

MEDICAID REBATE SUMMIT

A strategic-level, interactive forum guided by conference industry veterans and an advisory board, with representation from Mylan Pharmaceuticals Inc., Eli Lilly & Co., Wockhardt USA and Daiichi Sankyo, Inc.

FEBRUARY 14 - 15, 2013

PARK HYATT WASHINGTON, WASHINGTON, DC

Featured Medicaid Rebate Expert



Alice Valder Curran
Partner
Hogan Lovells

Co-Chair:



Jim Abrams, MBA
Director, Government
Pricing & Reporting
Mylan Pharmaceuticals

Co-Chair:



LaDonna Steiner
Associate General Counsel
Purdue Pharma

HIGHLIGHTS

MANAGED MARKETS POV ON AFFORDABLE CARE ACT

Derek Asay
Eli Lilly & Co.

George Bilyk
Janssen

Kent Rogers, MBA
Acorda Therapeutics

Matt Sheffield
Boehringer Ingelheim
Pharmaceuticals, Inc.

THE MANUFACTURERS POV ON THE ANTICIPATION OF THE FINAL RULE

Jim Abrams, MBA
Mylan Pharmaceuticals

Heather Dixon
Eli Lilly & Co.

Mike Hepburn
Janssen

Christopher Jackson
Bayer HealthCare LLC

Lisa McNair
Reckitt Benckiser

340B REGULATORY & OPERATIONAL CHANGES

Sharon Greeson, RPh
HP Enterprises

Christopher Hatwig, MS, RPh, FASHP
APEXUS/ 340B Prime Vendor Program

Lori Martin
Eli Lilly & Co.

CDR Krista Pedley, PharmD
HRSA Office of Pharmacy Affairs

Joann S. Prushinski
Genentech

MEDICARE PART B & D/THE DONUT HOLE

Jesse Mensah, Sr
Celgene

Lisa McNair
Reckitt Benckiser

THE FUTURE OF GOVERNMENT PRICING AND ITS ROLE IN REIMBURSEMENT

Christopher Jackson
Bayer HealthCare LLC

CORPORATE COMPLIANCE

Thomas Corcoran / Tarra DeShields
District of Maryland

Viveca Parker
Eastern District of Pennsylvania

Susan Winkler
District of Massachusetts

HEALTHCARE & GOVERNMENT ASSOCIATION INSIGHTS from:



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OVERVIEW

The **Medicaid Rebate Summit (MRS)** is a strategic-level, interactive forum guided by conference industry veterans and an advisory board, with representation from Mylan Pharmaceuticals Inc., Eli Lilly & Co., Wockhardt USA, Daiichi Sankyo and Fresenius-Kabi USA, to address solutions for:

- The interpretation of the Final Rule as best we know it
- The larger implications of health care reform and its financial and operational impact on the expansion of the Medicaid Drug Rebates program
- A resolution for disputes and foster relationships between drug manufacturers and state agencies in order to better serve the Medicaid population

In collaboration with a group of pharmaceutical and biotech manufacturers, The Conference Forum has developed the summit to provide the latest insight on Medicaid Drug Rebates.

Pre-Conference Workshop

This ABCs Bootcamp workshop on **Wednesday, February 13** is designed for professionals either new to the Medicaid Rebate space or for those looking for a refresher course on the basics. After attending the workshop, delegates will feel more comfortable and understand what the requirements are to participate in the Medicaid Drug Rebate Program. At the conclusion of this workshop, attendees will understand how Medicaid Drug Rebates affect and are driven by a manufacturer's commercial business and what to keep in mind.

Day One

On **Thursday, February 14**, the summit opens with **Alice Valder Curran** on the anticipation of the **Final Rule** where she breaks down best practices and leads an **extensive Q&A** with the audience. The day continues with an **Enforcement panel** with US Attorney Offices, followed by leading **Health Care Association** voices on working through the challenges of Health Care Reform and the expansion on MDRP.

Also featured on February 14 is a **POV from Managed Markets** including Eli Lilly, Pfizer, Acorda, Johnson & Johnson and Express Scripts, as well as an hour dedicated to one-on-one time with **MDRP consultants** to work through your challenges. The day concludes with **Track Choices** on AMP Calculations, Software Requirements, Regulatory and Compliance, 340B and Medicare Part B&D.

Day Two

On **Friday, February 15**, **CMS** is invited to work with our attendees on bridging gaps between manufacturers and CMS. Back-to-back POV Fireside Chats follow with **Healthcare Foundations and Manufacturers** where they address:

- How to anticipate for 51 solutions for Medicaid Expansion?
- What is happening with State Exchanges and how will they be rolled out?
- What will be the predominant model?
- What is happening on the state level?
- Best practices and implementation of the anticipated final rule

February 15 continues with strategic and operational preparation for the **Financial Impact of MCO Expansion** and Health Care Exchanges, followed by **State representative** voices and a concluding session on the **Future of Government Pricing and its Role in Reimbursement**.

Networking, Meeting Tool & Post-Conference Webinar

Breakfast, luncheons, breaks, a reception and round-table sessions are included in the event to allow for plenty of networking. As a delegate you will have access to our **meeting planning tool** to set up meetings **in advance of the summit** with fellow attendees. There will also be a separate room dedicated to semi-private meetings to support the networking of ideas and solutions. The summit also includes a **post-conference webinar on advancements in the Final Rule**.

Take advantage of the early-bird pricing, group discounts and special pricing for non-profits, government employees and small biotechs. Please contact us at service@theconferenceforum.org for any questions.

We look forward to seeing you on February 13 in Washington, DC.

CONFERENCE LEADERSHIP
Jim Abrams, MBA

Director, Government Pricing & Reporting
Mylan Pharmaceuticals, Inc.

Steven Benz

Associate General Counsel, Government Affairs
Eli Lilly & Co.

Marijo Bustos

Supervisor, Chargebacks
Fresenius-Kabi USA

Alice Valder Curran

Partner
Hogan Lovells

Heather Dixon

Director, Government Price Reporting
Eli Lilly

Paula Grist

Senior Director, Government Programs and Pricing
 Compliance
Wockhardt USA

Ed McAdam

Senior Director, Contracting Pricing and Analytics
Daiichi Sankyo, Inc.

LaDonna Steiner

Associate General Counsel
Purdue Pharma

SPEAKING FACULTY
Jim Abrams, MBA

Director, Government Pricing and Reporting
Mylan Pharmaceuticals

Marci Anderson

Senior Auditor
**VA Office of Inspector General, Office of Contract
 Review**

Derek Asay

Senior Director, Government Strategy, Federal Accounts
 Quality Managed Healthcare Services
Eli Lilly

George Bilyk

Health Care Policy Director
Janssen

JoAnn Bute

Senior Manager, Government Pricing and Compliance
Amneal Pharmaceuticals

Kevin Cast

Vice President, Strategy and Contracting
Express Scripts

Chris Cobourn

Senior Vice President, Commercial Compliance
CIS

Thomas Corcoran

Assistant US Attorney, Civil Division
District of Maryland

John Coster, PhD, RPh

Senior Vice President, Government Affairs
National Community Pharmacists Association

Alice Valder Curran

Partner
Hogan Lovells

Tarra DeShields

Assistant U.S. Attorney, Civil Division
District of Maryland

Heather Dixon

Director, Government Price Reporting
Eli Lilly

Audrey Fletcher

Director of Government Programs
CIS

Sharon Greeson, RPh

NCXIX Pharmacy Director, State & Local Health & Human
 Services
HP

Edmund Haislmaier

Senior Policy Fellow, Health Policy Studies
Heritage Foundation

Christopher A. Hatwig, MS, RPh, FASHP

President
APEXUS/ 340B Prime Vendor Program

Mike Hepburn

Senior Director, Government Contracts
Janssen R&D, LLC

Rich Holsapple, RPh

Pharmacy Services Manager, Oregon MMIS
HP Enterprise Services

Christopher Jackson

Counsel II
Bayer HealthCare LLC

Ann Kaplan

Vice President & Deputy General Counsel
PhRMA

Julie Khani

Vice President of Public Policy
National Association of Chain Drug Stores

Mitch Lazris

Partner

Hogan Lovells

Lori Martin

Manager, Contract Administration

Eli Lilly

Paula Martins

Director, Government Contracts

Daiichi Sankyo, Inc.

Jesse Mensah

Senior Manager, US Pricing Compliance

Celgene

Ed McAdam

Senior Director of Contracting, Pricing and Analytics

Daiichi Sankyo, Inc.

Lisa McNair

Senior Government Pricing & Contracts Analyst

Reckitt Benckiser

Jennifer Norton

*Senior Director, Pricing & Contract Administration -
Managed Markets*

Vertex Pharmaceuticals, Inc.

Brian Osberg

Program Director, Healthcare Division

National Governors Association

Viveca Parker

Assistant US Attorney, Civil Division United States

Eastern District of PA

CDR Krista Pedley, PharmD

Director

HRSA Office of Pharmacy Affairs

Erica Petersohn

Director of Government Programs

CIS

Bill Phillips

Director of Government Programs

CIS

Joann S. Prushinski

340B Account Management Team

Genentech, Inc.

Kent Rogers, MBA

Vice President of Managed Markets

Acorda Therapeutics

Matt Sheffield

Executive Director, National Government Affairs

Boehringer Ingelheim Pharmaceuticals, Inc.

LaDonna Steiner

Associate General Counsel

Purdue Pharma

Laurel Todd, MBA

Managing Director of Reimbursement & Health Policy

BIO

Aaron Vandervelde

Principal, Health Analytics

Berkeley Research Group, LLC

**PRE-CONFERENCE WORKSHOP -
WEDNESDAY, FEBRUARY 13, 2013**

This ABCs Bootcamp workshop is designed for professionals either new to the Medicaid Rebate space or for those looking for a refresher course on the basics. After attending the workshop, delegates will feel more comfortable and understand what the requirements are to participate in the Medicaid Drug Rebate Program. At the conclusion of this workshop, attendees will understand how Medicaid Drug Rebates affect and are driven by a manufacturer's commercial business and what to keep in mind. Attendees will understand what it means to participate in the MDRP as a manufacturer.

Part A:

- An introduction to the MDRP program
- Understanding the language/acronyms
- The agencies and calculations involved

Part B:

- The building blocks on how to work in the government space, reporting, processes, and gray areas
- Dealing with your product lines to include new products and discontinued products
- Class of trade/How to assign classes and how to reclassify customers
- Who your customers?
- Data and calculations
- Where is your data coming from and what needs to be used

Part C:

- The challenges and opportunities
- Understanding SPAP and what are the considerations?
- The impact on payment and claims processing
- Opportunities for analysis
- Mergers and Acquisitions, what kinds of things should you be thinking about

DAY ONE - THURSDAY, FEBRUARY 14, 2013

8:00 am

Registration & Breakfast

8:30 am

Co-Chairs' Welcome

Jim Abrams, MBA

Director, Government Pricing and Reporting, Mylan Pharmaceuticals

LaDonna Steiner

Associate General Counsel, Purdue Pharma

8:45 am

Alice Valder Curran on the Anticipation of Implementation of the Final Rule

Industry veteran, Alice Valder Curran is one of the most knowledgeable voices on drug price reporting obligations under the Medicaid, Medicare, and Public Health Service programs. Alice leads an interactive session to help us understand the anticipated changes of the Final Rule to include the following:

- Guidelines for interpreting the final rule
- How to de-risk the process: ridding ambiguity in the final rule
- How to address changes to AMP calculations from top-down or build-up
- Strategies to prepare for retroactive implementation
- How to handle Bona fide service fees
- Changes for Authorized generics

Alice Valder Curran

Partner, Hogan Lovells

9:30 am

Q&A with Audience

9:30 am

Enforcement Panel for Maintaining Corporate Compliance

Some manufacturers have faced litigation no matter how they interpret calculations. Hear directly from US Attorney's Office on what they look for and how you can protect your company. In this session, the Department of Justice provides a first-hand look and the background of why they took enforcement actions against pharmaceutical companies.

- Explanations for recent enforcement actions on branded pharmaceutical companies
- Guidance and clarification on avoiding enforcement actions

Moderator:

Mitch Lazris

Partner, Hogan Lovells

Panelists:

Thomas Corcoran

Assistant US Attorney, Civil Division, District of Maryland

Tarra DeShields

Assistant US Attorney, Civil Division, District of Maryland

Viveca Parker

Assistant US Attorney, Civil Division United States, Eastern District of Pennsylvania

Susan Winkler

Assistant US Attorney, Chief Health Care Fraud Unit, US Attorney's Office for the District of Massachusetts (invited)

10:30 am

Networking Break

11:00 am

Leading Health Care Association Voices on the Challenges of Health Care Reform and the Expansion of the Medicaid Drug Rebates Program

Hear representatives from industry health care associations share their insights to changes to government programs to help manufacturers and States better prepare for the impact of MDRP changes:

- Health Care Reform in 2014
- Impact of the New Congress
- Future Medicaid Expansions
- Anticipation of the Final Rule

John Costner, PhD, RPh

Senior Vice President, Government Affairs, National Community Pharmacists Association

Ann Kaplan

Vice President, The Pharmaceutical Research and Manufacturers of America

Julie Khani

Vice President of Public Policy, National Association of Chain Drug Stores

Laurel Todd, MBA

Managing Director of Reimbursement & Health Policy, Biotechnology Industry Organization

11:45 am

MDRP Consulting and Legal Speed Meeting Hour

The Medicaid Rebates Consulting Hour is designed to give all attendees an opportunity to meet one-on-one or in small group meetings to get specific questions answered. The conference facilitators will assist with the sign up system and meeting rooms.

12:45 pm

Luncheon

2:00 pm

POV from the Managed Markets and a Large Pharmaceutical Service Provider on the Expansion of the Affordable Care Act

In this session, manufacturers and a large pharmaceutical service provider explore how the Affordable Care Act and the Expansion of Medicaid will impact rebate liability. The panel will address the following questions:

- How will the expansion of Medicaid affect manufacturers' contract liability?
- What should you expect in terms of rebates or contracting changes and opportunities?
- How will the rebate mix of Medicaid Rebates vs. Commercial Rebates affect manufacturers?

Panelists:

Derek Asay

Senior Director of Government Strategy, Federal Accounts and Quality Managed Healthcare Services, Eli Lilly & Co.

George Bilyk

Health Care Policy Director, Janssen

Kevin Cast

Vice President of Strategy and Contracting, Express Scripts

Kent Rogers, MBA

Vice President of Managed Markets, Acorda Therapeutics

Matt Sheffield

Executive Director, National Government Affairs, Boehringer Ingelheim Pharmaceuticals, Inc.

3:00 pm

Track One: Final Rule and Other Implementation Updates

Chaired by:

Heather Dixon

Director, Government Price Reporting, Eli Lilly & Co.

3:00 pm

Implementing Anticipated New Additions to AMP Calculations

- New formulations of existing products and how to handle 5-I's
- How should you treat line extensions?
- Inclusion and exclusion criteria for class of trade?
- Addressing specialty pharmacy products

Chris Cobourn

Senior Vice President, Commercial Compliance, CIS

3:45 pm

Software Changes to Meet the Implementation of the Final Rule

Discuss strategies for collecting the right data for internal analysis and calculations for reporting activity. Find out what software companies are doing to help meet the changes necessary for the preparation of the Final Rule and what you can do in advance to make the process smoother.

- How the Final Rule is impacting software changes
- What to anticipate and how to make the transition

Jennifer Norton

Senior Director, Pricing & Contract Administration - Managed Markets, Vertex Pharmaceuticals, Inc.

3:00 pm**Track Two: 340B, Government Pricing and Reimbursement**

Chaired by:

Ed McAdam*Senior Director, Pricing & Analytics, Daiichi Sankyo, Inc.***3:00 pm****340B Regulatory Changes and Compliance Issues**

In this session, PHS and OPA representatives address the latest compliance and regulatory changes, including:

- Duplicate discounts
- Penny pricing
- The 340B user fee
- Medicaid exclusion files
- Improving the Integrity of the 340B Program

Panelists:

Christopher A. Hatwig, MS, RPh, FASHP*President, APEXUS/ 340B Prime Vendor Program***Ann Maxwell***Regional Inspector General, OIG Office of Chicago (invited)***CDR Krista Pedley, PharmD***Director, HRSA Office of Pharmacy Affairs***3:30 pm****Operational Impact of 340B Changes and Expansion for Manufacturers**

- Best practices for processing 340B rebates and calculations
- What software changes should you be making to incorporate the expansion of the 340B program
- How are 340B entities going to bill the state?

Panelists:

Sharon Greeson, RPh*NCXIX Pharmacy Director, State and Local Health Care and Human Services, HP Enterprises***Lori Martin***Manager, Contract Administration, Eli Lilly & Co.***Joann S. Prushinski***340B Account Management Team, Genentech***Aaron Vandervelde***Principal, Health Analytics, Berkeley Research Group, LLC***4:30 pm****Medicare Part B & D/The Donut Hole****Marci Anderson***Senior Auditor, VA Office of Inspector General, Office of Contract Review***4:30 pm****Medicare Part B & D/The Donut Hole**

Making sense of the donut hole continues to be a massive challenge. Hear lessons learned since implementation and discuss the future operational and financial impact of closing the donut hole including:

Medicare Part D: The Donut Hole

- Addressing operational issues of Medicaid Part D and the Donut Hole
- What do we know and what don't we know about dealing with the Donut Hole
- Forecasting and managing the financial impact of the Donut Hole
- Impact on Generic Manufacturer's Rules, information and processes for effective dispute resolution

Medicare Part B on Average Sales Price and the Management of Specialty Pharma

- Developing an Effective Pricing Strategy Action Plan
- Case Study Example

Jesse Mensah, Sr.*Manager, U. S. Pricing Compliance, Celgene***Lisa McNair***Senior Government Pricing & Contracts Analyst, Reckitt Benckiser***5:00 pm****Networking Reception****DAY TWO - FRIDAY, FEBRUARY 15, 2013****8:00 am****Breakfast****8:30 am****Co-Chairs' Welcome****Jim Abrams, MBA***Director, Government Pricing and Reporting, Mylan Pharmaceuticals***LaDonna Steiner***Associate General Counsel, Purdue Pharma*

8:40 am

Audience Q&A with CMS

This session allows the audience to ask questions to CMS representation to help bridge gaps between manufacturers and CMS. The discussions focus on compliance, operational and technical changes to the MDRP processes as well as addressing current manufacturers questions.

Moderated by:

LaDonna Steiner

Associate General Counsel, Purdue Pharma

with invited CMS representatives

9:10 am

Audience Q&A Time

9:30 am

Healthcare Foundations POV on Medicaid Expansion

A dual perspective from two Leading healthcare foundations join together to discuss Medicaid expansion and to address the following:

- How to anticipate for 51 solutions for Medicaid Expansion?
- What is happening with State Exchanges and how will they be rolled out?
- What will be the predominant model?
- What are the current state processes?

Edmund Haislmaier

Senior Policy Fellow, Health Policy Studies, Heritage Foundation

Brian Osberg

Program Director, Healthcare Division, National Governors Association

10:00 am

The Manufacturers POV: Fireside Chat on Best Practices to Prepare for the Implementation of the Anticipated Final Rule

Industry Veteran-Led Discussion

This manufacturers' panel is dedicated to sharing strategies and planning for the final rule. More specifically:

- How can we best prepare for the Final Rule? What should we or can we be doing now?
- What are the best practices for implementation of the Final Rule?
- How to address changes to AMP Calculation Methodology?

- What can we do to gain comfort that the data we receive from third party customers is accurate?
- How can we retain profitability moving forward?

Panelists:

Jim Abrams, MBA

Director, Government Pricing and Reporting, Mylan Pharmaceuticals

Heather Dixon

Director, Government Pricing Reporting, Eli Lilly & Company

Mike Hepburn

Senior Director, Government Contracts, Janssen

Christopher Jackson

Counsel II, Bayer HealthCare LLC

Lisa McNair

Senior Government Pricing & Contracts Analyst, Reckitt Benckiser

10:45 am

Medicaid Claims and Government Pricing Source Data Analytics; Evaluating Upstream Data to Prevent Downstream Issues

During this session, members of the CIS Team will share their expertise in compliance and commercial strategies and review various sources of data that feed into Medicaid rebating and government pricing calculation processes and discuss:

- Best Practices in validating Medicaid rebates and GP calculations
- Potential impact of inaccurate source data
- Ways to minimize revenue leakage and non-compliance with government programs through source data analysis
- Methods for analyzing and forecasting the impact of Government Programs on future revenue streams

Panelists:

Chris Cobourn

Senior Vice President, Commercial Compliance, CIS

Audrey Fletcher

Director of Government Programs, CIS

Erica Petersohn

Director of Government Programs, CIS

Bill Phillips

Director of Government Programs, CIS

11:15 am

Networking Break**MCO Expansion and Health Care Exchanges – Two-Part Session**

11:45 am

Part I: Strategic Preparation for the Financial Impact of MCO Expansion and Health Care Exchanges

Industry leaders and state agencies look at trends in MCO expansion and its financial impact. Learn what steps you can take now and how to prepare going forward.

- How will it affect commercial contracts?
- How to plan for financial impact of more lives?
- How will MCO expansion affect rebate dollars?
- What is going to be the shift to Managed Medicaid from FFS?
- As states start getting MCOs together, how are they submitting claims?

Paula Martins

Director Government Contracts, Daiichi Sankyo, Inc.

LaDonna Steiner

Associate General Counsel, Purdue Pharma

12:20 pm

Part II: Operational Preparation Needed to Support MCO Expansion and Health Care Exchanges

This session addresses current concerns with the shift to use Medicaid drug rebates in managed care as well as Fee for Service reimbursements changes not only processes within rebates, but also the financial mix of government and commercial rebates. This session highlights operational and system changes to a growing Medicaid MCO market, including:

- Status updates on claim-level data access
- How to avoid duplicate discounts: Learn how to set up systems for validation
- Strategies for working with counter-data from MCO entities and reconcile data with the drug rebates associated with it

Rich Holsapple, RPh

Pharmacy Services Manager, Oregon MMIS, HP Enterprise Services

1:00 pm

Luncheon Break

2:30 pm

States & Manufacturers Discuss Healthcare Policy Changes and Processes to Work More Efficiently Together

Interactive Session

3:30 pm

Future of Government Pricing and its Role in Reimbursement

As changes to reimbursement are occurring differently across each government program, what will be the benchmark for government contract profitability going forward?

- How are companies implementing a new methodology?
- How can you forecast the financial impact of a new benchmark?
- The status of appropriate benchmarks to use for reimbursement by the states

Christopher Jackson

Counsel II, Bayer HealthCare LLC

4:00 pm

Conference Concludes

REGISTRATION

	Conference Only	Conference & Workshop
Early-Early Bird - Before December 7, 2012	\$1,295	\$1,695
Early Bird - Before January 11, 2013	\$1,495	\$1,795
Standard - After January 11, 2013	\$1,695	\$1,995

The conference fee includes the program, morning coffee/tea, luncheons and conference documentation.

Discount Programs

Group Registration – Receive a 10% discount off each registration when two or more colleagues from the same company register online.

Large group discounts available.

Please contact Service@theconferenceforum.org or call 646-350-2580 for any questions on discount rates.

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If you are unable to attend and would like to register a substitute, please email Service@theconferenceforum.org. Please ask your substitute to provide identification on-site.

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Ten or more business days prior: A full refund less the administration fee of \$295, or a pass to another event valid for two years from the date of issue.

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To cancel and receive a refund or pass, please email Service@theconferenceforum.org or call 646-350-2580.

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VENUE

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For reservations, call 888-421-1442 and ask for the Medicaid Rebate Summit group rate or use the following link: <https://resweb.passkey.com/go/GTCFF>.

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The hotel offers:

Restaurant, Bar & Lounge

- Blue Duck Tavern—American cuisine with an open kitchen restaurant featuring the region’s freshest produce, floor-to-ceiling glass wine display, a Chef’s table seating up to 18 guests, and the first Molteni range in Washington, DC
- Lounge—serving breakfast, lunch, and dinner with “Capitol Hill” glass-enclosed booths flanking a stylish marble and glass bar
- Tea Cellar—offering more than 50 rare and vintage teas, and featuring a glass humidor to store, display and age tea

Recreational Facilities

- Sky-lit indoor swimming pool and whirlpool
- 24-hour fitness center with state-of-the-art cardiovascular and weight equipment
- Spa Room

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