The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 1402
INTRODUCER:	Senators Aronberg and Justice
SUBJECT:	Drug Prescriptions
DATE:	March 14, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Pre-meeting**
2.			CM	
3.			GO	
4.			HA	
5.				
6.				

I. Summary:

The bill prohibits a pharmacy benefits manager, an insurance company, or an electronic transmission intermediary; a retail, mail order, or Internet pharmacy; or other similar entity from licensing, transferring, using, or selling, for any commercial purpose, records of information relating to drug prescriptions containing certain identifiable data regarding patients and prescribers. The bill specifies permissible uses of such information, including the collection, use, transfer, or sale of medical information about an individual for commercial purposes, identified by zip code, geographic region, or medical specialty, if that information does not identify the patient or prescriber.

A violation of the provisions of the bill is a deceptive and unfair trade practice under part II, ch. 501, F.S., and is punishable as provided in s. 501.2075, F.S., relating to civil penalties.

This bill creates one undesignated section of law.

II. Present Situation:

Health Care Information Companies

Since the early 1990s, health care information companies have bought electronic records of prescriptions from pharmacies and other sources and linked them with information about doctors that is licensed from the Physician Masterfile of the American Medical Association.[1] These

[1] See Robert Steinbrook, M.D., "For Sale: Physicians' Prescribing Data," The New England Journal of Medicine June 29, 2006. Found at < http://content.nejm.org/cgi/content/full/354/26/2745 > (Last visited on March 14, 2009).

information companies have then compiled and sold individual physicians' prescribing data to pharmaceutical manufacturers. The largest of these companies, IMS Health, the leading global provider of market intelligence to the pharmaceutical and healthcare industries, reported revenues of $2.2 billion in 2007.[2] Sales to the pharmaceutical industry account for approximately 80 percent of IMS Health's revenue.[3] IMS Health's prescription tracking reporting services are designed to monitor prescription activity and to track the movement of pharmaceutical products out of retail channels. Prescription tracking services are used by pharmaceutical companies to facilitate product marketing at the prescriber level. In the United States, IMS Health monitors prescription activity from retail pharmacies, long-term care and mail service pharmacies using a patented statistical methodology to project the prescription activity of nearly 1.4 million individual prescribers on a weekly and monthly basis.[4]

Drug Detailing

According to a former pharmaceutical representative, drug representatives use a number of psychological, educational, and sales techniques to change the prescribing habits of physicians.[5] Drug detailing is a practice used by a pharmaceutical company sales representative to tailor their sales pitch to individual physician prescribers to influence their prescribing habits.[6] Pharmaceutical companies use prescriber-identifiable data to tailor marketing approaches for specific providers and to measure the effectiveness of their marketing efforts. A subset of pharmaceutical representatives may use data that has been collected on the individual physician prescriber to enhance their marketing efforts. In the year 2000, brand-name drug manufacturers spent roughly $4 billion on detailing.[7]

The American Medical Association Physician Data Restriction Program

In response to complaints by physicians about pharmaceutical sales agents having access to their prescribing histories, the American Medical Association has developed the Physician Data Restriction Program (PDRP).[8] Under the PDRP, which was launched in 2006, physicians can deny all sales representatives access to their individual prescribing data. The restriction is limited to sales representatives and their direct supervisors. Physicians will not be able to deny access to other officials at pharmaceutical companies. The PDRP allows physicians to register complaints against sales representatives or pharmaceutical companies who they believe are using their prescribing data inappropriately. Through licensing agreements with health care information organizations, the American Medical Association can exert influence over how they and their pharmaceutical clients use prescribing data. These licensing contracts require the pharmaceutical

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[2] See IMS Health 2007 Annual Report. Found at < http://imshealth.com/deployedfiles/imshealth/Global/Content/Static%20File/IMS_2007_Annual_Report.pdf > (Last visited on March 14, 2009)
[3] *Id.*
[4] *Id.*
[5] See Shahram Ahari and Adriane Fugh-Berman, M.D., "Following the Script: How Drug Reps Make Friends and Influence Doctors," PLoS Medicine April 2007.
[6] See *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163at 170 (D.NH 2007).
[7] See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 54-55 (1st Cir.2008).
[8] See "AMA Program Helps Protect Prescribing Information – Q & A with American Medical Association Trustee Jeremy A. Lazarus. MD". Found at < http://www.ama-assn.org/ama1/pub/upload/mm/371/pdrp_qa_final.pdf > (Last visited on March 14, 2009)

companies to honor the PDRP physician opt outs. Companies found to be in violation could lose access to the American Medical Association data altogether.[9]

New Hampshire Prescription Information Law

The State of New Hampshire passed the Prescription Information Law in 2006.[10] The New Hampshire law prohibits prescription information records which contain patient or prescriber identifiable data from being transferred, licensed, sold, or used for most commercial purposes. The New Hampshire law prohibits the use of prescriber-identifiable data for "physician jobbing or detailing." "Physician detailing" is a practice used by pharmaceutical company sales representatives to tailor their sales pitch to individual prescribers based on the prescriber's past prescription writing habits. The State of New Hampshire law sought to limit the impact on state health care costs by eliminating the use of "physician detailing" as a tool used by pharmaceutical sales representatives in their promotion of brand name drugs. A federal appeals court reversed and vacated an earlier decision[11] and upheld the right of states to prohibit the use or sale of prescriber-identifiable data that is used in pharmaceutical marketing.[12]

Deceptive and Unfair Trade Practice Act

The Deceptive and Unfair Trade Practice Act (act) is codified in part II, ch. 501, F.S. The act is enforced by the office of the state attorney if a violation of the part occurs in or affects the judicial circuit under the office's jurisdiction or the Department of Legal Affairs if the violation occurs in or affects more than one judicial circuit or the office of the state attorney defers in writing or fails to act within 90 days after a written complaint has been filed. The act provides an enforcement mechanism against unfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce.

III. Effect of Proposed Changes:

The bill prohibits a pharmacy benefits manager, an insurance company, or an electronic transmission intermediary; a retail, mail order, or Internet pharmacy; or similar entity from licensing, transferring, using, or selling, for any commercial purpose, records of information relating to drug prescriptions containing certain identifiable data regarding patients and prescribers. The term "commercial purpose" is defined to mean advertising, marketing, promotion, or any activity that could be used to:

- Influence sales or market share of a pharmaceutical product;
- Influence or evaluate the prescribing behavior of an individual health care professional; or
- Evaluate the effectiveness of a professional pharmaceutical sales force.

The bill authorizes the use of such records for the limited purpose of pharmacy reimbursement; formulary compliance; health care management; utilization review by a health care provider,

[9] Id.
[10] See 2006 N.H. Laws § 328, codified at N.H.Rev.Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) (the Prescription Information Law).
[11] See *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163(D.NH 2007).
[12] See *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 54-55 (1st Cir.2008) (upholding a statute regulating the data mining of physician prescription histories as commercial speech).

insurance provider, or agent of the health care provider or insurance provider; health care research; or as otherwise provided by law.

The bill does not prohibit the dispensing of prescription drugs to a patient or to the patient's authorized representative, the transmission of prescription information between an authorized prescriber and a licensed pharmacy, the transfer of prescription information between licensed pharmacies, the transfer of prescription records that may occur if ownership of a pharmacy is changed or transferred, educational communications given to a patient about the patient's health condition or adherence to a prescribed course of therapy, or the provision of other information about a drug being dispensed, treatment options, or clinical trials.

The bill does not prohibit the collection, use, transfer, or sale of medical information about an individual for commercial purposes, identified by zip code, geographic region, or medical specialty, if that information does not identify the patient or prescriber.

A violation of the provisions of the bill is a deceptive and unfair trade practice under part II, ch. 501, F.S., and is punishable as provided in s. 501.2075, F.S., relating to civil penalties. Under s. 501.2075, F.S., any person, firm, corporation, association, or entity, or any agent or employee of the foregoing, who is willfully using, or has willfully used, a method, act, or practice declared unlawful under s. 501.204, F.S., or who is willfully violating any of the rules of the Department of Legal Affairs adopted under part II, ch. 501, F.S., is liable for a civil penalty of not more than $10,000 for each such violation. The penalty may be waived by a court under certain circumstances when full restitution or reimbursement of actual damages has been paid to the consumers or governmental entities that have been injured by the unlawful practice or rule violation.

The bill provides an effective date of July 1, 2009.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

To the extent that information relating to drug prescriptions containing certain identifiable data regarding patients and prescribers may be characterized as commercial speech it may be protected under the First Amendment of the U.S. Constitution from unwarranted governmental regulation to the extent that it concerns a lawful activity that is not misleading or fraudulent, and may be restricted only if the government's interest in doing so is substantial, the restrictions directly advance the government's asserted interest, and the restrictions are no more extensive than necessary to serve that interest.[13] A court examines four factors to determine whether a government restriction on free speech is permissible:

- Whether the expression concerns a lawful activity and is not misleading;
- Whether the government's interest is substantial;
- Whether the restriction directly serves the asserted interest; and
- Whether the restriction is no more extensive than necessary.[14]

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Companies that benefit financially from pharmaceutical market intelligence activities may experience a reduction in their revenues.

C. Government Sector Impact:

Officials at the Department of Health report that the bill will not have any fiscal impact on the department's resources.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[13] See generally, *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Commission of New York*, 447 U.S. 557, 564, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980).
[14] *Id.*

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.