

Privacy Interests in Prescription Data, Part I

Prescriber Privacy

For several years, concern has been growing about the privacy implications that arise from the use and disclosure of prescription data. More specifically, the impugned transactions involve the sale or transfer of prescription data from pharmacies to commercial

Prescription data, which include drug details and possibly diagnoses, are more clearly information about a patient; less clear, however, is whether such data can identify the specific patient in question. Prescription data, as they are released to commercial data brokers, won't contain any directly identifiable information, but will include information such as age and gender. Geographic information about where the patient lives is sometimes inferrable based on the location of the dispensing pharmacy and prescriber. Even such limited information might, in some circumstances, be sufficient to re-identify patients. So, although prescription data are clearly about the patient, the second privacy issue that arises is whether such data contain fields that—taken together or combined with other publicly available data—can possibly identify the individual involved.

In this first part of our series, we focus on physicians' privacy interests in prescription data.

Prescriber Information in Canada

In Canada, the commercial sale of prescription data is presently governed by private-sector privacy legislation or other related laws and regulations. Different jurisdictions have taken different approaches.

Federally, the Personal Information Protection and Electronic Documents Act (PIPEDA; <http://laws.justice.gc.ca/en/P-8.6/>) de-

data brokers, subsequent processing of the data by commercial data brokers, and their eventual resale to pharmaceutical companies in the form of prescribing patterns or practices. These patterns or practices provide pharmaceutical companies with the historical trends they need to better target marketing efforts aimed at individual physicians through more intense, precise, and unique detailing strategies. Evidence suggests that such strategies are successful in influencing physicians' prescribing habits.¹⁻⁴ Whether this influence gives rise to professional conflicts of interest, introduces undue bias in clinical decisions by favoring brand-name drugs over generic equivalents, results in less-than-optimal treatment for patients, and ultimately increases health-care costs are important ethical and policy issues that extend beyond this article's scope. The purpose of this two-part article is to focus only on the privacy implications arising from the sale or transfer of prescription data, with respect to both prescribers and patients in Canada and the US.

Prescription Records and Related Privacy Issues

Most privacy laws generally define personal information as *identifiable* information *about* an individual and require that individual's consent before such personal information can be collected, used, or disclosed, absent some applicable exception. The release of prescription data to commercial data brokers raises two different privacy issues, one with respect to prescribers and the other with respect to patients.

There are two types of prescription data depending on the source: retail pharmacies and hospital pharmacies. In both cases, prescription data will typically include some unique identifier of the prescriber, which, in combination with other available data, can easily reveal the prescriber's name. So, although prescription information is clearly—or at least readily—identifiable with respect to the prescriber, the first privacy issue is whether it constitutes information about that prescriber rather than merely information about his or her work.

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defines personal information broadly to mean information about an identifiable individual. In 2001, Canada’s former privacy commissioner, George Radwanski, found that prescription data, whether individual prescriptions or overall prescription patterns, don’t constitute physicians’ personal information within the meaning of PIPEDA.⁵ In the context of a specific complaint against IMS Health Canada (a global company that provides “market intelligence” to pharmaceutical and healthcare industries), the former commissioner didn’t regard prescription data as information about the physician in any meaningful sense, but rather as information about something “once removed, namely the professional process that led to its issuance.” In Radwanski’s view, this information was conceptually more akin to work-product information than personal information. Consequently, he concluded that such data fall outside PIPEDA’s scope and could be disclosed without consent. (For a good overview of the present commissioner’s position on the concept of “work product,” as it has evolved over time, see www.privcom.gc.ca/parl/2007/sub_070222_e.asp.)

More recently, the Alberta Court of Queen’s Bench adopted a more technical approach in answering a similar question.⁶ Applying specific provisions in Alberta’s Health Information Act (HIA), the court found that of all the prescription data elements IMS Health had collected from pharmacies across Alberta, only the physician’s name constituted “health services provider information” as expressly defined in the act (see www.qp.gov.ab.ca/Documents/acts/H05.CFM). However, because the physician’s name is also among the types of health provider information that can be disclosed under the available business-card exception, the court held the non-consensual sale of prescription

records to third parties to be permissible. It rejected the counter-argument that the business-card exception shouldn’t apply in this case because releasing the physician’s name with all the other data elements in the prescription record would reveal “other information about the health services provider.” The court refused to interpret this phrase broadly enough to mean any other information about the provider but rather chose to limit its analysis to only those prescribed elements contained within the statutory definition of “health services provider information.” (Recently, Alberta’s government introduced Bill 52, which would amend HIA by, among other things, removing “health services provider information” from the definition of personal information altogether; see www.assembly.ab.ca/bills/2008/pdf/bill-052.pdf.)

In British Columbia, the Personal Information Protection Act (PIPA) expressly excludes both contact and work-product information from its definition of personal information (see www.webcitation.org/5dpX47Weo). Whether prescription data constitutes physicians’ personal information, which requires their consent before third parties can use or disclose it, or whether they escape the consent requirement by falling under PIPA’s contact or work-product exclusions, has never undergone formal examination. In British Columbia, the release of prescription records for commercial

[citation.org/5dpVugOMF](http://www.webcitation.org/5dpVugOMF)). The professional prohibition is worded broadly enough to ban any commercial “release of information or an abstract of information obtained from a prescription, which would permit the identity of the practitioner or the patient to be determined” (see subsection 35(3) of the by-laws).

In Quebec, the Act Respecting the Protection of Personal Information in the Private Sector takes yet another approach by treating professional information as the professional’s personal information and expressly allowing third parties to collect, use, and disclose it, but subject to the conditions listed in Article 21.1 (see www.webcitation.org/5dpVpGzhC). Quebec’s Commission d’accès à l’information (CAI) might, after consulting with the relevant professional bodies, authorize persons to collect information about professionals’ activities (in this case, physicians’ prescribing data) without consent, provided that

- the individual client (here, the patient) receiving the professional service can’t be identified;
- the professional receives periodic notification about intended uses and valid opportunity to opt out; and
- security measures are in place to ensure that the personal information remains confidential.

The authorized person can in turn disclose professional information

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purposes is prohibited altogether under By-Law 5 of the Council of the College of Pharmacists of British Columbia (see www.web

www.web to third parties without consent only if

- the authorized person com-

municates the information in a combined form that doesn't allow others to identify any spe-

er large commercial data broker) challenged this law's constitutionality, claiming that the prohibition

self has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.⁹

The provisions aim to restrict the use and transfer of prescription information for narrowly defined commercial ends to level the bargaining power between sellers and buyers.

- specific professional act;
- the professional is periodically given valid opportunity to opt out;
- third parties receiving the information undertake to use it only for intended purposes; and
- the authorized person reports annually to the CAI on how it's implementing these conditions.

Moreover, to maximize transparency, the CAI publishes, in its annual report, a list of all authorized persons allowed to disclose professional information under these provisions.

Prescriber Information in the US

In the US, the debate has taken a somewhat different turn. Commercial data brokers aren't covered under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (see www.hhs.gov/ocr/regtext.html). Nevertheless, several states have attempted to restrict the commercial use, transfer, or sale of prescription records via sector-specific statutes, many of which have recently been challenged.

For example, New Hampshire adopted a Prescription Information Law that prohibits anyone from using, transferring, or selling prescription information for commercial purposes, including "advertising, marketing, promotion or any activity that could be used to influence sales or market share of a pharmaceutical product."⁷ IMS Health and Verispan (another

impermissibly restricts their First Amendment right to free speech. At first instance, the US District Court for New Hampshire agreed with the plaintiff companies and ordered the offending provisions unenforceable by way of permanent injunction.⁸

More recently, however, the majority of the US First Circuit Court of Appeals reversed this decision, declaring that the challenged portions of the law seek principally to regulate the data brokers' conduct, not their free speech, and therefore don't violate the First Amendment.⁹ (Note that IMS Health and SDI, which has since acquired Verispan, issued a joint press release on 16 December 2008 announcing that the companies have filed a motion with the First Circuit Court of Appeals requesting a rehearing of this decision.)

According to the majority of the Court of Appeals, the provisions aim to restrict the use and transfer of prescription information for narrowly defined commercial ends to level the bargaining power between sellers and buyers—that is, by eliminating detailers' ability to ratchet up their marketing tactics and by restoring the integrity of physician decision-making processes. Such provisions don't significantly touch on the core values protected by the freedom of speech and hence fall outside the scope of the First Amendment:

In other words, this is a situation in which information it-

Furthermore, the majority decision of the Court of Appeals went on to hold that even if the law did infringe on commercial speech, it's nonetheless constitutionally permissible because it directly advances a substantial governmental interest and restricts speech no more than necessary. Of the several governmental interests advanced by the US Attorney General, the majority of the Court of Appeals restricted its analysis to only healthcare costs. It didn't address the important privacy arguments raised by the Attorney General or the Electronic Privacy Information Centre (EPIC) that intervened as *amicus curiae*, or "friend of the court." Consequently, this case provides no further enlightenment on the risks to prescriber or patient privacy posed by the commercial use, transfer, or sale of prescription data.

Interestingly, the majority of the Court of Appeals in this case appeared more willing than the lower court to grant New Hampshire some legislative discretion. As the first state that attempted to formulate novel public policy on this cutting-edge issue, New Hampshire should be granted some "elbow room" in the legislative approach it chooses to adopt to deal with the growing social and economic problems associated with detailing practices. Indeed, other states that have since followed suit by introducing similar laws are looking to the New

Hampshire experiment to determine how to move forward.

For instance, Maine's Act to Amend the Prescription Privacy Law¹⁰ also forbids prescription drug information intermediaries from using, selling, or transferring—for any marketing purpose—prescription information, but only of those prescribers who have chosen to opt out of such transactions by filing for confidentiality protection. In this respect, the Maine law is less prohibitive than its New Hampshire equivalent, which doesn't have a similar opt-out provision. The Maine law is also consistent with the opt-out approach facilitated by the American Medical Association through its Physician Data Restriction Program (see www.ama-assn.org/ama/pub/category/12054.html). Companies nonetheless challenged the Maine law on the grounds that it, too, violates their right to free speech. In a motion for preliminary injunction, the US District Court of Maine heard several policy arguments, including claims both for and against prescribers' right to privacy, and considered whether the sale of prescription data constitutes unauthorized use of a professional work product. The court found sufficient evidence to conclude that the Maine law violates companies' First Amendment right and granted a temporary injunction against its enforcement until the case could be permanently decided on its merits.¹¹ The ultimate outcome of this case will likely be affected by the result of the New Hampshire Court of Appeals.

The Vermont legislature has postponed enforcing a similar amendment to its laws until 1 July 2009 (see www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2008/acts/ACT089.htm). The relevant prohibition in the Vermont law is different than both the New Hampshire and Maine laws, in that it prohibits data brokers from using, transferring, or

selling for marketing purposes any prescriber-identifiable prescription information unless the prescribers in question have given their *opt-in* consent—that is, their express agreement beforehand. The Vermont amendment is also the subject of ongoing litigation, and its fate will likewise be affected by the outcome of the New Hampshire appeal.

As you can see from our survey, the commercial use, transfer, and sale of prescription data have come under significant legal scrutiny in several jurisdictions across both Canada and the US, but through a different lens.

In Canada, legal analyses have turned mostly on assessing the privacy interests at stake. If we were to draw a conclusion based on the Canadian jurisprudence to date, the practice appears to be generally permissible in most jurisdictions we surveyed (with the exception of British Columbia), either because it is excluded from the scope of privacy regulation altogether, is exempt from consent requirements on an exceptional basis, or is permitted subject to numerous conditions, checks and balances.

In the US, legal analyses have been mostly constitutional in nature, based on First Amendment arguments raised by commercial data brokers. In light of the recent US Court of Appeals' decision, such constitutional arguments might have received a fatal blow, and laws restricting the use and transfer of prescription data for commercial uses could be here to stay. Although patient and prescriber privacy interests were among the broad public policy arguments raised by parties seeking to support the legislative intent, these privacy arguments were seemingly not the most persuasive. Rather, in the end, it was the state's interest

to contain healthcare costs that carried the day, not its interest in protecting privacy.

So far, what appears to be common in both Canada and the US is this: in cases in which decision-makers have expressly examined privacy arguments raised by various parties, their rationale consistently began with the assumption that patient-related information is clearly nonidentifiable. For the most part, they regarded patient re-identifiability as unlikely and set it aside as a nonissue from the outset, moving on rather hastily to address the issue of prescriber privacy. In the second part of this article, we will begin to question this assumption and challenge the basic premise that patients can never be re-identified from prescription data disclosed to commercial data brokers. □

Acknowledgments

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Advertiser Index

January/February 2009

Advertiser	Page
Black Hat 2009	Cover 4
Infosec World 2009	Cover 2
MIT Press	11

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