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Second Circuit Court of Appeals Finds Vermont Prescriber Data-Restriction Law Unconstitutional

HealthcareIndustry

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On November 23, 2010, the U.S. Court of Appeals for the Second Circuit dealt a blow to a controversial public policy trend in which states are restricting the use of information about physician prescribing habits in pharmaceutical marketing.

States like New Hampshire, Maine, and Vermont, all of which have prescriber data-restriction laws, contend that the laws advance their states' interests in protecting public health, protecting the privacy of prescribers and prescribing information, and in containing prescription drug costs. But many health care quality advocates believe that the laws could have the unintended consequence of stifling quality-improvement efforts that rely on the free flow of patient de-identified health care information.

When filling prescriptions, pharmacies in Vermont collect information, including the prescriber's name and address, the name, dosage, and quantity of the drug, the date and place the prescription is filled, and the patient's age and gender. Pharmacies sell this prescriber-identifiable data to data-mining companies that aggregate it to reveal individual physician prescribing patterns and sell it primarily to pharmaceutical manufacturers. The data is stripped of patient information, to protect patient privacy.

Vermont's prescriber data-restriction law, passed in 2007, prohibits pharmacies, health insurers, data-mining companies, and other "similar" entities from selling, licensing, or exchanging for value records containing prescriber-identifiable information for prescription drug marketing or promotion. Marketing is defined to include advertising, promotion, or any activity that is intended to be used or is used to:

- Influence sales or the market share of a prescription drug;
- Influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug;
- Market prescription drugs to patients; or
- Evaluate the effectiveness of a professional pharmaceutical detailing sales force.

The law permits the sale, transfer, or use of prescriber-identifiable data for other purposes, including pharmacy reimbursement, prescription drug formulary compliance, and patient care management, among others.

IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc., three data-mining companies, filed suit to enjoin enforcement of the Vermont law in August 2007. The companies argued that the law violated their freedom of speech under the First Amendment and that it restricted commercial activities outside of Vermont in violation of the dormant

Commerce Clause. The U.S. District Court for the State of Vermont upheld the law, finding it to be a constitutional restriction on commercial speech under the test set forth in the Supreme Court's decision in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York,* and finding that it did not violate the Commerce Clause. In reversing the District Court's decision, the Second Circuit Court of Appeals found that the law's attempt to influence the prescribing conduct of physicians by restricting the speech of data-mining companies, pharmaceutical manufacturers, and others does not directly advance the state's interests. The Second Circuit Court found that Vermont has more direct, less speech-restrictive means to obtain its goal of constraining prescription drug costs, such as academic detailing, which is a form of non-commercial outreach to prescribers designed to ensure their medication choices are consistent with medical evidence, support patient safety, and are cost-effective.

Health care quality-improvement advocates argue that the Vermont law and others like it could impede the potential of emerging health information technology ("health IT") tools to improve patient care and public health. With the advent of health IT tools like electronic health records, which make it easier than ever to collect, exchange, aggregate, analyze, and communicate health information, health care providers' performance can be evaluated and improved. However, quality advocates argue that Vermont's data-restriction law could cause enough uncertainty to prevent pharmacies and data-mining companies from making prescriber data available at all – for quality-improvement efforts or otherwise. Manatt has filed amicus curiae briefs on behalf of a number of stakeholders in the Vermont and New Hampshire cases making this and other arguments.

With the Second Circuit Court's decision, the debate over the policy implications of states' implementation of prescriber data-restriction laws is poised to continue. Because the U.S. First Circuit Court of Appeals found in favor of Maine's and New Hampshire's prescriber data-restriction laws while the Second Circuit Court found against Vermont's law, the issue could go to the Supreme Court.

For questions or for more information, contact William Bernstein at 212-830-7282 or Susan Ingargiola at 212-790-4639.

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<sup>1</sup>Vt. Stat. Ann. tit. 18, § 4631(a).
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² *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434 (D. Vt. 2009). back to top