



June 16, 2009

Fact Sheet

Reducing the Impact of Pharmaceutical Marketing to Physicians and Promoting Appropriate Prescribing and Drug Safety

The pharmaceutical industry spends nearly \$30 billion annually on marketing. The majority (including samples) is spent on direct marketing to physicians (Donohue, NEJM, 2007).

Nationwide, prescription drug spending rose 500% (from \$40.3 billion to 200.7 billion) between 2000 and 2005 (Kaiser Family Foundation, 2007).

This fact sheet was created in collaboration with



The Physician Payments Sunshine Act (S.301) and Vermont's 2009 Gifts Ban and Disclosure Law (S.48)

The Physician Payments Sunshine Act (S.301) requires drug, biologic, and medical device manufacturers to report certain gifts and payments ("transfers of value") made to physicians or a physicians' practice. The information will be registered in a national and publicly accessible online database. Companies failing to report incur financial penalties. On June 8, 2009 Vermont Governor Jim Douglas signed into law **An Act Related to the Marketing of Prescribed Products (S.48)**, which bans most gifts to health care professionals and requires public reporting by pharmaceutical and device companies of allowable expenses to health care professionals and other groups.

Which types of payments are banned under Vermont law?

While the Physician Payments Sunshine Act (PPSA) does not limit any payments or financial relationships, Vermont's law bans most gifts, including anything of value provided to a health care provider for free, meals, entertainment, travel, subscriptions and advances. The following items are exempted from the ban:

- samples of a prescribed product for free distribution to patients;
- the short-term loan of a medical device for evaluation and the provision of medical device demonstration and evaluation units;
- clinical articles, medical journals and other items that serve a genuine educational function for the benefit of patients;
- scholarships for medical students, residents and fellows to attend major conferences;
- rebates and discounts provided in the normal course of business; and
- labels approved by the federal Food and Drug Administration

As introduced, S.301 would not pre-empt the Vermont gifts ban.

Who is required to report payments?

The PPSA requires all entities (and their subsidiaries and affiliates) that produce, prepare, propagate, compound, convert, process, market, or distribute drugs, devices, or medical supplies covered under Medicare, Medicaid, or SCHIP.

Vermont's law requires reporting by pharmaceutical, biological product, and medical device manufacturers, as well as any person who is engaged in the production, preparation, propagation, compounding, processing, packaging, repacking, distributing, or labeling of prescribed products.

Who are covered recipients?

All physicians and physician practices are covered recipients under PPSA. Also reportable are transfers of value to "an entity or individual at the request of or designated on behalf of a covered recipient" (e.g. third parties paying physicians on behalf of a manufacturer).

Under Vermont law, covered recipients for the gifts *ban and disclosure* include physicians, physician assistants, nurse practitioners, other health care professionals, hospitals, nursing homes, pharmacists, health benefit plan administrators, and anyone else authorized to dispense or purchase for distribution prescribed products in Vermont. In addition, Vermont requires *reporting* of payments to academic institutions and professional, educational and patient organizations representing or serving health care providers or consumers.

What types of payments must be reported?

The PPSA requires disclosure of transfers of value to all covered recipients. The Act specifies standard descriptors, including:

- compensation;
- food, entertainment or gifts;
- travel; consulting fees or honoraria;
- funding for research; funding for education;
- stocks or stock options;
- ownership or investment interest in a manufacturer or distributor. In addition to manufacturers, group purchasing organizations must; and
- any other economic benefit as described by the secretary

The Vermont law requires that companies report payments and gifts not covered under the state's gifts ban.

Exemptions

	PPSA	Vermont law
Rebates and discounts	✓	✓
Product samples for patient use	✓	✓
Payments for clinical trials*	✓	✓
Royalties		✓
Licensing fees		✓
Payments until the aggregate annual total per company, per covered recipient, reaches \$100 (at which point all payments must be disclosed retroactively)	✓	
Educational material provided for the benefit of patients	✓	
Demonstration units of medical devices for use of 90 days or less	✓	
In-kind items used for the provision of charity care	✓	
Dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security	✓	

✓ exempted from reporting requirement

* both the PPSA and Vermont law require payments for clinical trials be disclosed

after the earlier of the date of the approval of the prescribed product by the Food and Drug Administration or two calendar years after the date the payment was made

What other information must be included with disclosure reports?

Both the PPSA and Vermont law require that reports include:

- the name of the recipient;
- the recipient's address;
- the date the payment was made;
- the value of the payment;
- a standardized description of the nature of the payment (e.g. consulting fee, food, travel)
- the prescribed product associated with the payment;
- a unique identifier (state board number in Vermont and Medicare billing number in PPSA)

In addition, the Vermont law requires reporting of the type of recipient (e.g. doctor, clinic, pharmacist, hospital).

Neither the PPSA nor the Vermont law allow for reporting exemptions based on trade secret declarations.

How will disclosed payments data be shared with the public?

The PPSA and Vermont law each require all data from industry disclosures to be posted to a publicly available and searchable Internet website.

How often must companies report?

Both the PPSA and Vermont law require annual reporting of applicable payments and gifts.

How would the PPSA impact Vermont's law?

As written, the PPSA would narrowly pre-empt state laws. While the PPSA would not limit Vermont's ability to enforce its gifts ban, it would prevent the collection of the same payments information for the same purposes as PPSA. We interpret S.301 as allowing Vermont and other states to continue to collect information not reportable under the PPSA, such as payments to health care providers other than physicians and to academic institutions. Under the PPSA, the Secretary of Health and Human Services must submit annual reports to each state with state-specific data gathered through disclosure reports.

The scope of state pre-emption in PPSA is one of the open questions being considered by the Senate Finance Committee.

For more information on the Physician Payments Sunshine Act (S.301), visit:

http://www.prescriptionproject.org/sunshine_act