MISSISSIPPI LEGISLATURE REGULAR SESSION 2004

By: Representative Howell

To: Insurance

HOUSE BILL NO. 61

AN ACT TO CREATE THE PHARMACY BENEFIT MANAGEMENT REGULATION ACT; TO PROVIDE DEFINITIONS; TO REQUIRE THAT PHARMACY BENEFIT MANAGERS RECEIVE A LICENSE FROM THE COMMISSIONER OF INSURANCE AND A CERTIFICATE OF AUTHORITY FROM THE STATE BOARD OF PHARMACY BEFORE OPERATING IN THIS STATE; TO REQUIRE THE FILING OF CERTAIN ANNUAL STATEMENTS; TO PROVIDE FOR FINANCIAL EXAMINATIONS; TO PROVIDE FOR CERTAIN ASSESSMENTS AND FEES; TO PROVIDE THAT CONTRACTS BETWEEN PHARMACIES AND PHARMACY BENEFIT MANAGERS SHALL BE FILED WITH THE COMMISSIONER OF INSURANCE BEFORE EXECUTION; TO PROVIDE FOR ENFORCEMENT; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. This act shall be known and cited as the "Pharmacy Benefit Management Regulation Act."

SECTION 2. This act establishes standards and criteria for the regulation and licensing of pharmacy benefit managers. The purpose of this act is to promote, preserve and protect the public health, safety and welfare by and through effective regulation and licensing of pharmacy benefit managers.

SECTION 3. For purposes of this act:

(a) "Board of Pharmacy" or "board" means the State Board of Pharmacy empowered to regulate pharmacy benefit managers including granting a certificate of authority to a company.

(b) "Cease and desist" is an order of the board prohibiting a pharmacy benefit manager or other person or entity from continuing a particular course of conduct, which violates this act or its rules and regulations.

(c) "Commissioner" means the State Insurance Commissioner.

(d) "Enrollee" means an individual who has been enrolled in a pharmacy benefit management plan.

(e) "Insolvent" or "insolvency" means a financial situation in which, based upon the financial information required by this act for the preparation of the pharmacy benefit manager's annual statement, the assets of the pharmacy benefit manager are less than the sum of all of its liabilities and required reserves.

(f) "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 thirty (30) days.

(g) "Multi-source drug" means a drug that is stocked and is available from the three (3) or more suppliers.

(h) "Pharmacist's 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.

(i) "Pharmacist" means any individual properly licensed as a pharmacist by the State Pharmacy Board.

(j) "Pharmacy" means any appropriately licensed place within this state where drugs are dispensed and pharmacist services are provided.

(k) "Pharmacy benefits manager" or "PBM" means a business that administers the prescription drug/device portion of health insurance plans on behalf of plan sponsors, insurance companies, unions and health maintenance organizations.

(l) "Pharmacy benefit management plan" means an arrangement for the delivery of pharmacist services in which a pharmacy benefit manager undertakes to pay for, or reimburse, any of the costs of pharmacist services for an enrollee on a prepaid or insured basis which (i) contains one or more incentive arrangements intended to influence the cost or level or pharmacist services between the plan sponsor and one or more pharmacies with respect to the delivery of pharmacists services; and (ii) requires

or creates benefit payment differential incentives for enrollees to use under contract with the pharmacy benefit manager. A pharmacy benefit plan does not mean any employee welfare benefit plan (as defined in Section 3(1) of the Employee Retirement Income Security Act of 1974, 29 USCS Section 1002(1), which is self-insured or self-funded.

(m) "Plan sponsors" means the employers, insurance companies, unions and health maintenance organizations that contract with a PBM for delivery of prescription services.

(n) "Usual and customary price" means the price the pharmacists 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. No person or organization shall establish or operate a pharmacy benefit manager in this state to provide pharmacy benefit management plans without obtaining a certificate of authority from the State Board of Pharmacy in accordance with this act and all applicable federal and state laws. All PBMs providing pharmacy benefit management plans in this state shall obtain a certificate of authority from the State Board of Pharmacy every four (4) years.

Any organization or person may apply to the board to obtain a certificate of authority to establish and operate a PBM in compliance with this act if the organization obtains from the commissioner an annual license to do business in this state. A nonrefundable application fee of Five Hundred Dollars ($500.00) shall accompany each application for a certificate of authority.

The board may suspend or revoke any certificate of authority issued to a pharmacy benefit manager under this act or deny an application for a certificate of authority if it finds:

(a) That the pharmacy benefit manager is operating significantly in contravention of its basic organizational document.

(b) The pharmacy benefit manager does not arrange for pharmacist's services.

(c) That the pharmacy benefit manager has failed to meet the requirements for issuance of a certificate of authority as set forth in this act and all applicable federal and state laws.

(d) That the pharmacy benefit manager is unable to fulfill its obligation to furnish pharmacist's services as required under its pharmacy benefit management plan.

(e) The pharmacy benefit manager is no longer financially responsible and may reasonably be expected to be unable to meet its obligations to enrollees or prospective enrollees.

(f) The pharmacy benefit manager, or any person on its behalf, has advertised or merchandised its services in an untrue, misrepresentative, misleading, deceptive or unfair manner.

(g) The continued operation of the pharmacy benefit manager would be hazardous to its enrollees.

(h) The pharmacy benefit manager has failed to file an annual statement with the commissioner in a timely manner.

(i) The pharmacy benefit manager has otherwise failed to substantially comply with this act and any rules and regulations under this act.

When the certificate of authority of a pharmacy benefit manager is revoked, such organization shall proceed, immediately following the effective date of the order of revocation, to wind up its affairs and shall conduct no further business except as may be essential to the orderly conclusion of the affairs of such organization. The board may permit such further operation of the organization as the board may find to be in the best interest of enrollees to the end that the enrollees will be afforded the greatest practical opportunity to obtain pharmacist's services.

SECTION 5. The commissioner shall not issue an annual PBM license to do business in this state to any PBM providing pharmacy benefit management plans until he is satisfied that the pharmacy benefit manager:

(a) Has paid all fees, taxes and charges required by law;

(b) Has made any deposit required by this act;

(c) Has the minimum capital and surplus requirements specified by the commissioner;

(d) Has filed a financial statement or statements and any reports, certificates or other documents the commissioner considers necessary to secure a full and accurate knowledge of its affairs and financial condition;

(e) Is solvent and its financial condition, method of operation and manner of doing business are such as to satisfy the commissioner that it can meet its obligations to all enrollees; and

(f) Has otherwise complied with all the requirements of law.

This PBM license shall be in addition to the certificate of authority required by the board. A nonrefundable license application fee of Five Hundred Dollars ($500.00) shall accompany each application for a license to transact the business in this state. The fee shall be collected by the commissioner and paid directly into a special fund that shall provide expenses for the regulation, supervision and examination of all entities subject to regulation under this act.

The PBM license shall be signed by the commissioner or a duly authorized agent of the commissioner and shall expire on the next June 30 after the date on which it becomes effective.

All PBMs providing pharmacy benefit management plans shall obtain an annual renewal of its PBM license from the commissioner. The commissioner may refuse to renew the PBM license of any

pharmacy benefit manager or may renew the license, subject to any restrictions considered appropriate by the commissioner, if it finds an impairment of required capital and surplus or if it finds that the pharmacy benefit manager has not satisfied all the conditions set forth in this act. The commissioner shall not fail to renew the license of any pharmacy benefit manager transacting business in this state without giving the pharmacy benefit manager ten (10) days' notice and giving it an opportunity to be heard. The hearing may be informal, and the commissioner and the pharmacy benefit manager may waive the required notice.

SECTION 6. (1) Each PBM providing pharmacy management benefit plans in this state shall file a statement with the commissioner annually by March 1. The statement shall be verified by at least two (2) principal officers and shall cover the preceding calendar year. Each pharmacy benefit manager shall also send a copy of the statement to the board.

(2) The statement shall be on forms prescribed by the commissioner and shall include:

(a) A financial statement of the organization, including its balance sheet and income statement for the preceding year;

(b) The number of persons enrolled during the year, the number of enrollees as of the end of the year and the number of enrollments terminated during the year; and

(c) Any other information relating to the operations of the pharmacy benefit manager required by the commissioner under this act.

(3) If the pharmacy benefit manager is audited annually by an independent certified public accountant, a copy of the certified audit report shall be filed annually with the commissioner by June 30.

(4) The commissioner may extend the time prescribed for any pharmacy benefit manager for filing annual statements or other

reports or exhibits of any kind for good cause shown. However, the commissioner shall not extend the time for filing annual statements beyond sixty (60) days after the time prescribed by subsection (1) of this section. Any pharmacy benefit manager which fails to file its annual statement within the time prescribed by this section may have its license revoked by the commissioner or its certificate of authority revoked or suspended by the board until the annual statement is filed. The commissioner may waive the requirements for filing financial information for the PBM if an affiliate of the PMB is already required to file such information under current law.

SECTION 7. (1) In lieu of or in addition to making its own financial examination of a pharmacy benefit manager, the commissioner may accept the report of a financial examination of other persons responsible for the pharmacy benefit manager under the laws of another state certified by the insurance supervisory official, similar regulatory agency or the state health commissioner of another state.

(2) The commissioner shall coordinate financial examinations of a PBM that provides pharmacy management benefit plans in this state to ensure an appropriate level of regulatory oversight and to avoid any undue duplication of effort or regulation. The pharmacy benefit manager being examined shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund that shall provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this act.

SECTION 8. (1) The expense of administering this act, including the cost incurred by the commissioner and the board, shall be assessed annually by the commissioner against all pharmacy benefit managers operating in this state. Before determining the assessment the commissioner shall request from the board an estimate to all expenses for the regulation, supervision

and examination of all entities subject to regulation under this act. The assessment shall be in proportion to the business done in this state.

(2) All fees assessed under this act and paid to the commissioner shall be deposited in a special fund that shall provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this act.

The commissioner shall assess each PBM annually for its just share of expenses. The assessment shall be in proportion to the business done in this state. The commissioner shall provide the board an amount from the special fund to cover all expenses incurred by the board for the regulation under this act.

The commissioner shall give each PBM notice of the assessment, which shall be paid to the commissioner on or before March 1 of each year. Any PBM that fails to pay the assessment on or before the date herein prescribed shall be subject to a penalty imposed by the commission. The penalty shall be ten percent (10%) of the assessment and interest for the period between the due date and the date of full payment. If a payment is made in an amount later found to be in error, the commissioner shall, (a) if an additional amount is due, notify the company of the additional amount and the company shall pay the additional amount within fourteen (14) days of the date of the notice, or, (b) if an overpayment is made, order a refund.

If an assessment made under this act is not paid to the commissioner by the prescribed date, the amount of the assessment, penalty and interest may be recovered from the defaulting company on motion of the commissioner made in the name and for the use of the state in the appropriate circuit court after ten (10) days' notice to the company. The license of any defaulting company to transact business in this state may be revoked or suspended by the commissioner until it has paid such assessment.

SECTION 9. Any PBM that contracts with a pharmacy or pharmacist to provide pharmacist's services through a pharmacy management plan for enrollees in this state shall file such contract forms with the commissioner thirty (30) days before the execution of such contract. The contract forms shall be deemed approved unless the commissioner disapproves such contract forms within (30) days after filing with the commissioner. Disapproval shall be in writing, stating the reasons therefor and a copy thereof delivered to the PBM. The commissioner shall develop formal criteria for the approval and disapproval of PBM contract forms.

The PBM is required to provide a contract to the pharmacy that is written in plain English, using terms that will be generally understood by pharmacists.

Any PBM that contracts with a pharmacy or pharmacist to provide pharmacist's services through a pharmacy management plan for enrollees in this state on behalf of any health plan sponsors shall be identified as the agent of such health plan sponsors. The health plan fiduciary responsibilities shall transfer to the contracting PBM.

Each contract shall apply the same coinsurance, co-payment and deductible to covered drug prescriptions filled by a pharmacy provided who participates in the network.

Nothing in this section shall be construed to prohibit a contract from applying different coinsurance, co-payment and deductible factors between generic and brand name drugs that an enrollee may obtain with a prescription, unless such limit is applied uniformly to all pharmacy providers in the insurance policy's network.

No pharmacy benefit management plan shall mandate any pharmacist to change an enrollee's maintenance drug unless the prescribing physician and the enrollee agree to such plan.

A pharmacy's participation in any plan or network offered by a PBM is at the option and the discretion of the pharmacy. The pharmacy's participation or lack of participation in one (1) plan shall not effect their participation in any other plan or network offered by the PBM.

Any PBM that initiates an audit of a pharmacy under the provisions of the contract shall limit methods and procedures that are recognized as fair and equitable for both the PBM and the pharmacy. Extrapolation calculations in an audit are prohibited. PBMs shall not recoup any monies due from an audit by setoff from future remittances until the results of the audit are resolved and finalized by both the PBM and the pharmacy. In the event the findings of an audit cannot be finalized and agreed to by both parties, then the commissioner shall establish an independent review board to adjudicate unresolved grievances.

Prior to the terminating a pharmacy from the network the PBM must give the pharmacy a written explanation of the reason of termination thirty (30) days before the actual termination unless contract termination action is taken in reaction to (a) loss of the pharmacy's license to practice pharmacy or loss of professional liability insurance; or (b) conviction of fraud or misrepresentation in the contract. The pharmacy may request and receive within thirty (30) days a review of the proposed termination by the board before such termination.

The pharmacy shall not be held responsible for actions of the PBM or plan sponsors and the PBM or plan sponsors shall not be held responsible for the actions of the pharmacy.

SECTION 10. The board and the commissioner shall develop formal investigation and compliance procedures with respect to complaints by plan sponsors, pharmacists or enrollees concerning the failure of a pharmacy benefit manager to comply with the provisions of this act. The commissioner may refer complaints received under Section 13 of this act to the board. If the board

or the commissioner has reason to believe that there is a violation of this act, it shall issue and serve upon the pharmacy benefit manager concerned, a statement of the charges and a notice of a hearing to be held at a time and place fixed in the notice, which shall not be less than thirty (30) days after notice is served. The notice shall require the pharmacy benefit manager to show cause why an order should not be issued directing the alleged offender to cease and desist from the violation. At such hearing, the pharmacy benefit manager shall have an opportunity to be heard and to show cause why an order should not be issued requiring the pharmacy benefit manager to cease and desist form the violation.

The board may make an examination concerning the quality of services of any pharmacy benefit manager and pharmacists with whom the pharmacy benefit manager has contracts, agreements or other arrangements pursuant to its pharmacy benefit management plan as often as the board deems necessary for the protection of the interests of the people of this state. The pharmacy benefit manager being examined shall pay the cost of the examination.

SECTION 11. PBMs shall use a current and nationally recognized benchmark to base reimbursements for medications and products dispensed by provider pharmacies as follows:

(a) For brand (single source) products the average wholesale price (AWP) as listed in First Data Bank (Hearst publications) or Facts and 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 and 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. In the event a multi-source product has no BLP price, then it shall be

treated as a single source branded drug for the purpose of valuing reimbursement.

SECTION 12. (1) No PBM or its representative may cause or knowingly permit the use of (a) advertising that is untrue or misleading; (b) solicitation that is untrue or misleading; or (c) any form of evidence of coverage that is deceptive.

(2) No pharmacy benefit manager, unless licensed as an insurer, may use in its name, contracts or literature (a) any of the words "insurance," "casualty," "surety," "mutual"; or (b) any other words descriptive of the insurance, casualty or surety business or deceptively similar to the name or description of any insurance or fidelity and surety insurer doing business in this state.

(3) No PBM shall discriminate on the basis of race, creed, color, sex or religion in the selection of pharmacies for participation in the organization.

(4) No pharmacy benefit manager shall unreasonably discriminate against pharmacists when contracting for pharmacist services.

(5) The PBM shall be entitled to access to usual and customary pricing only for comparison to the reimbursement of a specific claims payment made by the PBM. Usual and customary pricing is confidential and any other use or disclosure by the PBM is prohibited.

(6) A PBM may not move a plan to another payment network unless it receives written consent from the plan sponsor.

(7) No PBM shall receive or accept any rebate, kickback or any special payment or favor or advantage of any valuable consideration or inducement for switching a patient's drug product unless it is specified in a written contract that has been filed with the commissioner thirty (30) days before the execution of such contract.

(8) Claims paid by the PBM shall not be retroactively denied or adjusted after seven (7) days from adjudication of such claims. In no case shall acknowledgement of eligibility be retroactively reversed. The PBM shall be allowed for retroactive denial or adjustment in the event (a) the original claim was submitted fraudulently; (b) the original claim payment was incorrect because the provider was already paid for services rendered; or (c) the services were not rendered by the pharmacists.

(9) No PBM shall terminate a pharmacy from a network because (a) they express disagreement with a PBM's decision to deny or limit benefits to an eligible person; (b) a pharmacist discusses with a current, former or prospective eligible person any aspect of such person's medical condition or treatment alternatives whether a covered service or not; (c) of the pharmacist's personal recommendations regarding selecting a PBM based on the pharmacist's personal knowledge of the health needs of such person; (d) of the pharmacy's protesting or expressing disagreement with a medical decision, medical policy or medical practice of a PBM; (e) the pharmacy has in good faith communicated with or advocated on behalf of one or more of the pharmacy's current, former or prospective person regarding the provisions, terms or requirements of the PBM's health benefit plans as they relate to the needs of such persons regarding the method by which the pharmacy is compensated for services provided under such agreement with the PBM.

(10) No PBM shall terminate a pharmacy from a network or otherwise penalize a pharmacy solely because of the pharmacy's invoking of the pharmacy's right under this agreement or applicable law or regulation.

(11) Termination from a network for reason of competence and professional behavior shall not release the PMB from the obligation to make any payment due to the pharmacy for services

provided in special circumstances post-termination to the eligible persons at less than agreed upon rates.

(12) Participation or lack of participation by a pharmacy in a plan or network cannot effect participation in any other plan or network offered by the PBM.

SECTION 13. Any disclosures from the PBM to the enrollees shall be written in plain English, using terms that will be generally understood by lay readers and a copy of the disclosure shall be provided to all pharmacies that are members of the network. The following shall be provided to the PBM's enrollees of a pharmacy benefit management plan at the time of enrollment or at the time the contract is issued and shall be made available upon request or at least annually:

(a) A list of the names and locations of all affiliated providers.

(b) A description of the service area or areas within which the PBM shall provide pharmacist's services.

(c) A description of the method of resolving complaints of covered persons, including a description of any arbitration procedure, if complaints may be resolved through a specified arbitration agreement.

(d) A notice that the pharmacy benefit manager is subject to regulation in this state by both the State Board of Pharmacy and the Commissioner of Insurance.

(e) A prominent notice included within the evidence of coverage, providing substantially the following: "If you have any questions regarding an appeal or grievance concerning the prescription coverage that you have been provided, which have not been satisfactorily addressed by your plan, you may contact the Insurance Commissioner." Such notice shall also provide the toll-free telephone number, mailing address and electronic mail address of the Insurance Commissioner.

SECTION 14. The enrollee in a pharmacy benefit management plan has the right to privacy and confidentiality in regard to pharmacist's services. This right may be expressly waived in writing by the enrollee or the enrollee's guardian.

SECTION 15. (1) If a PBM becomes insolvent or ceases to be a company in this state in any assessable or license year, the company shall remain liable for the payment of the assessment for the period in which it operated as a PBM in this state.

(2) In the event of an insolvency of a PBM, the commissioner may, after notice and hearing, levy an assessment on pharmacy benefit managers licensed to do business in this state. Such assessments shall be paid quarterly to the commissioner, and upon receipt by the commissioner shall be paid over into an escrow account in the special fund. This escrow account shall be solely for the benefit of enrollees of the insolvent PBM.

SECTION 16. This act shall take effect and be in force from and after July 1, 2004.