By: Representative Howell

To: Insurance

HOUSE BILL NO. 402

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

- BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:
- 12 **SECTION 1.** This act shall be known and cited as the
- 13 "Pharmacy Benefit Management Regulation Act."
- 14 SECTION 2. This act establishes standards and criteria for
- 15 the regulation and licensing of pharmacy benefit managers. The
- 16 purpose of this act is to promote, preserve and protect the public
- 17 health, safety and welfare by and through effective regulation and
- 18 licensing of pharmacy benefit managers.
- 19 **SECTION 3.** For purposes of this act:
- 20 (a) "Board of Pharmacy" or "board" means the State
- 21 Board of Pharmacy empowered to regulate pharmacy benefit managers
- 22 including granting a certificate of authority to a company.
- 23 (b) "Cease and desist" is an order of the board
- 24 prohibiting a pharmacy benefit manager or other person or entity
- 25 from continuing a particular course of conduct, which violates
- 26 this act or its rules and regulations.
- 27 (c) "Commissioner" means the State Insurance
- 28 Commissioner.
- 29 (d) "Enrollee" means an individual who has been
- 30 enrolled in a pharmacy benefit management plan.

- 31 (e) "Insolvent" or "insolvency" means a financial 32 situation in which, based upon the financial information required 33 by this act for the preparation of the pharmacy benefit manager's
- 34 annual statement, the assets of the pharmacy benefit manager are
- 35 less than the sum of all of its liabilities and required reserves.
- 36 (f) "Maintenance drug" means a drug prescribed by a
- 37 practitioner who is licensed to prescribe drugs and used to treat
- 38 a medical condition for a period greater than thirty (30) days.
- 39 (g) "Multi-source drug" means a drug that is stocked
- 40 and is available from the three (3) or more suppliers.
- 41 (h) "Pharmacist's services" includes drug therapy and
- 42 other patient care services provided by a licensed pharmacist
- 43 intended to achieve outcomes related to the cure or prevention of
- 44 a disease, elimination or reduction of a patient's symptoms or
- 45 arresting or slowing of a disease process as defined in the rules
- 46 of the board.
- 47 (i) "Pharmacist" means any individual properly licensed
- 48 as a pharmacist by the State Pharmacy Board.
- 49 (j) "Pharmacy" means any appropriately licensed place
- 50 within this state where drugs are dispensed and pharmacist
- 51 services are provided.
- 52 (k) "Pharmacy benefits manager" or "PBM" means a
- 53 business that administers the prescription drug/device portion of
- 54 health insurance plans on behalf of plan sponsors, insurance
- 55 companies, unions and health maintenance organizations.
- (1) "Pharmacy benefit management plan" means an
- 57 arrangement for the delivery of pharmacist services in which a
- 58 pharmacy benefit manager undertakes to pay for, or reimburse, any
- 59 of the costs of pharmacist services for an enrollee on a prepaid
- or insured basis which (i) contains one or more incentive
- 61 arrangements intended to influence the cost or level or pharmacist
- 62 services between the plan sponsor and one or more pharmacies with
- 63 respect to the delivery of pharmacists services; and (ii) requires

or creates benefit payment differential incentives for enrollees

65 to use under contract with the pharmacy benefit manager. A

66 pharmacy benefit plan does not mean any employee welfare benefit

67 plan (as defined in Section 3(1) of the Employee Retirement Income

68 Security Act of 1974, 29 USCS Section 1002(1), which is

69 self-insured or self-funded.

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70 (m) "Plan sponsors" means the employers, insurance 71 companies, unions and health maintenance organizations that 72 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:

94 (a) That the pharmacy benefit manager is operating 95 significantly in contravention of its basic organizational

97	(b)	The	pharmacy	benefit	manager	does	not	arrange	for
98	pharmacist's	servi	ces.						

- 99 (c) That the pharmacy benefit manager has failed to
 100 meet the requirements for issuance of a certificate of authority
 101 as set forth in this act and all applicable federal and state
 102 laws.
- 103 (d) That the pharmacy benefit manager is unable to
 104 fulfill its obligation to furnish pharmacist's services as
 105 required under its pharmacy benefit management plan.
- 106 (e) The pharmacy benefit manager is no longer
 107 financially responsible and may reasonably be expected to be
 108 unable to meet its obligations to enrollees or prospective
 109 enrollees.
- 110 (f) The pharmacy benefit manager, or any person on its 111 behalf, has advertised or merchandised its services in an untrue, 112 misrepresentative, misleading, deceptive or unfair manner.
- 113 (g) The continued operation of the pharmacy benefit
 114 manager would be hazardous to its enrollees.
- 115 (h) The pharmacy benefit manager has failed to file an 116 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 120 121 manager is revoked, such organization shall proceed, immediately following the effective date of the order of revocation, to wind 122 up its affairs and shall conduct no further business except as may 123 be essential to the orderly conclusion of the affairs of such 124 organization. The board may permit such further operation of the 125 organization as the board may find to be in the best interest of 126 enrollees to the end that the enrollees will be afforded the 127 128 greatest practical opportunity to obtain pharmacist's services.

129 SECTION 5.	The	commissioner	shall	not	issue	an	annual	PBM
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- 130 license to do business in this state to any PBM providing pharmacy
- 131 benefit management plans until he is satisfied that the pharmacy
- 132 benefit manager:
- 133 (a) Has paid all fees, taxes and charges required by
- 134 law;
- 135 (b) Has made any deposit required by this act;
- 136 (c) Has the minimum capital and surplus requirements
- 137 specified by the commissioner;
- 138 (d) Has filed a financial statement or statements and
- 139 any reports, certificates or other documents the commissioner
- 140 considers necessary to secure a full and accurate knowledge of its
- 141 affairs and financial condition;
- 142 (e) Is solvent and its financial condition, method of
- 143 operation and manner of doing business are such as to satisfy the
- 144 commissioner that it can meet its obligations to all enrollees;
- 145 and
- (f) Has otherwise complied with all the requirements of
- 147 law.
- 148 This PBM license shall be in addition to the certificate of
- 149 authority required by the board. A nonrefundable license
- 150 application fee of Five Hundred Dollars (\$500.00) shall accompany
- 151 each application for a license to transact the business in this
- 152 state. The fee shall be collected by the commissioner and paid
- 153 directly into a special fund that shall provide expenses for the
- 154 regulation, supervision and examination of all entities subject to
- 155 regulation under this act.
- The PBM license shall be signed by the commissioner or a duly
- 157 authorized agent of the commissioner and shall expire on the next
- 158 June 30 after the date on which it becomes effective.
- 159 All PBMs providing pharmacy benefit management plans shall
- 160 obtain an annual renewal of its PBM license from the commissioner.
- 161 The commissioner may refuse to renew the PBM license of any

- 162 pharmacy benefit manager or may renew the license, subject to any
- 163 restrictions considered appropriate by the commissioner, if it
- 164 finds an impairment of required capital and surplus or if it finds
- 165 that the pharmacy benefit manager has not satisfied all the
- 166 conditions set forth in this act. The commissioner shall not fail
- 167 to renew the license of any pharmacy benefit manager transacting
- 168 business in this state without giving the pharmacy benefit manager
- 169 ten (10) days' notice and giving it an opportunity to be heard.
- 170 The hearing may be informal, and the commissioner and the pharmacy
- 171 benefit manager may waive the required notice.
- 172 **SECTION 6.** (1) Each PBM providing pharmacy management
- 173 benefit plans in this state shall file a statement with the
- 174 commissioner annually by March 1. The statement shall be verified
- 175 by at least two (2) principal officers and shall cover the
- 176 preceding calendar year. Each pharmacy benefit manager shall also
- 177 send a copy of the statement to the board.
- 178 (2) The statement shall be on forms prescribed by the
- 179 commissioner and shall include:
- 180 (a) A financial statement of the organization,
- 181 including its balance sheet and income statement for the preceding
- 182 year;
- 183 (b) The number of persons enrolled during the year, the
- 184 number of enrollees as of the end of the year and the number of
- 185 enrollments terminated during the year; and
- 186 (c) Any other information relating to the operations of
- 187 the pharmacy benefit manager required by the commissioner under
- 188 this act.
- 189 (3) If the pharmacy benefit manager is audited annually by
- 190 an independent certified public accountant, a copy of the
- 191 certified audit report shall be filed annually with the
- 192 commissioner by June 30.
- 193 (4) The commissioner may extend the time prescribed for any
- 194 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. 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.

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(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.

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

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

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.

All fees assessed under this act and paid to the

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.

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260	SECTION 9. Any PBM that contracts with a pharmacy or
261	pharmacist to provide pharmacist's services through a pharmacy
262	management plan for enrollees in this state shall file such
263	contract forms with the commissioner thirty (30) days before the
264	execution of such contract. The contract forms shall be deemed
265	approved unless the commissioner disapproves such contract forms
266	within (30) days after filing with the commissioner. Disapproval
267	shall be in writing, stating the reasons therefor and a copy
268	thereof delivered to the PBM. The commissioner shall develop
269	formal criteria for the approval and disapproval of PBM contract
270	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.
- 351 (b) For generic drug (multi-source) products, maximum
 352 allowable cost (MAC) shall be established by referencing First
 353 Data Bank/Facts and Comparisons Baseline Price (BLP). Only
 354 products that are compliant with pharmacy laws as equivalent and
 355 generically interchangeable with a federal FDA Orange Book rating
 356 of "A-B" will be reimbursed from a MAC price methodology. In the
 357 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.
- 364 (2) No pharmacy benefit manager, unless licensed as an
 365 insurer, may use in its name, contracts or literature (a) any of
 366 the words "insurance," "casualty," "surety," "mutual"; or (b) any
 367 other words descriptive of the insurance, casualty or surety
 368 business or deceptively similar to the name or description of any
 369 insurance or fidelity and surety insurer doing business in this
 370 state.
- 371 (3) No PBM shall discriminate on the basis of race, creed, 372 color, sex or religion in the selection of pharmacies for 373 participation in the organization.
- 374 (4) No pharmacy benefit manager shall unreasonably
 375 discriminate against pharmacists when contracting for pharmacist
 376 services.
- 377 (5) The PBM shall be entitled to access to usual and
 378 customary pricing only for comparison to the reimbursement of a
 379 specific claims payment made by the PBM. Usual and customary
 380 pricing is confidential and any other use or disclosure by the PBM
 381 is prohibited.
- 382 (6) A PBM may not move a plan to another payment network 383 unless it receives written consent from the plan sponsor.
- 384 (7) No PBM shall receive or accept any rebate, kickback or
 385 any special payment or favor or advantage of any valuable
 386 consideration or inducement for switching a patient's drug product
 387 unless it is specified in a written contract that has been filed
 388 with the commissioner thirty (30) days before the execution of
 389 such contract.

- Claims paid by the PBM shall not be retroactively denied 390 391 or adjusted after seven (7) days from adjudication of such In no case shall acknowledgement of eligibility be 392 393 retroactively reversed. The PBM shall be allowed for retroactive 394 denial or adjustment in the event (a) the original claim was 395 submitted fraudulently; (b) the original claim payment was incorrect because the provider was already paid for services 396 rendered; or (c) the services were not rendered by the 397 398 pharmacists. No PBM shall terminate a pharmacy from a network because 399
- 400 (a) they express disagreement with a PBM's decision to deny or limit benefits to an eligible person; (b) a pharmacist discusses 401 402 with a current, former or prospective eligible person any aspect 403 of such person's medical condition or treatment alternatives 404 whether a covered service or not; (c) of the pharmacist's personal 405 recommendations regarding selecting a PBM based on the pharmacist's personal knowledge of the health needs of such 406 407 person; (d) of the pharmacy's protesting or expressing disagreement with a medical decision, medical policy or medical 408 409 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 410 411 current, former or prospective person regarding the provisions, 412 terms or requirements of the PBM's health benefit plans as they relate to the needs of such persons regarding the method by which 413 414 the pharmacy is compensated for services provided under such agreement with the PBM. 415
- (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.
- 420 (11) Termination from a network for reason of competence and 421 professional behavior shall not release the PMB from the 422 obligation to make any payment due to the pharmacy for services H. B. No. 402

- 423 provided in special circumstances post-termination to the eligible
- 424 persons at less than agreed upon rates.
- 425 (12) Participation or lack of participation by a pharmacy in
- 426 a plan or network cannot effect participation in any other plan or
- 427 network offered by the PBM.
- 428 **SECTION 13.** Any disclosures from the PBM to the enrollees
- 429 shall be written in plain English, using terms that will be
- 430 generally understood by lay readers and a copy of the disclosure
- 431 shall be provided to all pharmacies that are members of the
- 432 network. The following shall be provided to the PBM's enrollees
- 433 of a pharmacy benefit management plan at the time of enrollment or
- 434 at the time the contract is issued and shall be made available
- 435 upon request or at least annually:
- 436 (a) A list of the names and locations of all affiliated
- 437 providers.
- 438 (b) A description of the service area or areas within
- 439 which the PBM shall provide pharmacist's services.
- 440 (c) A description of the method of resolving complaints
- 441 of covered persons, including a description of any arbitration
- 442 procedure, if complaints may be resolved through a specified
- 443 arbitration agreement.
- (d) A notice that the pharmacy benefit manager is
- 445 subject to regulation in this state by both the State Board of
- 446 Pharmacy and the Commissioner of Insurance.
- 447 (e) A prominent notice included within the evidence of
- 448 coverage, providing substantially the following: "If you have any
- 449 questions regarding an appeal or grievance concerning the
- 450 prescription coverage that you have been provided, which have not
- 451 been satisfactorily addressed by your plan, you may contact the
- 452 Insurance Commissioner." Such notice shall also provide the
- 453 toll-free telephone number, mailing address and electronic mail
- 454 address of the Insurance Commissioner.



456	plan has the right to privacy and confidentiality in regard to
457	pharmacist's services. This right may be expressly waived in
458	writing by the enrollee or the enrollee's guardian.
459	SECTION 15. (1) If a PBM becomes insolvent or ceases to be
460	a company in this state in any assessable or license year, the
461	company shall remain liable for the payment of the assessment for
462	the period in which it operated as a PBM in this state.
463	(2) In the event of an insolvency of a PBM, the commissioner
464	may, after notice and hearing, levy an assessment on pharmacy
465	benefit managers licensed to do business in this state. Such
466	assessments shall be paid quarterly to the commissioner, and upon

SECTION 14. The enrollee in a pharmacy benefit management

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, 2003.

receipt by the commissioner shall be paid over into an escrow

account in the special fund. This escrow account shall be solely

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