



November 19, 2009

Bill Comparison

Physician Payments Sunshine

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).

The Physician Payments Sunshine provisions in House and Senate health care reform bills would require drug and medical device manufacturers to report certain gifts and payments ("transfers of value") made to physicians and certain other entities ("covered recipients"). The information would be available in a single public website. The initiative provides transparency, but does not limit financial relationships.

Senate version: Included in the Patient Protection and Affordable Care Act of 2009 (H.R. 3590, section 6002). Released: November 18, 2009 by the Senate Majority Leader.

House version: Included in Affordable Health Care for America Act of 2009 (H.R. 3962, section 1451). Released: October 29, 2009 by the Speaker of the House.

<i>Who would have to report?</i>	Senate	House
All U.S. drug, device, biologics, and medical supply manufacturers (and other entities under common ownership. Not pharmacies)	✓	✓
All U.S. drug, device, biologics, and medical supply distributors (and other entities under common ownership. Not wholesalers)		✓
<i>Who is considered a "covered recipient"</i>		
Physicians, teaching hospitals	✓	✓
Physician practices, non-physician prescribers; * pharmacies or pharmacists; health insurance providers; pharmacy benefit managers; hospitals; medical schools; sponsors of continuing medical education; patient advocacy or disease groups; organizations of health care professionals; biomedical researchers; group purchasing organizations		✓
<i>What is a transfer of value?</i>		
Cash and in-kind transfers, whether or not for services rendered.	✓	✓
Compensation; food, entertainment or gifts; travel; consulting fees; honoraria; research funding or grants; education or conference funding; stocks or stock options; ownership or investment interest; royalties or licenses	✓	✓
Charitable contributions	✓	

*Such as physician assistants or nurse practitioners, who are authorized to write prescriptions in most states.

<i>Who must disclose physician ownership interest?</i>	Senate	House
Manufacturers, group purchasing organizations	✓	✓
Hospitals and health care entities, distributors		✓
<i>What information would disclosures include?</i>		
Name of covered recipient, business address, physician specialty and national provider identifier, * value, date, and form of the payment.	✓	✓
The nature of the payment by listed descriptors	✓	
Name of the related drug or device if available, to the level of specificity available		✓
Name of the related drug or device when the payment is related to marketing, education, or research specific to the product	✓	
<i>Are there payments that are exempt from disclosure?</i>		
Individual payments and gifts valued at less than \$5		✓
Individual payments and gifts valued at less than \$10 until a recipient receives an aggregate total of \$100, at which point all payments of any value are disclosed	✓	
Patient educational materials	✓	
Discounts and rebates; loans of covered devices; items provided under warranty; in-kind charity items; a dividend or investment interest in a publicly traded security or mutual fund	✓	✓
Payments to a covered recipient who is a patient	✓	✓
Payments for the provision of health care to employees	✓	✓
Payments to a recipient who works solely for the reporting company		✓
Payments to a physician who is employed by a reporting company**	✓	✓
Payments made through a third party for an activity or service where the manufacturer is unaware of the recipient's identity	✓	
Payments made through a third party for an activity or service where the manufacturer is unaware of the recipient's identity and the activity or service does not market a product to the recipient		✓
Payments to a covered recipient who is also a licensed non-medical professional if the payment is for non-medical services; Payments solely related to a civil or criminal action	✓	

* NPI numbers are unique identifier codes for most individuals that receive Medicare reimbursement; NPIs will not be publicly available

** Both the House and Senate exclude these physicians from the scope of covered entities.

Are prescription drug and device samples reported?

Both the Senate and House require manufacturers to report information about samples; however, this information is not made public. While the Senate sunshine provision exempts samples from reporting, a separate section of the Senate health reform bill requires reporting of information on samples to HHS. The House Sunshine provision includes samples but specifies that this information will not become public.

Delayed reporting of payments for research or product development

Both bills permit a delay for payments made pursuant to clinical trials or “product development agreements”. Product development agreements are not defined.

For clinical trials of new products, the House bill allows a reporting delay until the earlier of two years or until the trial is posted on clinicaltrials.gov. For product development agreements concerning new products, the House allows a reporting delay until the earlier of two years or product approval.

The Senate allows a publication delay for payments related to new products until the earlier of four years or product approval. Product development agreements for “new applications” of existing technologies are also allowed this publication delay.

Would the bills affect existing state laws?

Both bills would prohibit states from collecting the same information required to be reported under this section. States will not be prevented from collecting other types of information *not* captured or excluded from reporting (with the exception of *de minimis* and threshold limits), or collecting any information for public health purposes or for legal proceedings. The House bill also provides for enforcement through the State attorneys general where the Secretary declines to bring action.

What are the penalties for non-compliance?

Senate and House: For each failure to report, fines of up to \$10,000 will be applied, not to exceed \$150,000 annually. For each knowing failure to report, fines of up to \$100,000 will be applied, not to exceed \$1,000,000 annually.

House: annual limit for knowing failure to report is the larger of \$1,000,000 or 0.1% of the total annual revenues of the manufacturer.

GAO report

The House bill requires a GAO study on the adequacy of reporting standards, the impact of the preemption provision on states, the types of payments delayed as related to research, and any changes in payment patterns as a result of efforts to evade reporting

Implementation

The House bill requires reporting and public posting of disclosures by 2011; the Senate bill by 2013.