

# State Law Update: Sunshine Act Disclosure Summit



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# AGENDA

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- **Sunshine Act pre-emption provision**
- **Status of state laws**
- **Next Steps: Where are we and where do we go from here?**

# SUNSHINE ACT PRE-EMPTION

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- **Effective January 1, 2012, Section 1128G(d)(3) of the SSA preempts any state or local law “that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the *type of information* (as described in the Sunshine Act) regarding such payment or other transfer of value.”**
- **Exceptions: No pre-emption if state law requires disclosure or reporting of information:**
  - √ Not of the type required to be disclosed or reported under the Sunshine Act
  - √ That is an exclusion under the Sunshine Act, except as to the exclusion for items with a value below \$10
  - √ By an entity or person other than an applicable manufacturer or covered recipient
  - √ To a federal, state or local government agency for surveillance, investigation, or other public health purposes or for health oversight purposes

## PROPOSED RULE – PRE-EMPTION

- **§ 403.914 Pre-emption of State laws.**

(a) *General rule.* In the case of a payment or other transfer of value provided by an **applicable manufacturer** to a **covered recipient**, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, **the type of information** regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart; (2) Governmental agencies include . . . (i) Agencies that are charged with preventing or controlling disease, injury, disability; (ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

# PROPOSED RULE -- PREEMPTION

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- **Where would this leave us?**

- √ Pre-emption for “types” of information that must be disclosed under Sunshine Act
- √ Exceptions to pre-emption are potentially broad
  - If of “a different type”
  - If within an exception under Sunshine Act, except for the *de minimis* amount exception
  - If imposed on entities other than “applicable manufacturers”
  - If payments disclosures are to entities other than “covered recipients”
  - If payment is of the “same type” but disclosure is required for a public health surveillance or investigation purpose
- √ No specific guidance from CMS on which state laws or regulations are preempted
- √ Unless CMS provides additional guidance in the Final Rule, states will have discretion to enact or potentially enforce laws without knowing where to draw the lines

## STATE OF THE STATES

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- **Ethics Code Requirements (DC, NV, CA, MA, CT, CO)**
- **Gift Bans (VT, MA, MN)**
- **Marketing Expense Disclosure Requirements (DC, VT, MA, WV, MN)**
- **Licensing requirements (DC)**
- **ME Disclosure Requirements (Repealed)**

## ETHICS CODE REQUIREMENTS (NOT PRE-EMPTED)

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- **DC, NV, CA, MA, CT, CO require compliance with either the PhRMA Code, the AdvaMed Code, or some other mandated ethics code**
  - √ DC – Requires sales representatives to certify compliance as part of licensing provisions
  - √ CA, NV, MA, and CT – Require annual certification of compliance with code of conduct
- **Ethics code requirements (and DC licensing requirement) are not pre-empted under the Sunshine Act**

# GIFT BANS (NOT PRE-EMPTED)

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- **VT, MA and MN**

- ✓ VT – Dec. 22, 2011 Guide to VT Prescribed Products – states that VT gift ban is not preempted
- ✓ MA – Dec. 28, 2011 letter from Madeleine Biondolillo to Pharmaceutical and Device Manufacturers – Sunshine Act will not preempt gift ban, fee assessments, or self-auditing requirements
- ✓ MN – no statement from AG yet re: preemption, but fair read of the Sunshine Act preemption provision is that gift ban will not be pre-empted



## **PAYMENTS BY ENTITIES THAT ARE NOT “COVERED MANUFACTURERS” (NOT PRE-EMPTED)**

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- **State laws that require payments by entities that are not “covered manufacturers” are not pre-empted**
  - √ E.g., Both the MA and VT laws cover payments to “any entity that: (a) is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, biologics, or medical devices, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis; or (b) is directly engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, biologics, or medical devices;”
  - √ These laws do not apply to licensed wholesale drug distributors, licensed hospitals, or registered retail pharmacies.
- **Definitions broader than the Sunshine Act**

## PAYMENTS TO ENTITIES OTHER THAN HCPS AND TEACHING HOSPITALS (NOT PRE-EMPTED)

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- **State laws requiring disclosure of payments to entities other than “covered recipients” under the Sunshine Act (physicians and teaching hospitals) are not pre-empted**
- **For example, VT and MA contain broader “covered recipient” definitions**
  - √ VT law requires disclosure of payments to VT health care providers (including hospitals, nursing homes, health plan administrators and others authorized to dispense or purchase prescription drugs), academic institutions in VT or providing services in VT, nonprofit hospital foundations in VT or providing services in VT, professional, educational and patient organizations representing or serving health care providers or consumers in VT or providing services in VT, and members of the Green Mountain Care Board
  - √ MA law requires disclosure of payments to physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, hospitals (whether teaching or not), nursing homes, and all other purchasers, prescribers, or dispensers of drugs, biologics, or medical devices.

## SUNSHINE ACT: “TYPES” OF DISCLOSURES (PRE-EMPTED)

- Consulting fee
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and lodging
- Education
- Research
- Royalty or license
- Current or prospective ownership or investment interests
- Charitable contribution
  - Any payment or transfer of value, made to an organization with tax-exempt status under the Internal Revenue Code of 1986, that is not more specifically described in another category
- Direct compensation for serving as a faculty or as a speaker for a medical education program
  - CMS interpreting as including *all* speaker programs, but may consider adding another category
- Grants
- Others identified by the Secretary

## PAYMENTS EXEMPT FROM DISCLOSURE UNDER SUNSHINE (NOT PRE-EMPTED)

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- **Sunshine Act exemptions include:**
  - ✓ **TOV of less than \$10, unless aggregate transfer to HCP exceeds \$100 in a calendar year**
  - ✓ Product samples that are not intended to be sold and are intended for patient use
  - ✓ Educational materials that directly benefit patients or are intended for patient use
  - ✓ Loans of medical devices for a short term trial period not to exceed 90 days, to permit evaluation of the device
  - ✓ Items or services provided under contract warranty, including replacement of a device where terms of the warranty are set forth in the purchase or lease agreement
  - ✓ A TOV to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

## PAYMENTS EXEMPT FROM DISCLOSURE UNDER SUNSHINE (NOT PRE-EMPTED) *(con't)*

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- √ Discounts (including rebates)
- √ In-kind items for the provision of charity care
- √ A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- √ Payments to provide health care to employees under a self-insured plan offered by an applicable manufacturer
- √ For covered recipients who are licensed non-medical professionals, transfers solely for non-medical professional services
- √ Payments solely for the services of the covered recipient with respect to expert or other services in connection with litigation matters
- √ TOV made indirectly to a covered recipient through a third party where the applicable manufacturer is unaware of the identity of the covered recipient

## **“TYPES” OF STATE DISCLOSURES NOT COVERED BY SUNSHINE (NOT PRE-EMPTED)**

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- **DTC Advertising Expenses: WV and DC**
- **Sample reporting: VT and DC**
- **Coupons, vouchers, starter packs, and discount cards: VT**
- **Disclosures of AMP, AWP, WAC or other pricing metrics: TX, VT, NM**
- **Reporting of any other types of payments not covered by the Sunshine Act requirements**

## SCOPE OF VT AND MA REPORTING REQUIREMENTS TO BE DETERMINED

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- **VT and MA disclosure laws impose broad requirements, which in certain ways go beyond Sunshine Act requirements:**
  - √ VT requires disclosure of: (a) scholarships or fellowships for medical students; (b) conference sponsorships; (c) articles or journals provided to HCPs; (d) medical device loans for short term periods and technical training on use of a medical device; (e) Payment of reasonable expenses necessary for technical training of HCPs on use of a medical device; (f) free OTC product samples; (g) donations to a clinic of prescription or OTC drugs; and (h) distribution of medical foods to HCPs
  - √ MA requires disclosure of any transfer of value of \$50 or more to a covered recipient in connection with the manufacturer's "sales and marketing activities," (e.g., intended to promote a product, evaluate effectiveness of sales force, or influence prescribing) excluding only: (a) payments in conjunction with genuine research and clinical trials; (b) provision of prescription drugs for use by patients or demonstration or evaluation units; (c) in-kind items for charitable care; (d) royalty payments; and (e) discounts and rebates

## VT STATEMENT RE: PRE-EMPTION

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- **VT December 22, 2011 statement on Sunshine Act pre-emption:**
  - √ Gift ban and sample reporting will be unaffected
  - √ Some, but not all, of the disclosure requirements will be pre-empted
  - √ “Federal law is narrower than Vermont’s law in several ways, however; for example, only physicians and teaching hospitals are covered recipients under the federal law. Therefore, manufacturers must take care to make all non-preempted disclosures regarding allowable expenditures and permitted gifts.”
  - √ Federal law does not prohibit duplicative disclosures – VT AG will accept duplicate disclosures (e.g. submit federal disclosures to the state)



## MA STATEMENT RE: PRE-EMPTION

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- **MA December 28, 2011 statement on Sunshine Act pre-emption:**
  - √ Sunshine Act pre-empts “any pertinent state law that requires the collection and reporting of the same data elements.”
  - √ Because CMS not requiring collection of data under Sunshine until after final rule is issued, MA view is that pre-emption has not yet begun.
  - √ Until final rule is issued, MA states that manufacturers “must continue to collect and submit disclosures on all covered recipients as currently defined, including physicians, nurse practitioners, physician assistants, pharmacists, dentists, clinics, clinical laboratories, all hospitals, nursing homes, and all other purchasers, prescribers, or dispensers of drugs, biologics, or medical devices.”
  - √ All other requirements of MA’s regulations will remain in effect, including the gift ban, the requirement to report instances of non-compliance with the gift ban, the annual registration requirement and associated fee, and the annual self-audit for compliance with the MA requirements.

## STATUS AND NEXT STEPS

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- **“Types” of disclosures required under the Sunshine Act are not clearly defined**
- **CMS has not yet articulated its view on the specific scope of federal pre-emption**
- **States have acknowledged that certain disclosure requirements will be pre-empted, but have not been specific**
- **States have not yet determined the scope of the “law enforcement” exception to pre-emption of state laws requiring disclosures of “the same type” of payments required under the Sunshine Act**
- **States have suggested duplicative disclosures**
- **Stay tuned but, in the meantime, continue to report under all state laws as required**