Vermont’s Gift Ban and Disclosure Laws

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Prescription drug cost-containment: Acts 80 and 89

• Acts 80 (2007) and 89 (2008) included:
  – Limits on access to prescriber data for marketing purposes unless prescriber “opts in” (18 V.S.A. § 4631)
    • *IMS Health, Inc. v. Sorrell*
  – Academic detailing program (18 V.S.A. § 4622)
  – Generic drug voucher pilot program
  – Regulation of pharmacy benefit managers (PBMs) (in 18 V.S.A. chapter 221)
Prescription drug cost containment: Act 59 (2009)

• Findings include:
  – 2007: $572 million spent in Vermont on prescription/OTC drugs and medical supplies
  – 2002: $377 million
    • 8.7% increase, higher than overall health care spending for the same period
  – Court in *IMS Health Inc. v. Sorrell* found research shows marketing to doctors affects prescribing
  – 2009 Institute of Medicine report found acceptance of meals and gifts influences doctors to prescribe a manufacturer’s medicines even when evidence indicates another drug would be better for the patient
Prescription drug cost containment: Act 59 (2009)

- More findings:
  - From July 1, 2007 to June 30, 2008:
    - Rx manufacturers reported spending $2,935,248 in Vermont on fees, travel expenses, and other direct payments to Vermont doctors, universities, and others for marketing purposes
    - Payments went to 2,280 of Vermont’s 4,573 licensed health care professionals
    - Approx. $2.1 million of the $2.9 million went to physicians
    - The top 100 individual recipients received almost $1,770,000
    - Expenditures on food were $861,911.70 (29.36%)
    - One individual received $15,793.78 in food for self/staff
Pharmaceutical Promotional Spending by Type, 2000-2006

Billions of Dollars

- ePromo
- Journal
- NP / PA
- Hospital-Based
- Events
- DTC
- Office-Based
Percentage of Physicians with Industry Relationship

Campbell and Campbell et al, NEJM: 2007

- Drug samples: 78%
- Gifts: 83%
- Reimbursements: 35%
- Payments for consulting: 18%
- Payments for serving as a speaker or on a speakers’ bureau: 16%
- Payments for serving on an advisory board: 9%
- Payments for enrolling patients in clinical trials: 3%
- Any of the above relationships: 94%
Perceived influence of pharmaceutical reps on prescribing


“You”

- A lot: 1%
- A little: 38%
- None: 61%

“Other physicians”

- A lot: 33%
- A little: 51%
- None: 16%

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Prescription drug manufacturer gift ban and disclosure reqts.

• Bans gifts from manufacturers of prescribed products to health care professionals, other providers, and Green Mountain Care Board (GMCB)
• Requires disclosure of allowable expenditures by manufacturers to Attorney general
• Some exceptions to gift ban and disclosure requirement
Sunshine provisions in ACA

• Requires manufacturers of prescribed products purchased by Medicare, Medicaid, or SCHIP to report information to HHS about transfers of value to physicians and teaching hospitals

• States are preempted for:
  – Duplicative reporting requirements
  – Began on January 1, 2012

• States are not preempted for:
  – Restrictions or prohibitions on transfers or gifts (“gift bans”)
  – Additional or different reporting requirements
Vermont’s gift ban and disclosure laws: who must comply?

- Manufacturers of “prescribed products”
  - Pharmaceutical companies
  - Excludes wholesale distributors of biologics, retailers, and pharmacists
  - Medical device companies
  - Manufacturers of biologics
Gifts to...?

• Bans certain gifts to:
  – Health care professionals
    • Includes doctors, nurses
  – Health care providers
    • Hospitals, nursing homes, pharmacists
  – Health benefit plan administrators
    • Insurers, PBMs
  – Anyone else authorized to dispense or purchase for distribution
  – Green Mountain Care Board members
What is a “gift”?  

- Anything of value provided to a health care provider or GMCB member for free; or  
- Any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to a health care provider, unless:
  - it is an “allowable expenditure,” or
  - the health care provider reimburses the cost at fair market value, or
  - it is one of the listed exceptions
What is an “allowable expenditure”?  
• Reasonable fees, payments, subsidies, or other economic benefits provided at fair market value  
• Includes: 
  – Research/clinical trial contracts  
  – Payment of expenses for CME/conferences  
  – Honoraria for faculty at CME/conferences  
  – Reasonable expenses for medical device training  
  – Royalties and licensing fees  
  – Interview expenses for a job with manufacturer
Exceptions to gift ban

- Samples
- Short-term (≤ 120 days) loans of medical devices
- Medical device demonstration units
- Clinical articles and journals
- Conference scholarships for medical students
- Rebates and discounts
- Labels approved by the FDA
- Donations to free clinics
- Patient assistance programs
- Fellowship salary support
- Coffee/snacks at conference booths
What must be disclosed?

• Value, nature, purpose of gift, name of the recipient
• To health care providers, GMCB members, academic institutions, hospital foundations, and provider/consumer organizations
• Exceptions:
  – Royalties and licensing fees
  – Rebates and discounts
  – Payments for clinical trials delayed until earlier of:
    • Approval or clearance of the product by FDA or
    • 4 calendar years
  – Interview expenses for health care professionals
  – Coffee/snacks at conference booths
  – Short-term loans of medical devices for trial
  – Products distributed as part of patient assistance program
Samples Disclosure

• Free samples of prescribed products must be disclosed

• Free samples of over-the-counter products must be disclosed if manufacturer has other allowable expenditures/permitted gifts to report
  – Name of product, recipient, number of units, and dosage
  – Limitations on public reporting of information
  – Does not apply to samples of prescribed products required to be reported under ACA, if any
Disclosure required

• Disclosures required to Attorney General by manufacturers
  – Annually by April 1
  – $500 fee if any expenditures to report
  – Health care professionals and providers do not disclose

• AG prepares annual report by October 1

• Information available on AG’s website
  – Searchable database
Resources

• Vermont AG’s website:
  – Prescribed products generally:
  – Guide to Vermont’s law: