

FDA Law Update

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Data Mining Bans and Restrictions

Pharmaceutical companies may face increasing hurdles in marketing their products to physicians as states begin to ban prescription data mining. To date, legal challenges to such state laws have largely failed. Prescription data mining is an important marketing tool for pharmaceutical companies.

Health information organizations ("HIOs") create prescriber profiles by buying prescription information (minus patient names) from pharmacies and cross-checking this information against a list of individual physician prescription identities that are purchased from the American Medical Association ("AMA").^[1] These prescriber profiles include information such as the physician's name, specialty, practice site, and which and how many prescriptions the physician writes and are sold to pharmaceutical companies to allow their salespeople to tailor marketing strategies to individual physicians. Currently, New Hampshire, Vermont, and Maine all have laws banning prescription data mining. Other states, including Hawaii, Maryland, Massachusetts, Nevada, New York, Washington, and the District of Columbia, have introduced legislation to limit data mining. The restrictions contained in both the existing and the proposed legislation target the sale and use of patient or prescriber data for marketing or commercial purposes. The legislation does not limit the sale and use of such data for purposes such as insurance reimbursement, dispensing prescriptions, utilization review, public health research, law enforcement, adverse effects reporting, or compliance with Medicaid or private insurance rules.

In 2006, New Hampshire passed the Prescription Privacy Law, which prevents patient and prescriber identifying data from being sold or used for advertising, marketing, promotion or any activity intended to influence sales or market share of a pharmaceutical product. The law was passed as a consumer protection and public health measure, and was intended to safeguard privacy in prescribing.

In 2007, the Vermont legislature passed a law banning all use of prescriber data for marketing purposes unless a physician explicitly agrees to waive the protections. Such a waiver would take the form of an opt-in provision at the time of licensure or renewal and would be managed by Vermont's professional licensing board.

Also in 2007, the Maine legislature passed the Maine Prescription Restraint Law, which established a state-sponsored opt-out process for physicians, physician assistants and nurse

practitioners to prevent access to practitioner specific prescribing data. Specifically, the legislation required the state's Board of Licensure to include in its licensure and renewal processes a confidentiality protection for prescribing data. Applicants must be informed that their prescription drug information is used for marketing purposes, and they must be instructed on how to opt-out of this data gathering system. Maine's law is generally considered a weaker alternative to the prescribing data protection systems in Vermont and New Hampshire.

As noted, legal challenges to the New Hampshire and Vermont laws by HIOs have been mostly unsuccessful. In *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), the First Circuit reinstated New Hampshire's ban after the law had been found unconstitutional by a United States District Court for the District of New Hampshire. The challenge to New Hampshire's law was based on a claim that the confidentiality law infringed free speech. The First Circuit concluded that the regulated data transfers did not embody restrictions on protected speech, and, even if it did, the law still passed constitutional muster. The court stated that "In combating this novel threat to cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands." On March 27, 2009, the HIOs filed a joint petition for a writ of certiorari with the U.S. Supreme Court. Thirteen *Amicus* briefs have been filed to date, including one by the State of Vermont. The Court has set a conference date of June 25, 2009.

HIOs have also independently challenged the Maine and Vermont laws, filing two separate suits in 2007. The U.S. District Court for the District of Maine struck down Maine's law, holding that it violated the free speech guarantee of the First Amendment. However, because Maine is within the First Circuit, it remains unclear whether the lower court's decision would be upheld on appeal. The Attorney General's office has yet to state whether they will wait for Supreme Court review of the First Circuit decision on the New Hampshire law or whether they will proceed with their appeal.

Finally, Vermont's data mining law was recently upheld by the U.S. District Court for the District of Vermont. Unlike the First Circuit, the U.S. District Court for the District of Vermont (a member of the U.S. Court of Appeals for the Second Circuit) held that prescriber data is protected speech under the First Amendment; however, it upheld the law because Vermont's restrictions satisfied the three-prong test used by courts to analyze commercial speech. The court also addressed the HIOs' dormant commerce clause claim, holding that HIOs could gather and sell data originating in other states but could not use or sell data originating in Vermont, even if that data had been transferred to a pharmacy's out-of-state parent company.

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[1] The prescription information is able to be sold despite federal privacy protections in HIPAA. The AMA has stated that it only sells physician prescription identity numbers to those clients who are licensed to received information from the U.S. Department of Commerce National Technical Information Service.