

A state law banning commercial use of prescription audit data is meant to protect physicians' privacy. But its effects on industry could be potentially damaging, as **Warren Ross** discovers

THE BATTLE OF NEW HAMPSHIRE

One day a sales rep in New Hampshire said to a cardiologist: “Doctor, you’re one of my target physicians.” When the doctor got home, he mentioned this to his wife, wondering how the rep knew what he prescribed. Earlier this year, his wife—Rep. Cindy Rosenwald—introduced a bill to ban the commercial use of prescription audit data. It passed and took effect in August. Coincidence?

Rep. Rosenwald explains that while she remembers this incident, her motive was not personal. Rather it was strictly a matter of public policy with two objectives: to protect the privacy of physicians and to put the brakes on the exploding cost of prescription drugs for both individual patients and the state’s Medicaid plan.

The NH law is the first to take effect, but copycat bills have been introduced in other, more populous states, while in Congress, Reps. Pete Stark and Frank Pallone have drafted similar legislation. A press release spells out their motivation: “Using prescription data that should remain private, pharmaceutical sales representatives currently hawk snake oil to doctors. The Prescription Privacy Protection Act would stop salespeople from influencing physicians’ medical decisions.”

This development has, understandably, triggered concern not only on the part of market research companies but also of the pharma industry that depends heavily on their audits. IMS Health and Verispan, the primary sources of prescribing data, announced: “The law would restrict the flow of prescriber information that is essential to improve the quality of healthcare and ensure patient safety.”

PhRMA, for its part, issued a statement that the NH law “could potentially damage continuing medical research and stymie efforts to communicate clearly and effectively with physicians regarding appropriate use of medicines.” And the American Medical Association (AMA), which is more than a disinterested observer since it generates income from research companies’ use of its Physician Masterfile, points out that the data generated by Rx surveys are “critical to improving the quality, safety and efficacy of providing patient care through the application of evidence-based medical research.” This potential consequence also has researchers up in arms, even though the NH law specifically permits non-commercial use of the data.

“Live free or die”

That’s the slogan featured on all NH license plates, and Rep. Rosenwald referred to it in explaining why she introduced House Bill 1346—and how it came to pass almost unanimously. NH folks, she says, don’t like people invading their privacy. In addition to concern about doctors’ privacy, she adds, the bill’s backers “thought it would help control spending on brand name drugs.” To illustrate what she sees as the problem, she says that NH’s Medicaid costs for Rx drugs have risen 84% in the last five years.

But not everyone in the state agrees. Among the law’s critics is Charles Arlinghaus, president of the Josiah Bartlett Center for Public Policy in Concord, the state capital. He sees several problems. Foremost are the unintended consequences, such as making Rx data unavailable to research physicians. “What the people voting for this didn’t think about,” he counters, “is that the database created by the tracking of prescriptions is not just extraordinarily valuable, it’s also very expensive to create, and its creation is only possible because of its

commercial use.” Take away those commercial uses, he says, and the data won’t be available to healthcare researchers and law-enforcement and Medicaid-abuse investigators either.

Then how did such a potentially damaging bill become law? Partly, Arlinghaus says, because pharma companies have been demonized. “Therefore, anything they want is viewed skeptically, and anything they don’t want is initially viewed favorably.” But primarily, he feels, it’s because the issues were not aired. “The bill sort of went through without people paying attention,” he says. Also, the head of the state medical society supported it and that pretty much neutralized the argument that the AMA’s Prescription Data Restriction Program (PDRP) made the law unnecessary. The program, which had just been adopted, permits any physician to keep his or her Rx data from being used for commercial purposes, using the so-called “opt-out” provision. According to Mark Frankel, AMA’s VP for database products, 4,200 doctors had registered for PDRP as of the end of September.

Nor does Arlinghaus see much hope of the law being repealed, admitting that “those of us who see it as a negative thing can’t point to any horrific danger resulting from it, nothing horrible like taxes going up. It sounds innocuous at first and...people’s initial reaction is that restricting prescription data is a good idea.” The point that research companies don’t collect patient data—federal law forbids it—somehow got lost. Oddly, when HMOs and other insurance companies use patient data, there is no comparable outcry. Robert Goldberg, PhD, VP of the Center for Medicine in the Public Interest, told *MM&M* that his HMO called to remind him to be tested for prostate cancer the day after he turned 50—the age when such tests are recommended. He finds it puzzling that such use of private information is considered OK.

The counterattack

Those with the most at stake are the companies that collect the data, and IMS Health and Verispan have jointly filed suit in federal court to have the NH law overturned. It’s expected to come to trial in January.



“The public good is best served by evidence-based medicine, improved transparency in the healthcare system, and continued use of and access to these data,” the two companies sum up their position. In order to make informed healthcare decisions, they maintain, there needs to be “access to more information, not less,” pointing out that the information they provide “extends well beyond pharmaceutical marketing, into such areas as drug safety, public health monitoring and patient treatment variability.” Among the agencies that use their data are the FDA, DEA, CDC, and the Departments of Defense and Labor.

They also say that it’s ironic that while the law recognizes the beneficial public health applications of prescription audit data by specifically exempting them from its provisions, “it effectively takes away the incentive for collecting these data.”

Many research physicians also depend on prescribing information. Randall Stafford, MD, of Stanford University has published 14 peer-reviewed articles that make reference to his use of IMS Health data. In an article in the *Archives of Internal Medicine* this year on off-label prescribing, Stafford *et al.* said: “We used nationally representative data from the 2001 IMS [NDTI] to define prescribing patterns by diagnosis for 160 commonly prescribed drugs.” They concluded, incidentally, that “off-label medication use is common in outpatient care, and most occurs without scientific support. Efforts should be made to scrutinize undervalued off-label prescribing that compromises patient safety or represents wasteful medication use.” As this conclusion indicates, Dr. Stafford does not have a pro-industry bias. Referring to his university’s efforts to limit reps’ access and forbid doctors from accepting any gifts, even pencils, he said: “It’s been a long time coming.”

Nonetheless, he shares the concerns of his research physician colleagues that the NH law might remain in effect or, worse, get copied. “These restrictions,” he says, “could have unintended consequences that the drafters of the bill might not have considered, and that would in fact interfere with efforts to monitor proper care.” He also makes the more general observation that recent trends have been in the direction

Key provisions of the New Hampshire law

Headed “Prescription Information to be Kept Confidential,” the bill declares that such information shall not be used, transferred, licensed or sold for any commercial purpose. It spells out that it applies to retail, mail order or Internet pharmacies, and defines commercial purpose as including advertising, marketing, promotion “or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual healthcare professional or evaluate the effectiveness of a professional pharmaceutical detailing sales force.”

The law does specify some exemptions, such as use of Rx data for pharmacy reimbursements and healthcare research. It also says that “nothing in this section shall prohibit the collection, use, transfer or sale of patient and prescriber de-identified data by ZIP code, geographic region or medical specialty for commercial purposes.”

It passed the lower house by voice vote, without debate or opposition. In the Senate there was some discussion, but the final vote was 18 in favor and only 4 against.

of introducing more transparency into medical practice so as to improve standards of patient care, and it seems “like a step in the wrong direction to restrict the availability of data rather than expand it.”

Ernst Berndt, PhD, makes a related but somewhat different point. Dr. Berndt, professor of applied economics and co-director of the Center for Biomedical Innovation at MIT, points to the FDA’s reliance on Rx data. “For example,” he says, “when a black box warning is issued or there is some more dramatic event, such as the withdrawal of a drug, the FDA wants to be able to track who is continuing to prescribe these drugs, what types of patients are using them and whether the patients are taking certain other drugs concomitantly. Having access to prescribing and dispensing data...enables the FDA better to monitor drug utilization at a very detailed geographical and sub-population level.”

What’s more, pharmacy-level prescription reports are available “almost in real time” and, unlike e-prescribing reports, are based on the number of prescriptions actually filled, not on the number written.

Dr. Goldberg describes the objective of the Center for Medicine and Public Interest as making medicine more predictive and preventive. The center collects data that can help identify prescribing errors and patient compliance issues. “A bill that would prevent those kinds of transactions is really overreaching,” he says. Privacy is critical, he agrees, but not at the expense of making data collection so onerous and prohibitively expensive “that you simply make it impossible to get the kinds of answers you want.” Academics like him, he says, have come to rely on commercial sources of Rx data, and he calls attempts to limit these sources “regulatory overkill and political grandstanding.”

Without commercially funded data collection, Goldberg asks, who would take over? “Do you really want the government as the sole possessor of information on physician and patient data?” But he doesn’t entirely let IMS Health off the hook, either. To a certain extent, he believes, IMS has brought its current problems on itself by not being sufficiently cooperative with medical researchers. “They did not anticipate the emerging value of their databases for public health purposes,” he claims, and sometimes researchers can’t afford their fees.

In response, IMS officials explain that they do want researchers to use their data and often do not charge for it. If the request is too complicated to make free use possible, they offer an academic discount. But the company admits that it’s possible that even such reduced charges are sometimes beyond what academic institutions can afford.

A still different perspective is introduced by Tom Stossel, MD, professor of medicine at Harvard Medical School, whose concern is that of both a hematology researcher and a citizen trying to understand what he sees as “a rampant anti-business movement in medicine.” That’s why his views appear not only in the *New England Journal of Medicine* but also in lay media like the *Wall Street Journal* and the *Washington Post*. A recent piece was headlined: “What’s Wrong with Money in Science?”

Dr. Stossel bases his transformation from what he terms “a typical academic socialist” to his experience of serving on the scientific advisory board of Biogen. “Not only was the science exciting,” he recalls, “but what these companies were doing was incredible.” He sees how “miraculously better medicine is today than when I started out, and it’s all because of private industry.” Hence he is critical of what he calls “sanctimonious, holier-than-thou emanations” from those who are

intelligent, but who lack his experience of working with industry. Their purpose, he suspects, is to ban sales forces from academic health centers so that “medical students and young physicians, who already think new technology comes from Santa Claus, will know even less about how companies work.” He is even more seriously concerned about the growing regulations about conflict of interest, so that, for instance, companies can no longer have NIH scientists on their advisory boards. That, he believes, is “preventing technology transfer.”

So while he admits that having a sales rep “standing on my doorstep harassing me is not a good thing,” he sees the NH law as yet another attempt to suppress information, adding simply: “Information is good.”

Fear of collateral damage

The possibility of this type of legislation spreading is obviously a concern to advertising agencies and other industry-related firms. Scott Cotherman, CEO of Corbett Accel Healthcare Group, says such laws “would severely limit the amount, quality and frequency of information provided to healthcare providers by...sales reps, educational communications partners and medical publishers.” Making targeted communications impossible would lead either to a saturation of less-than-relevant information to a wider audience, or the elimination of most communication altogether due to the prohibitive costs. In either case, he says, “the needs of healthcare providers would not be served.”

Cotherman and others appealed to the Coalition for Healthcare Communication to enter the fray, leading it to prepare a supporting brief in the pending lawsuit. The NH law “strikes at the very heart of the First Amendment by attempting to excise certain truthful communications from the marketplace of ideas,” says a preliminary draft.

John Kamp, the coalition’s executive director, reiterates the arguments that while the law cites consumer privacy issues, there are in fact no such issues, and that its provisions protecting research, government, and public policy use of the Rx data are meaningless since the database is unlikely to survive once commercial customers stop paying for it. As an example of the kind of public health damage that could result, Kamp recalls that in the early days of AIDS treatment it was hard to communicate with the small group of physicians who were treating HIV infection since they were not specialties but mostly widely scattered primary care physicians. It was only by tracking who was prescribing antiviral medication that they could be identified. Kamp, too, sees as a major concern the fact that similar legislation has already been considered in New York, Massachusetts, Pennsylvania, Illinois and California—representing roughly half of the national prescribing volume.

California considered such legislation even before NH. And while it did not pass, it alerted the state medical association to the fact that its members were not deriving any personal benefit from having prescriptions tracked. To correct this flaw, the California Medical Association started offering physicians better insight into the prescribing behaviors

What the law’s proponents say

The following points were raised in an article by Jake Whitney in *The New Republic*, titled “How drug reps know which doctors to target.”

- According to a 2004 survey sponsored by the AMA, about 25% of doctors were unaware of the practice of auditing their prescriptions. Some doctors see it as disruptive of their professional prerogatives; others resent the violation of their privacy.
- Buying and selling prescription records is a lucrative business and, perhaps as no other factor, it inflates the cost of drugs.
- AMA’s Prescription Data Restriction Program is just a self-policing measure to avoid more legislation and protect its own interests.

of themselves and their peers. In alliance with IMS, they launched a pilot program designed to provide PCPs with what the association calls “practice parameters in selected therapeutic categories.” Doctors who sign up will receive personalized reports so they can compare their own prescribing behavior with evidence-based guidelines. Migraine was chosen as the pilot category because, despite numerous national initiatives, it remains a seriously neglected condition. To wit: while 12% of the population suffers from migraine, only 3% have been diagnosed, and only half of those diagnosed have been prescribed appropriate medication. If the pilot program proves successful, negligent doctors will be made personally aware of their patients’ needs. And if it then catches on nationally, it could be that the initiative to keep the pharma industry from having access to Rx data will wind up improving patient care. After all, not all unintended consequences have to be bad. ■



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