

January 02, 2008

D.C. Ban on Rx Data Mining Could Face Legal Battles

by Zach Brennan

The Washington, D.C., Council last month joined a handful of states to vote in favor of restricting access to information about physicians' prescribing trends, but the narrowly passed ban is only the tip of the debate over the mining and selling of prescription data.

Data mining companies use software to search pharmacies' computer databases of prescription drug information and then sell the information to pharmaceutical companies. Drug companies' sales representatives then can track physicians' prescribing patterns and market particular prescription drugs to them.

The American Medical Association, which has licensed physician information to data mining companies for over 60 years, is joining pharmaceutical companies in arguing that the bans would impede medical research and other efforts to monitor the safety and efficacy of drugs.

But 12 state governments and the D.C. Council have proposed legislation in accordance with consumer and physician privacy groups that say data mining drives up prescription drug costs and interferes with physician practices. The D.C. Council is scheduled to hold a final vote on the measure on Jan. 8.

New Hampshire the First Test

New Hampshire in 2006 became the first state to pass such a ban, drawing a legal challenge from IMS Health and Verispan, data mining companies. In federal court, the firms argued that the bill violates free speech rights and restricts public health research. The court declared the ban unconstitutional, and now New Hampshire is appealing the ruling.

The recent Washington, D.C., ban could meet similar legal and logistical problems that New Hampshire is battling.

In a letter to Vincent Gray, chair of the D.C. Council, Michael Maves, AMA CEO, wrote that the "SafeRx Act of 2007 contains elements that attempt to distinguish it from the New Hampshire statute, but if enacted, it is likely to draw the same legal challenges filed in the other three states that have enacted legislation addressing this issue."

Those states include New Hampshire, Maine and Vermont. Maine also is appealing a court decision that overturned its ban.

According to Maves, the district's legislation could draw legal challenges because it "would inhibit the collection of important prescribing data that are used to analyze pharmaceutical utilization, prescribing trends, and most importantly, safety issues associated with prescription drugs."

The theory that such a ban could help patient privacy rights also is refuted by Maves, who writes that "the SafeRx Act of 2007 neither strengthens nor supersedes existing [HIPAA federal] law and therefore, fails to improve patient confidentiality protections."

Moreover, Maves argues that the "commercial collection" and use of prescription data generate revenue for developing databases used by government agencies, academia, medical researchers and businesses for a wide range of health care purposes, such as drug safety studies.

Karmen Hanson, senior health policy specialist for the National Conference of State Legislatures, said, "Because the cases in other states aren't resolved yet, it is likely that [the district's ban] would be challenged as well. That said, every case is different, and we have seen similar situations where legislation is challenged in one state and not in another for various reasons."

Benefits of Mining Ban, Role of Government

Critics of data mining charge that the information is used more for financial purposes and regulation of physicians' prescribing habits than for research.

"There's a cost problem: brand-name drug companies are using this information to try to get physicians to increase their proportion of their drugs being prescribed, and they're developing very sophisticated marketing techniques to do that," said Rob Restuccia -- executive director of the Prescription Project, which seeks to address conflicts of interest created by the pharmaceutical industry's marketing practices.

Data mining makes it possible for "the drug companies to tailor their marketing very specifically to individual physicians," Restuccia said.

He added, "The physicians realistically are not particularly organized to oppose [data mining] ... and relative to the power of the pharmaceutical industry, the AMA and the data mining industry, individual physicians are sort of outgunned."

Surveys of physicians who understand what data mining is are opposed to the practice, according to Restuccia, who believes that the appeals by New Hampshire and Maine to ban data mining will be successful.

Restuccia also said that some of the information obtained through data mining end up being "inaccurate information about health risks and might encourage the prescribing of newer drugs that may be riskier to patients than already-established treatments."

Although most of the data do not identify particular patients, Restuccia said he thinks that data mining creates privacy concerns and that patients "would be very upset to understand that this is being used."

Other Solutions To Data Mining, Future of Bans

The district's bill also would allow doctors to opt into a mining program, so physicians that see the benefits of such a program could still allow firms to obtain their prescription data from pharmacies.

Hanson said that some physicians could opt-in to the program to help them track patient outcomes, while other physicians "would not opt in because they may feel that someone looking into their prescribing patterns and patient outcomes is no one else's business."

AMA also offers its own solution for physicians that wish to restrict certain data from being mined.

"A better approach to controlling access to prescribing data is offered by the AMA's Physician Data Restriction Program (PDRP)," Robert Mills, an AMA spokesperson, said, adding that nearly 12,000 physicians have chosen to protect their prescribing information through PDRP to "designate their prescription data as off-limits to drug salespeople and register complaints against drug companies or their sales staff who use the data inappropriately."

But Restuccia said the opt-out approach is not particularly well known among physicians.

Tommy Wells, D.C. Council member, also has said that physicians and other pharmaceutical companies should not police and monitor themselves.

Restuccia's Prescription Project is working with a number of other states, including Colorado and Massachusetts, to adopt legislation to ban data mining. "I think there's growing momentum around this and as states continue to grapple with the cost of pharmaceuticals, they will address this issue," Restuccia said.

More on the Web:

- "Washington, D.C., Gives Initial Approval To Rx Data Mining Ban," *iHealthBeat*, 12/12/07
- [AMA's Physician Data Restriction Program](#)
- "New Hampshire to Appeal Ruling on Drug Data Mining," *iHealthBeat*, 5/7/07
- [The Prescription Project](#)