

# Pharmacy Benefit Manager Licensure and Solvency Protection Act

## Section 1. Title.

This Act shall be known and cited as the Pharmacy Benefit Manager Licensure and Solvency Protection Act.

## Section 2. Purpose and Intent.

The purpose of this Act is to establish standards and criteria for the regulation, solvency and licensing of Pharmacy Benefit Managers. This Act is designed to promote, preserve, and protect the public health, safety, and welfare by and through effective regulation, solvency requirements and licensing of Pharmacy Benefit Managers.

## Section 3. Definitions.

For purposes of this Act:

- A. "Board of Pharmacy" or "Board" means the State Board of Pharmacy.
- B. "Commissioner" means the Commissioner of Insurance.
- C. "Covered Entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization, 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.
- D. "Covered Person" means a member, participant, enrollee, contract holder or policy holder 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.
- E. "Department" means Department of Insurance.
- F. "Health Benefit Plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the cost of health care services including prescription drug benefits.
- G. "Maintenance drug" means a drug prescribed by a practitioner who is licensed to prescribe drugs and used to treat a medical condition for a period greater than 30 days.
- H. "Multi-source drug" means a drug that is stocked and is available from three or more suppliers.
- I. "Pharmacist" means any individual properly licensed as a pharmacist by the Board.

J. "Pharmacist Services" includes drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the Rules of the Board. *DRAFTING NOTE: Use "the practice of pharmacy" definition in the state code.*

K. "Pharmacy" means any appropriately licensed place within this state where drugs are dispensed and pharmacist services are provided. *DRAFTING NOTE: Use the definition of "pharmacy" in the state code.*

L. "Pharmacy Benefits Management" means the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals.

M. "Pharmacy Benefits Manager" or "PBM" means a person, business or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity.

N. "Usual and Customary Price" means the price the pharmacist would have charged a cash paying (not a patient where reimbursement rates are set by a contract) patient for the same services on the same date inclusive of any discounts applicable.

#### **Section 4. Applicability and Scope.**

This Act shall apply to a PBM that provides claims processing services, other prescription drug or device services, or both to covered persons who are residents of this state.

#### **Section 5. Certificate of Authority to act as a PBM.**

A. No person or organization shall act or operate as a PBM in this state without a valid certificate of authority issued by the Department. The failure of any person to hold such a certificate while acting as a PBM shall subject such person to a fine of not less than \$5,000 or more than \$10,000 for each violation.

B. Each person seeking a certificate of authority to act as a PBM shall file with the Department an application for a certificate of authority upon a form to be furnished by the Department, which application shall include or attach the following:

(1) All basic organizational documents of the PBM, such as 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.

(2) The names, addresses, official positions and professional qualifications of the individuals who are responsible for the conduct of the affairs of the PBM, including all members of the board of directors, board of trustees, executive committee, 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 PBM.

(3) A Certificate of Compliance issued by the State Board of Pharmacy indicating that the PBM's plan of operation is consistent with the Pharmacy Practice Act and any regulations promulgated thereunder.

(4) Annual statements or reports for the 3 most recent years, or such other information as the Department may require in order to review the current financial condition of the applicant.

(5) If the applicant is not currently acting as a PBM, 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.

(6) The name and address of the agent for service of process in the state.

(7) 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.

(8) All incentive arrangements or programs such as 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 such disbursements.

(9) Such other information as the Commissioner may require.

(10) A filing fee of \$5,000.

C. The applicant shall make available for inspection by the Department copies of all contracts with insurers, pharmaceutical manufacturer or other persons utilizing the services of the PBM for pharmacy benefit management services. Certain contracts are subject to prior approval as provided in Section 10.

D. The Department shall not issue a certificate of authority if it determines that the PBM or any principal thereof 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

E. A PBM shall maintain a fidelity bond equal to at least 10 percent of the amount of the funds handled or managed annually by the PBM. However, the Department may require an amount in excess of \$500,000 but not more than 10 percent of the amount of the funds handled or managed annually by the PBM. A copy shall be provided to the Department.

## **Section 6. Certificate of Compliance issued by Board of Pharmacy.**

A. Each PBM seeking to become licensed in the state must submit its plan of operation for review in a format to be furnished by the Board of Pharmacy.

B. The Board will review the submission in order to determine if it complies with the Pharmacy Practice Act. The Board shall promulgate rules and regulations concerning, but not limited to, the format required, the filing fee, the requirements for re-certification and any other information

that it may require to complete its review. The fees collected shall be used solely for the purpose of regulating PBMs.

C. If the PBM's filing meets with Board approval, it shall be issued a Certificate of Compliance. Subsequent material changes in the plan of operation must be filed with the Board.

**Section 7. Disclosure of ownership or affiliation and certain agreements.**

A. Each PBM shall disclose to the Department any ownership interest or affiliation of any kind with: any insurance company responsible for providing benefits directly or through reinsurance to any plan for which the PBM provides services; or any parent companies, subsidiaries and other entities or businesses relative to the provision of pharmacy services, other prescription drug or device services or a pharmaceutical manufacturer.

B. The PBM must notify the Department in writing within five (5) calendar days of any material change in its ownership.

C. Every PBM shall disclose the following agreements:

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

2. Any agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the PBM or to pay money or other economic benefits to the PBM,

3. Any agreement or practice to bill the health plan for prescription drugs at a cost higher than the PBM pays the pharmacy,

4. Any agreement to share revenue with a mail order or internet pharmacy company and

5. Any agreement to sell prescription drug data including data concerning the prescribing practices of the health care providers in the state.

**Section 8. Maintenance of records; access; confidentiality; financial examination.**

A. Every PBM shall maintain for the duration of the written agreement and for 2 years thereafter books and records of all transactions between the PBM, insurers, covered persons, pharmacists and pharmacies.

B. The Department shall have access to books and records maintained by the PBM for the purposes of examination, audit and inspection. The information contained in such books and records is confidential. However, the Department may use such information in any proceeding instituted against the PBM or insurer.

C. The Commissioner shall conduct periodic financial examinations of every PBM in this state to ensure an appropriate level of regulatory oversight. The PBM shall pay the cost of the examination which shall be deposited in a special fund to provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this Act.

## **Section 9. Annual statement and filing fee required.**

A. Each authorized PBM shall file with the Department an annual statement on or before March 1<sup>st</sup>. The statement shall be in such form and contain such matters as the Department prescribes and include the filing fee established by the Department. It must include the total number of persons subject to management by the PBM during the year, 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.

B. The statement shall disclose all incentive arrangements or programs such as 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 such disbursements.

## **Section 10. Contracts; Agreements must be Approved; Prohibited Provisions.**

A. No person may act as a PBM without a written agreement between such person and the PBM.

B. A PBM shall not require a pharmacist/pharmacy to participate in one contract in order to participate in another contract. The PBM shall not exclude an otherwise qualified pharmacist/pharmacy from participation in a particular network solely because the pharmacist/pharmacy declined to participate in another plan or network managed by the PBM.

C. The PBM must file a copy with the Department of all contracts/agreements with pharmacies for approval not less than thirty (30) days before the execution of the contract/agreement. The Department shall consult with the Board on the criteria prior to promulgation. The contract shall be deemed approved unless the Department disapproves it within thirty (30) days after it is filed.

D. The written agreement between the insurer and the PBM shall not provide that the pharmacist/pharmacy is responsible for the actions of the insurer or the PBM.

E. All agreements shall provide that when the PBM receives payment for the services of the pharmacist/pharmacy that the PBM shall act as a fiduciary of the pharmacy/pharmacist who provided the services. The PBM shall distribute said funds in accordance with the time frames provided in this Act.

## **Section 11. Disclosures to Covered Person and Authorization for Substitutions.**

A. When the services of a PBM are utilized, the PBM must provide a written notice approved by the insurer to covered persons advising them of the identity of, and relationship between, the PBM, the insured and the covered person.

B. The notice must contain a statement advising the covered person that the PBM is regulated by the Department and has the right to file a complaint, appeal or grievance with the Department concerning the PBM. The notice shall include the toll-free telephone number, mailing address and electronic mail address of the Department.

C. The notice must be written in plain English, using terms that will be generally understood by the prudent layperson and a copy must be provided to the Department and each pharmacist/pharmacy participating in the network.

D. When a PBM requests a substitute prescription for a prescribed drug to a covered individual the following provisions apply:

(1) The PBM may substitute a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug.

(2) 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 subparagraph, the PBM 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 PBM as a result of the substitution and any potential effects on a patient's health and safety including side effects.

(3) The PBM shall transfer in full to the covered entity any benefit or payment received in any form by the PBM as a result of a prescription drug substitution under subparagraph (1) or (2).

## **Section 12. PBM Responsibilities to the Covered Entity.**

A. A PBM 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 PBM providing information under this section may designate that material as confidential. Information designated as confidential by a PBM and provided to a covered entity under this section may not be disclosed by the covered entity to any person without the consent to the PBM, except that disclosure may be made when authorized by a court.

B. A PBM shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the PBM and any prescription drug manufacturer or labeler, including, without limitation, rebates, formulary management and drug-switch (substitution) programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

C. A PBM shall disclose to the covered entity whether there is a difference between the price paid to retail pharmacy and the amount billed to the covered entity for said purchase.

D. The covered entity may audit the PBM's books and records related to the rebates or other information provided in sections A through C.

E. A PBM shall perform its duties exercising good faith and fair dealing toward the covered entity.

## **Section 13. PBM Responsibilities to Pharmacist/Pharmacy.**

A. A pharmacist/pharmacy may not be terminated or penalized by a PBM solely because of filing a complaint, grievance or appeal as permitted under this Act.

B. A pharmacist/pharmacy may not be terminated or penalized because it expresses disagreement with the PBM's decision to deny or limit benefits to a Covered Person or because

the pharmacist/pharmacy assists such Covered Person to seek reconsideration of the PBM's decision or because the pharmacist/pharmacy discusses alternative medications.

C. Prior to the terminating a pharmacy from the network, the PBM must give the pharmacy/pharmacist a written explanation of the reason for the termination at least 30 days prior to the termination date unless the termination is based on the (i) loss of the pharmacy's license to practice pharmacy or cancellation of professional liability insurance or (ii) conviction of fraud.

D. Termination of a contract between a PBM and a pharmacy or pharmacist, or termination of a pharmacy or pharmacist from a PBM's provider network shall not release the PBM from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist services rendered.

#### **Section 14. Medication Reimbursement Costs; Use of Index Required.**

PBMs 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:

A. For brand (single source) products the Average Wholesale Price (AWP) as listed in First Data Bank (Hearst publications) or Facts & Comparisons (formerly Medispan) correct and current on the date of service provided shall be used as an index.

B. For generic drug (multi-source) products, Maximum Allowable Cost (MAC) shall be established by referencing First Data Bank/Facts & Comparisons Baseline Price (BLP). Only products that are compliant with pharmacy laws as equivalent and generically interchangeable with a Federal FDA Orange Book rating of "A-B" will be reimbursed from a MAC price methodology. If a multi-source product has no BLP price, then it shall be treated as a single source branded drug for the purpose of determining reimbursement.

#### **Section 15. Timely Payments to Pharmacists/Pharmacies; Audits.**

A. If a PBM processes claims via electronic review then it shall electronically transmit payment within seven calendar days of said claims transmission to the pharmacist/pharmacy. Specific time limits for the PBM to pay the pharmacist for all other services rendered must be set forth in the Agreement.

B. Within 24 hours of a price increase notification by a manufacturer or supplier, the PBM must adjust its payments to the pharmacist/pharmacy consistent with the price increase.

C. Claims paid by the PBM shall not be retroactively denied or adjusted after seven days from adjudication of such claims except as provided in paragraph D below. In no case shall acknowledgement of eligibility be retroactively reversed.

D. The PBM may retroactively deny or adjust in the event (i) the original claim was submitted fraudulently; (ii) the original claim payment was incorrect because the provider was already paid for services rendered, or (iii) the services were not rendered by the pharmacist/pharmacy.

E. The PBM may not require extrapolation audits as a condition of participating in the contract, network or program.

F. The PBM shall not recoup any monies that it believes are due as a result of the audit by setoff until the pharmacist/pharmacy has the opportunity to review the PBM's findings and concurs with the results. If the parties cannot agree then the audit shall be subject to review by the Board.

#### **Section 16. PBM Prohibited Practices.**

A. A PBM shall not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of: influencing the prescriber's choice of therapy; influencing the patient's choice of pharmacist or pharmacy; or altering the prescription information, including but not limited to, switching the prescribed drug without the express authorization of the prescriber.

B. No agreement shall mandate that a pharmacist/pharmacy change a covered person's prescription unless the prescribing physician and the covered person authorize the pharmacist to make the change.

C. The insurer and the PBM may not discriminate with respect to participation in the network or reimbursement as to any pharmacist/pharmacy that is acting within the scope of his or her license or certification.

D. The PBM may not transfer a health benefit plan to another payment network unless it receives written authorization from the insurer.

E. No PBM may discriminate when contracting with pharmacies on the basis of co-payments or days of supply. A contract shall apply the same coinsurance, co-payment and deductible to covered drug prescriptions filled by any pharmacy, including a mail order pharmacy or pharmacist who participates in the network.

F. No PBM may discriminate when advertising which pharmacies are participating pharmacies. Any list of participating pharmacies shall be complete and all inclusive.

G. No PBM may mandate basic record keeping by any pharmacist or pharmacy that is more stringent than required by state or federal laws or regulations.

#### **Section 17. Complaint Process.**

A. The Department and the Board shall each adopt procedures for formal investigation of complaints concerning the failure of a pharmacy benefits manager to comply with this Act.

B. The Department shall refer a complaint received under this Act to the Board if the complaint involves a professional or patient health or safety issue.

C. The Board shall refer a complaint received under this chapter to the Department if the complaint involves a business or financial issue.

#### **Section 18. Adjustment or settlement of claims; compensation of PBM.**

Compensation to a PBM for any claims that the PBM adjusts or settles on behalf of an insurer shall in no way be contingent on claims experience. This section does not prohibit the compensation of a PBM based on total number of claims paid or processed.

**Section 19. Regulations.**

The Commissioner and the Board may promulgate regulations to carry out the provisions of this Act. The regulations may include the following: definition of terms, use of prescribed forms, reporting requirements, prohibited practices and enforcement procedures. The regulations shall be subject to review in accordance with general rules of administrative rulemaking and review of regulations.

**Section 20. Applicability of other laws and regulations.** (*DRAFTING NOTE: Use existing code sections to define the enforcement process including, grounds for license revocation, fines, suspension and reinstatement. If the State has an unfair trade practices act and/or a privacy/confidentiality act then this Act should be subject to those provisions. If not then this Act must include prohibitions against discrimination, false and misleading advertising and protections for privacy/confidentiality of covered person information.*)

**Section 21. Separability.**

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

**Section 22. Effective Date.**

This Act shall be effective (insert date). In order to continue to do business in this state, a PBM must obtain a Certificate of Authority from the Department within\_ninety (90) days after the effective date of this Act.

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