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S.P. 450	March 9, 2007

An Act To Assist Maine Pharmacies

Reference to the Committee on Business, Research and Economic Development suggested and ordered printed.

JOY J. O'BRIEN
Secretary of the Senate

Presented by Senator DIAMOND of Cumberland.
Cosponsored by Representative ROBINSON of Raymond.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA c. 117, sub-c. 13 is enacted to read:

SUBCHAPTER 13

PRESCRIPTION DRUG PRACTICES

§13831. Short title

This subchapter may be known and cited as "the Prescription Drug Practices Act."

§13832. Definitions

As used in this subchapter, unless the context otherwise indicates, the following terms have the following meanings.

1. Bureau. "Bureau" means the Bureau of Insurance.

2. Covered entity. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care or other limited benefit health insurance policies and contracts.

3. Covered individual. "Covered individual" means a member, participant, enrollee, contract holder or policyholder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

4. Generic drug. "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

5. Labeler. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, Section 207.20 (2006).

6. Pharmacist. "Pharmacist" means an individual licensed by this State to engage in the practice of pharmacy.

7. Pharmacy. "Pharmacy" means a retail drug outlet registered with the board.

8. Pharmacy benefits management. "Pharmacy benefits management" means the arrangement for the procurement of prescription drugs at a negotiated rate for dispensation within the State to covered individuals, the administration or management of prescription drug benefits provided by a health insurance plan for the benefit of beneficiaries or any of the following services provided with regard to the administration of pharmacy benefits:

A. Mail-order pharmacy services;

B. Claims processing, retail network management as defined by the department by rule and payment of claims to pharmacies for prescription drugs dispensed to beneficiaries;

C. Clinical formulary development and management services;

D. Rebate contracting and administration;

E. Certain patient compliance, therapeutic intervention and generic substitution program services; and

F. Disease management program services.

9. Pharmacy benefits manager. "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail-order pharmacy services.

10. Superintendent. "Superintendent" means the Superintendent of Insurance.

§13833. Certificate of authority

1. Certificate required. A person or entity is prohibited from acting or operating as a pharmacy benefits manager in this State without a valid certificate of authority issued by the bureau. The failure to obtain a certificate while acting or operating as a pharmacy benefits manager is a civil violation for which a fine of not less than $5,000 and not more than $10,000 may be adjudged.

2. Application. An application for a certificate of authority to act as a pharmacy benefits manager may be obtained from the bureau. The application must include or attach the following:

A. All basic organizational documents of the pharmacy benefits manager, including, but not limited to, the articles of incorporation, articles of association, bylaws, partnership agreement, trade name certificate, trust agreement, shareholder agreement and other applicable documents and all amendments to those documents;

B. The names, addresses, official positions and professional qualifications of the individuals who are responsible for the conduct of the affairs of the pharmacy benefits manager, including all members of the board of directors, board of trustees, executive committee, any other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or

association and any other person who exercises control or influence over the affairs of the pharmacy benefits manager;

C. A certificate of compliance issued by the board pursuant to section 13834 indicating that the pharmacy benefits manager's plan of operation is consistent with any rules adopted by the board;

D. Annual statements or reports for the 3 most recent years or such other information as the bureau may require in order to review the current financial condition of the applicant;

E. If the applicant is not currently acting as a pharmacy benefits manager, a statement of the amounts and sources of funds available for organization expenses and the proposed arrangements for reimbursement and compensation of incorporators or other principals;

F. The name and address of the agent for service of process in this State;

G. A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies or other administrative services to be provided;

H. All incentive arrangements or programs, including, but not limited to, rebates, discounts, disbursements or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company that relates to prescription drug or device services, including at a minimum information on the formula or other method for calculation and amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of these disbursements;

I. Other information as the bureau may require; and

J. A filing fee of $5,000.

3. Inspection. The applicant shall make available for inspection by the bureau copies of all contracts with insurers, pharmaceutical manufacturers or other persons using the services of the pharmacy benefits manager for pharmacy benefits management services.

4. Denial of certificate. The bureau shall not issue a certificate of authority if it determines that the pharmacy benefits manager or any principal of the pharmacy benefits manager is not competent, trustworthy, financially responsible or of good personal and business reputation or has had an insurance license or pharmacy license denied for cause by any state.

5. Fidelity bond. A pharmacy benefits manager shall maintain a fidelity bond equal to at least 10% of the amount of the funds handled or managed annually by the pharmacy benefits manager. The bureau may require an amount in excess of $500,000 but not more than 10% of the amount of the funds handled or managed annually by the pharmacy benefits manager. A copy of the bond must be provided to the bureau.

§13834. Certificate of compliance

1. Plan of operation submitted to the board. Each pharmacy benefits manager seeking to become certified under section 13833 in this State shall submit its plan of operation for review in a format determined by the board.

2. Rules. The board shall adopt rules, including, but not limited to, the review of the pharmacy benefits manager plan of operation, the format required, the filing fee for a certificate of compliance, the requirements for recertification under section 13833 and any other information that the board may require to complete its review. The fees collected must be used for the purpose of regulating pharmacy benefits managers.

3. Approval by the board. If the plan of operation is approved by the board, the board shall issue the pharmacy benefits manager a certificate of compliance. Any subsequent material changes in the plan of operation must be filed with the board.

§13835. Disclosure required

1. Disclosures of ownership interests and affiliations required. A pharmacy benefits manager shall disclose to the bureau any ownership interest or affiliation of any kind with:

A. Any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the pharmacy benefits manager provides services; or

B. Any parent company, subsidiary, other entity or business relating to the provision of pharmacy services or other prescription drug or device services, or a pharmaceutical manufacturer.

2. Material changes in ownership. A pharmacy benefits manager shall notify the bureau in writing within 5 calendar days of any material change in its ownership.

3. Disclosures of agreements. A pharmacy benefits manager shall disclose to the bureau the following agreements and practices:

A. An agreement with a pharmaceutical manufacturer to favor the manufacturer's products over a competitor's products, to place the manufacturer's drug on the pharmacy benefits manager's preferred list or formulary or to switch the drug prescribed by a patient's health care provider with a drug agreed to by the pharmacy benefits manager and the manufacturer;

B. An agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the pharmacy benefits manager or to pay money or other economic benefits to the pharmacy benefits manager;

C. An agreement or practice to bill a health plan for prescription drugs at a cost higher than the pharmacy benefits manager pays the pharmacy;

D. An agreement to share revenue with a mail order or Internet pharmacy company; and

E. Any agreement to sell prescription drug data, including data concerning the prescribing practices of health care providers in this State.

§13836. Records

1. Maintenance of records. A pharmacy benefits manager shall maintain for the duration of any written agreement and for 2 years thereafter books and records of all transactions between pharmacy benefits managers and insurers, covered persons, pharmacists and pharmacies.

2. Access to records. The bureau has access to books and records maintained by a pharmacy benefits manager for the purposes of examination, audit and inspection. The information contained in the books and records is confidential and may not be disclosed, except that the bureau may use this information in any proceeding instituted against a pharmacy benefits manager or insurer.

3. Financial examinations. The superintendent shall conduct periodic financial examinations of every pharmacy benefits manager in this State. The pharmacy benefits manager shall pay the cost of the examination. The examination fee must be used to offset expenses for the regulation, supervision and examination of all entities subject to regulation under this subchapter.

§13837. Annual statement; fee

1. Annual statement. A pharmacy benefits manager shall file with the bureau an annual statement and filing fee for renewing a certificate of authority under section 13833 on or before March 1st. The statement must be in the form and contain such information as the bureau prescribes, including the total number of persons subject to management by the pharmacy benefits manager during the year, the number of persons terminated during the year, the number of persons covered at the end of the year and the dollar value of claims processed.

2. Disclosure of incentive arrangements. The annual statement under subsection 1 must disclose all incentive arrangements or programs, including, but not limited to, rebates, discounts, disbursements or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company that relates to prescription drug or device services, including at a minimum, information on the formula or other method for calculation and the amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of these disbursements.

§13838. Contracts; prohibited provisions

1. Contract required. A person may not act as a pharmacy benefits manager without a written agreement between the person and the pharmacy benefits manager.

2. Participation in contracts. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network solely because the

pharmacist or pharmacy declined to participate in another plan or network managed by the pharmacy benefits manager.

3. Filings with the bureau. The pharmacy benefits manager shall file a copy with the bureau of all contracts and agreements with pharmacies for approval not less than 30 days before the execution of the contract or agreement. The bureau shall consult with the board on the criteria for contracts and agreements before the board's adopting rules concerning the criteria. The contract is deemed approved unless the bureau disapproves it within 30 days after it is filed.

4. Prohibition. The written agreement between the covered entity and the pharmacy benefits manager may not provide that the pharmacist or pharmacy is responsible for the actions of the insurer or the pharmacy benefits manager.

5. Fiduciary duties. All agreements must provide that when the pharmacy benefits manager receives payment for the services of the pharmacist or pharmacy the pharmacy benefits manager acts as a fiduciary of the pharmacy or pharmacist who provided the services. The pharmacy benefits manager shall distribute the funds in accordance with the time frames provided in this chapter.

§13839. Prohibited practices

1. Intervention prohibited. A pharmacy benefits manager may not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of:

A. Influencing the prescriber's choice of therapy;

B. Influencing the patient's choice of pharmacist or pharmacy; or

C. Altering the prescription information, including, but not limited to, switching the prescribed drug without the express authorization of the prescriber.

2. Changes to prescriptions. An agreement between a pharmacy benefits manager and a pharmacy may not mandate that a pharmacist or pharmacy change a covered person's prescription unless the prescribing physician and the covered person authorize the pharmacist to make the change.

3. Discrimination prohibited. The insurer and the pharmacy benefits manager may not discriminate with respect to participation in the network or reimbursement as to any pharmacist or pharmacy that is acting within the scope of licensure or certification.

4. Health benefit plan. The pharmacy benefits manager may not transfer a health benefit plan to another payment network unless it receives written authorization from the covered entity.

5. Copayments. A pharmacy benefits manager may not discriminate when contracting with pharmacies on the basis of copayments or days of supply. A contract must apply the same coinsurance, copayment and deductible to covered drug prescriptions filled by any pharmacy, including a mail-order pharmacy or pharmacist who participates in the network.

6. Participating pharmacies. A pharmacy benefits manager may not discriminate when advertising which pharmacies are participating pharmacies. Any list of participating pharmacies must be complete and all-inclusive.

7. Minimum record-keeping requirements. A pharmacy benefits manager may not mandate basic record keeping by any pharmacist or pharmacy that is more stringent than required by state or federal laws, rules or regulations.

§13840. Termination of agreements

1. Complaints, grievances and appeals. A pharmacy benefits manager may not terminate or penalize a pharmacist or pharmacy solely as a result of the pharmacist's or pharmacy's filing of a complaint, grievance or appeal as permitted under this subchapter.

2. Denial or limitation of benefits. A pharmacist or pharmacy may not be terminated or penalized because it expresses disagreement with the pharmacy benefits manager's decision to deny or limit benefits to a covered person or because the pharmacist or pharmacy assists the covered person to seek reconsideration of the pharmacy benefits manager's decision or because the pharmacist or pharmacy discusses alternative medications.

3. Written notice required. Before terminating a pharmacy or pharmacist from the network, the pharmacy benefits manager shall give the pharmacy or pharmacist a written explanation of the reason for the termination at least 30 days before the termination date unless the termination is based on the:

A. Loss of the pharmacy's license to practice pharmacy or cancellation of professional liability insurance; or

B. Conviction of fraud.

4. Obligation to pay for services rendered. Termination of a contract between a pharmacy benefits manager and a pharmacy or pharmacist, or termination of a pharmacy or pharmacist from a pharmacy benefits manager's provider network as defined by rule, does not release the pharmacy benefits manager from its obligation to make any payment due to the pharmacy or pharmacist for pharmacist services rendered.

§13841. Medication reimbursement costs

A pharmacy benefits manager shall use a current and nationally recognized benchmark to base the reimbursement paid to network pharmacies for medications and products. The reimbursement must be determined as follows:

1. Average wholesale price. For brand-name or single-source products, the average wholesale price, as listed in standard industry references, such as First DataBank or Facts and Comparisons, or successor references, correct and current on the date of service provided, must be used; and

2. Criteria for reimbursement. For generic drug or multisource products, the maximum allowable cost must be established by referencing the baseline price in standard industry references, such as First DataBank or Facts and Comparisons. Only

products that are compliant with federal pharmacy laws as equivalent and generically interchangeable with a federal Food and Drug Administration Orange Book rating of "A-B" may be reimbursed from a maximum allowable cost price methodology. If a multisource product has no baseline price, then it must be treated as a single-source brand-name drug for the purpose of determining reimbursement.

§13842. Processing of clean claims; audits

1. Payment of claims. A pharmacy benefits manager shall pay or deny a clean claim, as defined by rule, submitted by a pharmacy within 15 days after receipt by the pharmacy benefits manager if the claim was submitted electronically or within 30 days after receipt if the claim was submitted by other means.

A. A pharmacy benefits manager that fails to pay or deny a clean claim in accordance with this subsection shall pay a penalty to the bureau for a period beginning on the 45th day after receipt of the clean claim and ending on the clean payment date, or delinquent payment period, calculated as follows: the amount of the clean claim payment times 10% per annum times the number of days in the delinquent payment period divided by 365.

B. Beginning October 1, 2007, the bureau shall adopt rules that outline the collection procedures for the outstanding interest from claims under paragraph A. The bureau shall also adopt rules that transfer the remaining interests to the General Fund.

2. Adjustment of payments. Within 24 hours of a price increase notification by a pharmaceutical manufacturer or supplier, a pharmacy benefits manager shall adjust its payments to pharmacists or pharmacies consistent with the price increase.

3. Retroactive denial of claims prohibited. Claims paid by a pharmacy benefits manager may not be retroactively denied or adjusted after 7 days from adjudication of the claims except as provided in subsection 4. In no case may an acknowledgement of eligibility be retroactively reversed.

4. Retroactive denial or adjustment allowed. A pharmacy benefits manager may retroactively deny or adjust a claim if:

A. The original claim was submitted fraudulently;

B. The original claim payment was incorrect because the pharmacist or pharmacy was already paid for services rendered; or

C. The services were not rendered by the pharmacist or pharmacy.

5. Audits. The pharmacy benefits manager may not require extrapolation audits as a condition of participating in the contract or network.

6. Recuperation of funds. The pharmacy benefits manager may not recoup any money that the pharmacy benefits manager believes is due as a result of an audit by setoff until the pharmacist or pharmacy has the opportunity to review the pharmacy benefits manager's findings and concurs with the results. If the parties cannot agree, then the audit is subject to review by the board.

§13843. Disclosures to covered persons; authorization for substitutions

1. Written notice to covered persons. When the services of a pharmacy benefits manager are used, the pharmacy benefits manager shall provide a written notice approved by the insurer to a covered individual advising the individual of the identity of and relationship between the pharmacy benefits manager, the insured and the covered individual.

2. Notice requirements. The notice under subsection 1 must contain a statement advising the covered individual that the pharmacy benefits manager is regulated by the bureau and that the individual has the right to file a complaint, appeal or grievance with the bureau concerning the pharmacy benefits manager. The notice must include the toll-free telephone number, mailing address and electronic mail address of the bureau. The notice must be written in plain English, using terms that are generally understood by the prudent layperson, and a copy must be provided to the bureau and to each pharmacist and pharmacy participating in the network.

3. Substitute prescription. When a pharmacy benefits manager requests a substitute prescription for a prescribed drug for a covered individual the following provisions apply.

A. The pharmacy benefits manager may substitute a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug.

B. With regard to substitutions in which the substitute drug costs more than the prescribed drug, the substitution must be made for medical reasons that benefit the covered individual. If a substitution is being made under this paragraph, the pharmacy benefits manager shall obtain the approval of the prescribing health professional or that person's authorized representative after disclosing to the covered individual the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution and any potential effects on a patient's health and safety, including side effects.

C. The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution under paragraph A or B.

§13844. Complaints

1. Adoption of procedures. The bureau and the board must adopt procedures for formal investigation of complaints concerning the failure of a pharmacy benefits manager to comply with this subchapter.

2. Transfer of complaints. The bureau must refer a complaint received under this subchapter to the board if the complaint involves a professional or patient health or safety issue.

3. Referrals. The board must refer a complaint received under this subchapter to the bureau if the complaint involves a business or financial issue.

§13845. Settlement of claims

Compensation to a pharmacy benefits manager for any claims that the pharmacy benefits manager adjusts or settles on behalf of an insurer may not be contingent in any way on claims experience. This section does not prohibit the compensation of a pharmacy benefits manager based on the total number of claims paid or processed.

§13846. Responsibilities to the covered entity

1. Financial and utilization information. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this section may designate that information as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this section may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except that disclosure may be made when authorized by a court.

2. Disclosure of arrangements. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, but not limited to, rebates, formulary management and drug-switch, or substitution, programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

3. Price differentials. A pharmacy benefits manager shall disclose to the covered entity whether there is a difference between the price paid to the retail pharmacy and the amount billed to the covered entity for the purchase.

4. Audits. The covered entity may audit the pharmacy benefits manager's books and records related to the rebates or other information provided in subsections 1, 2 and 3.

5. Good faith. A pharmacy benefits manager shall perform its duties exercising good faith and fair dealing toward the covered entity.

§13847. Rules

The department shall adopt rules to implement this subchapter. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

SUMMARY

This bill establishes "the Prescription Drug Practices Act." It requires all pharmacy benefits managers operating in the State to acquire a valid certificate of authority to be issued by the Department of Professional and Financial Regulation, Bureau of Insurance. It establishes compliance and disclosure requirements for pharmacy benefits managers and prohibits certain practices by pharmacy benefits managers.