MAY 2006
Pharmaceutical Executive
FOR GLOBAL BUSINESS AND MARKETING LEADERS

More Than a Game of Keep-Away

The PDRP takes effect in July. The AMA explains how individual doctors can keep their prescribing habits safe from reps, and how pharma can keep using the anonymous data—if the industry polices itself.

For well over a decade, pharmaceutical representatives have had access to detailed information about the prescribing habits of the individual physicians they call upon. During that time, some physicians have protested—sometimes quite vehemently—that reps know too much about what they prescribe. State legislators have been listening. They have introduced a number of bills to keep all prescribing data away from salespeople—and sometimes away from whole companies. Now the American Medical Association (AMA) is seeking a compromise. On July 1, the AMA will introduce new procedures to give physicians some control over who sees information about the type and number of prescriptions they write. The Prescribing Data Restriction Program (PDRP) will take data away from reps and their direct supervisors, but leave it available to the company for marketing, compensation, and research. The rules allow the industry to retain access to prescribing data for most purposes, but they require companies to police their own sales forces. If they succeed, legislators will turn their attention elsewhere, and the industry can hang onto one of its most valuable data sources.

BY ROBERT A. MUSACCHIO AND ROBERT J. HUNKLER

By enrolling in PDRP, individual physicians in the United States can prevent sales representatives and other pharma employees who contact them from accessing information about their prescribing practices. The goal of the program is to strike a reasonable balance between the interests of those physicians who object to sales representatives knowing individual doctors' prescribing history and the interests of many other stakeholders (pharmaceutical companies, public health agencies, academia, and consumers) who benefit from insight into physicians' prescribing decisions.

For this to work, major players must regulate themselves, especially pharmaceutical companies and Healthcare Information Organizations. (HIOs are companies that acquire, aggregate, analyze, and resell prescription data and other medical information.) If the industry cannot police itself effectively, state legislatures are likely to pass laws banning reps' access to prescriber data. Legislation has been introduced in several states this year, but the prospect of the PDRP program has stalled most of the bills. Only effective self-regulation can keep such laws off the books.

The Crux of the Issue

Tracking physicians' prescribing behavior for marketing purposes is hardly new. Enterprising detail men were gathering data bit by bit from doctors and pharmacists in the 1940s, and some successful reps maintained such informal data sources in their territories over the course of years and decades. As database technology became more sophisticated and affordable, HIOs created systematic, nationwide directories that picture any given doctor's prescribing habits, broken down by product and volume of prescriptions. Such databases have been available for license since 1993.

From the beginning, HIOs have recognized the privacy rights of patients. They have always taken pains to work only with de-identified patient data. An individual prescription discloses little about the physician who wrote it, and from a legal perspective, does not constitute personal information about the prescriber.

While laws protecting personal health information of patients are constitutionally founded in principles of privacy, business or professional information has not received similar protection under federal and state court decisions in the United States. Thus, experts in US privacy law assert that collecting, releasing, and using a physician's prescribing information has been—and remains—perfectly legal. Denying the public access to professional information could set a dangerous precedent and hinder informed decisions about healthcare providers.

But such legalities do not comfort physicians who feel they have a right to keep their prescribing information private. Nor has a legal explanation appeased doctors who argue that sales representatives inappropriately pressure them to write a drug. Although physicians have not made many formal complaints to the AMA—at least compared with the millions of sales calls made each month—physicians complain bitterly about sales

Robert A. Musacchio is senior vice president of publishing and business services at the American Medical Association. He can be reached at robert.musacchio@ama-assn.org. **Robert J. Hunkler** is director of professional relations at IMS Health. He can be reached at rhunkler@us.imshealth.com

AMA PDRP IN CAPSULE

Full details of the program will be available via AMA Database Licensees (DBL). Here are the highlights:

- PDRP enrollment will begin on the AMA's Web site so that the program can take effect on July 1, 2006. Enrolling in the program is sometimes known as "election."
- Enrollment will remain in effect for three years from the date on which the AMA receives the physician's election.
- Pharmaceutical companies will have ample time (approximately 90 days from receiving a notice that a physician has enrolled) to make the internal system changes needed to suppress data from being released to restricted employees.
- Physicians may revoke the election at any time by notifying the AMA.
- Pharmaceutical employees having direct contact with physicians will be blocked from accessing restricted data on PDRP physicians. The blockouts apply to part-time and temporary sales employees and contractors, as well as full-time sales reps and first-line sales managers.
- Restricted data are defined as any product-level data regarding the prescribing practices of an identifiable physician who has made the PRDP election. This includes measures of prescription volume in absolute and percentage terms, the associated dollar value of a physician's prescribing, any indicators of change in these measures, as well as any means of ranking, benchmarking, or grouping physicians that may reveal prescribing habits for a particular product. Furthermore, sales representatives must not "reverse engineer" or re-identify any prescribing information of a PDRP physician.
- The restrictions do not apply to (a) deciles at the market or therapeutic class level, (b) segmented data that are not likely to reveal the actual or estimated activity of an individual physician, or (c) data on products ordered by physicians from pharmaceutical companies.
- A physician's participation in the PDRP has no bearing whatsoever on the AMA's "No Contact List," which has been in place for more than 20 years to prevent listed physicians' names from being licensed for marketing purposes.
- Compliance will be gauged by physician complaints to the AMA.
- Isolated and minor infractions will likely result in an investigation, followed by a warning. Those manufacturers who show a disregard for the program's requirements by maintaining a pattern of abuse may lose access to AMA data, and, if infractions continue, may subsequently lose access to HIO data.
- The information available to the "home office" will not change, regardless of physician enrollment in PDRP. This program will not affect headquarter business systems. As long as the industry complies with PDRP, the program will not restrict access to information used in efficient marketing and compensation practices.

representatives who wave data in their faces and point to discrepancies between what they said and what they wrote. Imagine the challenge to a physician's professionalism when he or she is told, "You promised me last month that you would write more of my product, but based on your prescription volume I can see that you haven't. Why is that?"

The Genesis of the Program

The PDRP did not spring to life overnight. It evolved, with support from the industry and HIOs, from "Best Practice Guidelines for Use of Prescribing Data by Industry," published by AMA in 2001. The guidelines support the confidentiality agreements that pharmaceutical companies enter when they purchase data from HIOs. They encourage pharmaceutical companies to, among other things, "Keep prescribing data confidential and expressly prohibit disclosure of prescribing data by sales representatives to any other party."

Although the guidelines attempted to prevent misuses of data and to preserve the inherent value of the information to other healthcare constituents, they did not entirely succeed. Some sales representatives did misuse data and, as a result of this behavior, physician complaints and negative sentiments intensified.

In 2004, several national and state medical societies, led by the American College of Physicians, formally requested the AMA to prohibit the release or sale of physician prescribing information. In order to gauge the severity of the issue and attempt to develop a solution, the AMA polled hundreds of America's physicians to determine their attitudes on the subject. The AMA Board of Trustees considered the findings of the survey and the floor discussions in the AMA's House of Delegates, and listened to representatives of the healthcare industry, as well as HIOs. Ultimately, the board recommended that a program be created to:

- Provide physicians listed in the AMA Masterfile with an "opt-out" mechanism to prevent details of their prescribing practices from being shared with pharmaceutical sales representatives and other "restricted employees"
- Explain to physicians how they can report inappropriate behavior on the part of pharmaceutical employees
- Work with HIOs to help physicians understand how information about their prescribing is used, and to create reports for physicians from the data to enhance their clinical practices.

This opt-out mechanism has grown into the PDRP. In addition to providing physicians with a choice about having their prescribing data released to reps, the AMA is in the process of refining and strengthening its best-practice guidelines. The revised guidelines further clarify appropriate uses of prescribing data and set forth certain expectations for representatives' behavior. The thinking is that by providing physicians with real options and by cutting down on the number and frequency of data abuses that physicians encounter, fewer physicians will want to enroll in the restriction program. Stricter enforcement of the guidelines, coupled with active self-monitoring on the part of pharmaceutical companies, can only help the situation.

INDUSTRY SELF-POLICING MAY BE THE ONLY WAY TO STOP STATE LEGISLATORS WHO WANT TO BAN SALES REPS, AND EVEN WHOLE COMPANIES, FROM USING PRESCRIBING INFORMATION.

Making the Case to Physicians

How many physicians choose to participate in the program remains to be seen. To make sure that physicians have all the facts before they decide whether to enroll, the AMA will be communicating with all of its members and affiliates beginning this month. In these communiqués, the AMA will explain what options are open to physicians, and emphasize the important role that prescribing information has in the healthcare market.

Although the industry has not actively promoted the usefulness of compiling and releasing prescribing data, physicians and the public have a vested interest in doing so because the data can:

Reduce healthcare costs Opponents of prescribing data have argued, erroneously, that using prescribing data to support pharmaceutical sales and marketing somehow burdens the healthcare system with additional cost. The facts suggest just the opposite. Prescribing data allow pharmaceutical promotion to be relevant and specific, making the whole process more cost-effective (and sparing physicians from being bombarded with extraneous promotional materials and sales calls).

Support appropriate levels of drug sampling If companies could not tell which physicians most needed samples, they would likely distribute them evenly, with the result that some physicians would have too many, and others too few. Again, this would add costs to the system and fail to support patients' needs.

Help prioritize the release of public safety news alerts Based on physician prescribing details, companies can identify which physicians need to be contacted first in the event of a newly identified side effect or a product recall.

Give physicians a unique view of their own practice HIOs are piloting information products to physicians (as recommended in the 2004 AMA board report) that can reveal important facts about a physician's own practice: the degree to which patients comply and persist with treatment, patients' use of generics, and how the physician's prescribing practices compare with those of his or her peers. The data can also be used to provide valuable information for pay-for-performance systems that drive improved clinical practices.

The initial program of this type is currently being piloted in California. Commenting on this initiative, Jack Lewin, MD, CEO of the sponsoring California Medical Association said, "We are optimistic that this program can put doctors on a more level informational playing field, grant them better insight into their own practices and those of peers, and ultimately lead to better patient care through better use of information."

Similarly, what is not widely known is that the pharmaceutical industry's commercial interest in the data ultimately makes possible a variety of other research applications. The industry underwrites the substantial costs that HIOs incur when collecting and processing the information. Without this

support, the data would not exist for use in:

- Evidence-based drug safety studies
- Public health monitoring to set and promote public health policy
- Outcome studies and pharmacoeconomic analyses that look at value vs. cost
- Bioterrorism surveillance
- Development of clinical practice guidelines
- Disease management programs
- Analysis of changes in government healthcare programs (e.g., the uptake of Medicare Part D coverage).

In general, prescribing data accelerates healthcare innovation and ultimately enables patients and providers to make better healthcare decisions. One of the hottest healthcare initiatives at the federal level is a push toward greater transparency of current healthcare practices. The public needs to be able to track and identify the quality of care and efficiency of practitioners. Banning access to prescriber information could reduce the benefits to consumers. Providing prescriber information to researchers, teaching hospitals, and diseases advocacy groups also helps consumers gain access to information about services, quality, and price within the healthcare market. Physicians and consumers alike are empowered to improve their healthcare decision making.

Physicians will have to choose whether to enroll in PDRP. The industry and HIOs can help by educating them on the broader implications of that decision.

Advice for Pharmacos

First and foremost, it is important for the industry that individual pharmaceutical companies comply in letter and spirit with the requirements of the PDRP. Companies that interpret their data-use contracts too narrowly will sabotage the success of the program and pave the way for legislation that imposes stricter measures on the industry. Such legislation, which would ban the use of prescribing data for marketing and other commercial purposes, has been introduced in six states, but the prospect of PDRP has stalled it in four.

THE PDRP STILL ALLOWS PHARMACEUTICAL COMPANIES TO USE PRESCRIBING DATA TO MAKE CRITICAL BUSINESS DECISIONS IN MARKETING AND SALES MANAGEMENT.

As it stands today, the PDRP still allows the industry to use prescribing data to make critical business decisions in marketing and sales management. The PDRP restricts only data about physicians who enroll in the program. The industry will be best served if each pharmaceutical company adopts a company-wide strategy to ensure that it respects physicians' wishes—rather than simply implementing a technical plan to manipulate data according to a contractual obligation.

Each pharmaceutical licensee should:

- Adjust processes to receive and implement the list of participating physicians.
- Install programs to restrict prescribing data on PDRP enrollees in field-force deliverables.
- Review reports with roll-up capabilities and determine the appropriate business rules.

Sales operations should:

- Have quality controls in place to ensure that reports to the field are compliant.
- Prepare reps for the changes they will see in their field reports.

Sales departments should:

- Retrain all sales representatives and sales operations personnel on the responsible handling of physician prescribing information. Disclosure of this information to anyone outside of the company is a violation of the HIO contract.
- Sales representatives must be cautioned against displaying or discussing prescribing data with physicians. Reps should use it for background purposes only—regardless of a physician's PDRP status. They must understand that, from the physician's perspective, "prescribing data are personal and sensitive in nature," as laid out in the AMA Best Practice Guidelines of 2001. It is absolutely inappropriate to use prescribing data to accuse, coerce, badger, or otherwise pressure a physician to prescribe a particular product.
- Inform sales representatives that they must never "reverse engineer" or re-identify any prescribing information of a PDRP physician.
- Train sales managers to support the nature and intent of the PDRP.
- Clarify the consequences for abuse and enforce applicable codes of conduct.
- Communicate the larger picture and explain what is at stake if the AMA PDRP fails.

The most important aspect of the PDRP cannot be read in the text of the regulations. Taken as a whole, the PDRP is a call for pharma to refine the approach companies currently take in their interactions with physicians. While few within the pharmaceutical industry will applaud the PDRP as a welcome turn of events, it is important to consider the program in context. First, it satisfies a long-expressed desire on the part of the industry's customers. Second, it serves as a workable alternative to more restrictive legislation and should deter professional organizations from seeking such measures. Third, even though it limits reps and their supervisors from accessing data on some physicians, it nonetheless enables companies to continue to run essential business applications that rely on prescriber data.

It is now up to the industry to see that the AMA PDRP satisfies physicians' desire for privacy. Successfully implementing the program will stem the call for further restrictions. Physicians, public health agencies, academia, and patients are all depending on manufacturers to regulate themselves.

© Reprinted from PHARMACEUTICAL EXECUTIVE, May 2006 AN ADVANSTAR PUBLICATION Printed in U.S.A.

Copyright Notice Copyright by Advanstar Communications Inc. Advanstar Communications Inc. retains all rights to this article. This article may only be viewed or printed (1) for personal use. User may not actively save any text or graphics/photos to local hard drives or duplicate this article in whole or in part, in any medium. Advanstar Communications Inc. home page is located at http://www.advanstar.com.