Compliance Primer

& How to Make the Most of PCF

Presented by
Maureen Ruane, JD, Director, MedPro Compliance Advisory Services
Cristina List, CPA, CCEP, Senior Manager, MedPro Compliance Advisory Services

Disclaimer

The Information Contained in This Presentation:

- Provides a high-level overview and reference of relevant terminology & resources;
- Is not intended to provide an exhaustive explanation of the relevant regulations nor should it be used in place of a thorough review of the regulations as they apply to your organization's situation;
- Is not, and should not be relied upon as, legal advice.
- Should a legal issue or matter exist or arise concerning these topics, legal counsel should be consulted for advice specific to the issues, facts, and circumstances presented.

Our Presenters

Maureen Ruane, JD
Director,
MedPro Compliance Advisory Services

Cristina List, CPA, CCEP
Senior Manager,
MedPro Compliance Advisory Services

Our Agenda

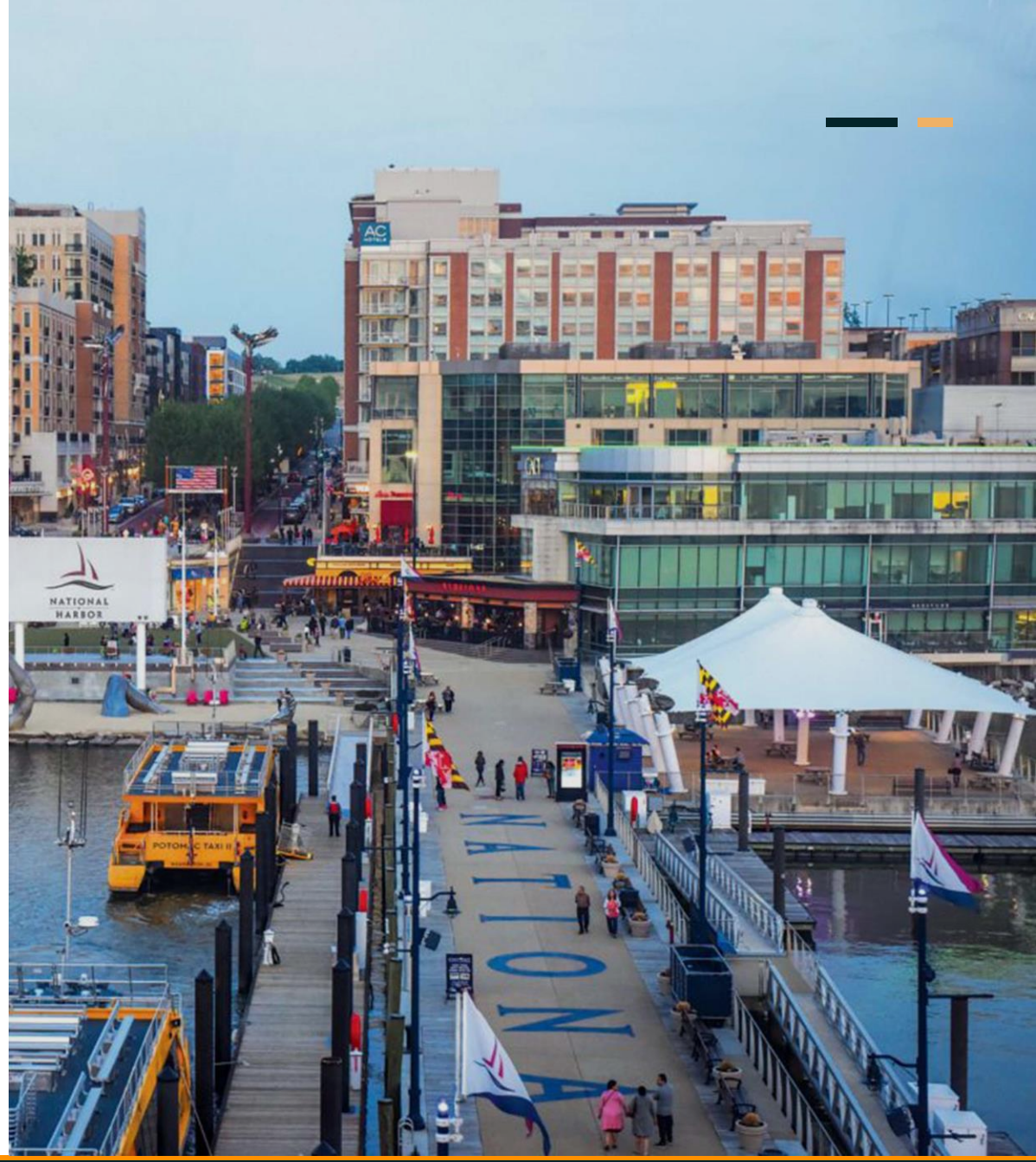
Welcome & Introductions

Basic Laws, Regulations
and Effective Compliance Overview

Compliance Hot Topics
and Recent DOJ & OIG Guidance

How to Make the Most of PCF

Q&A



Basic Laws, Regulations and Effective Compliance Overview

Audience Survey

How Long Have You Worked in Healthcare Compliance?	What Is the Scope of Your Organization's Disclosure Requirements?	Which Industry Type Best Describes Your Company?
Less than one year	US Only	Biotech Manufacturer
One to three years		Pharmaceutical Manufacturer
More than three years	US and International	Medical Device Manufacturer

Basic Laws and Regulations

Anti-Kickback Statue (AKS) vs. Eliminating Kickbacks in Recovery Act (EKRA) vs. Travel Act

Do not induce or reward business reimbursable by….

False Claims Act (FCA)

Do not lie to the government by submitting false claims…

Federal and Jurisdictional Transparency Reporting Requirements

Do not hide transfers of value from the government…

Federal Food, Drug, and Cosmetic Act (FD&C Act or FDCA)

Do not injure consumers with your products…

Seven Elements of an Effective Compliance Program

- Designated Compliance Officer & Committee
- Written Policies & Procedures
- Effective Training & Education
- Effective Lines of Communication
- Internal Monitoring & Auditing
- Incentives & Disciplinary Measures
- Investigations & Remedial Measures

Additional Considerations:

- Third Party Risk Management
- Mergers & Acquisitions
- Transparency
- Industry Codes & Internal Policies

SOURCE: *Compliance Program Guidance (2003) | US Office of the Inspector General for the Department of Health and Human Services (OIG)*

Overall Compliance Program Effectiveness

Is Your Compliance Program Well Designed?

- Risk Assessment
- Written Policies & Procedures
- Effective Training & Communications
- Confidential Reporting Structure & Investigation Process
- Third Party Management
- Mergers & Acquisitions

Is Your Program Adequately Resourced & Empowered?

- Commitment by Senior & Middle Management
- Autonomy & Resources
- Compensation Structure & Consequence Management

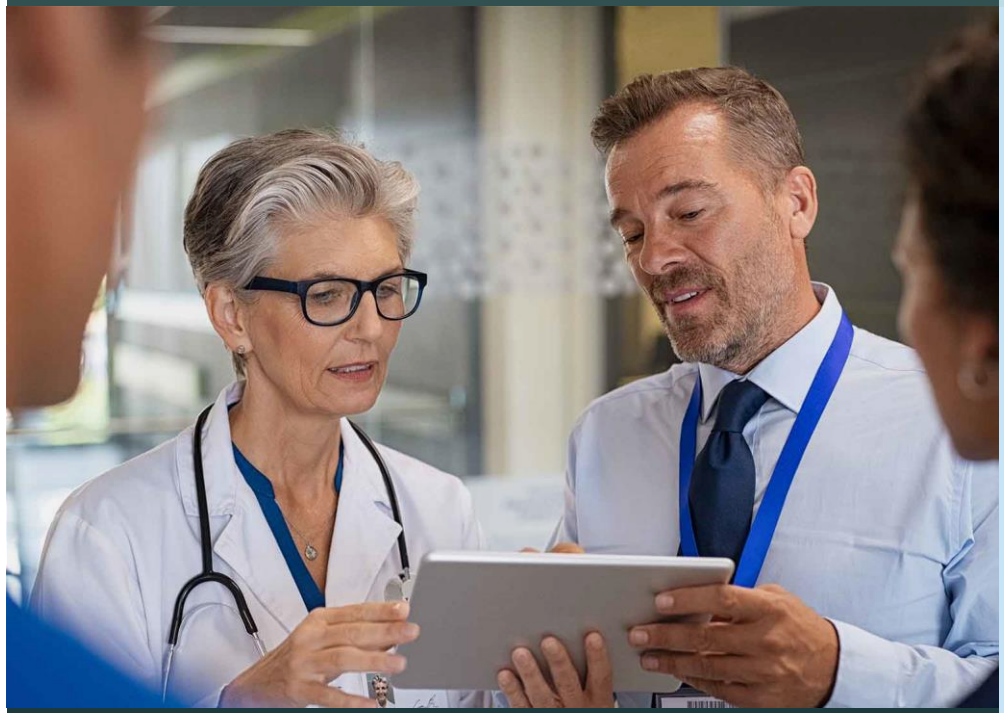
Does Your Compliance Program Work in Practice?

- Continuous Improvement, Periodic Testing, & Review
- Investigation of Misconduct
- Analysis & Remediation of Any Underlying Misconduct

Compliance Hot Topics and Recent DOJ & OIG Guidance

Hot Topic

Ephemeral Messaging Apps



- Updated March 2023, US DOJ, Criminal Division, *"Evaluation of Corporate Compliance Programs"*
- August 8, 2023, New DOJ Guidance on Corporate Compliance and Third-Party Messaging Platforms
- What the courts (federal and state) have to say?
  - *Fast v. GoDaddy.com LLC, No. CV-20-01448-PHX-DGC (D. Ariz. Feb. 3, 2022)*
  - *Stay updated!*

Hot Topic

Research and Clinical Trial Fraud

- Deputy Assistant Attorney General Arun G. Rao at the Food & Drug Law Institute's (FDLI) 2021 Enforcement, Litigation and Compliance Conference (Dec. 9, 2021)
  - *"Fabricated clinical trial data can have dangerous consequences if relied upon by the FDA, drug researchers and medical doctors when making material decisions about the safety, efficacy and clinical use of drug products."*
- What the courts (federal and state) have to say?
  - *USA v. Valdes, Font, Lopez and Tejeda (S.D. Fl. Feb. 23, 2021)*
    - *For details see, 'Tellus Clinical Research, Inc.'*
  - *Unlimited Medical Research, LLC, Dr. Yvelice Villaman Bencosme and Dr. Lisett Raventos (Miami, Florida)*
  - *Stay updated!*

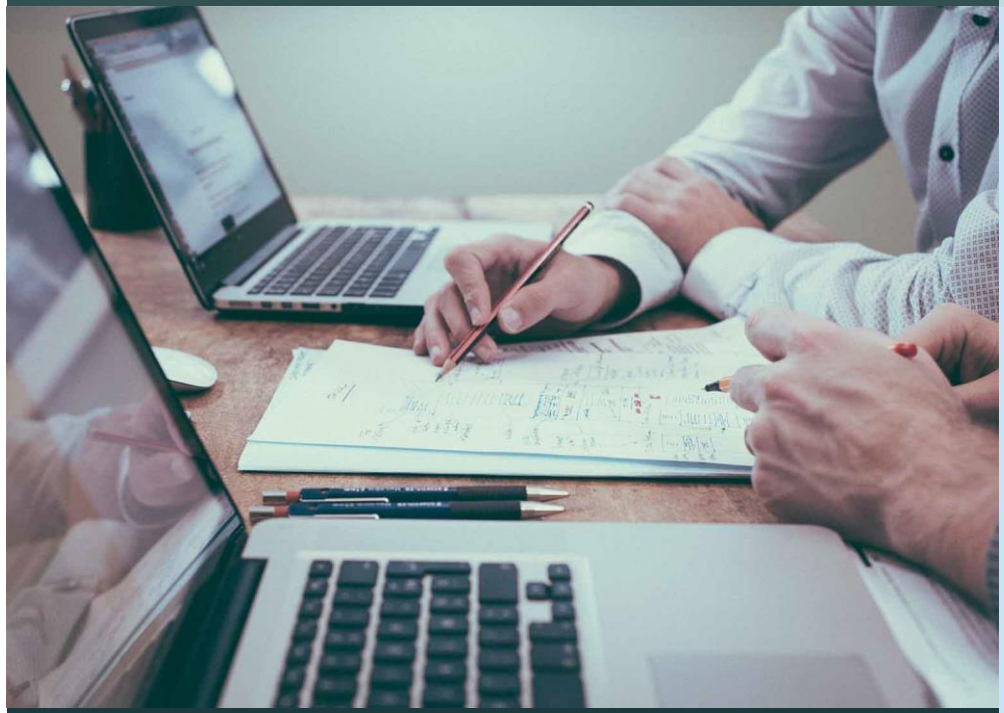
Hot Topic

To Disclose or Not to Disclose?

- DOJ continually seeks to encourage and incentive corporate entities to identify and investigate corporate misconduct through the operation of robust and effective corporate compliance programs, and then to promptly disclose the misconduct to the government.
- **Good news:** The government is ultimately seeking to motivate corporate entities to prioritize and fund corporate compliance efforts and work!
- The messages are loud and clear – *and will keep coming!*
- But actual decisions to disclose or not disclose are complicated and nuanced – *and should be considered most carefully.*

Hot Topic

Monitoring and Auditing



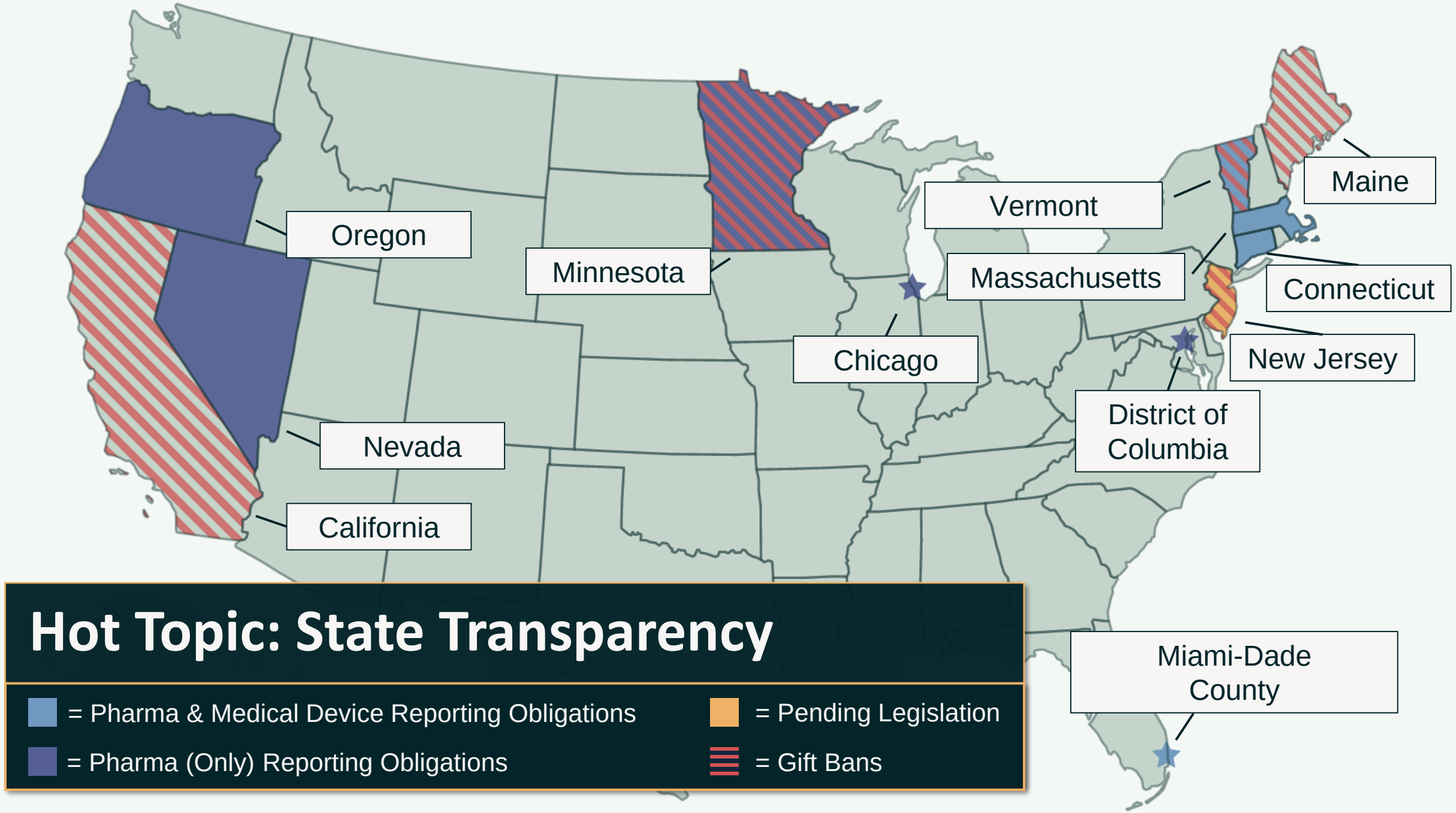
What is the Difference?

Monitoring Activities, Participants and Interactions

- **Attendance and Participation**
- **Debarment**
- **Attending the Event**
- **Ride-Along**

Auditing Activities, Participants and Interactions

- **Auditing Data**
- **Auditing Documentation**
- **Third Parties**


Oregon
Minnesota
Vermont
Maine
Massachusetts
Connecticut
Chicago
New Jersey
District of Columbia
Nevada
California
Miami-Dade County
Hot Topic: State Transparency
= Pharma & Medical Device Reporting Obligations
= Pharma (Only) Reporting Obligations
= Pending Legislation
= Gift Bans

State Trend: Focus on Interactions

OREGON

- No reportable spend threshold
- Requires registered reps to ***report the location & duration of interactions*** with healthcare providers

CONNECTICUT

- The ***number of contacts*** reps had with prescribing practitioners and pharmacists
- Materials or gifts of any value provided to a prescribing practitioner (including staff) or a pharmacist.

NEW JERSEY

- A list of ***all HCPs they contacted within*** the state;
- The number of times an HCP was contacted;
- The location & duration of each contact;

How to Make the Most of PCF

How To Make the Most of PCF

Network, Network, Network

Visit the Vendors

Be Present and Actively Participate at Sessions

Talk to the Speakers
(Even the Ones from the Government)

Connect on LinkedIn and Follow Up After the Conference

Go to the PCF Annual Members Meeting (typically in March)

Stay Connected

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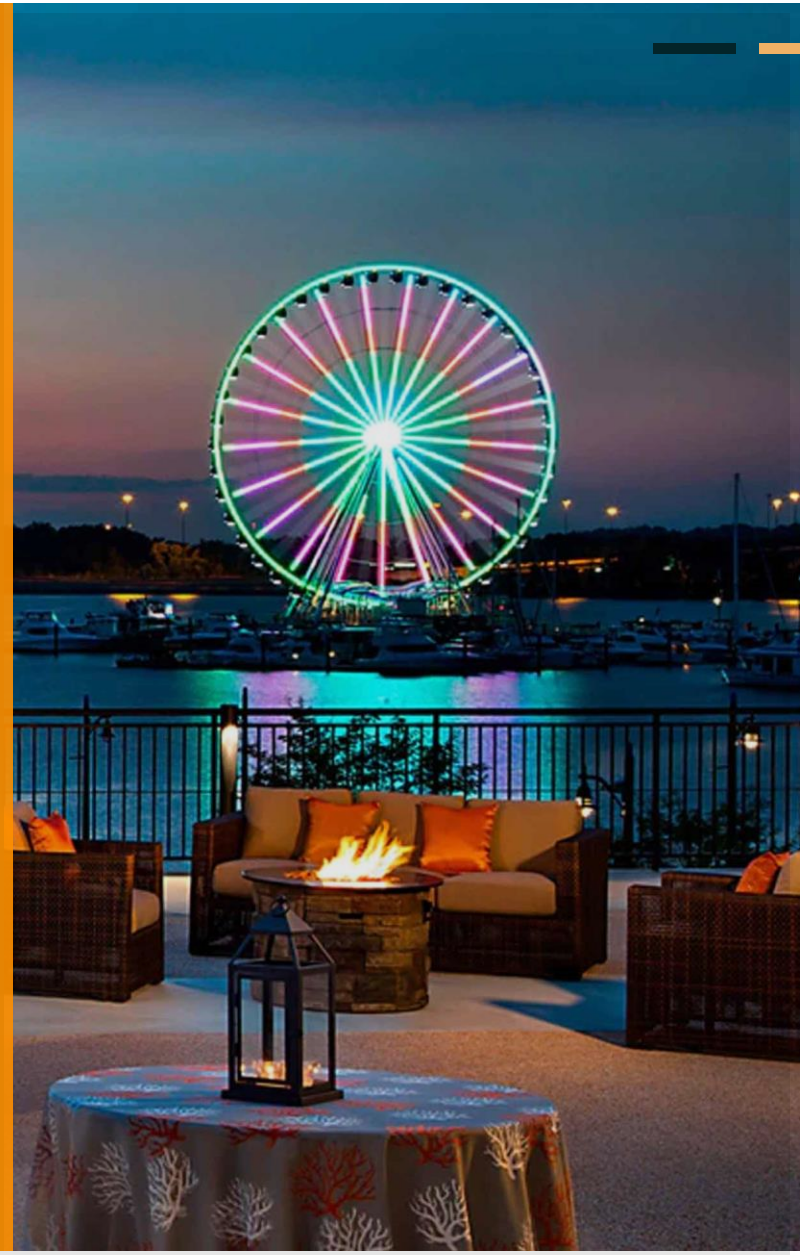
Follow us on LinkedIn @MedPro Systems

Compliance@MedProSystems.com




Questions?

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