

***Pharmacy Benefit Managers:
A Study of Prescription Drug
Management Practices and Policies***

**Report on House Bill 4402
and Senate Bill 704, Section 2
81st Legislature, Regular Session, 2009**



**Submitted by the
Texas Department of Insurance**

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Texas Department of Insurance

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August 1, 2010

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Dear Governors, Speaker and Chairmen:

In accordance with HB 4402 and SB 704, Section 2, of the 81st Texas Legislature, Regular Session, the Department of Insurance conducted a study to evaluate the ways in which pharmacy benefit managers use prescription drug information to manage therapeutic drug interchange programs and other drug substitution recommendations. As required by these statutes, this letter conveys a report that contains the results of this study, as well as recommendations for legislation during the 82nd Texas Legislative Session.

Thank you for the opportunity to provide this information and for your consideration of this report. Should you have any questions, please contact me; Carol Cates, Associate Commissioner of Government Relations, at 463-6123; or Katrina Daniel, Senior Associate Commissioner of Life, Health & Licensing, at 305-7342.

Sincerely,

A handwritten signature in cursive script that reads "Mike Geeslin".

Mike Geeslin
Commissioner of Insurance

C: Members, Senate Committee on State Affairs
Members, House Committee on Insurance
Members, Senate Committee on Health and Human Services
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Pharmacy Benefit Managers: A Study of Prescription Drug Management Practices and Policies

Executive Summary

In response to the 81st Texas Legislature's enrollment of House Bill 4402 and Senate Bill 704, the Texas Department of Insurance ("Department" or TDI) conducted an interim study of the practices and policies of pharmacy benefit managers (PBMs) and other similar entities surrounding generic substitution, therapeutic interchange, formulary changes, and the associated communications between pharmacy benefit managers, patients, pharmacists, and prescribing health care professionals.

The Department reviews health insurance policy forms and health maintenance organization (HMO) contract forms prior to approval to verify that they contain the required benefits and comply with Texas statutes. However, the Department does not review or approve the content of drug formularies. Coverage of prescription drugs is not a required benefit in health insurance or HMO products that are issued in Texas.

In conducting this study, the Department sought and received input from the Texas State Board of Pharmacy and the Texas Medical Association, as well as input from stakeholders representing pharmacy benefit managers, physicians, pharmaceutical manufacturers, health benefit plan issuers, and individual consumers of pharmaceutical products. The Department also directed surveys to all Texas licensed pharmacy benefit managers and to selected Texas licensed health insurers and HMOs that self-administer pharmacy benefits or contract with a PBM to administer pharmacy benefits for fully insured plans. We also sought physician input on this issue by developing a survey tool that was accessible from the Texas Medical Association's website and TDI's website. Finally, we reviewed complaints filed with the Department relating to prescription drug coverage for calendar years 2008 and 2009.

Summary of Findings

- PBMs intervene in the delivery of enrollee prescriptions in a variety of ways according to their general company policies and their contractual agreements with health insurers, health maintenance organizations, and plan sponsors. Intervention may occur for several reasons, including safety concerns, potential drug interactions, step therapy requirements, other formulary provisions, availability of generic alternatives, or preference for certain branded drugs. These interventions are usually in the form of phone calls to prescribing practitioners, and they occur when the PBM processes a prescription or a claim for a prescription that triggers some attempt to intervene.
- PBMs have the ability to affect drug utilization and sales volume by including specific drugs on their national formularies, and may receive manufacturer rebates in exchange for preferred formulary placement.

- PBMs may recommend, in accordance with in-house formulary research, that practitioners consider prescribing a preferred brand drug or the generic of a brand drug. These recommendations stem from the reasons for intervention above and serve to align prescribed treatment with the drug formulary.
- PBMs reported to TDI that they do not participate in the changing of a prescribed drug to a different drug in the same therapeutic class without the consent of the prescriber. This practice is illegal. However, it should be noted that several physicians reported to TDI that such changes do occur without their permission.
- PBMs review their formularies regularly and make changes on a quarterly or annual basis. This could result in changing the patient's cost sharing obligation for the next plan year. Formulary changes are usually motivated by safety, efficacy or cost-savings concerns. PBMs have Pharmacy and Therapeutics (P&T) committees that study the safety and efficacy of pharmaceuticals and these committees recommend and often effectuate formulary changes.
- In the course of a PBM's formulary changes, drugs may be added, removed, or moved to a different benefit tier. Such changes usually take place on a quarterly or annual basis. In instances where a drug is reported to be dangerous for patients, the drug would be removed immediately. When safety is not the motivating factor, the removal may be based on efficacy if the P&T committee determines the formulary includes a sufficient variety of other drugs in the same class that provide better outcomes, have fewer side effects, or are more cost-effective.
- Health insurers and health maintenance organizations are required by Texas Insurance Code Chapter 1369, Subchapter B, to continue to make a drug available to any enrollee at the same copayment benefit level until the plan's renewal date regardless of whether the drug has been removed from the formulary or moved to a higher formulary tier. However, this statute only applies to persons covered by large employer health benefit plans and does not extend these protections to persons covered by individual or small employer health benefit plans.

Recommendations

As required in HB 4402 and SB 70, the Department offers the following recommendations for the Legislature's consideration:

- Extend enrollee protections of Chapter 1369, Subchapter B to include small employers and individual health benefit plan enrollees. Currently the requirements apply only to enrollees in large group plans.
- Clarify that appeals for independent review of a denied prescription drug claim are paid by the carrier, and the decision of the review is binding on the carrier. Direct TDI to promulgate a standard notice informing enrollees of these protections.
- Amend the Insurance Code to state limitations in prescribed drug amounts constitutes an adverse determination that may be appealed by an enrollee.
- Require carriers/PBMs to post accurate and complete drug formularies online for physician accessibility when prescribing medications for patients.

Introduction and Overview

In response to the 81st Texas Legislature's enrollment of House Bill 4402 and Senate Bill 704, the Texas Department of Insurance conducted an interim study of the practices and policies of pharmacy benefit managers and other similar entities surrounding generic substitution, therapeutic interchange, formulary changes, and the associated communications between pharmacy benefit managers, patients, pharmacists, and prescribing health care professionals.

This report is limited to the prescription drug management activities of PBMs and other similar entities that are performed on behalf of fully-insured health benefit plans. While self-funded benefit plans (such as those administered by the Employees Retirement System of Texas, the Teacher Retirement System of Texas and other large employers) may be impacted by some of these findings, this report is not designed to address self-funded plans since they are not subject to TDI oversight.

The provisions of HB 4402 and SB 704, Section 2, are identical and direct the Texas Department of Insurance to "conduct a study to evaluate the ways in which pharmacy benefit managers use prescription drug information to manage therapeutic drug interchange programs and other drug substitution recommendations made by pharmacy benefit managers or other similar entities."

In addition, the legislation mandates that the study include information regarding pharmacy benefit managers:

- (1) intervening in the delivery or transmission of a prescription from a prescribing health care practitioner to a pharmacist for the purposes of influencing the prescribing health care practitioner's choice of therapy;
- (2) recommending that a prescribing health care practitioner change from the originally prescribed medication to another medication, including generic substitutions and therapeutic interchanges;
- (3) changing a drug or device prescribed by a health care practitioner without the consent of the prescribing health care practitioner;
- (4) changing a patient cost-sharing obligation for the cost of a prescription drug or device, including placing a drug or device on a higher formulary tier than the initial contracted benefit level; and
- (5) removing a drug or device from a group health benefit plan formulary without providing proper enrollee notice.¹

¹ House Bill 4402 and Senate Bill 704 as Enrolled by the 81st Texas Legislature.

Pharmacy Benefit Managers

Health insurers and health maintenance organizations that provide coverage for prescription drugs may self-administer their pharmacy benefit plan or contract with a pharmacy benefit manager (PBM). A PBM is an administrator of pharmacy benefits for HMOs, health insurers (collectively, “carriers”), self-insured employers, and self-insured governmental entities. “In addition to offering their basic services – claim processing, record keeping, and reporting programs – PBMs offer their customers a wide range of services including drug utilization review, disease management, and consultative services.”² They do not have direct relationships with enrollees, but rather interact between carriers and pharmacies and between carriers and pharmaceutical manufacturers. PBMs are not insurers, but a PBM that collects premiums or contributions from or adjusts or settles claims for Texas residents must hold a certificate of authority as a third party administrator (TPA) pursuant to Texas Insurance Code Chapter 4151. PBMs are not (necessarily) a pharmacy or directly regulated under the pharmacy code. Instead, contracts between PBMs and carriers must ensure that pharmacy benefit operations comply with insurance statutes and regulations and the PBM’s relationship with pharmacies may not violate pharmacy rules. Furthermore, PBMs that own mail order pharmacies must be licensed and adhere to rules governing pharmacy practices. The following outlines the many functions and relationships in which PBMs participate.

PBMs develop networks of local pharmacies in which enrollees can fill prescriptions.

By contracting with local retail pharmacies, PBMs establish a network of pharmacies that have agreed to accept the dispensing fee offered by the PBM. This allows patients the ability to fill their prescriptions at a wide choice of pharmacies. National PBM networks include nearly all chain pharmacies, and most PBMs contract with 90 percent of pharmacies in the region that they serve.³ Fees to pharmacies include both payment for the drug itself which is usually a discounted average wholesale price and a dispensing fee. Pharmacists spend significant amounts of time educating enrollees about drugs and potential side effects, as well as contacting the prescribing practitioner to request permission to substitute in cases where the prescribed drug does not have a preferred status or is not covered on the enrollee’s formulary.

PBMs manage claims adjudication between health plans and pharmacies.

When enrollees in health plans purchase prescription drugs from a pharmacy, the PBM is responsible for confirming the enrollee is insured, verifying plan coverage of the

² “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain.” The Health Strategies Consultancy LLC for The Kaiser Family Foundation. March 2005, <http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf>

³ Improving Health Care: A Dose of Competition. Federal Trade Commission and Department of Justice. July 2004. Chapter 7. http://www.usdoj.gov/atr/public/health_care/204694.pdf

prescribed drug, determining payments owed by the carrier and transmitting enrollee copayment information to the pharmacy. Carriers compensate PBMs for the payment owed to pharmacies and the PBM passes this payment on to pharmacies. In this way, PBMs are the “middle men” between pharmacies and carriers.

Some PBMs operate mail order pharmacies.

Some PBMs operate their own mail order pharmacies. These pharmacies must be licensed in the state where they are located as well as in each state to which they deliver drugs. The pharmacists employed in these pharmacies are generally licensed by their home state, but some states also require mail order facilities to employ a pharmacist licensed in their state. Texas does not have this requirement.

Owning a mail order pharmacy allows the PBM to act as both pharmacy and PBM, thus removing the usual “middle man” structure, and to achieve significant cost savings for the carrier. This is possible by operating high volume pharmacies that process 90-day prescriptions very efficiently. Furthermore, the PBM is able to pursue formulary compliance by contacting patients and prescribing practitioners when a prescription for a non-preferred brand is received and requesting that the prescriber consider the drug preferred by the carrier or PBM. To promote the use of the mail order option, carriers often offer incentives such as reduced copayments to enrollees who obtain maintenance medications from the mail order pharmacy. In some cases, enrollees may even be required to go through the PBM’s mail order pharmacy to receive maintenance medications.

PBMs negotiate prices with pharmaceutical manufacturers.

PBMs also act as middle men between carriers and pharmaceutical manufacturers. While pharmacy claims adjudication is a helpful service, the true value that PBMs offer to carriers is their negotiated prices for prescription drugs. By negotiating on behalf of many carriers and representing a large customer base, PBMs are able to obtain lower prices from pharmaceutical manufacturers. These lower prices often influence the decision to place discounted drugs on preferred tiers in order to encourage utilization of lower cost drugs.

PBMs maintain formularies on behalf of carriers.

PBMs create formularies, or lists of covered drugs, that have been researched by the PBM’s Pharmacy and Therapeutics Committee and recommended for inclusion on the formulary based on medical research of a drug’s safety, outcomes and efficacy. However, drug cost also influences formulary placement.

Some carriers that have internal P & T Committees may contract with a PBM that will allow the carrier to retain control over the formulary. Other carriers or employers may ask a PBM to tailor a formulary to more specifically meet the needs of their enrollees. However, stakeholders report that a PBM’s standard formulary is generally considered comprehensive by many purchasers and is usually selected by carriers and employers without amendment. While PBMs have incentives to create formularies that are

attractive to carriers and their enrollees, PBMs may also profit by their power to affect a particular drug's sales volume by including the drug on their national formulary.

PBMs receive pharmaceutical manufacturer rebates for promoting sales through formulary placement.

The Federal Trade Commission conducted a study to analyze the impact of pharmacy benefit managers on prescription drug prices in 2005 and determined the following:

When a therapeutic class contains a number of competing drug products that have similar therapeutic effects, PBMs can use the formulary to promote the sales of particular brand drugs within the class...The formulary, therefore, can enhance sales of a particular drug product regardless of which pharmacy a consumer purchases from, as long as the pharmacy is part of the PBM's network and is subject to the PBM's formulary controls.⁴

Since supply-side practices can directly influence drug sales and utilization, pharmaceutical manufacturers compete to ensure that their products are included on PBM formularies. Drug manufacturers accomplish this by paying rebates to PBMs in the form of "formulary payments" to obtain formulary status for their drugs and/or "market-share payments" to encourage PBMs to dispense their drugs.⁵ These payments may be structured in different ways, but they are generally based on a percentage of wholesale prices multiplied by the volume of drugs sold under the plans managed by a PBM.

Rebate payments are a controversial issue for PBMs, in part because they have historically lacked transparency. Some carriers contract for "guaranteed pricing" of their pharmacy benefits, allowing PBMs to keep all manufacturer rebates resulting from drugs purchased by the carriers' enrollees. Under a guaranteed pricing structure, the carrier pays the PBM a small administrative fee, or potentially none at all. Recently, there has been a strong push by self-insured government plans for transparency, especially in contracting. This often results in contracts that include a modified "pass through pricing" structure. Under pass through pricing, the plan pays the PBM a more substantive administrative fee, but the PBM must pass on all rebate payments resulting from drugs purchased by the plan's enrollees. However, this can be problematic for an agency's budgeting process; the total rebate amounts are uncertain, so the net cost of pharmacy benefits cannot be known in advance.

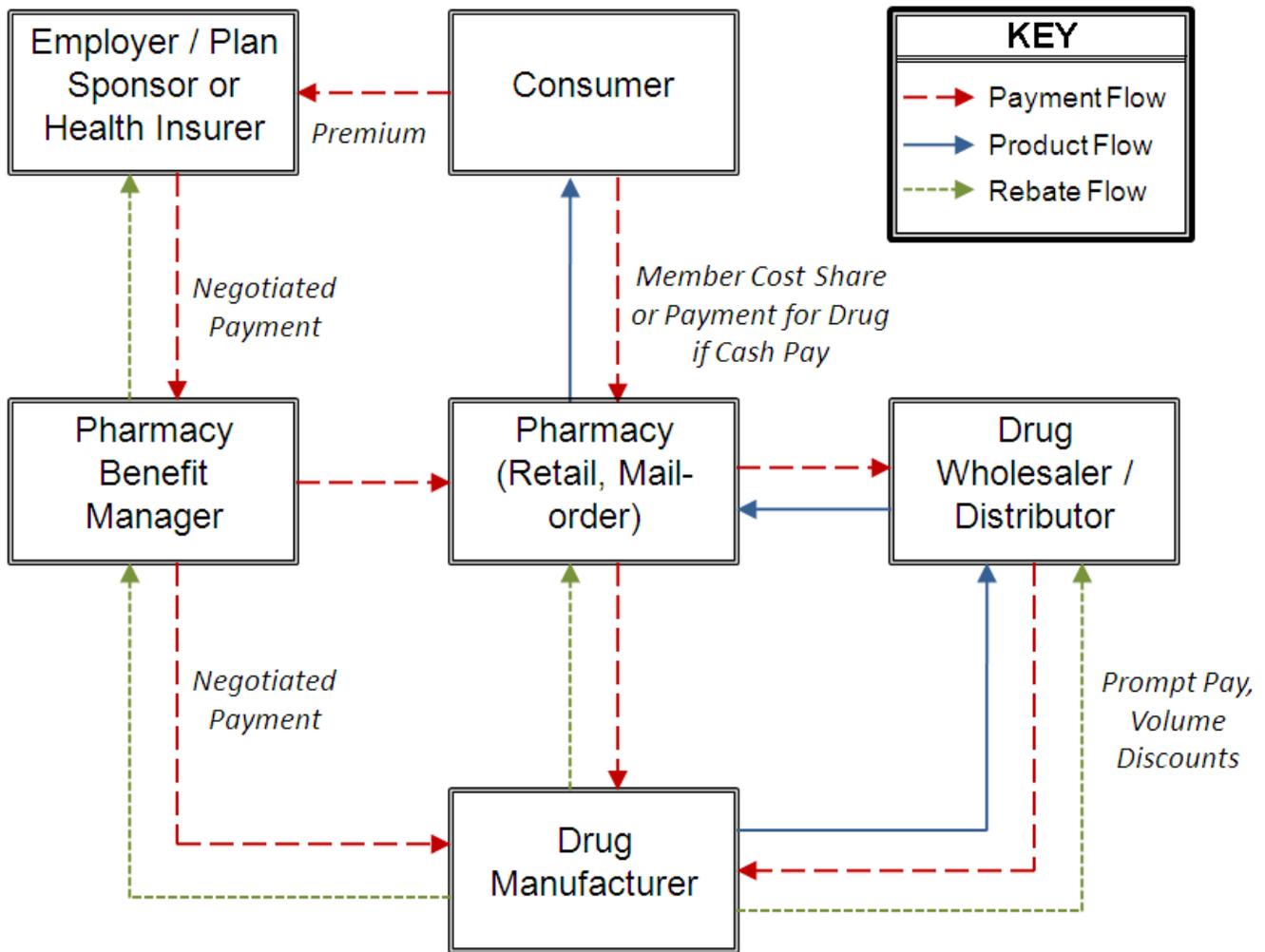
⁴ "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies". FTC. August, 2005.

<http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>

⁵ Ibid.

The following chart illustrates the business relationships in which PBMs play a role.⁶

Flow of Goods and Financial Transactions Among Players in the U.S. Commercial Pharmaceutical Supply Chain



Source: The Health Strategies Consultancy LLC

⁶ "Follow the Pill: Understanding the U. S. Commercial Pharmaceutical Supply Chain." The Health Strategies Consultancy LLC for The Kaiser Family Foundation. March 2005. <http://www.kff.org/rxdrugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf>

Drug Switching

Drug switching generally refers to generic substitution or therapeutic interchange and is a significant source of controversy. Therapeutic interchange is the main source of contention, pitting carriers seeking cost savings against practitioners who resent the interference posed by interchange requests, which are sometimes seen as unfairly questioning the prescribing practitioner's professional judgment. Brand to brand therapeutic interchange is especially contentious among practitioners who question the motives of PBMs.

Generic Substitution

Generic substitution is fairly straight forward and is often pursued by carriers in order to reduce plan costs. Expiration of a brand drug's patent allows generic manufacturers to compete in the market by offering generic equivalent drugs. Once these generics are approved by the FDA, they may be substituted for the brand unless the prescribing practitioner has written the prescription to be dispensed as written (DAW). When the prescription contains this designation, the patient must be asked and agree to the generic substitution. If the patient refuses to agree, the health benefit plan may require the patient to pay a higher copayment and/or the difference between the cost of the generic drug and the cost of the brand drug. Texas law does not restrict the carrier's ability to charge higher copayments for branded drugs even when the generic drug is not suitable for the patient due to medical reasons. Laws governing generic substitution in other states are summarized in Appendix A.

Therapeutic Interchange

Therapeutic interchange "typically involves switching a patient from a prescribed drug that is not on a plan sponsor's formulary to a therapeutically similar, but chemically distinct, formulary drug that is listed on the formulary and is in the same therapeutic class as the prescribed drug."⁷ Therapeutic interchange can consist of changing from one brand of a drug to another brand or changing from one brand to the generic of a different brand. Carriers and enrollees can achieve cost savings from these switches if the replacement drug works effectively, without complicating side effects, which could result in additional medical care expenses.

Therapeutic interchange requires approval from the prescribing practitioner. In the retail pharmacy setting, this could mean a patient may have to wait while the pharmacist calls the prescriber. The switch may not be attempted or successful the first time that an enrollee fills the prescription; however, if a PBM has a therapeutic interchange program in place for the therapeutic class of drug in question, the PBM may follow up with the prescribing practitioner to request a switch to an alternative drug for the refill prescription. If the prescription goes through a mail order facility, there is a better

⁷ Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies. Federal Trade Commission. August 2005. <http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf>

chance of the therapeutic interchange being requested before the first prescription is processed.⁸

⁸ Cost Containment Strategies for Prescription Drugs: Assessing the Evidence in the Literature. Jack Hoadley for The Kaiser Family Foundation. March 2005. <http://www.kff.org/rxdrugs/7295.cfm>

Formulary Changes

In past years, the Department received many complaints from insurance consumers concerning mid-year changes to drug formularies and the lack of access to certain drugs due to formulary restrictions. Formulary changes usually involved the removal of a previously covered drug from the formulary or the reassignment of a drug to a higher formulary copayment tier. When choosing a health plan, consumers often base their choice on whether their physicians participate in the plan's provider network, whether the drugs they require are on the plan's formulary, and the drugs' copayment amounts. If drugs are removed from the formulary during the contract period, consumers may be locked into a plan that no longer covers the prescription drugs they need for the remainder of the group's contract period. Consumers viewed this tactic as a "bait and switch" because the formulary change often occurred soon after the group health plan's effective date.

In 1999 the 76th Texas Legislature responded to this concern with the enrollment of SB 1030.⁹ This bill required issuers of large employer group health plans to provide any enrollee with a prescription drug that was approved or covered under the plan at the same contracted benefit level until the end of the contract period regardless of whether the drug was removed from the formulary.

SB 1030 also stated that if the plan issuer refused to provide benefits for a non-formulary drug that the enrollee's physician determined is medically necessary, the refusal will constitute an adverse determination under Insurance Code Chapter 4201. Adverse determinations may be appealed and reviewed by an independent review organization (IRO) and the decision of the IRO is binding. These protections under SB 1030 were not, however, extended to small group plans or individual plans.

SB 1030 also required group health plan issuers using a drug formulary to disclose the following information in the plans' coverage documents:

- An explanation of what a drug formulary is, the method used to determine which drugs will and will not be covered, and how often the formulary is reviewed;
- An explanation that the enrollee can contact the carrier to determine if a specific drug is covered; and
- The time limit for the carrier's response.

SB 1030 does not, however, require the group health plan issuer to notify enrollees, either in the coverage documents or by separate notice, of their right to receive a covered drug at the contracted benefit level for the balance of the contract period even though the drug is removed from the formulary. In addition, the statute does not require the issuer to notify enrollees of their right to appeal the issuer's denial of a medically necessary drug that is not on the formulary to an IRO.

⁹ Codified as Texas Insurance Code, Chapter 1369, Subchapter B.

Appeals of adverse determinations under Insurance Code Chapter 4201 are filed with the Department for assignment to an IRO for review and decision. Although complaints have been filed with the Department because medically necessary, non-formulary drugs have been refused, staff in the Department's IRO Assignment Section is unable to locate any requests for IRO reviews of drug denials, which may be due in part to the fact that enrollees may not be aware of these appeal rights.

PBMs - Regulatory Structure

The following excerpt from the Senate Committee on Health and Human Services and Senate Committee on State Affairs Joint Interim Report to the 80th Legislature provides a valuable account of the regulatory structure surrounding PBMs.

PBMs are not regulated as insurance companies but rather as third-party administrators (TPAs). Typically, they do not sponsor benefit plans for an enrolled population but rather primarily perform certain financial services for carriers and employers. The Texas Department of Insurance (TDI) is authorized under Chapter 4151, Texas Insurance Code, to license and regulate PBMs as administrators. These provisions are geared more toward basic financial practices and business controls as opposed to how PBMs conduct themselves in the marketplace.

Under state regulation, PBMs are required to obtain a certificate of authority from TDI and to maintain a fidelity bond to protect against an act of fraud or dishonesty by the PBM in exercising its powers and duties as an administrator. In addition, PBMs are allowed to provide services only under specific written agreements with clients. PBMs are also subject to laws prohibiting fraud, unfair and deceptive acts or practices, and unfair claims settlement practices.

Like with other TPAs, the Commissioner may audit PBMs to regulate compliance with the legal standards established in the Insurance Code. Such audits may include examination under oath and on-site inspections of written agreements, financial statements, or anything related to the transaction of business by and the financial condition of the administrator.

PBMs are also subject to areas of specific oversight. Chapters 843 and 1301, Texas Insurance Code, govern the operation of Health Maintenance Organizations and Preferred Provider Benefit Plans and also provide some regulatory authority over PBMs. Most notably are the sections related to the prompt payment of claims. The law imposes a more stringent standard for timely payment of pharmacy claims than for other medical claims. Under these provisions, pharmacy claims must be paid not later than the 21st day after the date the claim is affirmatively adjudicated. All other health claims must be paid within 45 days.

TDI also regulates PBMs through laws that govern specific pharmacy benefit standards. Chapter 1369, Texas Insurance Code, governs benefits related to prescription drugs and devices and related services. This chapter addresses prescription drug coverage requirements and the regulation of formularies. This includes consumer notice requirements as to what drugs are on a formulary, how those drugs were chosen, as well as requirements for continuation of coverage when drugs fall off a formulary in the middle of a plan year. An appeals process for coverage denials is also set forth.

While the regulatory authority outlined above provides a broad range of tools to oversee the PBM industry, self-funded and government sponsored plans are

generally exempted from state regulation. The Employee Retirement Income Security Act of 1974 (ERISA) is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry. ERISA preempts most state laws that seek to impose more stringent regulations or oversight of these types of plans. Government sponsored plans are generally exempt from state regulation. Only 25 percent of Texans are enrolled in health plans over which the state has great statutory and regulatory authority.

In addition to the authority granted to TDI to regulate PBMs, the Texas State Board of Pharmacy (TSBP) also has jurisdiction over some activities performed by PBMs. As discussed previously, many PBMs own and operate their own mail-order pharmacies. When operating in this capacity, regulatory authority falls primarily to the TSBP. The agency operates under various provisions of Texas law, primarily those contained under Subtitle J, Pharmacy and Pharmacist, Texas Occupations Code. The TSPB licenses all pharmacies operating in Texas (except those in federal facilities), and any out of state mail-order pharmacies that fill prescriptions and deliver them to Texas residents. As with all pharmacies operating in the state, PBMs that own and operate retail or mail-order pharmacies that fill prescriptions for Texans are encompassed by the regulatory powers granted to the TSBP.

Both TDI and the TSBP have authority to investigate complaints related to PBMs. Each agency deals with complaints falling under their regulatory jurisdiction and refers other claims to the appropriate regulatory entity. The agencies provide detailed information online about their complaint process, including an online complaint form. Toll-free numbers to call or fax in complaints are also available.

Complaints originating at TDI have remained fairly constant over the past couple of years, about 38 complaints per year. The majority of these have been related to claims processing such as denial of a claim, unsatisfactory settlement offers, or delays in claim handling. TDI resolves complaints almost exclusively without need for litigation.

Complaints initiated at the TSBP relating to PBMs make up only about 10 percent of the overall complaints fielded by that office. Dispensing errors, improper packaging, confidentiality violations, and incorrect counseling are just a few of the concerns received by the agency. Probably the most serious complaint, unauthorized substitution, is rare and in almost all cases ultimately determined to be unfounded.¹⁰

¹⁰ Senate Committee on Health and Human Services and Senate Committee on State Affairs Joint Interim Report to the 80th Legislature, December 2006.
<http://www.senate.state.tx.us/75r/senate/commit/c610/c570.c610.InterimReport79.pdf>

Survey Development

To better understand the roles and procedures of pharmacy benefit managers in Texas, TDI developed and distributed separate surveys to PBMs, insurance carriers/HMOs, and Texas physicians. When creating these surveys, TDI sought and received input from the Texas State Board of Pharmacy and the Texas Medical Association as well as from stakeholders representing PBMs, physicians, pharmaceutical manufacturers, carriers, and individual consumers of pharmaceutical products. Many of the survey questions were derived from information provided by these stakeholders. Following is a brief description of each survey.

PBM Survey

TDI distributed surveys to licensed third party administrators that were identified as providing PBM services in Texas. In addition to administering pharmacy benefits for insurers and HMOs, PBMs administer pharmacy benefits for self-funded, employer-sponsored health benefit plans and self-funded government plans. These self-funded (also called self-insured) employer-sponsored plans are exempt from state regulation under the federal Employees Retirement and Income Security Act (ERISA). Consequently, TDI requested survey respondents to only provide information pertaining to fully insured health benefit plans. Information received from PBMs that contract only with self-funded plans is not included in the survey findings.

Insurance Carrier/HMO Survey

The Department distributed surveys to licensed insurance carriers and HMOs that wrote over 85 percent of the fully insured major medical health insurance premiums in Texas in calendar year 2009. These health insurers and HMOs may either self-administer their prescription benefits or contract with a PBM to administer prescription benefits. Respondents were requested to provide information that pertained only to fully insured health benefit plans.

Physician Survey

Although the Department has no regulatory authority over physicians and cannot compel them to respond to a TDI survey, the Department recognizes the value of their perspective on this issue. The Department worked with the Texas Medical Association (TMA) to obtain physician input, and TMA agreed to place a link on their website to a TDI-sponsored physician survey. TDI also placed a survey link on the physician/provider homepage on the TDI website.

Survey Findings

The Department sent surveys to 17 licensed third party administrators that were identified as providing PBM services and requested information specific to fully-insured health benefit plans issued in Texas. Eight PBMs returned completed surveys, while nine PBMs indicated they do not provide PBM services for insured health benefit plans.

In addition, the Department sent separate surveys to HMOs and health insurers with the largest reported premium volume in the individual large employer and small employer group markets. TDI asked insurers and HMOs (collectively, “carriers”) to indicate whether they self-administer their pharmacy benefits or contract with a PBM to administer pharmacy benefits. Ten carriers reported they self-administer their pharmacy benefits while 18 reported they contract with a PBM for these services.

The Department compared the information furnished by PBM-contracting carriers to the information received from PBMs to screen for possible inconsistencies. Unless otherwise indicated, we did not include information received from PBM-contracting carriers in this report to the extent that it duplicated the data provided by PBMs.

Use of prescription drug information

PBMs and carriers report they use prescription drug information in a variety of ways. Primarily, they use drug information in formulary development and when considering changes to the formulary. The majority of respondents report their respective Pharmacy and Therapeutics Committees are responsible for the clinical review and for recommending additions and deletions to lists of drugs approved for formulary consideration. The P&T Committees, comprised of family practice and specialty physicians and pharmacists, generally meet quarterly to consider new FDA-approved drugs and new information on current formulary and non-formulary drugs. The Committees conduct evidence-based reviews of new drugs against current products using information such as published, peer-reviewed literature, FDA-approved package inserts, clinical outcome data, reported side effects, safety alerts, and recall notices. Committee decisions are based on therapeutic outcomes, safety, and efficacy as well as the number and performance of other formulary drugs in the same therapeutic class. The majority of respondents stated decisions are based predominately on the results of the clinical review while drug cost is a secondary consideration.

Interventions to influence drug selection

PBMs and carriers reported they intervene in the delivery of prescriptions in accordance with contractual agreements with plan sponsors and their general company policies. Such interventions could occur because of safety concerns, drug interactions, step therapy requirements, other formulary provisions or the availability of generic and preferred brand drugs.

All PBMs and carriers influence drug selection by the inclusion of the drug on the formulary and by the tier placement which determines the enrollee’s copayment

amount. Approximately 75% of PBMs and carriers utilize various methods to encourage selection of generic and preferred brand drugs. Most respondents have developed programs to educate their general enrollee populations and their prescribers about the availability of lower cost formulary drugs. Some respondents send additional materials to enrollees who have been identified as taking non-preferred products to inform the enrollee about available preferred drugs in the same therapeutic class. Enrollees are encouraged to share the information with their prescribing practitioners.

Some employers have elected to include step therapy provisions for drugs in certain therapeutic classes. Step therapy requires that an enrollee first try a less costly drug in the same therapeutic class before receiving the more expensive alternative drug. When a prescription is presented at the pharmacy, the respondent's online system will automatically advise the pharmacist of the step therapy requirements, provide a list of formulary generic drugs, and request information showing that the enrollee tried one of the generics but it was not effective. This request will require that contact be made with the prescriber (either by the pharmacist or the enrollee) to obtain the requested information or, if the generic has not been tried, to determine if the prescriber will agree to prescribe the generic drug.

Other respondents advise that interventions occur when a prescription for a non-formulary or non-preferred drug is presented at the pharmacy. The pharmacist is electronically notified of the drug's status and provided a list of formulary generic or preferred brand drugs. The pharmacist is encouraged to contact the prescribing practitioner to discuss prescribing an appropriate drug from the formulary list. These interventions require additional time from the pharmacist and may delay filling of a prescription, especially on weekends or after hours when a physician is unavailable or may not be easily contacted.

Recommending that prescribers change from the originally prescribed drug to another drug, including generic substitution and therapeutic interchange

PBMs and carriers actively promote generic substitution when appropriate and point out that generic substitution is permitted in Texas unless the prescriber indicates that generic substitution is not authorized in the manner prescribed by Texas law.

PBMs and carriers advise that when a prescription for a non-formulary drug is presented to the pharmacist, the prescriber will be contacted to determine if the prescriber is willing to change the prescription to a therapeutically equivalent brand or generic drug that is covered under the formulary. This contact is usually made by the pharmacist, who may be obligated to negotiate substitutions or interchanges with the prescriber under the terms of the PBM's contract. If the prescriber agrees to change the prescribed drug, a new prescription is requested. This practice enables the enrollee to receive a therapeutically equivalent formulary drug which may result in a lower out of pocket cost to the consumer. While providers or patients may decline to approve the substitution and opt for the originally prescribed non-formulary drug, patients will pay more out of pocket to exercise this choice.

Changing a drug or device without the consent of the prescribing practitioner

All PBMs and carriers report that they do not engage in therapeutic interchange or switch patients from a prescribed drug to a chemically different drug in the same therapeutic class without contacting and obtaining the approval of the prescribing practitioner. The Senate Committee on Health and Human Services and Senate Committee on State Affairs Joint Interim Report to the 80th Legislature reached the same conclusion and included the following statement based on PBM complaint information from the Texas Board of Pharmacy: “Probably the most serious complaint, unauthorized substitution, is rare and in almost all cases ultimately determined to be unfounded.”¹¹

In conducting this study, the Department reviewed all consumer complaints received by the Department in calendar years 2008 and 2009 that relate to prescription drug benefits provided by fully-insured health benefit plans. A total of 151 complaints met these criteria but none of these complaints contained allegations that a therapeutic interchange had occurred either with or without the prescriber’s approval.

Although the Department has not received complaints about unauthorized therapeutic interchange, five of the 16 physicians who responded to the Department’s survey stated that a patient’s prescribed drug had been substituted or interchanged without their approval. It is noted that complaints regarding unauthorized therapeutic interchanges would fall under the authority of the Texas Board of Pharmacy, which may explain why the Department has not received complaints on this subject.

Changing an enrollee’s cost share, including placing a drug on higher formulary tier than the initial contracted benefit level, and removing a drug from the formulary without proper notice.

PBMs and carriers report they add drugs to their formularies at various times such as when new generics receive FDA approval. They may also remove drugs from their formularies or move drugs to different formulary tiers, but pursuant to SB 1030 (TIC Chapter 1369, Subchapter B) issuers of large employer group health plans must continue to make a drug available to any enrollee at the contracted benefit level until the plan’s renewal date regardless of whether the drug has been removed from the formulary. This language also prohibits changing the enrollee’s copayment amount or moving a drug to a higher formulary tier prior to the renewal date. All surveyed carriers reported they comply with the requirements of this statute.

Drug quantity restrictions

The Department’s review of complaint files for calendar years 2008 and 2009 revealed that, while TDI we did not receive complaints that carriers changed copayment amounts, many complaints involved quantity limitations on formulary drugs. Some carriers have strictly limited the quantities of particular medications that the carrier will

¹¹ Ibid.

cover for a single patient for a certain period, usually 30 days. If a patient's condition requires stronger or more frequent dosages, the patient can, in some cases, appeal this limitation. If successful, the patient can obtain additional dosages but may be charged multiple copayments. If the appeal is unsuccessful, the patient must pay the full cost of any additional quantities needed during the time period. The available information did not clearly indicate whether the imposition of quantity limits began on the plan renewal date or during the contract year. Some argue that imposing a quantity limitation represents a *de facto* increase in the copayment charged and should be prohibited until a health plan's renewal date. Others assert that Texas Insurance Code Chapter 1369, Subchapter B should be amended to allow enrollees to appeal to an independent review organization when the carrier refuses to cover or allow the full quantity of the medication as prescribed by the patient's health care practitioner.

Physician Perspective

In conducting this study the Department received input from representatives from the Texas Medical Association and also from Texas physicians in response to the survey tool.

Information provided by these sources indicated that physicians do not have easy access to their patients' formularies. While PBMs and carriers report they make their *preferred* drug lists available online, *specific* formularies developed at a carrier's or employer's request may vary significantly. Not all preferred drugs are included in all formularies, and the drugs on a specific enrollee's formulary may not completely match this preferred drug list. In addition, some self-administering carriers and PBM contracting carriers offer step therapy and quantity limit requirements as options to plan sponsors. These formulary requirements may not appear in the online formulary information available to practitioners.

According to physicians, the fact that current Texas statutes do not require patients' drug formularies be available online compounds physician frustration and defeats efforts to comply with formulary requirements. Physicians and patients need easy, online access to the patient's drug formulary that includes the copayment tier, step therapy requirements, and quantity limit amounts for each drug.

Physician representatives support greater use of electronic-prescribing (e-prescribing) technology which allows the physician and patient to view the patient's formulary and the copayment requirement of each drug online. Using this technology a physician can determine while the patient is in the office if an appropriate drug is listed in the patient's formulary. This helps avoid time consuming follow up calls between the physician, patient, and pharmacist. E-prescribing technology requires some initial set up costs, and some physicians may not be familiar with this process. However, the value of the technology has been recognized and its use is growing.

Physicians provided a wide range of opinions regarding drug substitution practices. Some physicians expressed significant frustration with this process, and indicated that their prescribing patterns are not impacted by intervention requests. Other physicians indicated they understand the need for such interventions, and they usually comply with these requests because of the financial interest of their patients.

Recommendations

As required in HB 4402 and SB 704, TDI offers the following recommendations for consideration:

Strengthen Texas Insurance Code Chapter 1369, Subchapter B

- Extend the protections of Chapter 1369, Subchapter B to individual and small employer plans.
- Ensure that enrollees are informed of their appeal rights by requiring that the protections afforded by Texas Insurance Code (TIC) §1369.056 be disclosed in the coverage documents issued to enrollees and in a notice to enrollees that is delivered annually and/or when the issuer refuses to provide a non-formulary drug. Section 1369.056 currently states:

“Sec. 1369.056. ADVERSE DETERMINATION. (a) The refusal of a group health benefit plan issuer to provide benefits to an enrollee for a prescription drug is an adverse determination for purposes of Section 4201.002 if:

(1) the drug is not included in a drug formulary used by the group health benefit plan; and

(2) the enrollee's physician has determined that the drug is medically necessary.

(b) The enrollee may appeal the adverse determination under Subchapters H and I, Chapter 4201.”

- Amend TIC 1369.056 to state that the enrollee does not pay the cost for the independent review of an adverse determination under Subchapters H and I, Chapter 4201, Texas Insurance Code, and the carrier must comply with the decision of the independent review organization. (Currently, the cost of an independent review under Subchapters H and I, Chapter 4201 is paid by the utilization review agent or the carrier that issued the adverse determination.)
- Direct the Department to promulgate a notice which shall disclose that the enrollee does not have to pay the cost for an appeal to an independent review organization and that the independent review organization's decision is binding on the carrier.
- Amend Texas Insurance Code Chapter 1369, Subchapter B, to state that the refusal of a group health benefit plan issuer to provide benefits for the full quantity of a drug, as prescribed, due to quantity limitation provisions is an adverse determination that may be appealed under Subchapters H and I, Chapter 4201.

Promote Electronic Prescribing (e-prescribing) technology

E-prescribing) is a growing use of technology that could result in significant cost savings for carriers, reduced administrative costs for PBMs, and reduced time and administration costs for both pharmacists and prescribing practitioners. Expanded use of this technology could also alleviate concerns about PBM interference in prescribers' treatment choices. Successful implementation of e-prescribing processes would allow a prescriber to view a patient's formulary options within the therapeutic class online and to discuss the selected drug and its copayment level with the patient before prescribing. This technology is extremely relevant to concerns about how insurers, administrators and pharmacists interact with prescribing practitioners. Furthermore, it could help to better involve patients in understanding their coverage options and in making their health care decisions.

Only four of the 16 physician respondents to TDI's Physician Survey indicated they have access to their patients' drug formularies. One physician stated that many formularies are not readily available. When the prescribed drug is declined, alternatives are not always offered so the physician has to guess what drugs will be covered.

A review of randomly selected PBM and carrier websites revealed the following:

- Some PBMs and self-administering carriers post their preferred drug lists on their websites but state that even though a drug is on the preferred list, it may not be on a patient's formulary due to client/employer preference. Such online approved drug listings may be of limited value to prescribers.
- Online lists of preferred drugs indicate whether a drug is subject to quantity limits but do not disclose what those limits are. This information is critical to a physician's treatment decision, as it would be problematic to prescribe a drug if the patient could not receive the drug in the quantities needed to treat patient's health condition.
- Some websites do not permit viewing the entire formulary but will indicate formulary status if the provider enters a query for a particular drug. Physicians indicate such practices are time consuming and discourage compliance with formulary requirements.

The Legislature may wish to consider methods to promote the use of e-prescribing. Physician representatives advise that the Medicare program offers bonus payments to encourage the use of e-prescribing. The state could also promote use of this technology in programs over which the Legislature has authority, including Medicaid, Children's Health Insurance Program, and benefit plans covering state employees, teachers, and state college and university employees.

Amend Chapter 1369, Subchapter B: Require that patient drug formularies be available online

Consider amending Texas statutes to require that patient-specific drug formularies be available online 24 hours a day, 7 days a week. Without access to specific formularies prescribers are unable to determine whether a particular drug will be covered, which could delay a patient's access to necessary care and create additional administrative burdens for both physicians and pharmacists.

Currently, Texas Insurance Code Chapter 1369, Subchapter B, states that enrollees may contact the carrier to determine if a drug is on the formulary. Carriers have 3 business days to respond.

Carriers should be required to provide the patient's formulary online just as copayment, coinsurance and other coverage information is provided via links to the enrollee identification number and/or group number.

The state may also wish to require all carriers to disclose the quantities that will be covered per month for each drug that is subject to quantity limitations. Ideally, this information should be available online along with the formulary and should be accessible to prospective enrollees before they make a plan selection.

Formulary Requirements Related to Specific Medical Conditions

During the course of this study, stakeholders presented information urging the Department to recommend that generic substitution and therapeutic interchange should be restricted for certain health conditions because of potential negative outcomes caused by drug switching. Responses received from PBMs and self-administering carriers indicated that each respondent excluded some drug classes from generic substitution or therapeutic interchange programs but these drug classes differed somewhat among respondents.

Stakeholders advised the Department that some states have restricted therapeutic interchange or generic substitution for certain health conditions and provided recommended statutory language for consideration. However, the Department lacks the necessary medical and pharmaceutical expertise to reach any conclusions on this issue but agrees the issue warrants additional consideration by the Legislature.

Appendix A: State Laws or Statutes Governing Generic Substitution by Pharmacists

Each state has rules concerning generic substitutions. The chart presented here indicates which states **allow for** generic substitution by pharmacists. However generic substitution is not permitted when "Brand Only" or similar wording is indicated by the prescriber. The chart also notes which states **mandate** generic substitution under those circumstances. It indicates which states allow dispensing of a brand name medication if that is requested by a patient.

Also listed are states which mandate dispensing the brand name medication if that is what is indicated by the prescriber. Each state's specific wording requirements for prescriptions are given in the far right column. For the two states where a specific exception is made for anticonvulsant medications (Hawaii) or narrow therapeutic range medications (North Carolina), which includes antiepileptic drugs, that indication is given in bold type. Any questions should be referred to your pharmacist.

State	Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Allows for Brand if Requested by Patient	Mandates Brand Only if Indicated by Physician	To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally
Alabama	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
Alaska	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Medically Necessary" must appear on the prescription.
Arizona	Yes	No	Yes	Yes	Clearly display on the prescription "DAW" or other wording indicative of Substitution not Permitted.
Arkansas	Yes	No	Yes	Yes	In the physician's handwriting, indicate that the product ordered should not be substituted.
California	Yes	No	Yes	Yes	In the physician's handwriting, the words "Do not substitute" must appear on the prescription.
Colorado	Yes	No	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" must appear on the prescription.

State	Allows for Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Mandates Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Allows for Brand if Requested by Patient	Mandates Brand Only if Indicated by Physician	To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally
Connecticut	Yes	No	Yes	Yes	In the physician's handwriting, indicate that the product ordered should not be substituted.
Delaware	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
Florida	No	Yes	Yes	Yes	In the physician's handwriting, the words "Medically Necessary" must appear on the prescription.
Georgia	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" must appear on the prescription.
Hawaii	No	Yes	Yes	Yes	In the physician's handwriting, the words "Brand Medically Necessary" must appear on the prescription. Mandates Brand Only for Anticonvulsant Medications.
Idaho	Yes	No	Yes	Yes	Physician must indicate "Brand Only" by checking the "Brand Only" box on the prescription.
Illinois	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
Indiana	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
Iowa	Yes	No	Yes	Yes	Physician shall communicate to Pharmacist that product should not be substituted.
Kansas	Yes	No	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" must appear on the prescription.
Kentucky	No	Yes	Yes	Yes	In the physician's handwriting, the words "Do not substitute" must appear on the prescription.
Louisiana	Yes	No	Yes	Yes	Physician must indicate "Brand Only" by checking the "Dispense as Written or DAW" box on the prescription.

State	Allows for Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Mandates Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Allows for Brand if Requested by Patient	Mandates Brand Only if Indicated by Physician	To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally
Maine	No	Yes	No	Yes	In the physician's handwriting, the words "Dispense as Written", "DAW", "Brand", or "Brand Necessary" must appear on the prescription.
Maryland	Yes	No	Yes	Yes	Physician shall communicate to Pharmacist that product should not be substituted.
Massachusetts	No	Yes	No	Yes	In the physician's handwriting, the words "No substitution" must appear on the prescription.
Michigan	Yes	No	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" or "DAW" must appear on the prescription.
Minnesota	No	Yes	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" or "DAW" must appear on the prescription.
Mississippi	Yes	No	Yes	Yes	Physician shall communicate to Pharmacist that product should not be substituted.
Missouri	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
Montana	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Medically Necessary" must appear on the prescription.
Nebraska	Yes	No	Yes	Yes	In the physician's handwriting, the words "Dispense as Written", "DAW" or similar statements must appear on the prescription.
Nevada	No	Yes	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" must appear on the prescription.
New Hampshire	Yes	No	Yes	Yes	Physician must specify that the Brand is Medically Necessary.
New Jersey	No	Yes	Yes	Yes	Physician must initial next to the option "Do not Substitute" on the prescription.

State	Allows for Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Mandates Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Allows for Brand if Requested by Patient	Mandates Brand Only if Indicated by Physician	To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally
New Mexico	Yes	No	Yes	Yes	In the physician's handwriting, the words "No substitution" or "No sub" must appear on the prescription.
New York	No	Yes	No	Yes	In the physician's handwriting, "DAW" must appear on the prescription.
North Carolina	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written". Narrow Therapeutic Range Drugs must be dispensed as originally prescribed.
North Dakota	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" must appear on the prescription.
Ohio	Yes	No	Yes	Yes	In the physician's handwriting, the words "Dispense as Written" or "DAW" must appear on the prescription.
Oklahoma	Yes	No	Yes	Yes	Physician shall communicate to Pharmacist that product should not be substituted.
Oregon	Yes	No	Yes	Yes	In the physician's handwriting, the words "No substitution" or "N.S" must appear on the prescription.
Pennsylvania	Yes	No	Yes	Yes	Physician shall communicate to Pharmacist that product should not be substituted.
Rhode Island	No	Yes	Yes	Yes	In the physician's handwriting, the words "Dispense as Brand Name Necessary" must appear on the prescription.
South Carolina	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
South Dakota	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" must appear on the prescription.

State	Allows for Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Mandates Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician	Allows for Brand if Requested by Patient	Mandates Brand Only if Indicated by Physician	To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally
Tennessee	No	Yes	Yes	Yes	In the physician's handwriting, the words "Dispense as Written", "DAW", or other language of intent must appear on the prescription.
Texas	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" or "Brand Medically Necessary" must appear on the prescription.
Utah	Yes	No	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written" OR in the physician's handwriting, the words "Dispense as Written" must appear on the prescription.
Vermont	No	Yes	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" or "No substitution" must appear on the prescription.
Virginia	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Necessary" must appear on the prescription.
Washington	No	Yes	Yes	Yes	Sign the prescription signature line labeled "May not Substitute" or "Dispense as Written".
West Virginia	No	Yes	Yes	Yes	In the physician's handwriting, the words "Brand Medically Necessary" must appear on the prescription.
Wisconsin	Yes	No	Yes	Yes	In the physician's handwriting, the words "No substitutions" or "N.S" must appear on the prescription.
Wyoming	Yes	No	Yes	Yes	In the physician's handwriting, the words "Brand Medically Necessary" must appear on the prescription.

Source: http://professionals.epilepsy.com/page/statutes_by_pharmacists.html