

# Aggregate Spend: An Update on State Laws and Regulations

Fifth Annual Summit on Disclosure for Drug, Device and  
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# Federal “Sunshine Act” and Preemption of State Laws

- The federal statute preempts any statute or regulation of a state that requires an applicable manufacturer to disclose or report, in any format, the same type of information regarding the payment or transfer of value required to be reported under the federal statute.
- The statute provides an exception for information reported to a federal, state or local governmental agency for public health reporting purposes.

# General State Law Landscape

- Currently, the following states have enacted aggregate spend laws:

STATE AGGREGATE SPEND LAWS	
California	District of Columbia
Nevada	Vermont
Massachusetts	Minnesota
Connecticut	West Virginia

# Recent Changes in State Laws

- Minnesota
- Massachusetts
- Vermont
- Maine
- Pending Legislation

# Minnesota

- On January 8, 2013, the Minnesota Board of Pharmacy indicated that it will not require wholesale drug distributors and manufacturers to submit annual disclosure reports for the 2012 calendar year.
- The Board stated that the Sunshine Act preempts the requirements of Minn. Stat § 151.47(f).
- The Board will ask the Minnesota Legislature to repeal §151.47 of the law, but will continue to keep the gift ban requirements of its statute.

# Massachusetts

In July 2012, Governor Patrick amended M.G.L. ch. 111N to:

- Permit payments for reasonable expenses necessary for technical training on a medical device;
- Allow for the provision of, or payment for, modest meals and refreshments in connection with non-CME educational presentations.

# Massachusetts

The final amendments to the regulations provided:

- Modest Meals are allowed, provided the company files quarterly reports.
- “Modest Meal” defined as food and/or drinks judged by local standards and similar to what a HCP might purchase when dining at his/her own expense.
- Expenses Related to Training for medical devices, including travel and lodging are allowed without the previous requirement of a purchase agreement.
- Federal preemption applies for all spend already collected under the Affordable Care Act.

# Vermont

Vermont frequently amends its aggregate spend reporting law, recent amendments passed include:

- Calendar year reporting starting in 2013 for allowable expenditures and gifts – April 1<sup>st</sup> is the new deadline;
- Removal of prescription eyeglasses, sunglasses or eyewear from the definition of prescribed products;
- Banning the provision of over the counter *products* such as lotions, eye drops or similar products to physicians for free distribution to patients after Jan 1, 2013. The gift ban exception will only apply to over-the-counter drugs, nonprescription medical devices and nonprescription durable medical equipment; and
- Changes to reporting of over-the-counter products and donations of certain items to free clinics.



# Maine

- In 2011, the Maine legislature repealed its aggregate spend and reporting law 22 MRSA §2698-A.
- Pharmaceutical companies are no longer required to report marketing costs, or disclose prices or clinical trials to the State of Maine.

# Pending Legislation

- States seemed to be in a holding pattern while they awaited the final “Sunshine” regulations, now that the regulations have been finalized, it will be interesting to see if more states repeal or expand their disclosure laws.

# The Other Side of Aggregate Spend

- With more data regarding the amount of dollars provided to physicians readily available, medical schools, clinical research centers and healthcare systems are also monitoring spend.
  - These institutions are ensuring their HCPs are adhering to institutional policies; and
  - Often assist their physicians to correct erroneous payment data reported by industry.
- Physicians are also becoming more cognizant of their public image and many physicians are opting out of events, meals or all ties to industry.

# Global Transparency – Aggregate Spend Beyond the United States

- Transparency and aggregate spend reporting are becoming global requirements.
- Countries such as: Australia, Denmark, France, Slovakia, India, Japan, Netherlands and UK have enacted some type of transparency law or code.
- The EU Government is currently working on a voluntary code.

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