Jill C. Fike
Director

Brian Scott Johnson
Deputy Director

Senate Research Office
204 Paul D. Coverdell Legislative Office Building
18 Capitol Square
Atlanta, Georgia 30334

Telephone
404.656.0015

Fax
404.657.0929

THE FINAL REPORT OF SENATE STUDY COMMITTEE ON PRIOR APPROVALS FOR PRESCRIPTION DRUGS

COMMITTEE MEMBERS

Senator Jack Murphy, Chairman
District 27

Senator Ed Harbison
District 15

Senator Lee Hawkins
District 49

Senator Ralph Hudgens
District 47

Senator Bill Jackson
District 24

Prepared by the Senate Research Office
2008

COMMITTEE FOCUS, CREATION, AND DUTIES

The Senate Study Committee on Prior Approvals for Prescription Drugs was created from Senate Resolution 1285 and continues the work and findings of 2007's Senate Prescription Drug Study Committee. Like its predecessor, the Committee is charged with examining the practice of prior authorization with the understanding that that the current statutes related to substituting generic prescription drugs in place of name brand drugs, as found in Article 5 of Chapter 4 of Title 26, do not adequately address how the prior authorization process should be carried out in such situations. Senate Resolution 1285 also questions whether prior authorization is a cost-effective, necessary, equitable practice, and if it is in the best interest of the health and welfare of Georgia citizens. Moreover, the Resolution contends that many treating physicians are opposed to the imposition of prior authorization requirements by insurers and pharmacy benefit management companies (PBMs) as these practices are costly and unnecessarily time consuming for doctors, medical staff, and patients.

Since the 2008 Senate Study Committee on Prior Approvals for Prescription Drugs is essentially a continuation of 2007's Senate Prescription Drug Study Committee, this report chronicles the findings of both Committees and refers to both Committees collectively as one. However, the report's recommendations are those of the 2008 Committee members. A copy of the 2007 Committee's final report can be found at: http://www.legis.ga.gov/legis/2007_08/senate/committeereports.htm

Senator Jack Murphy of the 27th was appointed as the Committee's Chairman. The other members serving on the Committee were: Senator Gloria Butler of the 55th (2007 only), Senator Ed Harbison of the 15th (2008 only), Senator Lee Hawkins of the 49th, Senator Ralph Hudgens of the 47th, Senator Bill Jackson of the 24th (2008 only), and Senator John Wiles of the 37th (2007 only). The 2008 Committee met on July 29, 2008, September 4, 2008, and October 29, 2008.

The Committee heard testimony from the following individuals and organizations: Dr. Barry Jones; Mr. Patroski Lawson, Senior Government Affairs, and Ms. La Tosha Owen of Solvay Pharmaceuticals, Inc.; Ms. Ellen Yeager of Mental Health America of Georgia; Mr. Robert Highsmith of Express Scripts; Dr. Ed Weisbart, the Chief Medical Officer for Medical Affairs for Express Scripts; Ms. Larisa Noble, Pharmacist; Ms. Judy Gardner, the President of the Georgia State Board of Pharmacy; Mr. Rick Allen, the Deputy Director of the Georgia Drugs and Narcotics Agency; Dr. Jane Keith, the Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); Mr. John April of Wellpoint PBM; Mr. Brian Looby and Dr. Todd Williamson of the Medical Association of Georgia (MAG); Ms. Caroline Holley and Dr. Ronald Koenig of BCBS; Mr. Jerry Dubberly, Deputy Director Medical Assistance Policy Section for the Department of Community Health (DCH); Mr. Mark D. Trail, Chief of the Medical Assistance Plans for DCH; Ms. Dorothy Roberts, University System of Georgia (USG) System Benefits Administrator; Ms. Amanda Seals, Executive Director for Government Relations for USG; Dr. Joy A. Maxey, pediatrician and former President of MAG; Mr. John C. Heavener of the Georgia Retail Association; Mr. Bruce Lott, Director of State Government Relations for Mylan, Inc.; Ms. Karen Coulter, RN and COO of Sherwood Clinical; Mr. Charles Craig, President of BioScience; Ms. Sheila Humberstone of Troutman Sanders representing Medco; Mr. J. Russell Teagarden, Vice President of Clinical Practices and Therapeutics for Medco; and orthopedic surgeon, Dr. James Mueller.

COMMITTEE FINDINGS

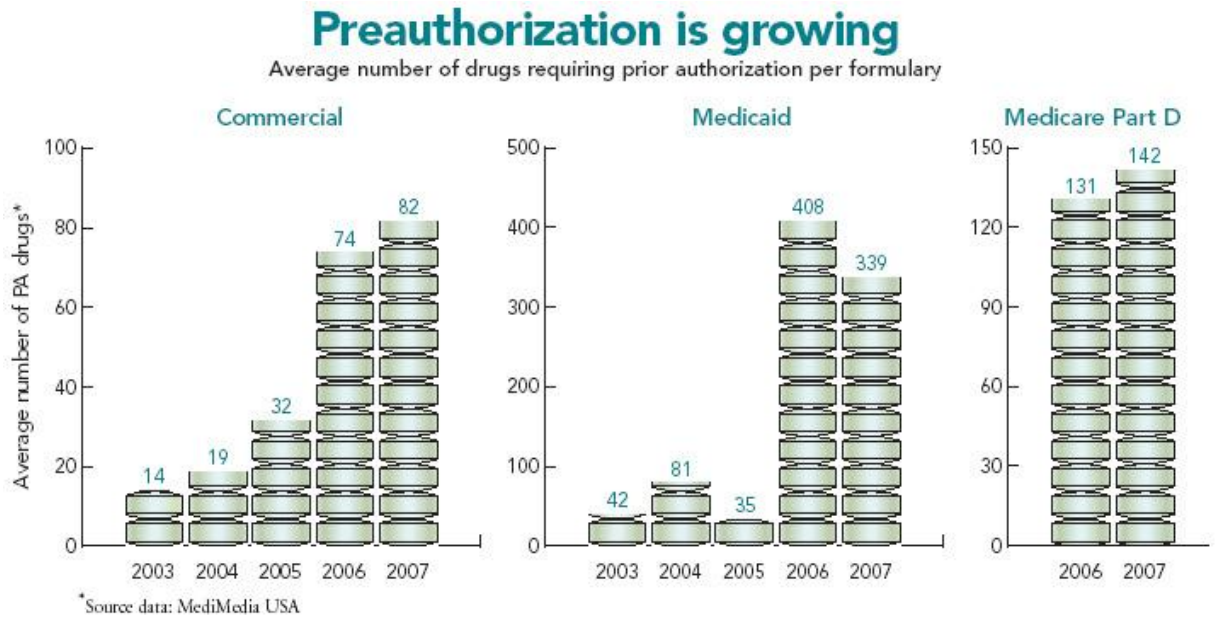
Background

Traditionally, insurers use a number of utilization controls on the use of services to control costs and to ensure that only medically necessary services are reimbursed. Consequently, an insurer may apply a cost-saving process on prescription drugs, such as: a requirement for prior authorization, exclusion of specific drugs, limits on the number of brand name drugs that can be prescribed for a patient, or a requirement that drugs be on a "preferred" list in order to be covered. Prior authorization simply means that the insurer requires the prescribing provider to seek prior approval from the insurer or PBM for an otherwise covered outpatient drug.

For many years, traditional prior authorization systems have focused on potential abuse based upon the number of prescriptions. However, more recent prior authorization requirements are being implemented in a much more complex environment. Not only are insurers seeking to control the number of prescriptions, but they are also attempting to regulate the types drugs being prescribed.

While a number of processes are being used, the most common are described here. First, many insurers require the use of generic drugs whenever possible. Second, insurers establish lists of preferred drugs known as a formulary, in which case, prior authorization is required before a drug not on the list can be dispensed. Insurers may also impose limits on the number of prescriptions that may be filled for an individual, or allowed a limited supply, i.e., 30 days, to be filled. The primary intent of these practices is to control costs. It is important to remember that prior authorization may only last for a short period of time, and rarely lasts more than six months. After it expires, the process between physician and insurer must be repeated.

Utilization controls over drug prescriptions can result in restricted patient access – individuals with the most severe needs and the least ability to pay out of pocket for medical services may be deprived of the medications they need. In addition to increasing the pain and anxiety of beneficiaries, the lack of necessary medications can result in more extensive and expensive medical procedures.



A Word on Generic Prescription Drugs

The Study Committee learned that doctors and patients regularly run afoul of the prior authorization process when a specific name brand drug is prescribed for which the insurer requires a generic drug instead. A brand name drug is the first version of a particular drug marketed by a specific drug company.

Brand name drugs are exclusive and are protected by a patent. This exclusivity helps drug manufacturers recoup research, development, and marketing costs through higher prices.

When a drug patent expires, other companies may produce a generic version of the brand name drug. A generic medication is basically a copy of the brand name drug and is marketed under its chemical name. A generic drug may have a different color or shape than its brand name counterpart, but it must have the same active ingredients, strength, and dosage form (i.e., pill, liquid, or injection), and provide the same effectiveness and safety as its brand name counterpart. Specifically, generic drugs must meet the following criteria when compared to their brand name counterparts:

- Ability to deliver the same amount of active ingredient into the bloodstream in the same amount of time;
- Identical bioavailability; and
- Identical bioequivalency.

Bioavailability refers to the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action. Bioequivalence refers to equivalent release of the same drug substance from two or more drug products or formulations. This leads to an equivalent rate and extent of absorption from these formulations. Underlying the concept of bioequivalence is the notion that, if a drug product contains a drug substance that is chemically identical and is delivered to the site of action at the same rate and extent as another drug, then it is equivalent and can be substituted for that drug product.[1]

Methods used to define bioequivalence can be found in the Code of Federal Regulations, and include:
1. Pharmacokinetic (PK) studies,
2. Pharmacodynamic (PD) studies,
3. Comparative clinical trials, and
4. In-vitro studies.

The choice of study used is based on the site of action of the drug and the ability of the study design to compare drug delivery to that site by the two products.[2]

The statistical methodology for analyzing these bioequivalence studies is called the two one-sided test procedure. Two situations are tested with this statistical methodology. The first of the two one-sided tests determines whether a generic drug, when substituted for a brand name drug, is significantly less bioavailable. The second of the two one-sided tests determines whether a brand name drug, when substituted for a generic, is significantly less bioavailable. Based on the opinions of FDA medical experts, differences of up to 20 percent for each of the above tests is determined to be 'insignificant' or allowable, and therefore, desirable for all drug products.[3] In essence, generics are only required to have 81 percent of the bioavailability of that of the name brand drug. This disparity in bioavailability can lead to severe side effects in some patients.

Compounding the issue of bioavailability, is that manufacturers may use different tints, dyes, and fillers such as sugars, starches, and waxes in a generic drug that are not present in its brand name equivalent.[4] Such inactive ingredients can trigger side-effects in certain people. This, as well as the bioavailability issues, are the major reasons why physicians will prescribe brand name drugs over their less-expensive generic equivalent.[5] This almost always triggers a preauthorization.

Formularies and Prior Authorization

The primary reason why a certain prescribed brand name drug will set off a preauthorization is because the physician has prescribed a drug that is not on the health plan's drug formulary or there is a less-

[1] U.S. Office of Generic Drugs, *Approved Drug Products with Therapeutic Equivalence Evaluations;* 27th edition. Page vii. As found at: http://www.fda.gov/cder/orange/obannual.pdf
[2] 21 CFR 320.24
[3] U.S. Office of Generic Drugs, Page viii.
[4] Testimony presented by Ms. La Tosha Owen; Solvay Pharmaceuticals; August 21, 2007.
[5] Testimony presented by Dr. Barry Jones; August 21, 2007.

expensive generic equivalent available. Certain medications, typically due to a potential safety risk, also require prior authorization.[6]

A formulary is a list of prescription drugs that have been approved for payment by a health plan. Typically, a formulary is developed by a committee whose voting members are physicians and clinical pharmacists. The committee uses medical literature to verify that the formulary drugs chosen are clinically effective and safe. The committee also reviews and updates the formulary quarterly to assist physicians in prescribing medically appropriate and cost-effective medications.[7]

Formularies are used to control the cost and utilization of prescription drugs without triggering a preauthorization. Moreover, and depending on their health care coverage, patients may have a lower copayment amount when a formulary medication is selected. Doctors and pharmacists use the formulary to aid them in selecting the medications best suited for a patient's needs. The medications are generally chosen based on the following criteria:

- Safety;
- Efficacy;
- Unique qualities of the medication compared to available alternatives; and
- Cost of the medication if the first three criteria are equal.

Formularies vary in their restrictiveness:

1. Closed Formularies: Provide coverage only for medications on the formulary;

2. Open Formularies: Provide coverage for both listed and non-listed drugs (Physicians are encouraged to prescribe listed drugs); and

3. Tiered Formularies: Encourage the use of formulary drugs by charging higher copayments for non-listed drugs. The tiered system also favors generics by charging the lowest copayment for generics.[8] Generally, a three-tier benefit design looks like this:

Tier 1	Generic drugs	Lowest copayment
Tier 2	Formulary brand name drugs	Medium copayment
Tier 3	Non-formulary brand name drugs	Highest copayment

In essence, regardless of the type of formulary being utilized by the insurer, doctors are required to obtain prior authorization for certain drugs for one or more of the following reasons:

1. Has a potential for adverse reaction if not used correctly;
2. Has a high risk of misuse or of being prescribed inappropriately;
3. May only be a benefit when prescribed for certain uses, based on FDA guidelines;
4. May provide less clinical value than another drug in the same therapeutic class; or
5. Has a lower-cost brand or generic alternative that is equally effective for most individuals.

Dr. Ronald Koenig of BCBS pointed out that, all things being equal, the insurer or PBM will always select the least expensive drug; although quality will never be compromised by value.[9]

Prior Authorization, Rebates and The State Health Benefit Plan

On several occasions, the Committee heard testimony on how the prior authorization process has benefited cost-saving measures within the State Health Benefit Plan (SHBP). These savings occur in two ways: by substituting more expensive brand name drugs for generic drugs; and by substituting a particular drug for an equivalent drug for which its manufacturer provides a rebate (whether generic or not).

[6] Testimony presented by Dr. Jane Keith, Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); and Mr. John April of Wellpoint PBM; November 1, 2007.
[7] Ibid.
[8] Testimony presented by Dr. Jane Keith, Pharmacist Program Manager for Blue Cross/Blue Shield of Georgia (BCBS); and Mr. John April of Wellpoint PBM; November 1, 2007.
[9] Testimony presented by Dr. Ronald Koenig of BCBS; November 1, 2007.

DCH claims that prior authorization saved the SHBP over $37.5 million in 2007.[10] Of this amount, $17.5 million was credited to receiving various manufacturer rebates while the remaining savings were acquired through the actual prior authorization process of denying claims and substitutions.[11] By restricting or prohibiting prior authorization, DCH has warned the Committee that the rebates would be jeopardized and that the $17.5 million it is saving could not possibly be realized in future years. Moreover, DCH contends that prohibiting prior authorization would endanger, what DCH terms, the "sentinel effect" of prior authorization. The Sentinel effect involves using prior authorization to change the prescribing habits of providers. That is, once the physician knows that a drug will require prior authorization, that physician will cease to prescribe that particular drug and choose a suitable alternative.[12] But this is the exact reason providers scorn the prior authorization process – it essentially overrides their ability to practice medicine and creates the impression that PBMs and insurers are really the ones practicing medicine when it comes to prescribing drugs.

Drawbacks of Prior Authorization

Increasingly, physicians, pharmacists, and patients have been faced with dealing with the many obstacles imposed by the prior authorization process. Physicians especially resent the idea, whether perceived or actual, of insurers "practicing medicine." Moreover, there is a belief that the insurance industry's aim is to pressure doctors into prescribing generics as often as possible; the argument being that if a doctor is aware that she will have to spend a considerable amount of time dealing with prior authorization in order to prescribe a brand name product, she will stop prescribing that drug even if she believes it is the better choice.[13]

Cost to Physicians: Time and Money

As noted previously, insurers assert that prior authorization reduces the cost of health care and allows prescription drugs to be more affordable for plan members. But even when that is the case, prior authorization increases practice costs because of the extra time and additional staff needed to deal with the process. Prior authorization also consumes a lot of a physician's time. In addition to time spent with patients – listening, examining, speaking with them, explaining the diagnosis, prognosis, and possible solutions, and determining the referrals and tests – a physician is also required to carefully study the particular insurer's formulary in a world in which it is not unusual for a patient to be prescribed five or more drugs at the same time. Dr. Todd Williamson of the Medical Association of Georgia testified that it can add at least five minutes of additional work per drug per patient for a physician or his staff.[14] Even if the economic and time-consuming burden of prior authorization can be reduced, physicians resent the micromanagement it represents. Clearly, from the physician's perspective, the ultimate insult from prior authorization, aside from the aggravation and the expense, is the erosion of physician knowledge and prescriptive power.

Inconvenience to Patients

One of the most frustrating aspects of prior authorization is that it poses an increased burden and nuisance not only to the physician and pharmacist, but to the patient as well. If the patient takes his prescription to the pharmacy and it requires prior authorization, he might have to stand around or return later to pick up his medication while the pharmacist calls the physician's office or the insurer. In a world in which most people are already pressed for time, prior authorization only serves to add to our sense of daily haste.

Administrative Cost and Burden to Insurers

What first may appear to fly in the face of logic, at least one insurer is critical of PBMs and the excessive financial and administrative burden of the prior authorization process. The increasing costs are leading some insurers to cease seeking prior authorizations altogether. As reported in American Legislative

[10] Testimony presented by Mr. Jerry Dubberly, Deputy Director Medical Assistance Policy Section for DCH; July 29, 2008.

[11] It is important to note that, except for its $980,135 administrative fee for managing the SHBP, in no instance does the PBM receive any of the revenue or savings from the prior authorization process. However, this is not entirely true for other privately run health plans and an issue of concern for the Committee.

[12] Testimony presented by Mr. Jerry Dubberly, Deputy Director Medical Assistance Policy Section for DCH; July 29, 2008.

[13] Testimony presented by Dr. Barry Jones; August 21, 2007.

[14] Testimony presented by Dr. Todd Williamson of the Medical Association of Georgia; November 1, 2007.

Exchange Council's (ALEC) publication, *The State Factor*, "UnitedHealth saved $110 million in administrative expenses and experienced a 26 percent decrease in member complaints the year after."[15]

Rebates and Transparency

As explained above, DCH's relationship with PBMs regarding the SHBP and drug rebates is transparent, with the rebate money being passed on to the State. However, this is generally not the case with other health plans and has caught the attention of the courts and other state legislatures. It is widely understood that outside of administrative fees, PBM's earn their money through rebates from manufacturers and on the difference between what the PBM charges the employer or health plan for a prescription and what it pays pharmacies for it, minus the dispensing fee. This latter practice is known as the "spread." Rebates and spreads vary widely, depending on the drug, the manufacturer, and the PBM payer.[16] This has troubled several state legislatures as well as Attorneys General for the simple fact that few employers, health plans and members know what the true costs are for prescriptions drugs. This concern is giving rise to fiduciary disclosure laws that require PBMs to operate with more transparency and to be accountable to the insurers and employers with whom they contract. To be fair, the committee understands that secrecy does not necessarily mean malicious intent. However, the only defense put forward by the PBMs in defense of this secrecy is that more transparency would jeopardize competition and undermine a PBM's ability to negotiate contracts.[17]

Over the past decade, PBMs have fought to limit fiduciary disclosure laws. Most recently, its trade group, the Pharmaceutical Care Management Association (PCMA), gained a victory in the District of Columbia when a Federal Appeals Court allowed a challenge to the D.C. PBM law to proceed. But new laws in Maryland and a recent $9.5 million settlement between Express Scripts and 28 states indicate that legislatures and Attorneys General are pressing for increased transparency within PBM operations.

The Express Scripts settlement is the third of its kind and marks an increased awareness and concern over PBM transparency. The behavior of the PBMs regarding transparency is the major aspect of all three settlements, as it is in the Maryland, D.C., North Dakota, and Maine laws – which are explained below.

State Legislation

The issue of whether PBMs must function as fiduciaries for their clients has been addressed recently by at least 13 state legislatures and the District of Columbia, according to the National Conference of State Legislatures (NCSL). But PCMA points out that since 2003, 31 states have rejected such legislation, "realizing these proposals would provide drug manufacturers the opportunity to charge consumers and employers higher drug prices." Indeed, PCMA contends that knowing that pricing would become public would make it much more unlikely for the manufacturers to provide the discounts that allow PBM members to save their clients money.

Maine

Maine's 2003 PBM fiduciary disclosure law, the *Unfair Prescription Drug Practices Act*, requires PBMs to pass on the volume-based discounts they get from manufacturers to their clients. It also requires a PBM who switches a prescribed drug: to get physician approval for the switch; tell the individual and the insurer the cost of both drugs; and reveal payments the PBM is receiving to make the switch. Maine's law, however, does not require PBMs to be regulated by the State.

In 2005, the federal First Circuit Court of Appeals ruled that Maine has the authority to regulate PBMs, rejecting the PCMA claim that the federal Employee Retirement Income Security Act (ERISA) exempted PBMs from state laws. Later that year, the U.S. Supreme Court refused to hear a PCMA challenge to the First Circuit's decision. Significant provisions of Maine's law include the following:

[15] Osvag, Kimberly, et al. "Preferred Drug Lists: Potential Impact on Healthcare Economics," *Vascular Health and Risk Management* (April 2008), 4(2): 403-413. As quoted in Brase, Twila R.N., P.H.N., "Evidence-Based Medicine: Rationing Care, Hurting Patients" ALEC's *The State Factor* (December 2008), 10.

[16] Sipkoff, Martin, "PBMs Raise the Curtain"; http://www.managedcaremag.com/archives/0609/0609.pbms.html

[17] Testimony presented by Mr. Robert Highsmith of Express Scripts; September 4, 2008.

MAINE
Title 22, Chapter 603, Subchapter 4, Section 2699
Prescription Drug Practices

• Provides that a PBM owes a fiduciary duty to a covered entity and must discharge that duty in accordance with the provisions of state and federal law and requires PBM to perform its duties with care, skill, prudence, and diligence in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

• Requires the PBM to notify the covered entity in writing of any practice that is a conflict of interest.

• Upon request by the covered entity, the PBM must provide all financial and utilization information relating to services to that covered entity.

• The PBM may designate any information provided to the covered entity as confidential and the information may not be disclosed without the permission of the PBM; except that disclosure may be ordered by a court. Also, this provision does not limit the Attorney General's use of its investigative authority.

• Requires the PBM to transfer in full to the covered entity any benefit or payment received as a result of a substitution.

• Requires the PBM to disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and any drug manufacturer or labeler, including formulary management, drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies, and data sales fees. The PBM may designate the information as confidential. However, disclosure may be ordered by a court and this provision does not limit the Attorney General's use of its investigative authority.

• Provides that a violation of the Act is a violation of the Maine Unfair Trade Practices Act and subject to a fine of not more than $10,000.

Sources: National Community Pharmacists Association; NCSL; Maine General Assembly.

District of Columbia

The District of Columbia passed a similar law in 2004, known as *the AccessRx Act*. It was also challenged by PCMA, but D.C. attorneys claimed that under the legal doctrine of *collateral estoppel*,[18] the First Circuit's decision in Maine protected the D.C. law. But in April, the Federal Court of Appeals for the District of Columbia unanimously rejected the argument – and the D.C. law continues to be litigated.

Maryland

Maryland was particularly active in addressing PBMs in 2008 by enacting five major pieces of legislation. Four of the bills that were signed by the governor in April provide that PBMs must: inform a purchaser that the PBM may solicit and receive manufacturer payments; pass through or retain the manufacturer payments; sell aggregate utilization information; and share aggregate utilization information.

2008 MARYLAND LEGISLATION

HB 120 Requires a PBM to disclose information to a prospective purchaser and a purchaser, specifying the manner in which disclosures must be provided and information remaining confidential.
HB 343 Prohibits a pharmacy benefits manager from substituting one prescription drug for the drug originally prescribed unless specified conditions are met.
HB 419 Requires an entity to register with the Insurance Commissioner before the person acts as, or represents itself as a PBM.
HB 580 Establishes requirements for a pharmacy and therapeutics (P&T) committee of a PBM; and requires a PBM to ensure that its P&T committee has specified policies and procedures.

Source: NCSL

[18] *Collateral estoppel* is the situation in which a judgment in one case prevents (estops) a party to that suit from trying to litigate the issue in another legal action. In effect, once decided, the parties are permanently bound by that ruling.

The amended statute contains the following provisions:

MARYLAND
Subtitle 16, Sections 15-1601 et seq
Pharmacy Benefits Managers

• PBM must register with the Insurance Commissioner and renew registration every 2 years. The Commissioner may suspend, deny, revoke, or refuse to renew a registration, PBM subject to administrative penalties.

• Prior to entering into a contract, the PBM must inform the purchaser that the PBM may solicit and receive manufacturer payments, pass through or retain those payments depending on the contract terms, sell aggregate utilization information, and share aggregate utilization information with other entities.

• PBM must offer to provide to the purchaser a report that contains net revenue and manufacturer payments.

• If a purchaser has a rebate sharing agreement, the PBM must offer to provide a report for each fiscal quarter and each fiscal year that contains information on the net revenues, prescription drug expenditures, manufacturer payments, and rebates.

• PBM may require purchaser to sign a nondisclosure agreement prior to releasing information.

• PBM must disclose at the time of contracting with a pharmacist, and at least 30 days before any contract change: the terms of reimbursement; process for verifying benefits and beneficiary eligibility; and dispute resolution and audit appeals process and procedures for verifying drugs included on the formularies used by the PBM.

• PBM may not request a therapeutic substitution unless the proposed substitution is for medical reasons that benefit the beneficiary or it will result in financial savings and benefits to the purchaser or the beneficiary.

• PBM must disclose certain information to the prescriber when the PBM directs the prescriber to make a substitution.

• If PBM receives payment from a manufacturer for making the substitution, that payment must be disclosed to the prescriber at the time of the solicitation.

• If a substitution occurs, the PBM must provide certain information to the beneficiary.

• PBM must maintain a toll free number for prescribers, pharmacists, and beneficiaries.

• PBM may not ship, mail, or deliver drugs through a non-resident pharmacy unless it holds a pharmacy permit from the Board of Pharmacy.

• Establishes requirements for a pharmacy and therapeutics (P&T) committee established by a PBM. Members of a P&T committee must sign a conflict of interest statement and a majority of the P&T committee members must be practicing physicians or pharmacists.

• PBM must have policies and procedures, including disclosure requirements, to address potential conflicts of interest and a process to evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs.

Sources: National Community Pharmacists Association; NCSL; Maryland General Assembly.

North Dakota

North Dakota law treats PBMs as administrators and requires them to be registered as an administrator with the Insurance Commissioner. PBMs are required to disclose any ownership interest by an insurer or a pharmaceutical manufacturer, and to notify the Commissioner in writing within five business days of any material change in the PBM's ownership.

A PBM may not exclude an otherwise qualified pharmacy from its network if the pharmacy accepts the terms, conditions, and reimbursement rates of the PBM's contract, and may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract.

A PBM must offer to their covered entities contracting options that must include:

- a transaction fee without a sharing of a payment received by the PBM:
- a combination of transaction fee and a sharing of the payment received by the PBM; or

- a transaction fee based on the covered entity receiving all of the benefits of payments received by the PBM.

Agreements between the PBM and the covered entity must include a provision allowing the covered entity to audit the PBM's books, accounts, and records as necessary to confirm that the benefit of a payment received by the PBM is being shared as required by the contract.

During an examination of a covered entity, the Insurance Commissioner may examine any contracts between the covered entity and the PBM in order to determine whether payments received from the PBM are being applied to reduce the covered entity's rates or have been distributed to covered individuals. In addition, the covered entity must disclose annually the benefits of the payments received and describe how the benefits received were applied toward reducing rates or distributed to covered individuals. Any information disclosed to the Commissioner is considered a trade secret.

2008 COMMITTEE RECOMMENDATIONS

Based on testimony, the Committee has determined that prior authorization is ultimately approved between 87 and 99 percent of the time. This only serves to reinforce the notion that prior authorization is not only unnecessary, but it is also an inconvenience, burden, and cost to providers, pharmacists, insurers, and patients.

Moreover, generics are only required to have 81 percent of the bioavailability of that of the name brand. Many newer drugs are developed so as to provide fewer and less damaging side effects than the original. Most drugs effect specific pathways and may be substituted for by less expensive drugs which may not even affect those same targets. The Committee believes that the best drug is most often selected by the provider and not by the insurer or PBM.

After studying the issues involving prior authorization and hearing the testimony presented by several witnesses, the Senate Study Committee on Prior Approvals for Prescription Drugs makes the following recommendations:

Prior Authorization Approval Deadlines
Require insurers to establish procedures to ensure that there is a response to a request for prior authorization for a prescription drug by telephone or other telecommunication device within 24 hours after it is received. If a prior authorization cannot be addressed within 24 hours, or if there is an emergency, then a 72-hour supply of the prescribed drug must be provided.

Reimbursements for Physicians and Patients
Physicians should be reimbursed by the insurer or the PBM when prior authorizations for that insurer or PBM exceed 10 in a 30-day period at the rate of $10.00 per prior authorization. In the event a patient is required to incur additional visits to a pharmacy as a result of the prior authorization process, the insurer or PBM must provide the patient with a 12 percent decrease in the charge for the prescription drug.

Nonpreferred Drugs
Patients should be allowed to continue using a nonpreferred drug if the drug has been removed from the PDL or if the patient has changed to a plan or provider that does not list the drug on its PDL.

Liability
The insurer or PBM should be liable for any adverse consequences to a patient if the insurer or PBM requires a different drug than that prescribed by the patient's physician.

PBM Oversight Committee
A PBM oversight committee should be established within the Insurance Commissioner's Office to advise the Legislature on the conduct of PBMs operating in Georgia. This conduct includes business practices involving drug prior authorization programs, rebate programs, the evolving certification process, and any regulations of the industry by other states.