Understanding Federal And State Disclosure Laws From All Corners

John P. Oroho, JD

PORZIO LifeSciences

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ROADMAP

Overview: Sunshine Act (Section 6002 – Transparency)

- Applicable Manufacturers & Group Purchasing Organizations
  - Definitions
  - Registration
  - Assumptions Documents & Legal Attestation
- Covered Recipients
  - Definitions
  - Registration
- Data Capture and Reporting:
  - Transfers of Value & Payments
  - Reporting (General, Research and Ownership)
- Data Submission:
- Dispute Process:
  - Timing
  - Process
  - Resources
- Beyond Data Capture:
  - Managing the Process
  - Policies and Procedures

Overview: Federal Samples (Section 6004 – Prescription Drug Sample Transparency)

Overview: Transparency on a State Level

- Timeline for Selected State Aggregate Spend & Marketing Disclosure Laws
- Categories of State Laws
- State Updates
- Other Considerations
- Reporting Forms

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Overview

Subtitle A – Section 6002 – Transparency Reports and Reporting of Physician Ownership or Investment Interests

("The Sunshine Act")

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2013 – 2014 Federal Reporting Timeline

08/01/2013

Data collection began

03/31/2014

Due date for Phase 1 Aggregate reports

06/1/2014

Phase 2, Step 1 opened – Registration to CMS Portal & Delegation of system user roles began

06/9/ 2014

Phase 2, Step 2 opened – Final submission of Data and Attestation period

06/30/2014

Close of Phase 2 (Phase 2 was extend until July 7, 2015)

7/14/2014 – 8/2/2014 (20 days) and 8/15/2014 – 9/8/2014 (25 days)

Review and Dispute Period (45 Days)

09/15/2014 Correction period for Industry began

09/30/2014 Public Data Became Available

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CMS.gov Centers for Medicare & Medicaid Services

Federal Law - Background

- P.L. 111-148 – The Patient Protection and Affordable Care Act ("PPACA")
  - Passed by House March 21, 2010 (with HR 4872)

- Title VI – Transparency and Program Integrity ("The Sunshine Act")
  - Subtitle A – Physician Ownership and Other Transparency
    - Section 6002 – Transparency Reports and Reporting of Physician Ownership or Investment Interests

    - Section 6004 – Prescription Drug Sample Transparency

February 1, 2013 - CMS released the Final Regulations:

- Regulations address requirements under 6002
- Regulations published with significant comments from CMS in the preamble

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What is the Sunshine Act?

The Sunshine Act requires Applicable Manufacturers and Applicable Group Purchasing Organizations (GPOs) to report to the Centers of Medicare & Medicaid Services ("CMS") any "**direct**" or "**indirect**" payment or other transfer of value provided to a Covered Recipient or any payment provided to a third party on behalf of a covered recipient during a calendar year.

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Federal Law- Preemption

PREEMPTION

The provisions under P.L. 111-148 preempt any state or local law or regulation that requires an applicable manufacturer to disclose or report the same information required by the law…

BUT

…does *not* preempt any state or local law or regulation that requires the disclosure or reporting of information not required to be disclosed or reported under the Federal law.

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Important Dates

March 23, 2010	• The Patient Protection and Affordable Care Act Signed into Law
February 1, 2013	• Regulations Finalized by CMS
August 1 – December 31, 2013	• Data Collection – First Reporting Period
September 30, 2014	• Information Published on Public Government Website
January 1, 2015	• 2015 Open Payments Cycle Registration and Data Submission Opens
March 31, 2015	• 2015 Open Payments Cycle Registration and Data Submission Opens
June 30, 2015	• Public Will Have Access to Data

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Applicable Manufacturers & Group Purchasing Organizations

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Key Term: Applicable Manufacturers

Applicable Manufacturer (AMs):

AMs means an entity that is operating in the United States and falls within one of the following categories:

- (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, re-packagers, re-labelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

- (2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Ownership & Assistance

- Common Ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities.
  - This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

- Assistance and Support means providing a service or services that are *necessary or integral* to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

- Question: Do we include an affiliated company that only provides clinical and/or research support?

Reporting Limitations

Report only payments and transfer of value related to covered drugs, devices, biologicals, or medical supplies if:

- AM has total (gross) revenues from covered product that constitute less than 10% of total (gross) revenue during the fiscal year preceding the reporting year
- AM falls under paragraph (2) of the definition and only provides assistance or support to an applicable manufacturer under paragraph (1) of the definition
- AM has separate operating divisions that do not produce any covered products (for example, animal health division)
- AM does not manufacturer a covered product except when under a written agreement to manufacturer the covered product for another entity, do not hold the FDA approval, licensure, or clearance for the covered product, and are not involved in the sale, marketing, or distribution of the product

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Key Term: Group Purchasing Organizations ("GPOs")

GPOs:

The Sunshine Act's implementing regulations define applicable GPOs as those that:

- Operate in the United States (meaning that they have a physical location within the U.S. or otherwise conduct activities in the U.S., either directly or through a legally-authorized agent); AND

- Purchase, arrange for purchase, or negotiate the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the purchasing entity itself.

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Industry Registration

Among other things, Industry Registration includes:

- Registration in CMS's Enterprise Portal at https://portal.cms.gov
- Submission and completion of corporate (entity) profile information
- Registration of authorized official(s)
- Delegate specific user roles (beyond the authorized official)
- Attest to submitted detailed data

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Covered Recipients

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Key Term: Covered Recipients

Physicians:

- Unless a physician is a bona fide employee of the applicable manufacturer reporting the payment, “Physicians” includes: (1) doctors of medicine and osteopathy, (2) dentists, (3) podiatrists, (4) optometrists, and (5) chiropractors.
- It does not include residents; however, it does include fellows.

Teaching Hospitals:

- Any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.
- CMS will publish a list of teaching hospitals 90 days prior to the start of data collection each year.

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Challenge: Identifying Teaching Hospitals

CMS published the List of Teaching Hospitals in October – includes 1100+ entities

Examples:

- ✓ The Eye Foundation Inc, Birmingham AL
- ✓ Mountainside Hospital Llc, Montclair, NJ
- ✓ Alegent Health Bergan Mercy Health System, Omaha NE
- ✓ Erie County Medical Center Corporation, Buffalo NY
- ✓ Oklahoma State University Medical Center Trust, Tulsa OK

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CMS FAQ 9002: Teaching Hospitals

Question: Are dental schools that are affiliated with universities and health care institutions, but do not match the name or address information provided on CMS' teaching hospital list, still considered teaching hospitals for the purposes of reporting?

Answer: The teaching hospital list compiled by CMS is a complete list of teaching hospital covered recipients. Applicable manufacturers and applicable group purchasing organizations should collect the TIN from a hospital, or in this case, dental school, that they believe is affiliated with a teaching hospital in order to correctly identify the teaching hospital's name and address from the list. Additionally, as discussed in the proposed and final rule, a teaching hospital is any institution that received payments under sections 1886(d)(5)(B), 1886(h) or 1886(s) of the Act. (FAQ9002)

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Covered Recipient Registration

Voluntary process, but is required if the covered recipient wants to review and dispute any of the data reported by AMs and GPOs.

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Covered Recipient Registration

- Includes:
  - User registration in CMS's Enterprise Portal; and
  - Physician and teaching hospital registration in the Open Payments system, and allows them to review and dispute data submitted by applicable manufacturers and applicable group purchasing organizations ("GPOs") prior to public posting of the data.

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Data Capture

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Key Terms: Transfers of Value & Payments

- Payments or other transfers of value
  - A transfer of *anything* of value:
    - This includes any direct or indirect payment or other transfer of value provided to a covered recipient or any payment provided to a third party on behalf of a covered recipient (e.g., honorarium, food, travel cost, textbooks, scientific reprints, etc)

- Indirect and Third party payments
  - The Sunshine Act defines indirect and third party payments as follows:
    - Indirect Payment: Payment to a covered recipient as a pass through payment from a third party (e.g., payment to a hospital for a preceptorship where a physician would receive all or a portion of the payment)
    - Third Party Payment: Payment to a third party at the request of or designated on behalf of a covered recipient (e.g., speaker designates that he wants his honorarium to be paid to a charity)

Payments Less than $10.18

- Individual payments Less than $10.18 are excluded unless the aggregate for the year exceeds $101.75
  - Small incidental items that are under $10.18 (e.g., pens and note pads) provided at large conferences are exempted from reporting requirements, including the need to track for aggregate purposes.

*When reporting small payments under the $10.18 threshold that aggregated to $101.75 or more for the year, manufacturers may report it as a single payment to a covered recipient if it falls within the same nature.

Three (3) Types of Reports

General Payments

- Includes payments and transfer of value given to a covered recipient (physicians, teaching hospital)
  - Includes payments made to group practices, other individuals or entities on behalf of a covered recipient

Research Payments

- Includes all payments and transfers of value made in connection with an activity that meets the definition of research and that are subject to a written agreement or research protocol

Physician Ownership and Investment Interest

- Any ownership or investment interests held by a physician or immediate family member in a manufacturer or GPO
  - Includes stocks, stock options, dividends, profits or other return on investment

General Payments Report

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General Payments: What Is Included in the Report?

- Name
  - Middle initial required
  - From NPPES
- Business address
  - *Primary* business address
- Specialty, for physicians
  - From manufacturers' internal records, using NPPES values
  - Include the taxonomy code
- National Provider Identifier ("NPI"), for physicians
  - From NPPES
- State license number and state of licensure of the recipient, for physicians
  - Up to five
- Physician Owner or Investor Flag
- Amount

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General Payments: What is Included in the Report? (continued)

- Date
  - Choose whether to report each payment as separate line item, or as a single line item using the first payment date as the reported date
  - Choose to report the activity date or payment date
  - Consistency within a “Nature” type
- Form – the method of the payment
- Nature – the reason for the payment
- Recipient of payment
  - Payment to a covered recipient as a pass through payment from a third party → report in the name of that covered recipient
  - Payment to a third party at the request of or designated on behalf of a covered recipient → report in the name of that covered recipient, and the name of the *entity* that received the payment or indicate "individual" if made to an individual
- Product
  - Drugs and biologicals: marketed name and the National Drug Code (or the name registered on clinicaltrials.gov)
  - Devices and medical supplies: marketed name, or the therapeutic area or product category
  - Also, “none” or “non-covered”
- Contextual information (optional)

General Payments: Nature of Payments

1. Consulting fee
2. Compensation for services other than consulting, including serving as faculty or a speaker at an event other than continuing education
3. Honoraria
4. Gift
5. Entertainment
6. Food and beverage
7. Travel and lodging (including the City, State, Country)
8. Education
9. Charitable contribution
10. Royalty or license
11. Current or prospective ownership or investment interest
12. Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
13. Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
14. Grant, or
15. Space rental or facility fee (teaching hospitals only)

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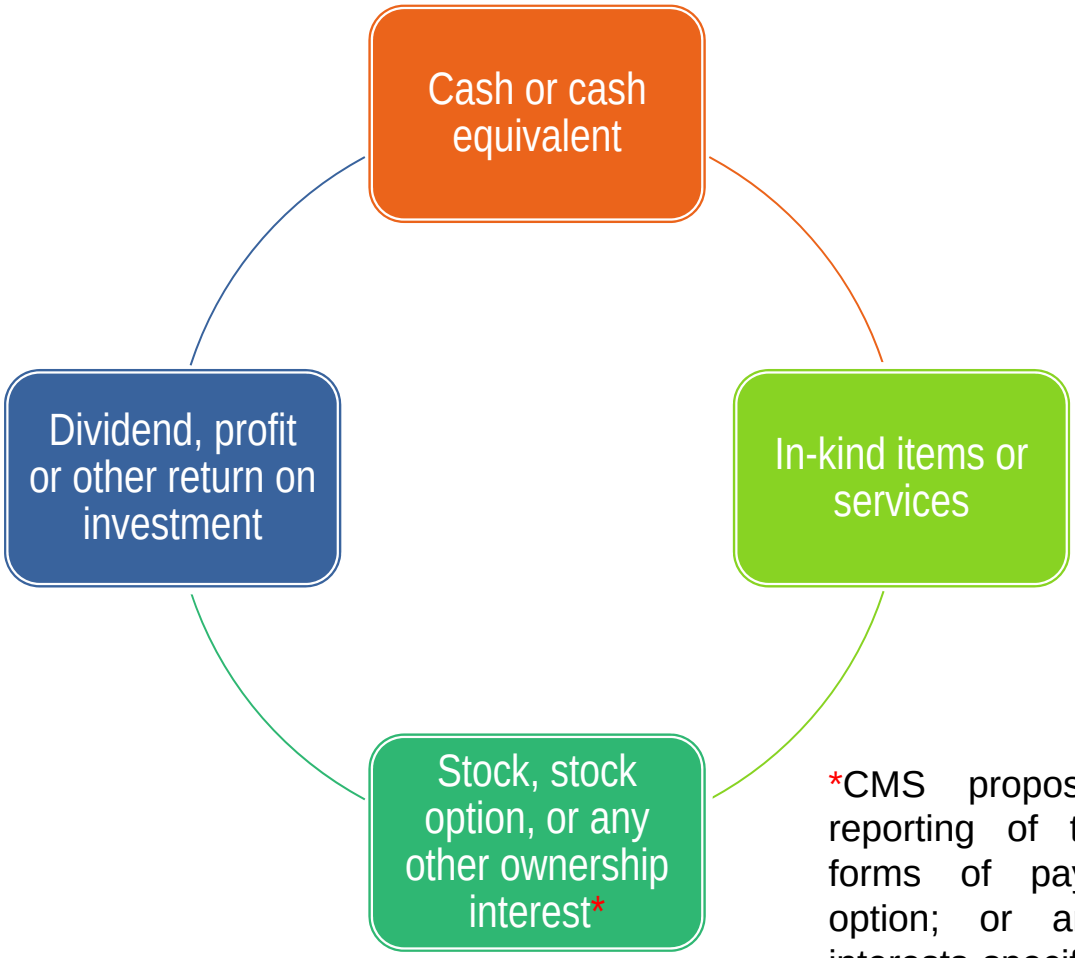
General Payments: Forms of Payment



*CMS proposes to require the reporting of the following distinct forms of payment: stock; stock option; or any other ownership interests specified in § 403.904(d)(3) to collect more specific data regarding the forms of payment. 79 FR 40383 (July 11, 2014).

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Challenge: Indirect Payments

- Indirect payments or transfer of value are excluded where the applicable manufacturer is unaware of the identity of the covered recipient.

- If manufacturer learns of the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year, manufacturer "knows".

Know, Knowing or Knowingly

- Means that a person, with respect to information:
  - Has actual knowledge of the information
  - Acts in deliberate ignorance of the truth or falsity of the information, or
  - Acts in reckless disregard of the truth or falsity of the information
- Requires no proof of a specific intent to defraud

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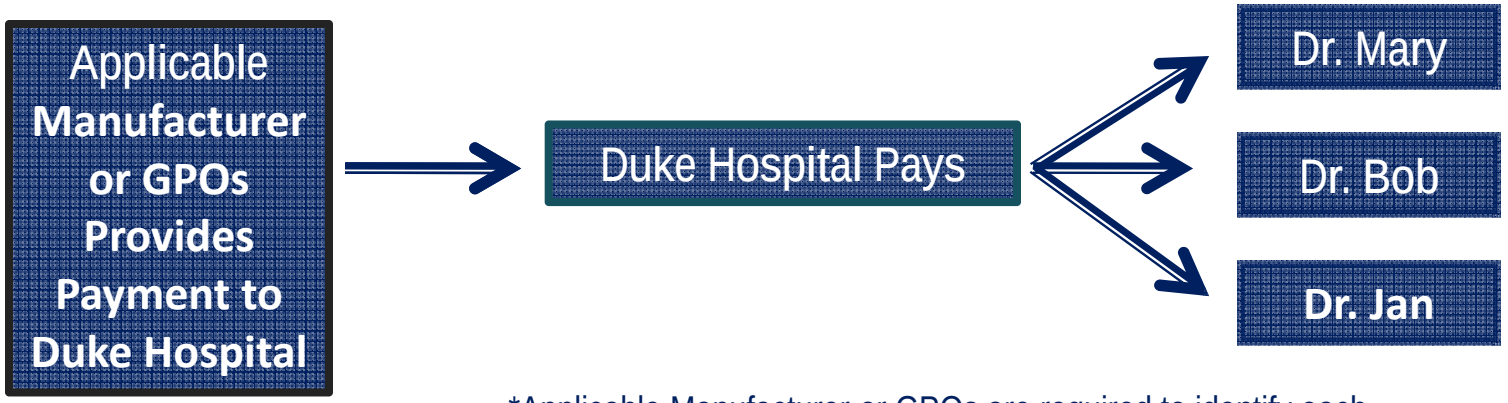
What is an Indirect Payment?

Reporting of Indirect Payment

Indirect Payment: The Sunshine Act defines an **"Indirect Payment"** as a payment provided to a covered recipient through an intermediary (e.g., a specialty society or research organization). The payment is considered indirect and reportable, if Applicable Manufacturers or GPOs:

- Requires, instructs, directs, or otherwise causes an intermediary to provide the payment or other transfer of value to a covered recipient.

Indirect Payment Example:



*Applicable Manufacturer or GPOs are required to identify each covered recipient who receives a payment or transfer of value, or any portion thereof, and report accordingly

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CMS FAQ8992: Indirect Payments

Question: Is a payment or other transfer of value considered indirect if an applicable manufacturer utilizes a market research company's services to conduct double-blinded market research with primary care physicians, which includes paying physicians for participating?

- Answer: No, a payment or other transfer of value provided to a market research company to conduct double-blinded market research with physicians is not considered an indirect payment. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value. Additionally, under section 1128G(e)(10)(A) of the Social Security Act, Open Payments excludes reporting of payments when an applicable manufacturer is unaware of the covered recipient, and the payment to the covered recipient is made indirectly through a third party, such as the market research company, in the above facts.

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What is a Third Party Payment?

Reporting of Third Party Payment

Third Party Payment: The Sunshine Act considers a payment provided to a third party at the *request of or designated* on behalf of a covered recipient to be a third party payment.

- Report in the name of that covered recipient, and the name of the *entity* that received the payment or indicate "individual" if made to an individual

Example of Third Party Payment

In this example, the reporting will be made against Dr. James indicating that the actual payment was made to *James MD and Associates, LLC*.

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Continuing Medical Education (CME) Payments

Payments related to compensation for speaking at continuing educational programs are exempt from the reporting requirements if ALL of the following conditions are met:

1. Event meets the accreditation or certification requirements for standards for continuing education with one of the following:
   a. The Accreditation Council for Continuing Medical Education
   b. The American Academy of Family Physicians
   c. The American Dental Association's Continuing Educational Recognition Program
   d. The American Medical Association
   e. The American Osteopathic Association
2. Applicable manufacturer does not directly pay the speaker
3. Applicable manufacturer did not select the covered recipient speaker or identified individuals to be considered as speakers for the program.

CMS FAQs: Continuing Medical Education

Question: Are payments provided to physicians for speaking at a continuing medical education event reportable?

- Answer: Speaker compensation at continuing education event such as Continuing Medical Education (CME) conference is not required to be reported by an applicable manufacturer if all of the following criteria are met: (1) the CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association, (2) the applicable manufacturer does not select or suggest the covered recipient speaker nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the accredited or certified continuing education programs; AND (3) the applicable manufacturer does not directly pay the covered recipient speaker.
(FAQ8165)

Question: Are payments provided as compensation to speakers at CME events run by CME providers that that are accredited or certified by accreditation or certification bodies other than those enumerated in 42 CFR § 403.904(g)(1)(i) eligible for the exclusion from reporting (assuming they also meet the other requirements for exclusion in § 403.904(g)(1))?

- Answer: No, the list of accrediting or certifying bodies in the final rule at 42 CFR § 403.904(g)(1)(i) is exhaustive; in order to qualify for the exclusion in § 403.904(g)(1), CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities in § 403.904(g)(1)(i) and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities. Payments to speakers at CME events that are not run by CME providers accredited or certified by one of the entities in § 403.904(g)(1) -- or that don't meet either or both of the other two requirements for exclusion in § 403.904(g)(1) -- are reportable payments or other transfers of value for Open Payments. We will consider modifications to this provision in possible future rulemaking.
(FAQ8398)

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CMS FAQs: Continuing Medical Education

Question: Are educational materials or items associated with an accredited or certified CME program that meets all three conditions, such as slides or handouts, included in the tuition fees for continuing education events excluded from reporting?

- Answer: Yes. Educational materials that are included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides, are excluded from reporting under Open Payments provided that the content does not contain any CME sponsor information, the content is related to the CME program, the value is de minimis, and the funds used for the materials came from the same CME program grant. (FAQ8388)

Question: Are payments for travel, lodging and meals to speakers and faculty of accredited or certified CME events that meet all three conditions established in the final rule included in the total compensations that are exempt from reporting?

- Answer: Yes. Lodging, travel and meals for speakers of an accredited or certified CME event meeting all three requirements in 42 CFR 403.904(g)(1) will be deemed to be included in the total speaker compensation and, therefore, exempt from reporting under Open Payments. However, travel, lodging and meals and all other natures of payments provided in conjunction with the accredited or certified CME event (with the exception of educational materials included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions, such as handouts, web downloads or printed slides) will need to be reported for physician attendees (who are not speakers). These payments would need to be reported under the appropriate nature of payment categories, such as food and beverage, travel and lodging, or entertainment, as appropriate. The excluding characteristic for meals is when allocating the cost of the meal among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable. (FAQ8386)

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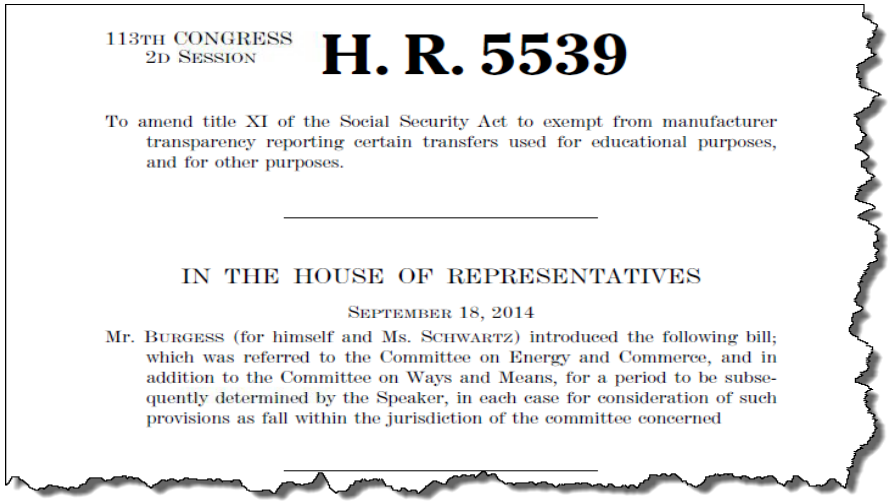
Bipartisan Bill to Exclude Educational Materials From Reporting
(CME and Medical Texts)



113TH CONGRESS
2D SESSION

H. R. 5539

To amend title XI of the Social Security Act to exempt from manufacturer transparency reporting certain transfers used for educational purposes, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 18, 2014

Mr. BURGESS (for himself and Ms. SCHWARTZ) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

Transparency Reports and Reporting of Physician Ownership or Investment Interests, Sec. 1128G. [42 U.S.C. 1320a-7h]

(B) Exclusions.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(iii) Educational materials that directly benefit patients or are intended for patient use, including peer-reviewed journals, journal reprints, journal supplements, and medical textbooks;

(xiii) A transfer of anything of value to a covered recipient who is a physician if the thing of value is intended solely for purposes of providing continuing medical education to the physician.*

*Proposed amendments in red font.

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Challenge: Reporting Food and Beverage

- When food and beverage are provided in a group setting, applicable manufacturers must calculate the per person value by dividing the entire cost of the food and beverage by the total number of both covered recipients and non-covered recipients who participated in the meal.

- The per person value must be reported as the payment or transfer of value for the covered recipients only.

  Example: Lunch served at a doctor's office costs $150 and the participants included 4 doctors and 6 staff members. The value reported for each covered recipient would be: $150/10 = $15.

Note: Buffet meals, snacks, soft drinks, or coffee generally available to all participants of a large scale conference or large scale event are exempted from reporting.

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Question: What is "large scale?"

CMS FAQs:
Food and Beverage

Question: Is a distributor required to report food and beverages that are provided during an open house for a new distributorship center opened by a distributor?

- Answer: Yes. If the distributor meets the definition of an applicable manufacturer, as defined by 42 C.F.R §403.902, food and beverages provided to covered recipients and physician owners or investors are required to be reported. The applicable manufacturer should divide the value of the food by the number of those who partook in the food. The value of the food still needs to be accounted for even if the event is a large scale event as long as the applicable manufacturer can identify the covered recipients of the food. (FAQ9140)

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Research Payments Report

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Research Payments: Written Agreements/Research Protocols

The aggregated amount of any payments for services included in the written agreement/research protocol, which may include:

- Costs associated with patient care (e.g., diagnostics, exams, lab expenses)
- Time spent by health care professionals treating patients and managing the study
- Provision of study drugs, devices, biologicals, and medical supplies or other in-kind items
- The payment amount should NOT include any payments for activities which are separate or segregable from the written agreement or research protocol or are paid through a method different than that of the research

Examples:

- Payments made directly to a physician for serving on a study steering committee or data monitoring committee that are not a part of the larger research payment should be reported separately.
- Payments for medical research writing and/or publication would be included in the research payment, if the activity was included in the written agreement or research protocol and paid as a part of the research payment.

Research Payments: Reporting

- Payments or transfers of value made in connection with research that are subject to a written agreement OR research protocol are subject to special reporting requirements

- Includes payments and transfers of value related to pre-clinical, phases I through IV clinical studies, and investigator-initiated research

Research-related payments must be reported to CMS separately and include the following information:

a. Name of the research institution, individual or entity receiving payment, and
b. Total aggregate amount of the research payment
c. Name of research study
d. Name(s) of any related covered drug, devices, biological, or medical supplies and the National Drug Code(s)
e. Indicate if eligible for delayed publication
f. Optional: clinicaltrials.gov identifier
g. Optional: Contextual information

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Challenge: Delayed Publication

Publication for research payments can be delayed in the following circumstances:

- Payment is related to the research/development of new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.
- Payment is related to a clinical investigation regarding a new product (drug, device, biological, or medical supply).
- If the Publication Includes a written agreement and research protocol between manufacturer and covered recipient. Have you reviewed your agreements? Are they up-to-date?

CMS does not publicly post delayed payments until:

- The date of approval, licensure or clearance of the covered drug, device, biological, or medical supply by the FDA, or
- Four calendar years after the date the payment or other transfer of value was made, whichever is earlier.

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Ownership or Investment Interests Report

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Ownership or Investment Interests: Reporting

Reports will Include:

- Name of physician
- Specialty, NPI and state license number of physician
- Physician primary business address
- Indication of whether ownership or interest held by physician or family member
- Dollar amount invested by physician or family member
- Value and terms of each ownership/investment interest
- Direct and indirect payments or other transfer of value provided to a physician holding ownership or investment interest, or on behalf of a physician holding such an ownership or investment interest must be reported.

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Ownership or Investment Interests

Each applicable manufacturer and GPO must report to CMS all ownership and investment interests held in the manufacturer or GPO by a physician or immediate family member of a physician.

Immediate family member includes the following:

- Spouse
- Natural or adoptive parent, child, or sibling
- Stepparent, stepchild, stepbrother, or stepsister
- Father-, mother-, daughter-, son-, brother-, or sister-in-law
- Grandparent or grandchild
- Spouse of a grandparent or grandchild

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Ownership or Investment Interests?

- Stock
- Stock options
- Partnership shares
- LLC memberships
- Loans
- Bonds
- Other financial instruments secured with entity's property or revenue

- May be direct or indirect

- Ownership or investment interest in a publicly traded security or mutual fund is excluded

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CMS FAQs: Ownership or Investment Interests

Question: For purposes of reporting physician ownership under section 1128(G)(a)(2) of the Social Security Act, does an "immediate family member" of a physician include the lawfully married same-sex spouse of a physician and family members that result from the lawful marriage of individuals of the same sex?

- Answer: Yes. "Immediate family member" is defined in the implementing regulations at 42 C.F.R. § 403.902 as any of the following: (1) Spouse; (2) Natural or adoptive parent, child, or sibling; (3) Stepparent, stepchild, stepbrother, or stepsister; (4) Father-, mother-, daughter-, son-, brother-, or sister-in-law; (5) Grandparent or grandchild; (6) Spouse of a grandparent or grandchild. The term "spouse" is genderneutral, and is properly read to include lawfully married spouses, including same-sex spouses. In United States v. Windsor, 570 U.S. __, 113 S. Ct. 2675 (2013), the Supreme Court ruled that section 3 of the Defense of Marriage Act, which had defined marriage for federal purposes as between opposite sex spouses, is unconstitutional. In light of this decision, the Department has instituted a policy of treating same-sex marriages on the same terms as opposite-sex marriages to the greatest extent reasonably possible. This FAQ clarifies Windsor's application to the requirement to report physician ownership under section 1128(G)(a)(2) of the SSA. For purposes of this reporting requirement, the same-sex spouse of a physician and the family members that result from same-sex marriages are considered "immediate family members" if the marriage was celebrated in a state or other jurisdiction, whether foreign or domestic, that permitted the marriage under its laws, or if the states(s) or other jurisdiction(s) where the couple lives recognizes the marriage as a legally valid marriage. (FAQ10014)

Reporting Exceptions

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What is Excluded From Reporting?

- Payment that is less than $10.18, unless the aggregate for year exceeds $101.75. All payments should be tracked in order to determine if the $101.75 threshold was met.
- Product samples intended for patient use
- Educational materials distributed for the benefit of patients or intended for patient use
- Loans of covered devices, not to exceed 90 days, to permit evaluation by a covered recipient
- Services/items covered under a warranty
- Transfer of anything of value to a covered recipient, when a patient, research subject, or participating in data collection, and not acting in his/her professional capacity
- Discounts, including rebates

What is Excluded From Reporting?

(Continued)

- In-kind items used to provide charity care
- Dividends/profit, ownership, or investment interest in a publicly traded security/mutual fund
- Payments for the provision of health care to the applicable manufacturer's employees under the plan provided by any manufacturer who offers a self-insured plan
- Payments provided to a covered recipient if the payment is solely for non-medical professional services
- Payments for a civil or criminal action or an administration proceeding
- Any indirect payment or transfer of value where the manufacturer is unaware of the identity of the covered recipient
- A payment or transfer made solely in the context of a personal, non-business related relationship

Educational Materials…

- Educational materials/items that directly benefit patients or are intended to be used by or with patients are excluded.

  Example: Anatomical models provided for patient education or a flash drive containing educational materials to be distributed to patients.

Question: Is a textbook donation to a medical center library for the general use of all employees reportable?

Answer: The textbook donation would be considered a reportable event if: 1) The medical center library is part of a teaching hospital; or 2) The donation was an indirect payment or transfer of value to a designated physician or group of physicians. Payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient, must be reported in the name of the covered recipient, as well as the name of the entity that received the payment at the covered recipient's request or designated on the covered recipient's behalf according to 42 C.F.R. § 403.904(c)(10). Additionally, an indirect payment, defined at § 403.902, is a payment or other transfer of value made by an applicable manufacturer to a covered recipient through a third party, where the applicable manufacturer requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient. However, CMS does not believe that a payment that ultimately is passed on to a covered recipient has to be reported if the applicable manufacturer "did not intend or expect that a covered recipient would receive any portion of the payment or other transfer of value." (78 Fed. Reg. 9489). (FAQ8986)

CMS FAQs: Educational Materials

Question: Are items or materials used to educate physicians, which may indirectly benefit patients, included in the education materials exclusion?

- Answer: No, the education material exclusion is limited to materials and items directly benefiting patients or intended for patient use as required by the Affordable Care Act Section 6002. Education materials, such as medical textbooks or journal reprints, that are educational to covered recipients but are not intended for patient use or directly beneficial to patients are not included in the exclusion. (FAQ8171)

Question: How should applicable manufacturers or applicable group purchasing organization determine the value of journal reprints provided to covered recipients?

- Answer: The value of a journal reprint should reflect the cost that an applicable manufacturer or applicable group purchasing organization paid to acquire the reprint from the publisher or other distributor. Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document clarifying any assumptions made to determine the value of journal reprints. (FAQ8370)

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Data & Report Submission

PORZIO LifeSciences

Data Submission:

Users in the role of Submitter should:

- Perform test file uploads and submit data files to validate the file structure of the file (Optional); and
- Utilize the error report produced by the Open Payments system to fix any data errors (if any) in submitted files (Mandatory).
- Users should use the Error Code List in conjunction with the Error Code Report.

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Data Submission

The Open Payments System will also allow:

- Submitters to perform final data submission/validate contents (which includes a series of checks to match the reported data to the appropriate physicians and teaching hospitals); and

- Attesters to attest to the accuracy of their submitted detailed 2013 payment or other transfer of value data, or ownership/investment interest data.

Data Submission: Attestation

The Open Payments System will allow:

- Applicable manufacturers and applicable GPOs to attest to the timeliness, accuracy and completeness of the data submitted. This is the final step in the data submission and reporting process. This step is mandatory.
- Data not attested to will not be considered as reported.
- Attesters, at a minimum, must select the following two checkboxes to proceed with the attestation process:
  - ❑ I am attesting that I am a Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization with the authority to attest to the information submitted to the Open Payments system.
  - ❑ I am attesting that the information reported is timely, accurate, and complete to the best of my knowledge and belief.

Data Submission: Assumption(s)

The Open Payments System will allow:

- Applicable manufacturers/GPOs to submit an assumptions document with their assumptions and methodologies when reporting payments or other transfers of value, or ownership or investment interests
  - Assumptions documents are voluntary
  - It will not be made available to the public, covered recipients or physician owners or investors, however, according to CMS, "we do not intend to use the assumptions document for prosecution, but acknowledge that the reporting based on the assumptions would be open to prosecution. Other HHS divisions, the Department of Justice (DOJ), or the Office of the Inspector General (OIG) could request access to the documents as part of an audit or investigation into an applicable manufacturer or applicable GPO."
  - Provides CMS with information to help identify areas where additional guidance and clarity is needed
  - If a statement within the assumptions document pertains to a particular section of the report, applicable manufacturers should explicitly refer to that section in the assumptions document
  - Assumptions cannot be longer than 4,000 characters (including spaces).

Dispute & Corrections

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Review and Dispute Period

45-Day Review and 15-Day Correction Period

- CMS will provide notification to manufacturers, GPOs and covered recipients when the data is ready for review.
- Covered Recipients and Physician Owners may review data and initiate a dispute during the 45-day period.
- If a dispute is resolved within the 45 days or the extra 15 days following the 45-day review period, CMS will publish the corrected data.
- If a dispute in the data cannot be resolved within 15 days following the 45 day review period, CMS will post the manufacturer's data as submitted and mark it as disputed.

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Communication & Disputes

Dispute Process:

- CMS will send out a notification when data is ready for review.
- Covered recipients log into a secure website to view data attributed to them.
- Covered recipients can initiate a dispute with the applicable manufacturer or GPO via the secured website
- Disputes must be resolved between the parties. Once a resolution is reached, CMS must be notified of the corrected data.
- CMS will update the website at least once annually with corrected information.

Communication: Pre-Submission & Post-Submission

- Being proactive: Considerations for pre-submission communications:
  - Who will handle, what is the message?
  - When – periodic, annually, just before submission?
  - How – in the field, via mail, fax, email?
  - What is the process to handle inquires and complaints?

- Being responsive: Considerations for the dispute process:
  - Who will handle – internal personnel, outside vendor?
  - How will you respond – via phone, in writing?
  - Difficult to plan before CMS provides more information…
  - Internal training programs?

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Beyond Data Capture

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HCP Identification and Remediation Issues in Data Capture

- Even the best data capture processes may result in data gaps… particularly regarding HCP data
  - How will your team address those data gaps?
    - What is your preferred data source?
    - When will gaps be identified and addressed?
    - Who will remedy those gaps?
    - Who will approve the remedy selected?
    - Where will the data be remedied? E.g., in a source system or in a reporting solution?
  - How do you document this process?

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Ensure Transparency When Developing a Customer Master

- A unique identifier is required for data integrity and to aggregate all spend data to the appropriate recipient
- Customer master data must be de-duped to avoid data redundancies
- Customer master records must contain the necessary data required for state and federal compliance reporting
- To ensure data integrity, modifications to existing records and creation of new records must follow Company SOP guidelines

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Develop Sustainable Training Efforts

- What is the scope of your companies training efforts?
- Who will be trained?
  - Value in training all vs. value in training some
- What will be covered?
  - Law?
  - Nuances?
  - Reporting tool?
  - Process/policies/procedures?
- How frequently will training occur?

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Ensure Effective Monitoring and Periodic Audits

- What is acceptable scope for your company?
- What methodology will you employ?
- What can be audited?
  - Data
  - Vendor data
  - Capture process
  - Remediation process
  - Reporting process
  - Sign-off/attestation process
  - Training records

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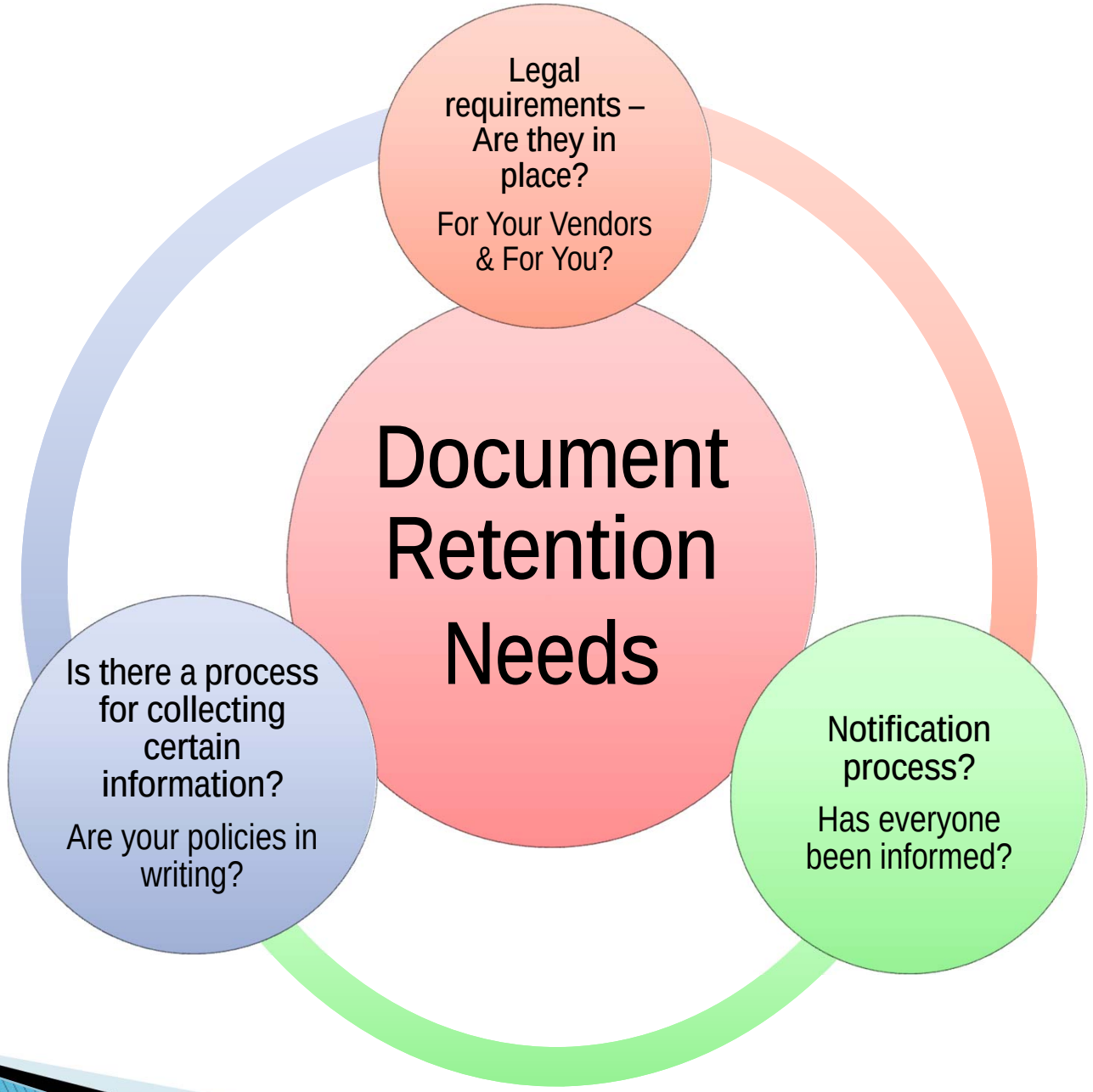

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Evaluate Language Within Vendor Contracts

- Do vendors know what data to provide, the proper format and your requirements?
  - How are you communicating with your vendors?
- Certain vendors should have their role in your reporting process spelled out in detail in an agreement, work order or scope of services (e.g., Speaker Program vendor).
- If your vendors interface with physicians on your behalf, do you want them addressing your reporting requirements?
  - If so, what are they saying? This should be spelled out in an agreement, work order or scope of service

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Standard Operating Procedures

- Aggregate Spend Policy/SOP
- Departmental Policies/SOP (e.g., Clinical Ops, Finance, etc.)
- Interactions with HCPs
- Grant Review + Funding
- Research + Development/Clinical Investigations

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Takeaways

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Takeaways: Federal Level

- The Sunshine Act requires Applicable Manufacturers and Applicable Group Purchasing Organizations (GPOs) to report to the Centers of Medicare & Medicaid Services ("CMS") any "direct" or "indirect" payment or other transfer of value provided to a Covered Recipient or any payment provided to a third party on behalf of a covered recipient during a calendar year.

- The 2015 Open Payments Program Cycle will Open on January 1, 2015 and will close on March 31, 2015.

- Key Players: Covered Recipients (Physicians and Teaching Hospitals) , Applicable Manufacturers, Group Purchasing Organizations, CMS, and FDA.

- A transfer of anything of value: which includes any direct or indirect payment or other transfer of value provided to a covered recipient or any payment provided to a third party on behalf of a covered recipient (e.g., honorarium, food, travel cost, textbooks, scientific reprints, etc)

- The Sunshine Act defines an "Indirect Payment" as a payment provided to a covered recipient through an intermediary (e.g., a specialty society or research organization).

- The Sunshine Act considers a payment provided to a third party at the request of or designated on behalf of a covered recipient to be a third party payment.

Takeaways: Federal Level

- Common Ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities.

- Assistance and Support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

- Three Types of Reports: 1) General Payments; 2) Physician Ownership ; 3) Research Payments.

- General Payments – Forms of Payment: Cash or cash equivalent; In-kind items or services; Stock, stock option, or any other ownership interest; or Dividend, profit or other return on investment.

- General Payments – Nature of Payments: Consulting fee; Compensation for services other than consulting, including serving as faculty or a speaker at an event other than continuing education; Honoraria; Gift; Entertainment; Food and beverage; Travel and lodging (including the City, State, Country); Education; Charitable contribution; Royalty or license; Current or prospective; ownership or investment interest; Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program; Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program; Grant, or Space rental or facility fees (teaching hospitals only).

Takeaways: Federal Level

- Does your company plan to communicate with physicians pre-submission?
- How does your company determine whether a meal or the provision of food/beverage is on a “large scale”?
- Has your company determined how it will track and capture the provision of article reprints by your company to each individual physician?
- Does your company have a written policy, standard operating procedure and/or work instructions in place to govern its aggregate spend reporting?
- Will your company submit an Assumptions Document?
- Has your company identified how, from a personnel standpoint, it will manage the dispute resolution period?

Takeaways: Federal Level

- Penalties
- Manufacturer/GPO that fails to submit required information:
  - $1,000 to $10,000 per item not reported
  - Total penalty not to exceed $150,000

- Manufacturer/GPO that knowingly fails to submit required information:
  - $10,000 to $100,000 per item not reported
  - Total penalty not to exceed $1,000,000

Overview

Subtitle A – Section 6004- Prescription Drug Sample Transparency

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Federal Disclosure Law: Drug Samples Disclosure

Beginning April 1, 2012, each manufacturer and authorized distributor of record of an applicable drug is required to report to the Secretary the following:

- For samples distributed by mail, the identity and quantity of drug samples requested and distributed during the preceding calendar year, aggregated by: The name, address, professional designation, and signature of the requesting practitioner or any individual that makes or signs for the request on behalf of the practitioner.
- For samples distributed by representative, the name, address, professional designation, and signature of the requesting practitioner or any individual that makes or signs for the request on behalf of the practitioner.

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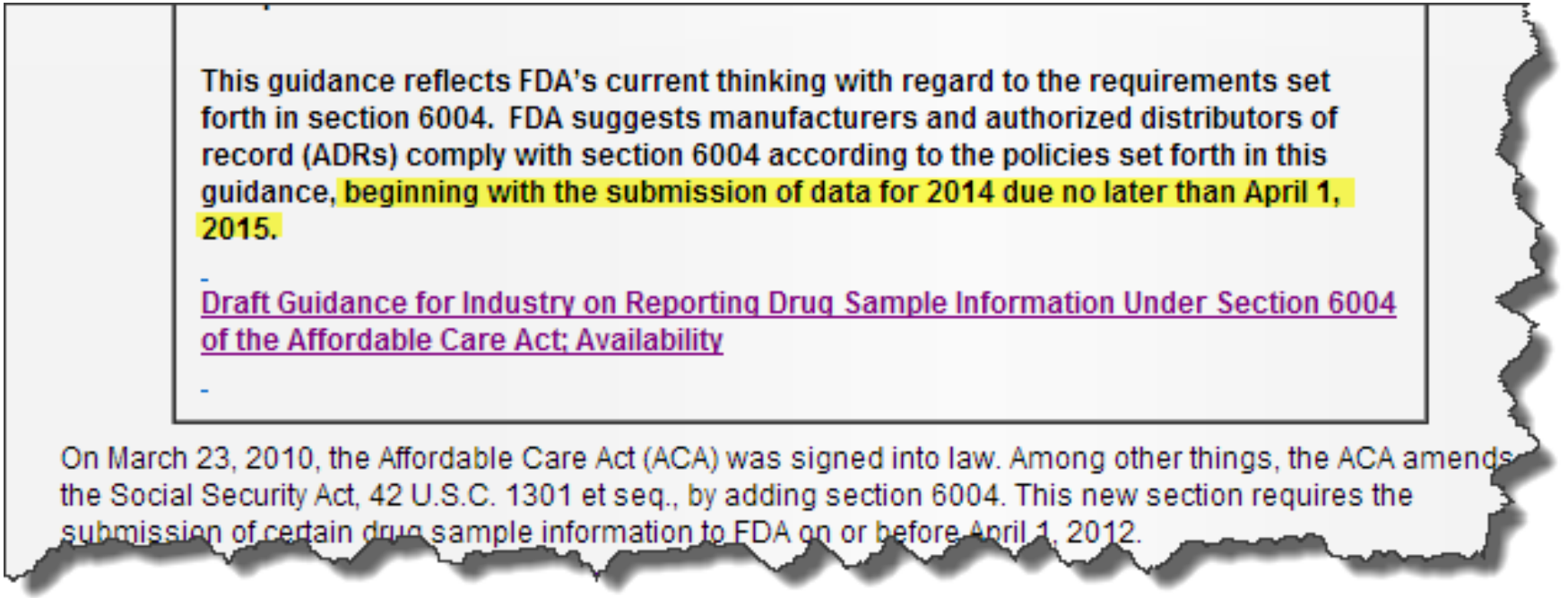
Applies only to drugs covered under federally funded program

Federal Disclosure Law: Drug Samples Disclosure



This guidance reflects FDA's current thinking with regard to the requirements set forth in section 6004. FDA suggests manufacturers and authorized distributors of record (ADRs) comply with section 6004 according to the policies set forth in this guidance, beginning with the submission of data for 2014 due no later than April 1, 2015.

Draft Guidance for Industry on Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act; Availability

On March 23, 2010, the Affordable Care Act (ACA) was signed into law. Among other things, the ACA amends the Social Security Act, 42 U.S.C. 1301 et seq., by adding section 6004. This new section requires the submission of certain drug sample information to FDA on or before April 1, 2012.

Draft Guidance for Industry on Reporting Drug Sample Information Under Section 6004 of the Affordable Care Act

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Overview

Transparency on the State Level

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Overview of General Categories of State Laws

Other topics covered by state laws, include:

- Gift & Meal Bans/Spending Limits
- Code of Conduct Adherence, including Annual Declaration of Compliance
- Lobbying Laws
  - E.g., applied when seeking inclusion on Medicaid Plans, Public Hospital Formularies
- Pharmaceutical Detailer Licensure & Continuing Education Requirement
- Price Disclosures
- Drug Sample Disclosures

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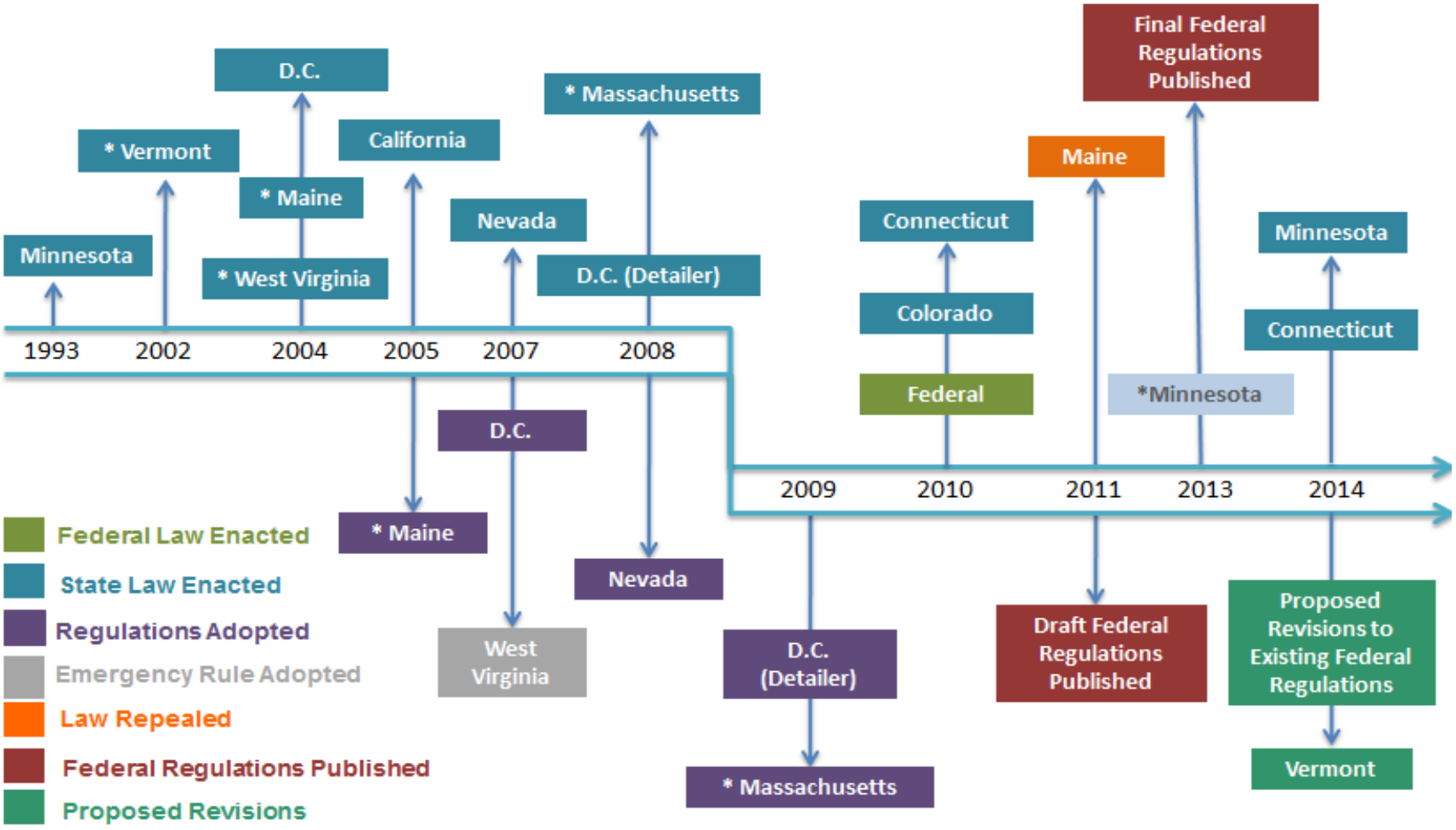
U.S. Marketing Disclosure & Limitation Laws – Enactment Dates



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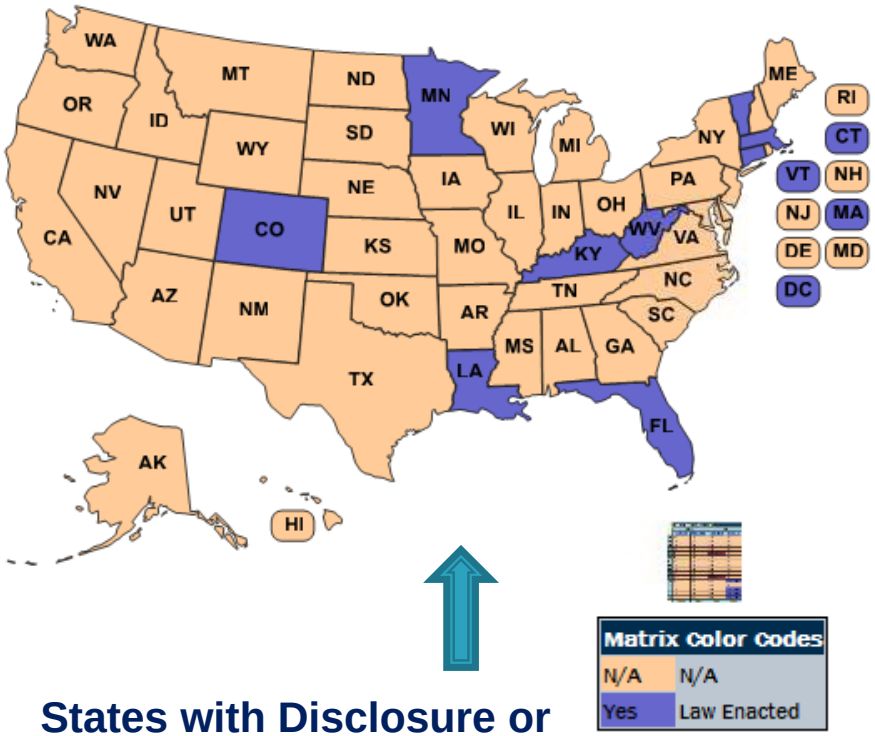
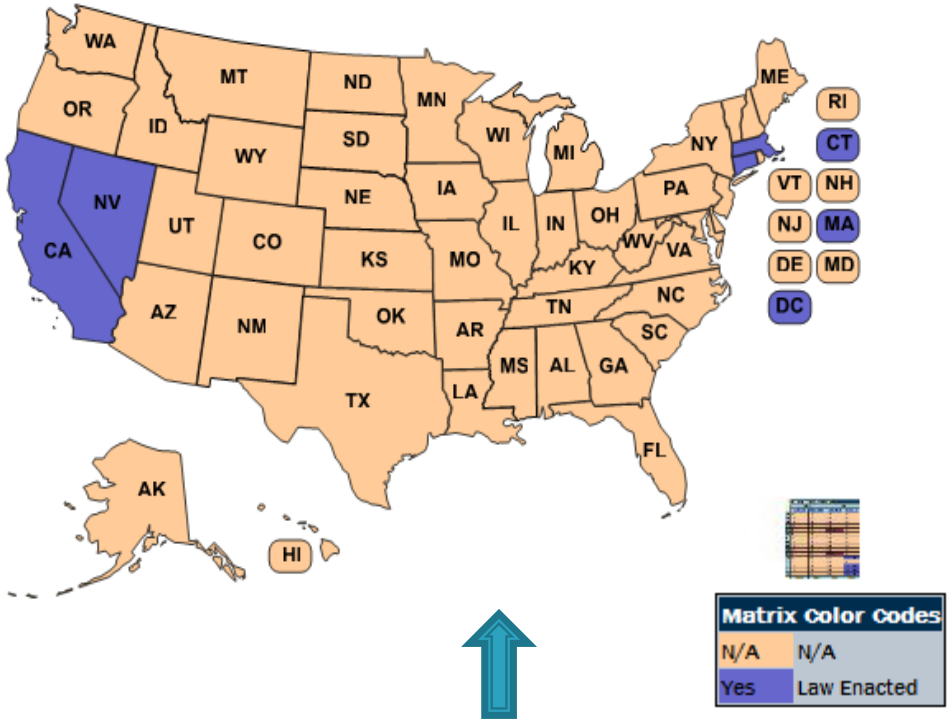
Overview of State Activities



States with Disclosure or Lobbying Laws



States with Code of Conduct Laws

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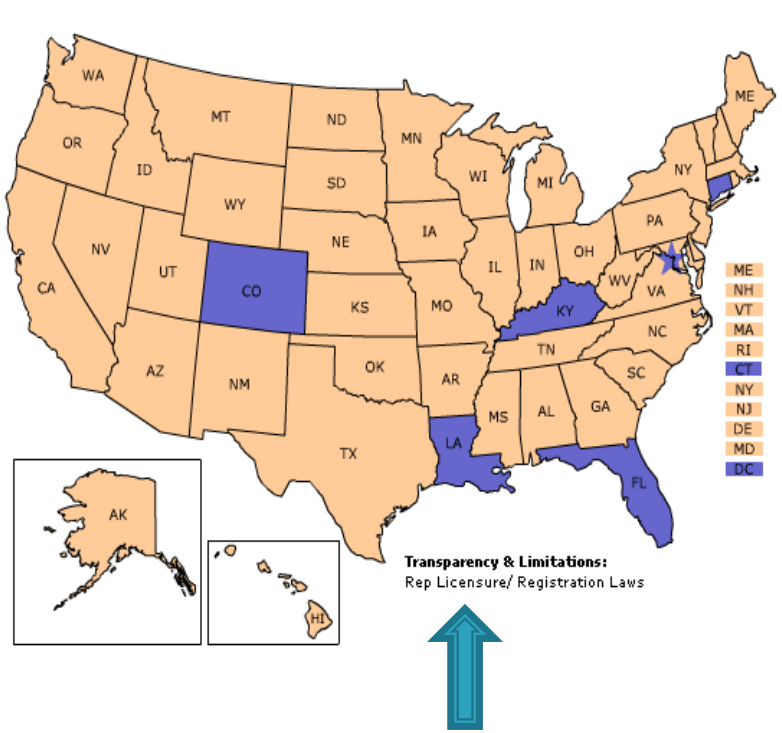
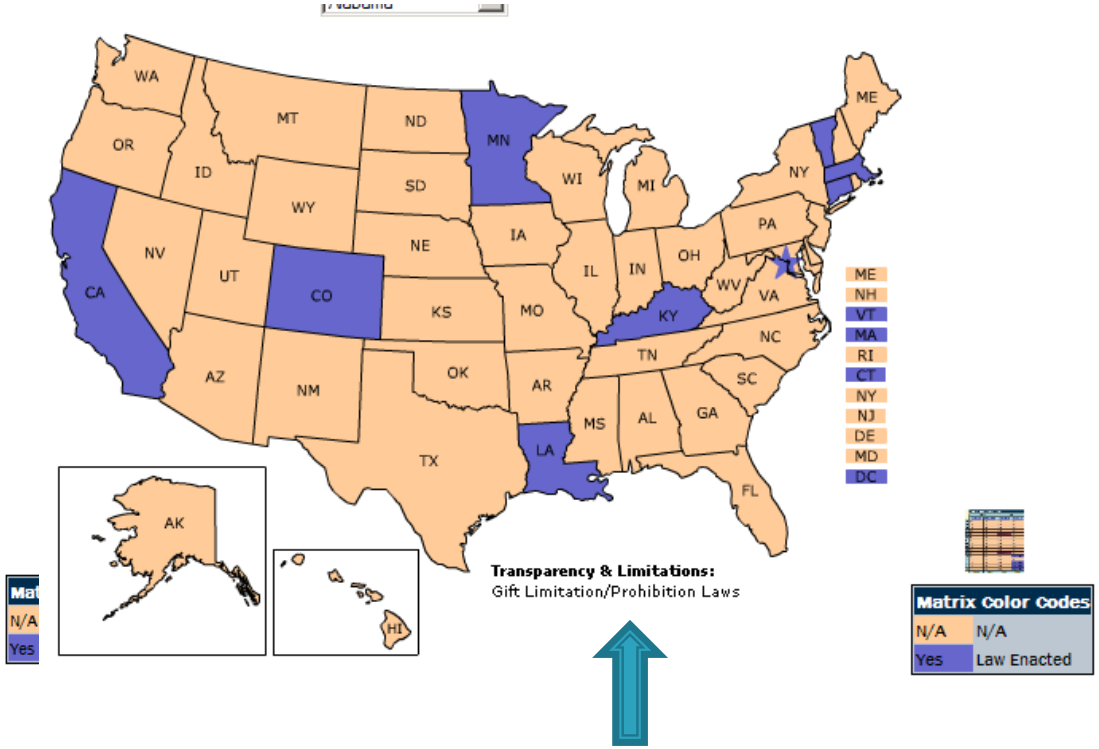
Overview of State Activities





States with representative Licensure Laws

States with Gift Prohibition Laws

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Overview

Disclosure and Spending Limits Law

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States with Payment Disclosure and Spending Limits Law

PAYMENTS DISCLOSURE

- D.C.
- MASSACHUSETTS
- VERMONT
- MINNESOTA (2014)
- WEST VIRGINIA
- CONNECTICUT*

SPENDING LIMITS

- CALIFORNIA (company-established)
- MINNESOTA

*Reporting is in the exact form of sunshine, but will be conducted on a quarterly basis and only apply to APRNs. No other information has been provide (regulations or guidelines). **First report is due July 1, 2015.**

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Gift & Meal Bans: Spending Limits

Some states impose requirements beyond disclosure. Healthcare provider expenditures may be limited or completely banned. For example:

Minnesota	Annual $50 per practitioner gift limit
Vermont	Only permissible expenditures are those that statute specifically permits
California	Company-determined annual “per healthcare provider” spend limit

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Enforcement Action in Vermont

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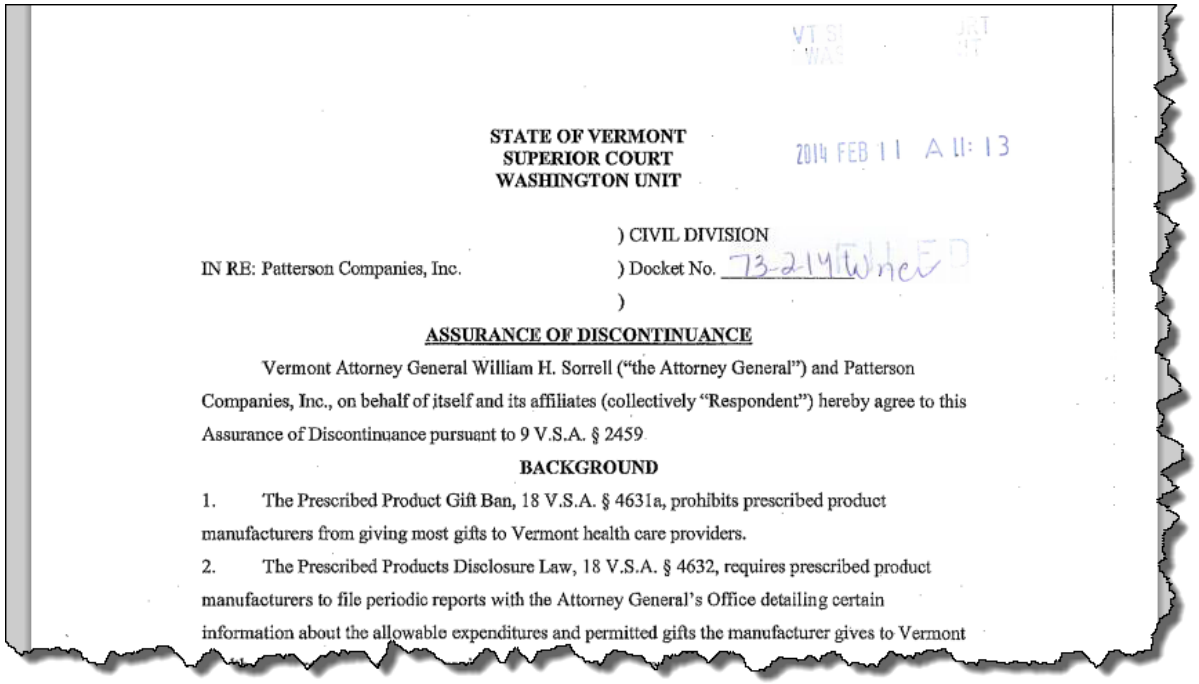
Vermont Assurances of Discontinuance

The Office of the Attorney General of Vermont provides public access to settlement documents and Assurance(s) of Discontinuance dating back to the Fall of 2010.



STATE OF VERMONT
SUPERIOR COURT
WASHINGTON UNIT

2014 FEB 11 A 11:13

) CIVIL DIVISION
IN RE: Patterson Companies, Inc.) Docket No. 73-2-14 Wncv
)

ASSURANCE OF DISCONTINUANCE

Vermont Attorney General William H. Sorrell ("the Attorney General") and Patterson Companies, Inc., on behalf of itself and its affiliates (collectively "Respondent") hereby agree to this Assurance of Discontinuance pursuant to 9 V.S.A. § 2459

BACKGROUND

1. The Prescribed Product Gift Ban, 18 V.S.A. § 4631a, prohibits prescribed product manufacturers from giving most gifts to Vermont health care providers.
2. The Prescribed Products Disclosure Law, 18 V.S.A. § 4632, requires prescribed product manufacturers to file periodic reports with the Attorney General's Office detailing certain information about the allowable expenditures and permitted gifts the manufacturer gives to Vermont

A list of settlement documents are publicly available on the Office of The Attorney General of Vermont's Website

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VT Assurances of Discontinuance

Company	Violation(s)	Settlement Date	Penalty (ies)
Patterson Companies, Inc.	Violation of the Prescribed Product Gift Ban (4631a) in the time period between July 1, 2009 and present (various gifts). Failure to file annal reports with the Attorney General's Office for those years (4632).	11-Feb-14	Civil penalties of $35,000.00 for violation of 4631a.$1,750.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, calendar year 2011 and calendar year 2012.$35,000.00 donation to Vermont Head Start.
Medline Industries, Inc.	Violation of the Prescribed Products Gift Ban and Disclosure Law during fiscal year 2010 and fiscal year 2011 (4631a) -- provided meals and various other gifts.	19-Dec-13	Civil penalties of $64,000.00 for violation of 4631a.
EMD Millicore Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, calendar year 2011, and calendar year 2012 (4632).	19-Nov-13	$1,750.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, calendar year 2011, and calendar year 2012.
ALK Abello, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Allesee Orthodontic Appliances, Inc.	Information N/A	18-Sep-13	Information N/A
Angelini Labopharm	Failure to file annual reports with the Attorney General's Office for fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$750.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010 and calendar year 2011.
Aspen Surgicial Products	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Bio Rad Laboratories, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
BridgePoint Medical, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.

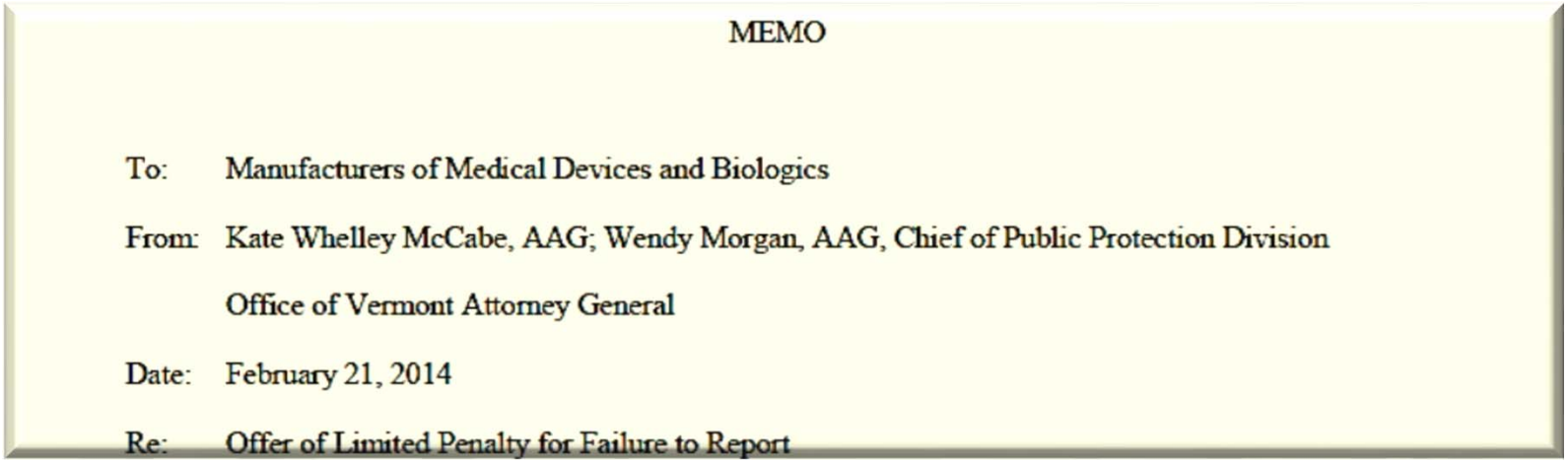
VT Assurances of Discontinuance

Company	Violation(s)	Settlement Date	Penalty (ies)
Carl Zeiss Vision, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011, and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Celleration, Inc.	Failure to file annual reports with the Attorney General's Office for calendar year 2011 (4632).	18-Sep-13	$250.00 fine in full payment of the registration fees owed under 4632 for calendar year 2011.
Cochlear Americas Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010 (4632).	18-Sep-13	$500.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010.
Dental Equiptment, LLC.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010 and calendar year 2011.
Dental Imaging Technologies Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Implant Direct Sybron International, LLC.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Instrumentarium Dental, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
KaVo Dental Technologies, LLC.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Kerr Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Magellan Diagnostics, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.

VT Assurances of Discontinuance

Company	Violation(s)	Settlement Date	Penalty (ies)
McKesson Medical Surgical, Inc.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
McKesson Medical Surgical Minnesota Supply, Inc.	Failure to file annual reports with the Attorney General's Office for calendar year 2011 (4632).	18-Sep-13	$250.00 fine in full payment of the registration fees owed under 4632 for calendar year 2011.
Metrex Research, LLC.	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Moore Medical, LLC.	Failure to file annual reports with the Attorney General's Office for fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$750.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2011 and calendar year 2011.
Nordian (US) Inc. and Affiliates	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Novartis Pharmaceutical Corporation	Violation of the Prescribed Product Gift Ban (4631a) in the time period between May 27, 2010 and December 31, 2011 -- provided meals.	18-Sep-13	Civil penalties of $36,000.00 for violation of 4631a.
Olympus Corporation of the Americas	Failure to file annual reports with the Attorney General's Office for the January 1, 2010 through June 30, 2010 reporting period (4632).	18-Sep-13	$250.00 fine in full payment of the registration fees owed under 4632 for the January 1,2010 through June 30,2010 reporting period.
Ormco Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.
Volcano Corporation	Failure to file annual reports with the Attorney General's Office for fiscal year 2010, fiscal year 2011 and calendar year 2011 (4632).	18-Sep-13	$1,250.00 fine in full payment of the registration fees owed under 4632 for fiscal year 2010, fiscal year 2011, and calendar year 2011.

Amnesty in Vermont



MEMO

To: Manufacturers of Medical Devices and Biologics

From: Kate Whelley McCabe, AAG; Wendy Morgan, AAG, Chief of Public Protection Division

Office of Vermont Attorney General

Date: February 21, 2014

Re: Offer of Limited Penalty for Failure to Report

- The Vermont Attorney General's Office has offered to accept a payment to the State in the amount of $10,000 per reporting period to settle failures to report under the Prescribed Products Gift Ban and Disclosure Law for prior reporting years

PORZIO LifeSciences

Overview

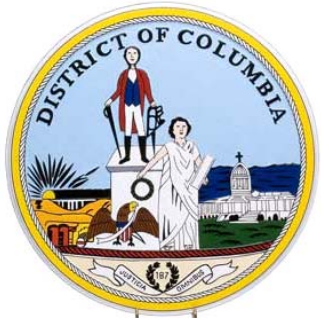
Marketing Codes of Conduct

PORZIO LifeSciences

Marketing Codes of Conduct

California
July 2005

District of Columbia
March 2008



Connecticut
May 2010

Nevada
October 2007

Massachusetts
January 2009

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Code of Conduct Adherence, Including Annual Declaration of Compliance

Some states require adherence to state-mandated code of conduct and/or annual declarations of compliance (e.g., with PhRMA Code, AdvaMed Code, OIG Guidance), as well as certifications that company conducted audit of marketing practices, provided adequate training, etc.

Nevada	Annual declaration of compliance to code of conduct, certification that annual audit conducted, training occurred, etc.
California	Annual declaration of compliance posted on company's website
Massachusetts	Annually certify it conducted an audit to monitor compliance

Adherence to Compliance Program/ Code of Ethics/Code of Conduct Statutes

	CA	CT	DC	MA	NV
Compliance Program/Marketing Code of Conduct/Code of Ethics Requirement					
Incorporate requirements from AdvaMed Code		x		x	x
Incorporate requirements from PhRMA Code	x	x	x	x	X* (or adopt indep. Code of conduct)
Incorporate requirements from OIG Guidance	x	x			
Continuing Education (CE) Requirements For Licensed Pharmaceutical Detailers			x		
Prescriber Data Provision that requires companies to implement means for HCPs to opt-out of data use by sales rep/marketing				x	
Company Policies/Procedures					
Submit Description of Investigation Policies				x	x
Provide Certification/ Declaration of Annual Audits	x			x	x
Drug Company Must Conduct Training for Employees/ Contractors		x	No, but see CE above	x	x
Company Imposed Spending limit	x				
Gift Limitations / Restrictions	x		x	x	

Overview

Other Categories of State Laws

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Lobbying Laws

Lobbying laws typically require:

- Lobbyist registration
- Quarterly or annual reporting of expenditures directed to public officials
- In addition, meal/gift limits or bans may apply

Some states (and Miami Dade County in Florida) have advised that their lobbying laws apply to drug companies when they interact with doctors or others who have authority to select products for inclusion on State Medicaid Plans or Public Hospital Formularies.

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Pharmaceutical Detailer Licensure & Continuing Education Requirement

- The District of Columbia requires licensure of sales representatives and others who market Rx drugs on a company's behalf.
- There is broad applicability. Companies who have promotional speaker programs are applying for licensure of physician speakers in D.C.
- A continuing education requirement exists for re-licensure.

What about Medical Science Liaisons?

Are they "promoting" products & therefore subject to licensure?

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Price Disclosures

Several states require quarterly price reporting (typically of the same prices reported to the federal government):

- States including New Mexico and Texas
- Vermont requires detailers to present Average Wholesale Price to healthcare providers of not only your own product, but also of other products in the same therapeutic class.

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Drug Sample Disclosures

Vermont is also the only state to require drug sample disclosures (including coupons and vouchers) with following details:

Recipient (*including License Number*)

- Date Sample Delivered
- Number of Samples
- Description
- Identity of Sample Product
- Product Name
- Units
- Dosage

Reports due April 1st for free samples or sample alternatives of prescribed products dispensed during the previous calendar year.

* The Attorney General will contract with academic researchers to release aggregate data regarding samples disclosed, without including the names or license number of the individual recipients.

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Medical Facility Policies

- Gift Giving to faculty, staff and students from industry representatives
- Site Access to medical school and faculty, staff and students
- Drug Sample distribution to faculty, staff and students to provide to patients
- Continuing Medical Education programs sponsored by industry
- Scholarships/Grants sponsored by industry
- Purchasing and Formulary Committees staffed by medical school personnel

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Example: University of Alabama at Birmingham School of Medicine

Guidelines for Relationship with Industry

The policy applies to employees and trainees

- Gifts/Meals: Prohibit employees and trainees from accepting gifts of any value or nature, including meals.
- Drug Samples: Prohibit employees and trainees from accepting free drug samples or vouchers for personal or family use.
    - Use of samples of inpatients is prohibited but permitted for use in outpatient clinics.
    - Industry representatives not permitted to leave samples of controlled substances.
- CME: Industry-sponsored educational events held on campus to be "fully compliant with ACCME guidelines."

Overview

State Updates

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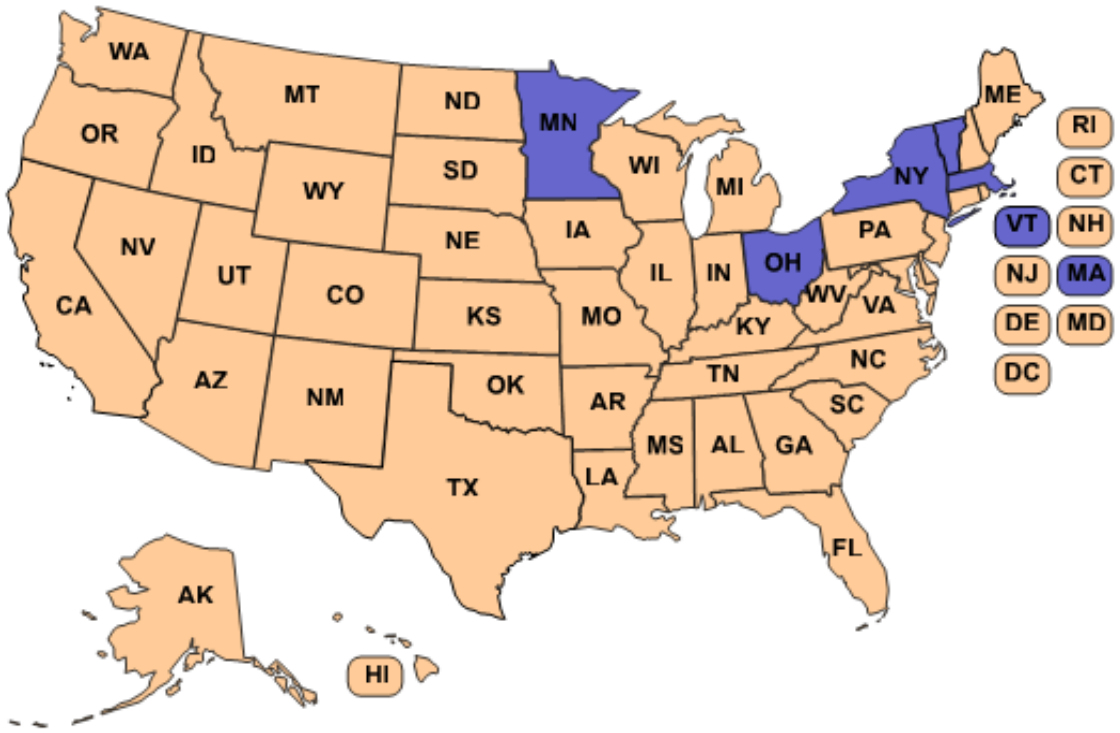
Pending Marketing Disclosure Bills



Matrix Color Codes	
N/A	N/A
Yes	Bill Pending

Transparency & Limitations:
Marketing Disclosure Bills

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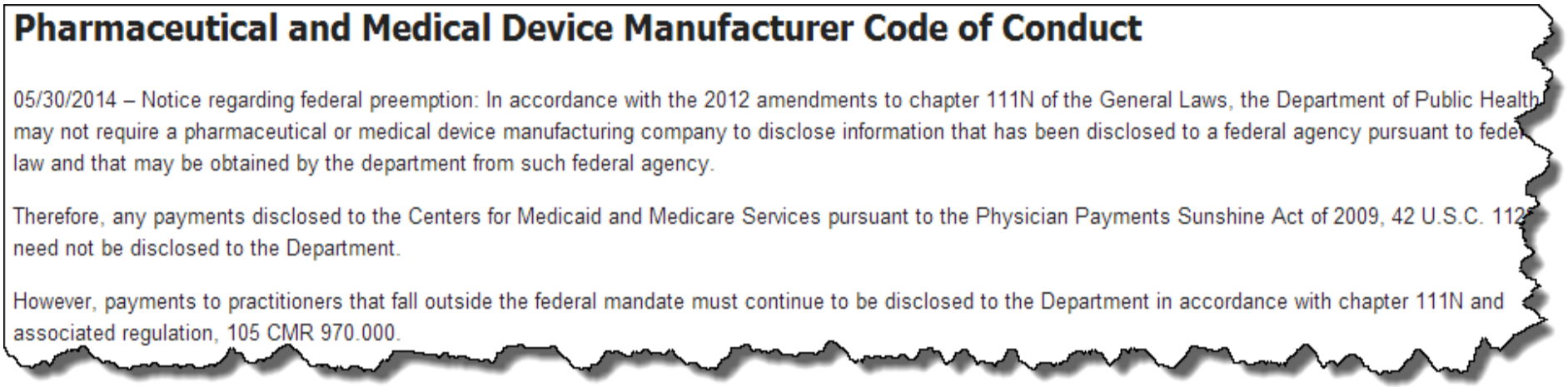
Massachusetts Update

- Massachusetts posts on its Department of Health Website a notice regarding federal preemption



Pharmaceutical and Medical Device Manufacturer Code of Conduct

05/30/2014 – Notice regarding federal preemption: In accordance with the 2012 amendments to chapter 111N of the General Laws, the Department of Public Health may not require a pharmaceutical or medical device manufacturing company to disclose information that has been disclosed to a federal agency pursuant to federal law and that may be obtained by the department from such federal agency.

Therefore, any payments disclosed to the Centers for Medicaid and Medicare Services pursuant to the Physician Payments Sunshine Act of 2009, 42 U.S.C. 112 need not be disclosed to the Department.

However, payments to practitioners that fall outside the federal mandate must continue to be disclosed to the Department in accordance with chapter 111N and associated regulation, 105 CMR 970.000.

Consistent with the regulation, the Department expects companies to continue to report all instances of non-compliance or be subject to a penalty (970.010) or enforcement action (970.011).

A guidance document regarding the new quarterly meal reports is being worked on, and will be released in the near future. Until that time, manufacturers should not take any action regarding the quarterly meal reports. Once guidance is released, it will be available in this location.

- Awaiting guidance on Quarterly Reporting of Meals

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STATE UPDATE:

Massachusetts

Modest meals and refreshments

- Pharmaceutical and medical device manufacturers are permitted to provide "modest meals and refreshments in connection with non-CME educational presentations for the purpose of educating and informing health care practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information."
- The presentation must occur "in a venue and manner conducive to informational communication."
- Definition: "Food and/or drink provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense."

STATE UPDATE:

Massachusetts

Quarterly Reports

- Companies with non-CME educational presentations in which modest meals and refreshments are provided, must submit quarterly reports, including:
  - The location of the non-CME presentation
  - A description of any pharmaceutical products, medical devices or other products discussed at such presentation
  - The total amount expended on such presentation
  - An estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation.

Pharmaceutical and Medical Device Manufacturer Code of Conduct

05/13/13: An updated covered recipient list reflecting any changes for CY2012 is now available in the manufacturers page.

Manufacturers are reminded that CY2012 disclosure reports are due by July 1st, 2013. Also, annual registration renewal will take place from July 5th through August 31st 2013. See the Manufacturer's page for updated instructions regarding these requirements.

A guidance document regarding the new quarterly meal reports is being worked on, and will be released in the near future. Until that time, manufacturers should not take any action regarding the quarterly meal reports. Once guidance is released, it will be available in this location.

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State Legislation

Massachusetts SB 1051

- Expands quarterly reporting requirement to include:
  - The total amount spent on the meals for such presentation;
  - The total amount spent on the venue for such presentation;
  - A description of presentation's content;
  - The total number of prescribers in attendance at such presentations;
  - The names of attendees at such presentations;
  - The names and credentials of presenters at such presentations; and
  - The total amount spent on other items of economic value provided at such presentation.

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Minnesota Updates

- On July 9, 2014, the Minnesota Board of Pharmacy, distributed a memo advising only drug manufacturers (no longer requires drug wholesalers) to file an annual disclosure report with the Board by May 1, 2015, identifying "all payments, honoraria, reimbursement, or other compensation, authorized under section 151.461, clauses (4) and (5), paid to practitioners in Minnesota during the preceding calendar year. **Data for the calendar year of 2014 is due May 1, 2015.**

- *There have been no changes to the gift ban, the ban is still in effect*

Date: July 9, 2014
To: Pharmaceutical manufacturers and drug wholesalers licensed by the Board
From: Cody Wiberg, Executive Director
Minnesota Board of Pharmacy
Re: Payment to practitioner reporting

require manufacturers to report payments made to physician assistants, nurse practitioners, veterinarians and dental therapists. Manufacturers should be tracking data for calendar year 2014 concerning payments made to nurse practitioners, physician assistants, dental therapists and veterinarians. That data will have to be reported to the Board by May 1, 2015. Manufacturers will receive instructions late this year about how to report.

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North Dakota Law

Effective August 1, 2013

Electronic Drug Prior Authorization and Transmission Limitations

Prohibits electronic transmission devices used to communicate a prescription to a pharmacist from using any means, or permitting any other person to use any means, to influence or attempt to influence through economic incentives the prescribing decision of a prescribing practitioner at the point of care.

Includes:

Advertising

Commercial Messaging

Popup Advertisement

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State Legislation

Vermont HB 350 (formerly known as H633) (ACT130) The Vermont General Assembly recently passed House Bill 350 ("HB 350"), which amends the list of allowable expenditures provided in the Law. Specifically, HB 350 adds certain sponsorships of educational programs offered by medical device manufacturers at national or regional professional society meetings to the list of allowable expenditures. In order to qualify as an allowable expenditure, the sponsored program must be at a "national or regional professional society meeting at which programs accredited by the Accreditation Council for Continuing Medical Education are also offered," so long as:

- (1) There are no payments made directly to a health care professional or pharmacist; and
- (2) The funding is used solely for bona fide educational purposes, except that the manufacturer may provide meals and other food for program participants.

HB 350 became effective on July 1, 2014.

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State Legislation

Vermont HB 278

- Exempts items of nominal value from the gift ban
- Removes “an officer, employee, agent, or contractor” of a health care professional from the definition of “health care professional.”

Detailed Status:

Status Header	Location	Full Status (Red = House Status, Green = Senate Status)
2/15/2013 HJ 21 P. 165	In Committee	Read First Time and Referred to the Committee on **Health Care**

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State Legislation

Vermont HB 836

- This bill would amend the Law by exempting the provision of meals or other food to a health care professional and his or her employees from the gift ban, so long as the meals are consumed **in** the health care professional's office.

Detailed Status:

Status Header	Location	Full Status (Red = House Status, Green = Senate Status)
2/4/2014 HJ 90 P. 294	In Committee	Read First Time and Referred to the Committee on **Health Care**

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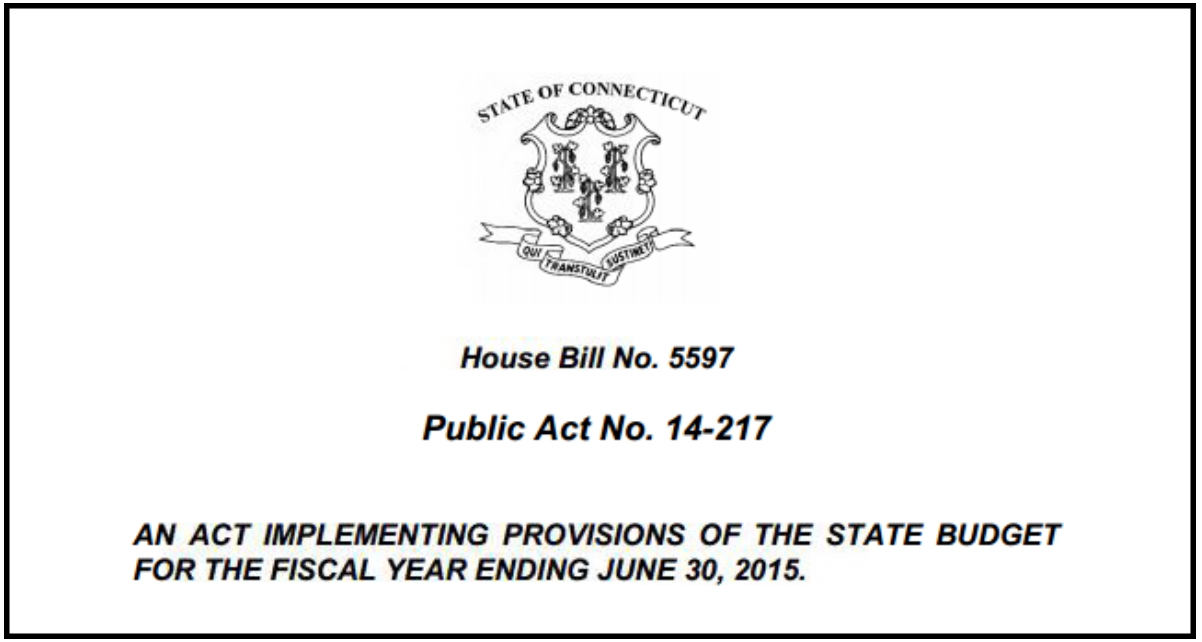
Passed Legislation in Connecticut



- This bill requires applicable manufacturer that provide a payment or other transfer of value to an advanced practice registered nurse, who is practicing in the state, to submit a report to the Commissioner of Consumer Protection no later than July 1, 2015, and quarterly thereafter.

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Takeaways: State Level

- State Laws are a fairly new phenomenon – beginning in 1993 with much activity in past five years & no two states are alike in their requirements
- Topics cover a wide range, including such diverse topics as Gift & Meal Bans/Spending Limit, Code of Conduct Adherence, and Pharmaceutical Detailer Licensure
- State law activity continues (e.g., statutory amendments, proposed new laws & new Guidance documents) despite passage of PPACA (i.e., the Federal "Sunshine Act")
- Medical facility policies, among other considerations, impose additional burdens on companies that must be considered.

Other Federal & State Laws – A Sampling:

- Mid-Level Practitioner Prescriptive Authority (e.g., physician assistants, nurse practitioners)
- Licensing Requirements
- Anti-Kickback Statutes
- False Claims Acts
- Privacy Laws

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Questions?

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Contact Information

John P. Oroho, JD
Executive Vice President, Chief Strategy Officer
Porzio Life Sciences, LLC
JPOroho@pbnlaw.com
973-889-4302

Sandra González, JD
Manager, Regulatory and Compliance Services
Porzio Life Sciences, LLC
SGonzalez@pbnlaw.com
973-889-4114

* * *

Porzio Life Sciences, LLC Website: http://www.porziolifesciences.com

Porzio Life Sciences, LLC Twitter: @PorzioLS

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Overview

State Appendix

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Appendix

Selected Requirements: State by State

(Illustrating the Diverse Approaches States Have Taken)

	CA	CO*	CT*	DC	FL*	KY *	LA*	MA	MN	NV	NY*	VT	WV
Marketing Code of Conduct/Code of Ethics	X		X	X***				X***		X			
Annual Certification of Compliance	X							X		X			
Gift Restrictions/Limits (Non-Lobbyist Laws)	X		X****	X**				X	X			X	
Reporting of Marketing Expenditures (Non-Lobbyist Laws)				X				X	X			X	X
Lobbyist Disclosure* of Marketing Expenditures		X	X		X	X	X				X		
Sale Rep Price Disclosure to Physicians												X	
Advertising Cost Reporting				X									X
Employee/Contractor Compensation				X									

* Many states have lobbying laws. This slide provides only a sampling. The states listed here are representative of those that have specifically determined that their lobbying laws encompass activities of drug or device sales representatives.

** Prohibits gifts to medication advisory committee members

***State Specific Code

****Quarterly Reporting on APRNs.

Appendix

District of Columbia
July 1st

Fill out electronically, print, and sign this "Company Information" sheet to authenticate the submission of the required annual report. This sheet should be submitted with the required filing fee of $5,000 made payable to D.C. Treasurer.	
Please enter the requested information in the space provided. For more information, refer to instructions in the fourth sheet.	
Manufacturer/Labeler Company	
Company Name:	
Company Address:	
Company City:	
Company State:	
Company Zip:	
Company Email:	
Company Phone:	
Company Fax:	
Individual Responsible for Submission	
Pursuant to 22 DCMR 1801.5 "The individual identified… shall be a member of senior management or senior level company official within the manufacturer's or labeler's company or corporate structure"	
Responsible Individual Name:	
Responsible Individual Title:	
Responsible Individual Address:	
Responsible Individual City:	
Responsible Individual State:	
Responsible Individual Zip:	
Responsible Individual Email:	
Responsible Individual Phone:	
Responsible Individual Fax:	
2013 Marketing Expenses	
Total Gift Expenses	
Total Advertising Expenses	
Total Aggregate Cost	
Total Marketing Expenses	$0.00
Pursuant to the District of Columbia Municipal Regulation 1801.4(c), a wet signature is to be submitted in conjunction with the filing of this report.	
I certify, under penalty of law, the information contained in this report is true and accurate to the best of my knowledge. I understand that providing false information or omission of information is unlawful.	

* *Filing Fee* $5000

(as of June 16, 2010)

Marketing Expenses

Total Gift Expenses (expenses associated with educational or informational programs, food, entertainment, gifts, trips, and travel)

Total Advertising Expenses (expenses associated with advertising, marketing, and direct promotion of prescription drugs via radio, television, magazines, newspaper, direct mail, and telephone communications)

Total Aggregate Cost (all payments to employees or contractors)

= Total Marketing Expenses

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Appendix

District of Columbia:
Pharmaceutical Detailer Application

GOVERNMENT OF THE DISTRICT OF COLUMBIA
DEPARTMENT OF HEALTH – HEALTH PROFESSIONAL LICENSING ADMINISTRATION

NEW LICENSE APPLICATION
Pharmaceutical Detailer

Please read instructions before completing this form. If you have any questions, call HPLA Customer Service at **1-877-543-5218,** Monday through Friday, 8:15AM to 4:45PM EST. **A charge of $65.00 will be imposed for dishonored checks (Public Law 89-208)**

SECTION 1. REQUESTED LICENSE TYPE/FEES (includes non-refundable application fee – see instructions)

☐	Pharmaceutical Detailer		$175.00
☐	CBC – Criminal Background Check (if using DC MPD service)	$50.00	$ ____.00
☐	Duplicate Licenses (limit 5)	_____ X $34.00 =	$ ____.00
Total Enclosed			**$ ____.00**

A decision will be made within sixty (60) days from receipt of the COMPLETED application and all supporting documents. This license will expire at 12:00 MIDNIGHT, the last day of February each even numbered year.

NOTE: Checks or money orders which are not made payable to **"DC Treasurer"** will be returned to you and your application processing will be delayed.

Make check or money order payable to DC Treasurer.

MAIL TO:
Department of Health
Health Professional Licensing Administration
Board of Pharmacy
899 North Capitol Street, NE
Washington, DC 20002

HPLA ONLY		
Check $	**Check #**	**Staff**
$ _ _ _ .00		

SECTION 2. APPLICANT NAME/DEMOGRAPHIC INFORMATION

Enter your name exactly as it should appear on the license. If your name has changed at any point since you first attended college or university, please

Florida: Jackson Health System

A Vendor Representative must register as a lobbyist in Miami-Dade County before visiting a JHS facility for the purpose of promoting the utilization of a product or service

JHS includes, but is not limited to:

- Jackson Memorial Hospital
- Holtz Children's Hospital
- Jackson Mental Health Hospital Center
- Jackson Memorial Rehabilitation Center
- Ryder Trauma Center
- Jackson North Medical Center
- Jackson South Community Hospital

Appendix

Massachusetts: Disclosure

July 1st

Massachusetts Example Disclosure Form

Company ID	Covered Recipient	Covered Recipient	Category Payment ID	Amount of Payment	Number of Events Reflected	Disclosure Report Period	License Type	License Number
CC9999	999999	John Smith	5000	100	1	2009	Physician	12345
CC9999	888888	Jane Smith	3000	300	1	2010	Registered Nurse	67890
CC9999	777777	Joe Smith	1000	500	1	2010	Pharmacist	23456
CC9999	555555	Smith Hospital	2000	1000	1	2010	Acute Hospital	45678

Unique ID Number	MA Payment Category Name	MA Payment Category Description
1000	Compensation for Bona Fide Services	Consulting, Speaker's Bureaus, etc.
2000	CMEs, third-party Conferences, or Meetings	Payments to CRs in Conjunction with CMEs, third-party conferences and meetings
3000	Grants/Educational Gifts	Grants and Educational Gifts to CRs
4000	Food	Meals Provided to CRs
5000	Education/Training	Payments to CRs in Conjunction with education and training
6000	Marketing Studies	Payments to CRs in conjunction with research other than genuine research
7000	Charitable Donation	Donations other than donations of presciption drugs, biologics or medical devices
8000	Other	Non-exempt payments to CRs of $50 or more

Mapping Expenditures with correct Category ID numbers

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Appendix

Vermont Clinical Trial Expenditure Reporting

What is Required for Disclosure?

- Gross compensation for Vermont locations or locations involved;
- Direct salary support per principal investigator and other HCPs per year; and
- Expenses paid on behalf of investigators or other HCPs for reviewing the clinical trial.

*Complete disclosure is required when the payment is more than 4 yrs old or the product has FDA approval *(whichever is sooner)*.

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Appendix

West Virginia

April 1st

Appendix A

Prescription Drug Advertising Expense Reporting Form

Please file your complete Appendix A with:
Governor's Office of Health Enhancement and Lifestyle Planning
Greenbrooke Building, 1124 Smith Street, Room 105
Charleston, West Virginia 25301

Name of Reporting Entity	
Reporting Period	

2.a. List below the **total amount** the reporting entity spent for advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups within the State of West Virginia.

Name of Reporting Entity	**Amount Spent**

2.b. List below the total number of West Virginia prescribers to whom the reporting entity provided directly or indirectly, **gifts, grants or payments of any kind in excess of one hundred dollars ($100.00) for the purpose of advertising prescription drugs.**

Annual Aggregate Amount of fees, food, entertainment, recreational activities, travel expenses, gifts, grants or other payments.	**Total Number of Prescribers**
$100.00 - $2,500.00	
$2,501.00 - $5,000.00	
$5,001.00 - $7,500.00	
$7,501.00 - $10,000.00	

Requires companies to report total amount spent on advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies and patient support or advocacy groups.

Requires companies to report gifts, grants or payments of any kind provided for the purpose of advertising prescription drugs.

Mail the disclosure report, along with any calculations used to determine expenses included in section 3.2.c to the following address:

Governor's Office of Health Enhancement and Lifestyle Planning (GOHELP)
One Davis Square
Suite 100 E
Charleston, WV 25301

Reporting Forms were due by April 1, 2014.

Appendix

West Virginia

2.c. List below the **direct-to-consumer advertising** which is directed at, received by or intended to be received by consumers **in this state**, the form of the advertising and the total amount expended for advertising.

Form of Advertising	Total Expenditure on Advertising

I certify upon information and belief that the information contained on this form is true, correct and complete.

Signature:	
Printed Name:	
Title:	
Date:	

Taken, sworn and subscribed before me, this .....day of .....,20.....

by .....

Notary signature	
Commission expires	

Seal:

No longer requires Companies to report the name of each prescription drug advertised via direct-to-consumer ("DTC") advertising.

No longer requires companies to report the name of any pharmacy, disease-specific patient support, and advocacy group.