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Prescription data opt-out law upheld in Maine

An appeals court rules that letting physicians refuse to release information for marketing purposes doesn't violate the rights of analysis firms.

By KEVIN B. O'REILLY, amednews staff. Posted Aug. 23, 2010.

A Maine law that allows physicians and other prescribers to opt out of having their prescribing data sold to health information firms and drugmakers for marketing purposes is constitutional, a federal court has ruled.

The 1st U.S. Circuit Court of Appeals ruling reversed a lower court decision in favor of plaintiffs IMS Health Inc., SDI Health LLC and Wolters Kluwer Pharma Solutions Inc. U.S. District Judge John A. Woodcock Jr. had ruled that the Maine law would unconstitutionally limit the data analysis firms' free speech rights. The appeals court's three-judge panel disagreed.

"The statute regulates conduct, not speech, and even if it regulates commercial speech, that regulation satisfies constitutional standards," U.S. Court of Appeals Chief Judge Sandra Lynch wrote in her Aug. 4 opinion. "The Maine statute constitutionally protects Maine prescribers' choice to opt in to confidentiality protection to avoid being subjected to unwanted solicitations based on their identifying data."

Due to a court injunction, the Maine law has never been implemented. The 1st Circuit Court lifted the injunction, though it is unclear when prescribers in the state will be able to use the law to opt out.

The appeals court in 2008 upheld a New Hampshire law that bans the sale of prescribing data for marketing purposes. IMS and its co-plaintiffs appealed that decision to the U.S. Supreme Court, which declined to hear the case.

Only 3 states regulate marketing of physician prescribing data.

The Maine ruling will help patients, said Meredith Jacob, pharmaceutical policy fellow at the American University Washington College of Law's Program on Information Justice and Intellectual Property.

"This decision reinforces the earlier 1st Circuit Court decision saying that the state can protect patients from invasive marketing practices that are bad for patients because they distort prescribing practices and increase the cost of health care," said Jacob, who helped draft a friend-of-the-court brief filed by the National Legislative Assn. on Prescription Drug Prices in the New Hampshire case.

The only other state with a prescribing data law is Vermont, which allows physicians to opt in to have their prescribing data available for marketing uses. A federal court upheld that state's law in April 2009. The health information firms appealed the decision to the 2nd U.S. Circuit Court of Appeals, which heard oral arguments last October but has yet to issue a ruling.

The firms are "exploring all legal options" regarding the Maine decision, said IMS spokesman Phil Oliva. They could ask for the entire 1st Circuit Court to review the decision or ask the Supreme Court to hear the case. The nation's top court is more likely to review the issue if the 2nd Circuit Court sides with the data analysis firms on the Vermont law, experts said. The New Hampshire and Vermont laws are in effect.

Other states hesitate

IMS, SDI and Wolters Kluwer said in a joint statement that state legislators outside New England consistently have declined to enact prescribing data marketing restrictions.

"Although the courts have split on these issues, over the past three years more than two dozen state legislatures have rejected passage of laws which restrict access to information about physician treatment practices," the companies said. "Everyone wants access to more information, not less. Increased transparency and access to information from many sources will produce better health outcomes, improve patient safety and lower health care costs."

No bill restricting the sale of prescribing data for marketing has gotten to the floor of a legislative chamber for a vote this year, experts said.

The Maine Medical Assn. did not officially oppose the opt-out law, but did not support it either, said Gordon H. Smith, the organization's executive vice president. The association believes the American Medical Association's Physician Data Restriction Program, which since July 2006 has allowed doctors to opt out of having their data shared with drug reps, is sufficient to address critics' concerns.

More than 26,000 physicians were enrolled in the AMA's data-restriction program as of this article's deadline. A 2009 AMA survey of physicians showed that, of doctors who offered an opinion on the matter, 96% were either satisfied or very satisfied with the Association's opt-out plan. More than half the doctors told a colleague about the program.

The AMA licenses Physician Masterfile information such as names, addresses, education credentials and DEA license numbers on about 1 million doctors to firms such as IMS. These companies also purchase prescribing information from pharmacies, then link prescribers to prescriptions and resell the data to drugmakers. Pharmaceutical companies use the information to track how well their sales representatives are faring in persuading physicians to prescribe their drugs.

This content was published online only.

ADDITIONAL INFORMATION:

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1st U.S. Circuit Court of Appeals decision in *IMS Health, Verispan and Source Healthcare Analytics v. Mills*, Aug. 4 (www.ca1.uscourts.gov/cgi-bin/getopn.pl?OPINION=08-1248P.01A)

American Medical Association Physician Data Restriction Program (www.ama-assn.org/go/prescribingdata)

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