



June 18-19, 2019

The Inn at Penn, a Hilton Hotel  
Philadelphia, PA



# AGGREGATE SPEND AND OPEN PAYMENTS CONFERENCE

Enhance reporting processes to ensure compliant, transparent and ethical interactions between life science manufacturers and healthcare professionals.

## FEATURED SPEAKERS



### CHAIRPERSON

**Heather McCollum, J.D.,  
MHA, CCEP-I**  
Director, Compliance  
**SHIONOGI**



### Robin Usi

Director, Division of Data and  
Informatics, Center for  
Program Integrity  
**CENTERS FOR MEDICARE  
& MEDICAID SERVICES**



### Joseph Mack

Senior Compliance Counsel  
**BAYER**



### Bernard Cooney

Assistant United States  
Attorney, District of New Jersey  
**U.S. DEPARTMENT OF  
JUSTICE**



### Sheea Sybblis

Senior Counsel  
**BOEHRINGER  
INGELHEIM**



### Charlene Davis

Associate Vice President and  
Head of Healthcare Compliance  
**SUN PHARMACEUTICAL  
INDUSTRIES**

## LEARNING OBJECTIVES



Expand provider  
coverage under the  
Sunshine Act



Develop effective  
collection processes  
for open payments  
information



Enhance ethics and  
enforcement when  
determining conflict  
of interest



Explore compliance  
on a multi-national  
level while protecting  
privacy



Examine transparency  
and operations from  
a company-wide  
perspective

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Dear Colleague,

The demand for transparency when looking at the relationship between life science manufacturers and health care providers is at an all-time high. Recent updates to the Physicians Payments Sunshine Act will increase the scope of responsibilities for manufacturers and HCPs alike. The current landscape surrounding aggregate spend and the open payments system also involves the discussion of conflicts of interest, ethical interactions, and physician kickbacks.

Interactions with HCPs can provide tremendous value to life science manufacturers but also presents risks for provider disputes or legal violations. Enforcement in the industry is constantly evolving on state, federal and global levels. With differences in reporting requirements, it is up to manufacturers to manage risk, maintain transparency and ensure compliance at all times, which can be extremely difficult.

ExL Events is proud to bring you the **10th Aggregate Spend and Open Payments Conference**. Over the course of two days, a diverse lineup of industry experts will discuss the best practices to ensure compliance, explore the ethical behaviors associated with HCP interaction and highlight the trends in state and federal enforcement. Over the past nine years, we have had the privilege in educating over 223 organizations and continue to provide thought-provoking sessions, interactive panels, and spotlight sessions which will allow attendees to:

- Explore Sunshine Act updates
- Learn state reporting and enforcement trends
- Understand compliance data and analytics
- Review price and spend transparency
- Explore the impact of speaker programs and high-risk areas
- Gain an understanding of global compliance, ethical standards, and expectations
- Enhance the business applications of open payments and transparency

Join us for this collaborative program to participate in discussions that analyze the most pressing topics involving open payments, transparency, and compliance within aggregate spend.

I look forward to welcoming you to Philadelphia this June!

Sincerely,

Brianna Conetta

## WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, med device, biotech and medical supply manufacturers with responsibilities in the following areas:

- ▶ Aggregate Spend
- ▶ Sunshine Act Compliance
- ▶ Transparency
- ▶ Open Payments System/Reporting
- ▶ Corporate/Regulatory/Risk Compliance and Ethics
- ▶ Government/Federal/State Reporting
- ▶ HCP Engagement
- ▶ Compliance/Transparency Data
- ▶ Spend Transparency
- ▶ Legal/Regulatory/Government/Medical Affairs
- ▶ Internal Auditing/Training
- ▶ General Counsel

This conference is also of interest to:

- ▶ Sunshine Act Reporting Vendors
- ▶ Data/Records/Reporting/Archive Management Vendors
- ▶ Law Firms/Consultants
- ▶ CROs

## VENUE INFORMATION

### The Inn at Penn, a Hilton Hotel

3600 Sansom St. / Philadelphia, PA 19104

To make reservations, please call (215) 823-6240 and request the negotiated rate for **ExL's June Meetings**. You may also make reservations online using the following weblink <https://bit.ly/2T48HJT>. The group rate is available until **Tuesday, May 28**. Please book your room early, as rooms available at this rate are limited.

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**"Great information and discussions!"**

—Supplier Partner, **COMPASS**

**"We gained a perspective on the industry as a whole and the progress made by our peers."**

—Senior Consultant, **DELOITTE**

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## 8:00 Registration and Continental Breakfast

8:45 **Chairperson's Opening Remarks**

**Heather McCollum, J.D., MHA, CCEP-I**, Director, Compliance, **SHIONOGI**

## Reporting & Data Management

9:00 **Analyze the Differences in State and Federal Reporting Regulations**

- Discuss the newest state legislation and interpret existing
- Reduce the complexity of data collection and understand common practices for both state and federal reporting
- Analyze interpretations of various state requirements
- Create synergy between reports made for federal agencies and state agencies

**Bill Friedrich**, Senior Manager, Compliance, **HIKMA PHARMACEUTICALS**  
**Margaret Rossini**, Director, Corporate Compliance and Monitoring Risk, **SANDOZ**

9:45 **Explore Compliance Dashboards and Develop Meaningful Data Visuals**

- Define what internal and external data points should be included in a compliance dashboard
- Discuss who the dashboard is useful to and why
- Analyze the metrics and educate personnel on key risk indicators

**Ishita Arora**, Compliance Consultant, **HORIZON PHARMA PLC**

## 10:30 Networking Break

11:00 **CMS Address: Updates to the Sunshine Act and Open Payments System**

**Robin Usi**, Director, Division of Data and Informatics, Center for Program Integrity, **CENTERS FOR MEDICARE & MEDICAID SERVICES**

11:45 **Make Strategic Business Decisions by Leveraging Technology and Transparency Data**

- Aggregate data into reports that are not misleading and are easily understood
- Analyze data collected for open payments reports to understand trends and context
- View investments of partnerships and assess risks vs. rewards
- Transform data into strategic business plans to drive success

**Bryan Stinehour**, Product Manager, **MEDISPEND**

## 12:30 Luncheon

1:30 **Optimize Aggregate Spend Data Collection, Validation and Reporting**

- Discover the advantage of collecting data before spend happens
- Learn efficient ways of connecting transactional spend sources, foundation systems, and reporting tools
- Gain practical tips for small to mid-size manufacturing companies
- Analyze the best practices for global transparency
- Discuss governance and define who owns what

**Sharon Muscato**, Director, Transparency and Compliance Operations, **ALEXION PHARMACEUTICALS**

2:15 **CASE STUDY: Manage Disputes Effectively and Organize Feedback to Improve Future Reporting Processes**

CASE  
STUDY

- Collaborate with HCPs prior to submissions to proactively decrease the volume of disputes
- Understand the review and dispute process, timeline, and other crucial deadlines
- Collect and organize data that can provide feedback to improve future reports

**Heather McCollum, J.D., MHA, CCEP-I**, Director, Compliance, **SHIONOGI**

## 3:15 Networking Break

## Transparency, Ethics & Compliance

3:45 **Understand the Landscape of State Transparency and Spend Restrictions**

- Discuss the newest amendments to state legislation and understand the potential internal and operational implications for transparency reporting and data collection
- Collaborate interdepartmentally to ensure that processes are efficient, compliant, and effective in managing transparency
- Cultivate a culture of understanding within your organization to aid the adoption of new processes for state reporting

**Sheea Sybblis**, Senior Counsel, **BOEHRINGER INGELHEIM**

4:30 **PANEL: Discuss High-Risk Areas and Emerging Trends in Transparency and Compliance**

PANEL

- Explore the real-world challenges associated with monitoring transparency compliance in potential areas of risk
- Analyze the relationship between drug pricing, proprietary interests/trade secrets, and transparency to proactively prepare your internal processes
- Gauge the importance of maintaining adequate data standards to effectively manage compliance programs

**Charlene Davis**, Associate Vice President and Head of Healthcare Compliance North America, **SUN PHARMACEUTICAL INDUSTRIES**

**Donna White**, Vice President, Contracts and Compliance, **CHIESI USA**

**Sheea Sybblis**, Senior Counsel, **BOEHRINGER INGELHEIM**

5:15 **Chairperson's Closing Remarks**

**Heather McCollum, J.D., MHA, CCEP-I**, Director, Compliance, **SHIONOGI**

## 5:30 Day One Concludes

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8:00 Continental Breakfast

8:45 **Chairperson's Recap of Day One**  
**Heather McCollum, J.D., MHA, CCEP-I, Director, Compliance, SHIONOGI**

9:00 **Utilize Aggregate Spend Data As Part of an Effective Auditing and Monitoring Program**  
 • Utilize data captures for Sunshine Reporting to strengthen existing compliance programs  
 • Learn how to identify key risk indicators and automate monitoring  
 • Understand how to prioritize areas of risk based on an annual risk assessment  
**Amy Valiante Ross, Compliance and Data Protection Officer, DRAGER**

9:45 **Define the Terms of Appropriate and Ethical Interactions Between Manufacturers and HCPs**  
 • Explore the complexities of the relationship between manufacturers and HCPs through a didactic and participatory framework  
 • Review various examples and scenarios related to appropriate and permissible interactions by manufacturers such as by field personnel, corporate office staff and HCPs  
 • Gain an understanding of the handling, reporting and compliance aspects related to food and beverage, travel, honoraria, and service hours  
 • Discuss and provide case study briefings on various types of disputes that are raised with regard to Open Payments data submissions  
**Kari Loeser, U.S. Healthcare Compliance Officer, RELYPSA**

10:30 Networking Break

11:00 **Explore Global Compliance Initiatives Through Foreign Regulations, the Sunshine Act, and GDPR**  
 • Define which foreign entities are applicable manufacturers/HCPs for reporting  
 • Discuss how to collect necessary information and navigate GDPR  
 • Recognize global regulations and operationalize processes to ensure transparency  
**Bryan Stefanski, Compliance Director, SIEMENS HEALTHCARE**  
**Natalia Morozkina, Compliance Manager, OTSUKA PHARMACEUTICAL COMPANIES**

11:45 **Utilize Open Payments Data to Quantify and Track the Value of HCP Partnerships**  
 • Define internal goals to outline appropriate interactions and assess partnerships  
 • Demonstrate positive collaborations with HCPs to communicate business goals  
 • Discuss FMV when partnering with HCPs  
 • Identify trends and KPIs that can judge the value of partnerships  
**Nicodemo Fiorentino, Esq., Senior Manager, Compliance Operations and Transparency, SUN PHARMA**

12:30 Luncheon

1:30 **Identify Compliance Obstacles and Streamline Processes Associated With Speaker Programs to Mitigate Risk**  
 • Discuss the best practices for mitigating human error when collecting and reporting aggregate spend data  
 • Track funds to ensure payments are delivered to the correct providers  
 • Optimize processes for data submission internally and externally  
**Avi Spira, Chief Compliance, Risk and Privacy Officer, FUJIFILM HOLDINGS AMERICA CORPORATION**  
**Stephen Shoop, Life Science Compliance Manager, FUJIFILM HOLDINGS AMERICA CORPORATION**

**PANEL**  
 2:15 **DOJ ENFORCEMENT PANEL: Current Trends and Relevant Ethical Considerations**  
 • Hear from current and former federal prosecutors regarding the landscape of enforcement  
 • Learn about recent kickback-related False Claims Act cases and discuss the Anti-Kickback Statute  
 • Discuss cutting-edge compliance issues in the C-Suite and the implications of business investments  
 • Explore what behavioral compliance looks like and examine ethical behaviors  
**Bernard Cooney, Assistant United States Attorney, District of New Jersey, U.S. DEPARTMENT OF JUSTICE**  
**Daniel Font, CIIP-US, CIPM, Director, Compliance Investigations, Policy and Training, DAIICHI SANKYO**  
**Joseph Mack, Senior Compliance Counsel, BAYER**

3:15 **Chairperson's Closing Remarks**  
**Heather McCollum, J.D., MHA, CCEP-I, Director, Compliance, SHIONOGI**

3:30 Conference Concludes



"Learned about strategies for implementing a compliance-driven data analytics program."

—Financial Data Analyst, **TERUMO MEDICAL CORPORATION**

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## Ways to Register

 **Phone:** 201-871-0474

 **Fax:** 253 663 7224

 **Online:** [Click Here](#)

 **Email:** [register@pmaconference.com](mailto:register@pmaconference.com)

 **Mail:** PMA Conference Management, PO Box 2303 Falls Church VA 22042

## Registration Fees for Attending ExL's 10th Aggregate Spend and Open Payments Conference

| <b>EARLY BIRD PRICING</b><br><i>Register by Friday, May 3, 2019</i> | <b>STANDARD PRICING</b><br><i>Register After Friday, May 3, 2019</i> | <b>ONSITE PRICING</b> |
|---|--|-----------------------|
| <b>\$1,895</b>  | <b>\$2,095</b>   | <b>\$2,295</b>        |

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For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four at one time). This is a savings of 25% per person.

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## Testimonials

"This gave me key takeaways to help improve compliance in my company."

—Clinical Affairs Manager, **INTEGRITY IMPLANTS**

"The greatest benefit was hearing others' processes so I can benchmark my company."

—Meetings Manager, **NOVO NORDISK**

## Media Partners



**TERMS AND CONDITIONS:** By registering for an ExL Events ("ExL") event, you agree to the following set of terms and conditions listed below:

**REGISTRATION FEE:** The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

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**\*\*Please Note:** There will be an administrative charge of \$300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.\*\*

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- Four weeks or more: A full refund (minus a \$295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
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- Five days or less: A voucher (minus a \$395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email [cancel@exlevents.com](mailto:cancel@exlevents.com) or fax your request to 888-221-6750.

**CREDIT VOUCHERS:** Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.

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