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California's Physician Prescribing Act: A History of Twists and Turns

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California Assembly Bill 262 (AB 262) was introduced in February, 2003, just a few months before the Health Information Portability and Accountability Act (HIPAA) Privacy Rule became effective in April, 2003. Back then the bill was aimed at preventing the disclosure by healthcare providers of patients' medical information for marketing purposes without prior patient authorization.

AB 262, as well as other state bills backed by the AMA and its state affiliates (AB 262 is sponsored by the California Medical Association), intended to "fix" the marketing provision of the HIPAA Privacy Rule. Under HIPAA, the fact that a covered entity (e.g., physician) receives payment for a non-oral communication to a patient does not automatically qualify the communication as "marketing." AB 262 as introduced, on the other hand, defined such communications as marketing requiring prior patient authorization.

Twists and Turns

Reading the history of this bill as it wends its way through the legislative process is like viewing the layers of an onion being peeled away. AB 262 started out as another attempt to prevent "patient information" from being used for marketing purposes under the guise of protecting patient privacy. Under intense lobbying by various interest groups, the authors dumped the patient privacy language and added provisions to protect physicians from being profiled by pharmaceutical marketers. Incredibly, the authors attempted to enlist the right of "physician privacy" as an argument!

The story of AB 262 is a cautionary tale about how certain healthcare stakeholders use privacy issues as a weapon to protect their own proprietary interests.

In July, 2003, the act was amended to add provisions about prescription data. The revised AB 262 would require modification to the California Business and Professions Code specifically relating to pharmacists, making it unlawful for pharmacists to directly or indirectly sell or otherwise transfer prescription data to any person.

In August, 2003, the act took a more physician-oriented approach and focused on "prescribing data of a physician" and specified that the release of such data by pharmacists is prohibited if a physician has placed his or her name on a certain list to be created by the Medical Board of California, with specified exceptions.

Data Vendors

A "Data Vendor," as defined by AB 262, is any entity that acquires physician prescribing data and sells or transfers that data for any commercial purpose and whose primary business is the collection of this data.

The bill originally required data vendors to register with the Attorney General and the Medical Board of California in order to lawfully receive prescribing physician data. Pharmacists would have been responsible for verifying that a data vendor is registered before releasing data to the vendor. The registration requirement, however, was struck from the bill on July 7, 2004.

Who are the data vendors?
The industry leader among the pharmaceutical data vendors is Connecticut-based IMS Health. IMS Health is a publicly traded corporation (ticker: RX) with annual revenues of approximately $1.3 billion and market capitalization of nearly $6 billion. Other major companies in the field include NDCHealth (annual revenue of approx. $450 million), Dendrite (annual revenue of approx. $320 million), and Verispan (annual revenue of approx. $100 million in 2002).

Then, in January and June, 2004, the HIPAA-like marketing provisions were struck from AB 262, leaving only the provisions regulating release of prescribing data by pharmacists. The bill was now focused on "Doctor Prescribing Data" and officially

became known as the “Physician Prescribing Practices Act.”

Where It Stands Today

Today, AB 262 seeks to regulate the use of prescribing data for marketing purposes and to protect the privacy interests of doctors by regulating the activities of pharmacists and “data vendors” like IMS Health (see box on previous page).

Specifically, AB 262 establishes a "Do Not Use" list at the California Medical Board where doctors could register to prohibit their information from being sold by data vendors. Pharmacists would be able to sell or release physician prescribing data to a data vendor only if the data vendor agrees to comply with the "Do Not Use" list maintained by the Medical Board.

California Medical Board

The Medical Board of California is the State agency that licenses medical doctors, investigates complaints, disciplines those who violate the law, conducts physician evaluations, and facilitates rehabilitation where appropriate.

Medical Board members are appointed by the Governor (12 physicians and 7 public members), the Speaker of the Assembly (1 public member), and the Senate Rules Committee (1 public member).

Uses of Prescriber Data

In order to understand how prescriber information is used, the California Senate Judiciary Committee sent questionnaires to six major pharmaceutical manufacturers: Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer, and Schering-Plough. Schering-Plough declined to respond to the Committee's inquiry. Eli Lilly, GlaxoSmithKiline, Johnson & Johnson, Merck, and Pfizer voluntarily provided responses to the questionnaire.

The responses received indicated that pharmaceutical manufacturers purchase information from data vendors for use in a wide range of activities, including marketing. For example, GlaxoSmithKline writes that prescription data is used by their company for a wide variety of purposes, including:

- research trial design,
- research and development purposes such as analysis of drug candidates to determine patient needs,
- recruitment of physicians for clinical trials,
- market research,
- market analysis,
- sales reporting,
- routine pharmaco-epidemiology and pharmaco-vigilance activities, including risk-benefit assessment of the public health significance of adverse events and other potential safety issues, and
- monitoring utilization patterns for drugs that are involved in FDA mandated risk-management programs.

All the other companies emphasized that the data played a significant role in their research and public health purposes. For example, Pfizer wrote that they use the data to notify prescribers in the event of significant regulatory events (e.g., a product warning or recall). The timeliness of such communications has enormous patient safety implications, a fact that was confirmed recently in connection with a recall involving counterfeit Lipitor, Pfizer's cholesterol-lowering medication. Because of the availability of prescriber data, they are able to timely alert providers who might have distributed the counterfeit product unwittingly.

GlaxoSmithKline wrote that with respect to research prescription data is often used to find physicians who treat the illnesses in question. Contacting doctors directly to help find patients is a highly efficient way to help lower R&D costs. In contrast, broad media advertising for patients is not only very costly to purchase, but also carries high administration costs and yields a small number of patients per dollar spent.

All the companies confirmed that the data is used for marketing purposes. Merck wrote that this information helps them to effectively target medically relevant resources such as samples and patient education materials to physicians. Lilly wrote that it used the information to ensure that sales territories are of appropriate and efficient size and also that sales representative compensation is drawn, in part, from this information.

Arguments in Favor

Organizations registering in favor of the bill included:

- AIDS Healthcare Foundation
- California Academy of Family Physicians
- California Alliance for Retired Americans
- California Medical Association (Sponsor)
- California Public Interest Research Group
- Consumer Federation of California
- Senior Action Network

The Judiciary Committee held several hearings on the collection and use of doctor prescribing data by data vendors. At these hearings, the California Medical Association (CMA), the AIDS Healthcare Foundation (AHF), and the California Alliance for Retired Americans (CARA) raised a number of concerns about the activities of the data vendors.

Witnesses from CMA objected to the marketing practices of manufacturers that obtained data from data vendors, particularly when sales representatives made sales pitches that revealed how much the representatives knew about the doctor's prescribing patterns. More generally, CMA argued that the collection and sharing of physician-identified prescribing data raises privacy and public health issues that should be addressed by the Legislature..

According to CMA, AB 262 will restrict drug companies' access to physician information and regulate the multi-million dollar practice of lobbying physicians to prescribe high-priced drugs. The CMA indicates that currently drug companies pay retail pharmacies to obtain a list of physicians and the brands of drugs they prescribe. By gathering data on the more than 260 million prescriptions filled annually in California, drug companies are able to develop profiles of individual doctors indicating how often they prescribe a competitor's drug. This information is gathered without the knowledge or consent of either the physician or patient.

As explained by CMA, individual companies rely on this data to identify which physicians are most likely to be influenced, based on statistical analysis, by sales representative. As one data collection company reported, “Research has shown that winning just one more prescription per week from each prescriber yields an annual gain of $52 million in sales.”

The AIDS Healthcare Foundation (AHF), the largest AIDS organization in the United States, indicates they have witnessed over the years the inappropriate tactics drug-marketing representatives have used to influence health care providers to use their products. Drug reps, according to AHF, rely on prescribing data to target physicians they believe can be convinced to switch to their products.

As indicated by AHF, studies have found that drug manufacturers spend approximately 16% of their budget on marketing and more than 4/5 of that money is spent on marketing directly to physicians. The use of prescribing data helps the drug rep to get the biggest bang for his or her buck, a bang that translates into huge costs for consumers and third party payors, including the State of California. As argued by AHF, this situation can lead to inappropriate and unnecessary prescriptions that impact the care of the patient. Often, claims AHF, drugs are prescribed that are not necessary, are not the best treatment and may come at a higher price than other therapeutically equivalent drugs.

Arguments in Opposition

Organizations registering in opposition to the bill included:

- Amgen, Inc.
- Aventis Pharmaceuticals, Inc.
- California Healthcare Institute
- California Pharmacists Association
- Endo Pharmaceuticals
- IMS Health Incorporated
- Quintiles Transnational
- Verispan
- Wyeth Pharmaceuticals

The data vendors and pharmaceutical industry responded with several arguments.

First, they argued that doctors should not have a privacy interest in their professional conduct. Privacy, they argued, is a right that has been afforded only to individuals in their personal capacity; an extension of the privacy right to professional conduct would be unusual and set a bad precedent for oversight of commercial conduct.

The data vendors also argued that doctors’ primary concern appears to be the marketing practices of sales representatives, and that regulation of data collection or sharing would be unjustified and detrimental to the many public health uses of the data.

The California Pharmacists Association (CPhA) is opposed to this measure for several reasons. As argued by CPhA, the recent amendments to this bill have placed language into the Pharmacy Act and requires pharmacists to monitor and regulate information flows between the pharmacies and the various entities with which the pharmacy comes in contact, and ensure certain information about physicians’ prescribing information is not released except for various permitted purposes. Failure to do so could subject pharmacists to criminal prosecution, civil liability and potential loss of license. CPhA also argues that physicians will be given a private right of action to enforce the legislation. Presumably, this right of action could be initiated against a pharmacist that has not

properly monitored information flows or adequately restricted the use of the information.

While CPhA is certainly supportive of retaining patient confidentiality, CPhA stated, pharmacists' time should be spent on the practice of pharmacy for patient's benefits, not on monitoring physician level data to protect professional interests of physicians.

IMS Health Incorporated, a "data vendor," is opposed to the creation of a "Do Not Use" list and restrictions on use of prescription information proposed by CMA. IMS argues that this bill will create HIPAA-type requirements for changes to computer systems, processes, documentation and training in order to avoid improper release of physician prescribing information. These requirements will add significant cost to the health care system, and deprive everyone of valuable health care resources directed at these efforts.

Other concerns raised by IMS include:

- increased costs relating to the collection of health care information, and adverse impact on the quality of such information, resulting in loss of important health care benefits;
- the many beneficial uses of physician prescribing data for research and economic analysis will be disrupted;
- will establish a costly regulatory scheme that will result in increased health care costs;
- efforts to provide information to physicians that's relevant to their practice will become less efficient, leading to more visits, telephone calls and materials to physicians to ensure important information reaches these physicians;
- creates a privacy right for physicians which is inconsistent with both state and federal laws; and
- there is no evidence that existing guidelines regarding physician information use and disclosure sponsored by the AMA do not work.

Other opponents indicate that the restrictions imposed by this measure will disrupt established practices utilized by drug manufactures, physician organization and medical plans in acquiring prescriber data. It will drive up the cost of certain medicines to consumers and result in a substantial increase in California health care costs.

Pharmaceutical manufacturers' and biotechnology companies' marketing costs will substantially increase because marketing programs will become less efficient, according to the industry. Access to healthcare information on prescriptions may become unavailable to public health officials and other agencies and research centers and this would curtail studies that greatly benefit patients, by allowing pharmaceutical manufacturers to educate physicians on new drug combination therapy.

What Next?

The current version of the bill does not seek to add provisions to the California Business and Professions Code, which would have held pharmacists responsible for compliance with the law. It also does NOT require data vendors to register with the Attorney General and the Medical Board of California in order to lawfully receive prescribing physician data.

The act will become operative only if, on or after January 1, 2006, there is an appropriation from the Contingent Fund of the Medical Board of California to fund the activities required of the board by the act, and sufficient hiring authority, as determined by the board, is granted to the board to provide staffing to implement the act, in which event the act shall cease to be operative five years after its operative date.

The bill was last amended on July 7, 2004 and sent to the Senate Committee on Appropriations, which will meet on August 8, 2004. From there it should go back to the Assembly for agreement on the amendments made in the Senate before a final vote in both houses.

Given the long history of this bill and its many twists and turns, there may be further surprises before it ever becomes law.

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