Recent enforcement cases • Congressional oversight on pricing and the relationship to price reporting issues • Price reporting risks under value-based contracting • The impact on enforcement trends of the Final AMP Rule • The potential for individual liability of certifiers, senior management, and others under DoJ's Yates Memorandum William A. Sarraille, Partner, **Sidley Austin**
4:30 Panel Discussion	**Current Legal Trends Affecting Pharmaceutical Manufacturers** After the success over the last couple of year's inaugural ground-breaking sessions, in-house lawyers from varied pharmaceutical manufacturers come together once again to discuss the trends in the rebate industry that are giving them the biggest headaches, and how they are dealing with the fallout from recent activity in the statutory and regulatory regime. This session will: • Discuss issues and challenges arising from CMS's Final Rule and other government agency updates • Identify areas of inter-departmental collaboration and where compliance issues arise <u>Moderator</u> Kave Niksefat, Executive Director, **Amgen** <u>Panelists</u> Josh O Harra, Assistant General Counsel, **Eli Lilly** Jonathan Connell, Senior Counsel**, Bristol-Myers Squibb** Christopher Jackson, Senior Director, Pricing Integrity**, The Medicines Company**
5:15	*Summit Concludes*
5:15	*MDRP Main Day One Cocktail Reception*

Track Three: Data Systems, Tools and Business Analytics	
2:30	**Turning a Regulation requirement into a Strategic Opportunity** Holly Schmidt, Senior Manager, **Deloitte** Cortnaye Swan, Senior Manager, **Deloitte**
3:15	*Afternoon Refreshments Break*
3:45	**Working with Data: Analyzing Different Data Sets** • How do you use different data sets to form a cohesive outcome and mine different data sets together? Lynn Buhl, **KPMG** William Lit, **KPMG**
4:30	**Optimizing GP Data and Calculations for Advanced Analyzation**

	Katherine Buckley, Principal, Pharmaceutical and Life Sciences Advisory, **PwC** Erinn Hutchinson, PwC, Principal, Pharmaceutical and Life Sciences Advisory, **PwC**
5:15	*Summit Concludes*
5:15	*MDRP Main Day One Cocktail Reception*

Track Four: State Policy Changes & Updates **Understand and comply with state Processes, Operations and Requirements** Rich Holsapple, Pharmacy Services Manager, **HP Enterprise Services (Oregon)**	
2:30 Panel Discussion	**MCO Medicaid – Proposed Invoicing Solution based on Date Dispensed - shared across the industry** Moderator Lynn Lewis, **IMS** Panelists Lisa Norton, Associate Consultant, Managed Healthcare Services, **Lilly USA** Michael Fahringer, Associate Manager, Government Contracts & Compliance, **Novo Nordisk** Cindy LeClair, **Kansas – HP** Maury Anderson, **Magellan** Kelly Geissler, Sr Analyst Govt Rebate Ops, **Johnson & Johnson** Maureen Slay PMP, Manager State Government and Rebates, Managed Markets and Government Affairs, **GSK** Lynn Lewis, Manager, Medicaid Rebates, **Sunovion Pharmaceuticals**
3:15	*Afternoon Refreshments Break*
3:45	**340B Guidance Implications: Focusing on the Impact of 340B Price Recalculations and Refunds due to Mega-Guidance** Marcy Imada, Principal, **Deloitte & Touche LLP** Christopher Hatwig, MS, RPh, FASHP, President, **Apexus**

4:30	**340B Guidance Implications** 340B providers, State Medicaid programs, and drug manufacturers are awaiting guidance from CMS on proposed 340B program changes made by HRSA in reaction to ACA rules and the emergence of Medicaid MCO programs. Medicaid's use of MCOs has injected private health plans into a once-public domain, however, those plans are still funded by public dollars and CMS has enforced the requirement that States invoice MCO utilization for Federal drug rebate. Because rebate is mandated to be collected on Medicaid MCO, States see Medicaid FFS and MCO as the same rebate eligible universe. 340B covered entities, however, want to treat Medicaid MCO differently than their Medicaid FFS population. Conflicting guidance and changes to the HRSA exclusion file are creating challenges for States trying to collect Federal rebate dollars. This session will focus on • CMS requirements from rule • Potential weaknesses we might continue to see (like potentially not addressing Orphan Designations, which probably neither states nor manufacturers want to work • around) • Why states should or should not encourage more 340B utilization • How 340B is treated with MCO claims, as more states move more FFS populations into MCOs
5:15	*Summit Concludes*
5:15	*MDRP Main Day One Cocktail Reception*

Track Five:	
2:30	Chris Coburn, Managing Director, **Huron Consulting**
3:15	*Afternoon Refreshments Break*
3:45	
4:30	

5:15	*Summit Concludes*
5:15	*MDRP Main Day One Cocktail Reception*

Main Conference Day Two: Thursday, September 22nd, 2016

7:00	Morning Networking Breakfast Discussion on "***Generations in the Workplace"*** sponsored by E&Y
8:15	*Chairpersons* Recap of Day One Edward McAdam, Vice President, Sales Administration, Pricing and Contract Solutions, **Fresenius Medical Care North America**
8:30	**Keynote Address** **Medicaid Reform To Eliminate Second Class Health Care for the Poor** Instead of a pathway to excellent health care for poor Americans, Medicaid expansion under the Affordable Care Act continued their second-class health care status, at a cost rising to $890 billion in 2024. My plan transforms Medicaid into a bridge program geared toward enrolling beneficiaries into affordable private insurance with the same access to doctors, specialists, and treatments as the general population. New Medicaid would include a private, limited-mandate insurance option. Current federal contributions would also seed-fund HSAs, creating assets and incentivizing healthy lifestyles to protect those assets. Federal funding would be contingent on meeting thresholds for enrollment into private coverage and HSAs. Scott W. Atlas, MD, David and Joan Traitel Senior Fellow, **Hoover Institution, Stanford University** <u>About Dr. Atlas</u> At Hoover, Dr. Atlas investigates the impact of government and the private sector on access, quality, pricing, and innovation in health care and is a frequent policy advisor to government and industry leaders in these areas. During the 2008, 2012, and 2016 presidential campaigns, he was a Senior Advisor for health care to candidates for President of the United States. His most recent book is entitled *Restoring Quality Health Care: A Six-Point Plan for Comprehensive Reform at Lower Cost.* Some of Dr. Atlas's previous books include *In Excellent Health: Setting the Record Straight on America's Health Care System* , *Reforming America's Health Care System*, and *Power to the Patient: Selected Health Care Issues and Policy Solutions.*
9:15	**Fireside Chat: External Counsel** <u>Moderator</u> Rick Zimmerer, Partner, **KPMG** <u>Panelists</u> Alice Valder Curran, Regional Managing Partner, **Hogan Lovells US LLP** John Shakow, Partner, **King & Spalding** William Sarraille, Partner, **Sidley Austin** Jeffrey Handwerker, Partner, **Arnold & Porter LLP**
10:15	**Future of Drug Pricing** Constance Wilkinson, **Epstein Becker Green**
10:45	**OIG Work Updates**

	• Recently completed OIG work on prescription drugs • Ongoing OIG work • OIG's strategic framework for future work on prescription drugs David Tawes, Regional Inspector General, **Department of Health & Human Services**
11:00 Panel Discussion	**Current Criminal and Civil Enforcement Activities to Improve Corporate Compliance** • The Wyeth bundling case and the importance of having and adhering to a compliance policy • The potential effect of payments to co-pay charities on price reporting obligations <u>Moderator</u> Josh O Harra, Assistant General Counsel, **Eli Lilly** <u>Panelists</u> Gregg Shapiro, Assistant United States Attorney, **District of Massachusetts**
11:30	*Morning Networking & Exhibit Break*
	Industry Trends to look forward to in 2016 & Beyond
12:00	**Manufacturer Release** Stephanie Trunk, Partner, **Arent Fox LLP**
12:30 Panel Discussion	**Alternative Pricing Arrangements and how this is Affecting Manufacturers** Alternative pricing arrangements are receiving attention from policymakers, payors, providers, manufacturers, and the public. However, while the use of these arrangements for pharmaceuticals is appealing in theory, it is hard in practice. Indeed, these models are still nascent and, at least at this point, remain relatively small-scale in order to allow the participants to work through the sizable operational, fiscal, legal, and other challenges with their implementation before taking on greater degrees of risk. This session will explore the operational, regulatory, and other considerations associated with the development and adoption of the following categories of alternative pricing arrangements: • Outcomes-based pricing • Indications-based pricing • Capped pricing • Try-before-you-buy <u>Moderator</u> Kristin Viswanathan, Director, Health Policy & Research, **Biotechnology Innovation Organization (BIO)** <u>Panelists</u> Frank Prybeck, Director, Government Pricing & Contract Administration, **Celgene Corporation** Chris Coburn, Managing Director, **Huron Consulting**
1:15	**Bringing It All Together: MDRP 2016 Summary & Critical Takeaways** John Shakow, Partner, **King & Spalding**
1:45	*Close of Conference: See you Next Year!*