

Federal and State Transparency – Meeting Obligations and Managing Risks

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and Aggregate Spend
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Agenda

- Introduction
- Individual State Requirements – A Closer Look
- Recap of Key Points
- Questions?



Federal and State Transparency – Why It's On Our Radar Screen

- Most aggregate spend states have requirements (in terms of covered recipients, reportable activities, or both) that will not be preempted by Federal Sunshine Act
- Company systems and protocols to track and report federal and state spending may be relatively new.
- Inconsistencies between Federal and State reports could trigger confusion and/or state enforcement activity.
- Some state obligations that were not publicly reported previously will be captured in Federal Sunshine reports.
- Federal Sunshine reports are likely to generate publicity, and media loves a “state angle”.

Vermont Obligations After Sunshine

- **Covered Recipients:** Residents, PA's, NP's, Pharmacists, Employees of Prescribers, Non-Teaching Hospitals/Clinics, Health Plans, Pharmacies, Universities, Non-Profit Foundations, Patient Advocacy Associations, Professional Associations
- **Reportable Activities:**
 - All activities for additional CR's
 - Samples of OTC drugs and devices
 - Demo units
 - Coupons/vouchers/co-pay cards
 - Patient starter kits
 - Accredited CME
 - Clinical spend prior to 8/1/13
 - Patient education and disease management materials
 - Anatomical models and charts
- **Special Considerations:**
 - No meals for doctors “practicing in Vermont”, unless part of contractual arrangement (e.g., speaking or consulting agreement)
 - No “non-certified” CME
- **Risks:** Payments for apparently restricted activities would be listed on Federal report



Massachusetts Obligations After Sunshine

- **Covered Recipients:** Residents, PA's, NP's, Pharmacists, Employees of Prescribers, Non-Teaching Hospitals/Clinics, Nursing Homes
- **Reportable Activities:**
 - All activities for additional CR's
 - Accredited CME
 - Anatomical models and charts
- **Special Considerations:**
 - Reporting not required under “de minimus” threshold of \$50 per covered recipient per event



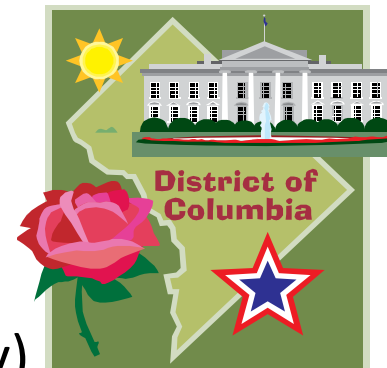
Minnesota Obligations After Sunshine

- **Covered Recipients:** Residents, PA's, NP's
- **Reportable Activities:**
 - All activities for additional CR's
- **Special considerations:**
 - \$50 limit on meals and physician educational items, per prescriber, per year
- **Risks:** Payments apparently in excess of annual limit would be listed on Federal report



District of Columbia Obligations After Sunshine

- **Covered Recipients:** All Licensed Health Care Providers (Nurses, CDEs, Reg. Dieticians, Lic. Nutritionist, Radiology Techs, etc.), Non-Teaching Hospitals/Clinics, Universities, Patient Advocacy Associations, Professional Associations, All Licensed Health Care Facilities (Hospice, LTC, Dialysis, etc.)
- **Reportable Activities:**
 - All activities for additional CR's
 - Employee costs (salaries/overhead)
 - All print and media advertising (local only)
- **Special Considerations:**
 - Reporting not required under “de minimus” threshold of \$25 per covered recipient per day



West Virginia Obligations After Sunshine

- **Covered Recipients:** Residents, PA's, NP's
- **Reportable Activities:**
 - All activities for additional CR's
 - All national and print media advertising divided by the population of WV
- **Special Considerations:**
 - Reporting is aggregated
 - De minimus threshold of \$100 per covered recipient



Louisiana Obligations After Sunshine

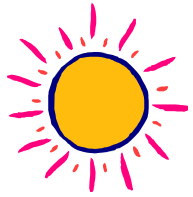
- **Special Considerations:**
 - \$50 limit on meals and educational items to any state employee, per year (most hospitals are state-owned)
- **Risks:** Payments apparently in excess of annual limit would be listed on Federal report



California Obligations After Sunshine

- **Special Considerations:**
 - Each company sets annual (fiscal year) limit on meals and educational items to any CA physician per year
- **Risks:** Payments apparently in excess of annual limit would be listed on Federal report





Final Thoughts . . .

- Even after Federal Sunshine Act is fully implemented and preemption kicks in, companies will have ongoing reporting obligations in a number of states.
- Determining what information is NOT reportable in certain states may cause added work.
- Companies' mistakes (or judgment calls) in complying with state restrictions on certain types of activities will be more visible once Federal reporting begins.
- Companies may want to consider identifying challenges and tracking/estimating resources devoted to compliance with state transparency obligations after Federal Sunshine is implemented (in case there is an opportunity to modify state requirements).