Brightening Up: The Effect of the Physician Payment Sunshine Act on Existing Regulation of Pharmaceutical Marketing

Igor Gorlach and Genevieve Pham-Kanter

Introduction

In 2008 pharmaceutical companies spent over $12 billion on product promotion and detailing aimed at U.S. health care practitioners.[1] Drug and device manufacturers rely on a workforce of detailers and physician speakers to reach health care practitioners and nudge their prescribing habits. To prevent undue influence and protect the public fisc, a number of states began regulating these marketing practices, requiring companies to disclose all gifts to practitioners, prohibiting the commercialized sale of prescription data, and prohibiting certain gifts altogether. The 2010 enactment of the Physician Payment Sunshine Act (PPSA) marks the first Congressional involvement in the regulation of disclosure related to pharmaceutical marketing. Overall, the Act improves transparency in pharmaceutical marketing to physicians and expands the regulation of disclosure of pharmaceutical marketing activities in important substantive ways.

Current Regulation of Pharmaceutical Marketing to Health Care Practitioners

The PPSA builds on an existing regulatory environment of state laws and quasi-voluntary industry measures. Between 1993 and 2011 a number of states and D.C. passed laws that (1) require manufacturers to disclose payments and gifts to physicians, (2) prohibit certain gifts altogether, (3) require the adoption of a compliance code, and (4) prohibit data mining of practitioners' prescribing patterns. Nine manufacturers also began publicly reporting certain marketing expenses to health care practitioners pursuant to corporate integrity agreements with the Department of Justice; and three more began publishing similar reports voluntarily. Consequently, on the eve of the new federal disclosure requirement, the data on pharmaceutical marketing to practitioners are scattered between a handful of state agencies (available upon a formal inquiry) and reports published on the manufacturers' websites which vary in their detail and, according to some analysts, their usability.[2]

Disclosure Laws

Six jurisdictions passed laws that require pharmaceutical manufacturers to disclose their spending on marketing to practitioners: Maine (2006), Massachusetts (2009), Minnesota (1994), Vermont (2002), West Virginia (2004), and the District of Columbia (2004). Maine repealed its law in September 2011 in response to the enactment of the PPSA, but the other state laws remain effective. Each disclosure law enumerates the marketing expenses that must be disclosed and those that are exempt from disclosure, determines whether and what public disclosure is required, and establishes penalties for non-compliance. The laws require manufacturers to file annual reports listing all the relevant marketing expenses in the state for the previous calendar year. These components are also present in the PPSA.

Overall, state disclosure laws exempt low-cost gifts, compensation for conducting clinical trials,[3] reimbursements of participation in certain educational

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events, and free sample drugs intended for patient use. Most disclosure laws require the disclosure of high-cost gifts, food and entertainment, travel reimbursement, and honoraria. Massachusetts and Vermont adopted a stricter catchall approach, requiring the disclosure of all marketing that is not specifically exempted, whereas D.C. and Minnesota enumerate the required and exempted categories. West Virginia is an outlier in its mandate, requiring manufacturers to report the aggregate cost of marketing and nothing more. In defining the applicable manufacturers, Massachusetts casts the widest net, covering all drug, biologic, and device manufacturers marketing their products directly or indirectly. The other states and D.C. focus on manufacturers and labelers that handle or distribute prescription products. The states define recipients as those who are licensed to prescribe medicine or those who are licensed to practice health care. Penalties under the laws vary from $1,000 per violation in D.C. to a misdemeanor in Minnesota.

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Early payments data collected under state disclosure laws were difficult to access because they required the submission of Freedom of Information Act requests or direct negotiations with state agencies to obtain.[4] Access has somewhat improved since, although currently only three states — Massachusetts, Minnesota, and Vermont — make payments information available on-line. A few problems of data usability and completeness have remained, however. Some firms, contrary to state requirements, reported payments in aggregated form rather than reporting payments made to individual physicians; payment reports were often handwritten or in formats that required members of the public wishing to analyze the data to re-enter by hand all information contained in reports; and in Vermont, many firms designated their payments as trade secrets and therefore not available to the public.[5] With the 2009 amendments to Vermont's law that abolishes the trade secrets designation for payments, and with the passage of a demanding disclosure requirement in Massachusetts, there should be future improvement in disclosure data availability and quality.

Gift Ban Laws

Several jurisdictions also passed laws banning certain gifts from pharmaceutical and device manufacturers to practitioners. Massachusetts (2009),[6] Minnesota (1994),[7] and Vermont (2009)[8] outlawed certain gifts directly by law, whereas California (2005),[9] Connecticut (2011),[10] Nevada (2007),[11] and the District of Columbia (2008)[12] require pharmaceutical and device companies to adopt and comply with the "Code on Interactions with Health Care Professionals," developed by the Pharmaceutical Research and Manufacturers of America (PhRMA's Code; discussed below). Finally, Colorado (2007)[13] banned certain gifts to physicians affiliated with state university hospitals, after the state passed a constitutional amendment to ban gifts to government employees and contractors.

PhRMA's Code, written in 2002 and updated to a stricter version in 2008, prohibits many of the same categories of gifts that are statutorily prohibited by state gift ban laws. Both the Code and state gift ban laws prohibit reimbursement of travel and entertainment, meals outside the office, direct payments except for services, honoraria to non-faculty, and items that are not intended for patient care. The statutory gift ban laws also share several of the Code's exemptions: consulting and speaker fees, contributions to sponsors of CME events, educational materials, and drug samples for patients. Colorado stands as an exception to the comparison, since its law – nested in an amendment to the state's Constitution – applies to pharmaceutical marketing only tangentially, and therefore lacks some policy detail.

Laws Requiring the Adoption of General Compliance Programs

Two states — California (2005) and Connecticut (2011) — require pharmaceutical companies to adopt compliance programs in accordance with the Office of Inspector General's "Compliance Program Guidance for Pharmaceutical Manufacturers."[14] The guidance lists several elements for companies to consider when creating a compliance program: (1) written policies,

(2) the designation of a compliance officer and other appropriate bodies, (3) a training program, (4) a line of communication between the compliance officer and all employees, (5) risk evaluation to monitor compliance, (6) development of policies to deal with employees and entities who are excluded from participation in federal health care programs, and (7) policies for investigating noncompliance. The autonomous nature of these laws and the broad language of the guidance assure that the requirement to adopt a compliance program is not onerous for the manufacturers.

ing the disclosure to travel, entertainment, and gifts. Other major pharmaceutical companies, such as Merck, GlaxoSmithKline, Johnson & Johnson, Novartis, AstraZeneca, and Pfizer began disclosing certain payments to physicians as well. Of the dozen pharmaceutical companies that currently publish their payments to physicians, only GlaxoSmithKline, Merck, and ViiV are not required to do so by a corporate integrity agreement with the Department of Justice.

Additionally, and more voluntarily, eleven of the 12 largest (by revenue) pharmaceutical companies are

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Data Mining Laws

Four states — Maine (2006), Massachusetts (2009), New Hampshire (2006), and Vermont (2007) — passed laws that limited the practice of data mining — collecting and selling physician-level prescription statistics. The prescription data were used by pharmaceutical companies to guide the companies' marketing efforts. The rationale for the laws was twofold: to protect physicians' privacy and to minimize abuse in pharmaceutical marketing to physicians. The laws were met with resistance from pharmaceutical intelligence companies, such as IMS Health, which challenged the laws in Vermont, Maine, and New Hampshire. After a few mixed rulings on the laws in the lower courts,[15] the U.S. Supreme Court struck the laws down in 2011 as unconstitutional restrictions on speech.[16] Although the Massachusetts data mining law has not been challenged, it is probably unenforceable after the Supreme Court's ruling.

Quasi-Voluntary Disclosure and Compliance by Pharmaceutical Companies

Besides state laws, the Department of Justice has negotiated settlements with several pharmaceutical companies, requiring the manufacturers to publish their payments to physicians. Eli Lilly was the first to announce its payments reporting as part of the settlement, stating in 2008 that it would begin disclosing physician payments in excess of $500.[17] Lilly first reported payments to physicians acting as advisors and speakers for the company, later expand-

among the signatories to PhRMA's Code, indicating an "intention" to abide by the Code. As discussed *supra*, however, only a few states monitor the commitment of the companies to these declared intentions.

The Physician Payment Sunshine Act and Proposed Rule

The Physician Payment Sunshine Act

In 2010 Congress passed the Patient Protection and Affordable Care Act,[18] comprising among its provisions the Physician Payment Sunshine Act.[19] The PPSA requires "applicable manufacturers" to disclose "payments or other transfers of value" to "covered recipients," beginning in January 2012. An 'applicable manufacturer' under the Act is "a manufacturer of a covered drug, device, biological, or medical supply [in the U.S.]."[20] The Act defines a 'covered recipient' as a physician or a teaching hospital;[21] and a 'physician' as a doctor of medicine, a dentist, a podiatrist, an optometrist, or a chiropractor,[22] thus excluding some health care professionals, such as nurse practitioners and physician assistants, who are authorized to prescribe medications in all of the states. The PPSA requires the disclosure of all payments or transfers of value — except those excluded by the statute — and provides several categories to classify the transfers of value when reporting. The Act also requires manufacturers to report their aggregate marketing expenses by state. The proposed rule under the PPSA, released by the Secretary of Health and Human Services in December 2011, clarifies the

definitions of the Act and the financial relationships covered.

The PPSA anticipates interaction with current state disclosure laws by including a narrowly-tailored preemption clause, which preserves nearly all existing state regulation of pharmaceutical marketing to health care professionals.[23] The clause preempts state laws that require the disclosure of the same types of transfers of value, between manufacturers and recipients covered by the PPSA. However, the PPSA does not preempt any state laws that (1) require the disclosure of a different type of information, (2) require the disclosure of information exempted from disclosure by the PPSA, (3) require disclosure relating to parties other than an applicable manufacturer and a covered recipient, as defined by the PPSA, and (4) requiring disclosure to a government entity "for public health surveillance, investigation, or other public health purposes or health oversight purposes."[24] As a result, states are free to regulate pharmaceutical marketing except where the PPSA requires the disclosure of the same type of payment or gift from an applicable manufacturer to a covered recipient.

Throughout the PPSA, Congress delegates the promulgation of details about disclosure and applicability to the Secretary of Health and Human Services, and requires the Secretary to establish procedures for the submission of information to CMS and for the public availability of information.

The 2011 Proposed Rule

In December 2011, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule (Rule) to implement the PPSA.[25] The Rule interprets several statutory definitions and elaborates on the form and content of the disclosure reports. Overall, the Rule moderately broadens the PPSA to assure completeness and accuracy of data, leaving room for an even broader implementation. Because CMS released the Rule over two months after the statutory deadline, the Rule also delays the implementation date for disclosure.

In interpreting the definition of an applicable manufacturer, the Rule proposes excluding manufacturers that only manufacture over-the-counter (OTC) drugs or devices that do not require pre-market approval, such as tongue depressors and elastic bandages. However, if a single product of the manufacturer falls under the statutory definition, the manufacturer would have to disclose all marketing expenses for all products. The Rule also elaborates on four of the fifteen nature-of-payment categories that manufacturers must use for each disclosed payment, restricting the definitions of "charitable contribution" and "research," and interpreting broadly the definition of "a speaker for a medical education program" as encompassing speaking fees in general.

The Effect of the PPSA on Existing Regulation

The Legal Effect of the PPSA

Although the preemption clause of the PPSA ostensibly leaves state laws intact, the Act creates an entangled federal-state disclosure system for the industry, as the PPSA's definitions of an "applicable manufacturer" and a "covered recipient" preempt state laws only where they concern those defined manufacturers and recipients. As a result, manufacturers will have to report payments to physicians and teaching hospitals to the U.S. Department of Health and Human Services; and separately report payments to other health care professionals in Vermont, Massachusetts, Minnesota, and D.C. A similar doubling in reporting applies to West Virginia, which mandates the disclosure of aggregate marketing expenses rather than transaction-level reports. There, companies will first have to report the aggregate cost of marketing to physicians and teaching hospitals under the PPSA, and then separately report the aggregate cost of marketing to other health care professionals under West Virginia's law.

In addition to dissecting the disclosure of marketing expenses, the PPSA also loosens the disclosure requirements in Vermont. Vermont requires the disclosure of all gifts regardless of value whereas the PPSA only requires the disclosure of gifts worth over $10. Where the PPSA preempts Vermont's law and imposes its own requirements, the Act also wipes out the requirement to disclose gifts worth less than $10. This interaction with Vermont's law is probably insignificant however, because currently available disclosures show that physicians rarely receive gifts worth less than $10.

The Practical Effect of the PPSA

Because there are important differences between the PPSA and the state disclosure laws, the PPSA could lead to a number of effects that were not observed at the state level. Empirically detecting these PPSA effects will be important but will be challenging: marketing payments were obviously not disclosed prior to the disclosure law, so we only have information on payments made *after* the law went into effect. Consequently, some effects of PPSA can only be inferred indirectly. In this section, we note some of the possible effects of PPSA and suggest, where feasible, ways to empirically detect these effects.

One important difference between PPSA and the state disclosures is that the federal law only requires the disclosure of payments that have been made to doctors of medicine and osteopathy, dentists, podiatrists, and chiropractors. The disclosures exclude payments made to other kinds of clinicians who also have prescribing authority, such as physician assistants and nurse practitioners. We predict that the narrower PPSA definition of what constitutes a recipient will lead to a shifting of payments towards non-reportable clinicians. Because payments to non-reportable health care practitioners are by definition not documented, one way to empirically detect this kind of shifting of payments will be to observe whether payments to reportable clinicians remain stable or decrease, particularly in states where physician assistants and nurse practitioners have broad prescribing authority.

Second, PPSA requires a relatively high standard of data accessibility relative to existing state laws. In particular, "the information submitted... [is to be] made available through an Internet website that is searchable and is in a format that is clear and understandable...[and]...contains information that is able to be easily aggregated and downloaded."[26] As noted earlier, only three states — Massachusetts, Vermont, and Minnesota — have made their disclosure information available on-line. In other states, the data are not available publicly, and in West Virginia, there is an explicit provision in the law that the data cannot be requested through the Freedom of Information Act. The net impact of this greater data accessibility is ambiguous. With greater ease of access, the payments information will be more amenable to analysis and scrutiny by patients, interested groups, and the media — and this additional scrutiny may curtail many kinds of industry-physician relationships. Some of these curtailed relationships may be essentially *quid pro quo* monetary exchanges for increased prescribing, but other discontinued relationships may be important for product innovation and development. If the public and media can, based on the disclosed information, discriminate well between payments made solely for marketing purposes and those made for services that are helpful for innovation, the net effect of data accessibility will be positive; if the disclosed information paints all payments, including those that foster innovation and improve public welfare, with a broad negative brush, data accessibility may curtail some useful kinds of payments.

Increased data accessibility generates incentives for firms to avoid public backlash, and firms could respond in both positive and negative ways. On the one hand, firms could cut back on gifts and obvious marketing-related payments, which are likely to cause the most public uproar; on the other hand, firms could respond by under-reporting payments or misclassifying payments into non-reportable categories, leaving actual payments unchanged.

Third, PPSA requires disclosure of an important new category that has not been truly tested in the states. It requires the reporting of payments for research, including clinical trials. Payments for clinical trials have traditionally been exempt from state disclosure laws, and Vermont only recently required

Table 1

Overview of State Laws Regulating Pharmaceutical Marketing to Practitioners

State	Disclosure	Gift Ban – Statutory	Gift Ban – PhRMA's Code	Data Mining	Compliance Program
California			2005-		2005-
Colorado		2007-			
Connecticut			2011-		2011-
D.C.	2004-		2008-		
Maine	2006-2011			2006-2007	
Massachusetts	2009-	2009-		2009-2011	
Minnesota	1994-	1994-			
Nevada			2007-		
New Hampshire				2006-2007	
Vermont	2002-	2009-		2007-2010	
West Virginia	2004-				

reporting for clinical trials, where payments for these trials must be reported four years after the trial has completed or at the time of product approval, whichever comes first. PPSA follows a similar model of allowing for delayed reporting of payments for research. Because these kinds of payments are likely to dwarf by multiple magnitudes payments related to physician practice, and because they reflect a different kind of industry-physician relationship, it is not clear how this information will be used, interpreted, or understood by the public, especially if there is an four-year delay in reporting. There is likely to be some controversy and dispute around the reporting of payments designated for research because the public may have difficulty distinguishing between "good" research payments (i.e., those used to contribute to the knowledge base and increase innovation) and "bad" research payments (i.e., those used to finance low-quality projects that are used primarily for marketing).

As the first step in federal regulation of disclosure of pharmaceutical marketing payments to practitioners, the PPSA is sweeping in its scope. Unlike state laws, the PPSA requires the disclosure of all marketing in the nation as well as state-level reports. The PPSA is also strict, establishing high penalties for violations, employing a "catchall" prohibition as well as a low

Table 2
State Statutes and Agency Regulations

State	Disclosure	Gift Ban – Statutory	Gift Ban – PhRMA's Code	Data Mining	Compliance Program
California			Cal. Health & Safety Code § 119402		Cal. Health & Safety Code § 119402
Colorado		Colorado Constitution, Art. XXIX, § 3.			
Connecticut			CT ST § 21a-70e		CT ST § 21a-70e
District of Columbia	D.C. Code §§ 48-833.01 et seq.; D.C. Mun. Regs. tit. 22-B, §§ 1800.1, et seq.		D.C. Code §§ 3-1207.41, et seq. and D.C. Code § 48–842.01, et seq.; D.C. Mun. Regs. tit. 17, §§ 8300, et seq.		
Maine	22 M.R.S. § 2698-A; 10-144-275 Me. Code R. §§ 2.01 et seq.			22 M.R.S.A. § 1711-E	
Massachusetts	Mass. Gen. Laws Ann. c. 111N, §§ 1-7; 105 C.M.R. § 970.000, et seq.	Mass. Gen. Laws Ann. c. 111N, §§ 1-7; 105 C.M.R. §§ 970.000, et seq.		105 C.M.R. § 970.005	
Minnesota	Minn. Stat. Ann. § 151.47	Minn. Stat. Ann. § 151.461			
Nevada			Nev. Admin. Code §§ 639.616 - 639.619		
New Hampshire				N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV)	
Vermont	18V.S.A § 4632	18V.S.A. § 4631a		18V.S.A. § 4631	
West Virginia	W.Va. Code § 16-29H-8; WV ADC § 210-1-1 et seq.				

Table 3

Comparison of Disclosure Provisions

	The PPSA	DC	MA	MN	VT	WV
Manufacturer	Drug, device, biologic, medical supply	Manufacturer or labeler of prescription drugs	Drug, biologic, device, manufacturing, directly or indirectly	Wholesale drug distributors	Manufacturer of prescribed products	Drug manufacturer, pharmaceutical manufacturer, and labeler of prescription drugs
Recipient	Physician Teaching hospital	All persons and entities licensed to provide health care in the District and their employees	A person authorized to prescribe, dispense, or purchase prescription drugs or medical devices	Practitioners (licensed doctors of medicine, physician assistants and nurses authorized to prescribe medicine)	Health care provider (a person authorized by law to provide professional health care service)	Prescribers (physicians or other health care professionals licensed to prescribe drugs)
$ Threshold	$10, unless aggregate annual exceeds $100	$25 per day per recipient	$50 per incident	$100 per recipient requires detailed disclosure	$0	$100
Consulting Fees	Disclose	Disclose	Catchall disclosure	Disclose	Catchall disclosure	n/a
Honoraria	Disclose	Disclose	Catchall disclosure	Disclose	Catchall disclosure	n/a
Gift	Disclose	Disclose	Catchall disclosure	n/a	Catchall disclosure	n/a
Entertainment and Travel	Disclose	Disclose	Catchall disclosure	n/a	Catchall disclosure	n/a
Food	Disclose	Disclose	Catchall disclosure	n/a	Catchall disclosure	n/a
Research/Clinical Trials	Disclose	Excluded	Excluded	n/a	Disclose	Excluded
Royalty or License	Disclose	n/a	Catchall disclosure	n/a	Excluded	n/a
Investment Interest	Disclose	n/a	Catchall disclosure	n/a	Catchall disclosure	n/a
Role in CME	Disclose	n/a	Catchall disclosure	n/a	Catchall disclosure	n/a
Grant	Disclose	Disclose	Catchall disclosure	n/a	Catchall disclosure	n/a
Product samples	Catchall disclosure	Disclose	Catchall disclosure	n/a	Catchall disclosure	n/a
Samples for Giveaway	Excluded	Excluded	Excluded	Excluded	Disclose	Excluded
Educational materials for patients	Excluded	n/a	Catchall disclosure	n/a	Catchall disclosure	n/a
Discounts and rebates	Excluded	Disclose	Catchall disclosure	n/a	Excluded	n/a
In-kind items for charity care	Excluded	n/a	Excluded	n/a	Catchall disclosure	n/a
Any share in a security and mutual fund	Excluded	n/a	Catchall disclosure	n/a	Catchall disclosure	n/a
Payment solely for non-medical professional services	Excluded	n/a	Catchall disclosure	n/a	Catchall disclosure	n/a

reportable threshold, and enjoying the backing of the U.S. Department of Justice. With the exception of its narrow definition of a recipient, which creates an unusual incentive to market to non-physician health care professionals, the PPSA is comparable to the broad disclosure laws of Massachusetts and Vermont. The new regulatory requirement increases the cost of compliance for manufacturers, and leaves the possibility of under-reporting as a result. Although federal enforcement can be more vigilant and effective than the enforcement in many states, the PPSA provides no systematic way to check for non-compliance or the submission of poor or inaccurate information.

The PPSA is broad in its geographic and policy scope, but the Act only addresses transparency, short of the existing state regulation of marketing conduct directly. It has yet been shown that disclosure alone affects the marketing practices of pharmaceutical companies or the opinion of consumers. The next incremental step is the requirement that all manufacturers adopt and comply with PhRMA's Code, which already bears their signatures. In the alternative, federal policymakers should consider a more objective statutory guidance on pharmaceutical marketing to health care practitioners. In addition, empirical research on both the intended and unintended consequences of PPSA will be important as policymakers seek a level of pharmaceutical marketing regulation that protects the public while not curtailing beneficial physician-industry relationships.

References

1. See Congressional Budget Office, "Promotional Spending for Prescription Drugs," Economic and Budget Issue Brief, December 2, 2009. This amount excludes the retail value of free product samples, direct-to-consumer advertising, and other expenditures such as research grants related to product use that may have promotional value.
2. See D. Wilson, "Data on Fees to Doctors is Called Hard to Parse," *New York Times*, April 13, 2010, at B3.
3. Except Vermont.
4. J. Ross, J. Lackner, P. Lurie, C. Gross, S. Wolfe, and H. Krumholz, "Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota," *JAMA* 297, no. 11 (2007): 1216-1223.
5. *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry*, Before the Special Committee on Aging, 110th Cong. 253 (2007) (statement of Peter Lurie, M.D., MPH, deputy director of Public Citizen's Health Research Group, Washington, DC).
6. 105 C.M.R. §§ 970.000, et seq.
7. Minn. Stat. Ann. § 151.461.
8. 18 V.S.A. § 4631a.
9. Cal. Health & Safety Code § 119402.
10. CT ST § 21a-70e.
11. Nev. Admin. Code §§ 639.616 - 639.619.
12. D.C. Mun. Regs. tit. 17, §§ 8300, et seq.
13. Colorado Constitution, Art. XXIX, § 3. (Amendment 41).
14. Cal. Health & Safety Code § 119402; CT ST § 21a-70e.
15. *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010); *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008); *IMS Health Inc. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010).
16. *Sorrell v. IMS Health, Inc.*, 131 S.Ct 2653 (2011).
17. Eli Lilly Press Release. *Lilly Set to Become First Pharmaceutical Research Company to Disclose Physician Payments*, September 24, 2008.
18. *Patient Protection and Affordable Care Act*, Pub. L. No. 111–148, 124 Stat. 119 (2010).
19. Sec. 6002. *Transparency Reports and Reporting of Physician Ownership or Investment Interests* (codified as 42 U.S.C.A. § 1320a-7h).
20. 42 U.S.C.A. § 1320a-7h(e)(2).
21. 42 U.S.C.A. § 1320a-7h(e)(5).
22. 42 U.S.C.A. § 1395x(r).
23. 42 U.S.C.A. § 1320a-7h(d)(3).
24. 42 U.S.C.A. § 1320a-7h(d)(3)(B)(iv).
25. Proposed Rule, Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, 76 Fed. Reg. 78742 (Dec 19, 2011).
26. Note that although reporting of NPI is reported, it will not be made available in the public data. We are unsure why this number will be withheld; the names of the physicians will be still be reported so they are identifiable.