| 1  | HOUSE BILL 126  |
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| 2  | 51st legislature - STATE OF NEW MEXICO - second session, 2014   |
| 3  | INTRODUCED BY   |
| 4  | Nora Espinoza   |
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| 8  | FOR THE LEGISLATIVE HEALTH AND HUMAN SERVICES COMMITTEE         |
| 9  |   |
| 10 | AN ACT  |
| 11 | RELATING TO HEALTH CARE; ENACTING THE PHARMACY BENEFIT MANAGER  |
| 12 | ACT; PROVIDING FOR LICENSURE OF PHARMACY BENEFIT MANAGERS;      |
| 13 | ESTABLISHING GUIDELINES AND NOTICE PROVISIONS FOR MAXIMUM       |
| 14 | ALLOWABLE COST FOR DRUGS AND FOR CHALLENGING MAXIMUM ALLOWABLE  |
| 15 | COST PRICING; PROVIDING FOR RULEMAKING BY THE SUPERINTENDENT OF |
| 16 | INSURANCE.  |
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| 18 | BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:    |
| 19 | SECTION 1. [ <u>NEW MATERIAL</u> ] SHORT TITLEThis act may be   |
| 20 | cited as the "Pharmacy Benefit Manager Act".                    |
| 21 | SECTION 2. [ <u>NEW MATERIAL</u> ] DEFINITIONSAs used in the    |
| 22 | Pharmacy Benefit Manager Act:                                   |
| 23 | A. "covered entity" means a person authorized                   |
| 24 | pursuant to the New Mexico Insurance Code to issue or provide   |
| 25 | coverage that includes prescription drug coverage;              |
|    | .194751.2   |
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1 Β. "covered individual" means a member, 2 participant, enrollee, subscriber, contract holder, dependent, policyholder or beneficiary of a plan, policy or contract 3 issued or provided pursuant to the New Mexico Insurance Code; 4 "drug" means an article: 5 C. recognized in an official compendium; 6 (1)7 (2) intended for use in the diagnosis, cure, 8 mitigation, treatment or prevention of disease in humans or 9 other animals and includes the domestic animal biological products regulated under the federal Virus-Serum-Toxin Act, 37 10 Stat 832-833, 21 U.S.C. 151-158, and the biological products 11 12 applicable to humans regulated under Federal 58 Stat 690, as amended, 42 U.S.C. 216, Section 351, 58 Stat 702, as amended, 13 and 42 U.S.C. 262; 14 other than food, that affects the (3) 15 structure or any function of the human body or the bodies of 16 other animals; and 17 intended for use as a component of (4) 18 19 Paragraph (1), (2) or (3) of this subsection; but "drug" does 20 not include a device or a device's component parts or accessories; 21 D. "formulary" means the list of prescription drugs 22 for which a covered entity will make reimbursement; 23 "maximum allowable cost price" means the maximum Ε. 24 reimbursement amount for a group of therapeutically and 25 .194751.2 - 2 -

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1 pharmaceutically equivalent multiple-source drugs that are 2 listed in the most recent edition or supplement of the United States food and drug administration's Approved Drug Products 3 with Therapeutic Equivalence Evaluations publication and for 4 which not fewer than three equivalent drugs are nationally 5 available: 6 "office of the superintendent" means the office 7 F. of superintendent of insurance; 8 "pharmaceutically equivalent drug" means a drug, 9 G. when compared to another drug, that: 10 contains the same active ingredients; (1)11 12 (2) is of the same dosage form and route of administration; and 13 is identical in strength or concentration; 14 (3) н. "pharmacy benefit management services" means 15 services related to the administration or management of a 16 prescription drug benefit provided by a covered entity, 17 18 including: 19 (1)retail pharmacy network management; 20 (2) pharmacy discount card management; claims payment to a retail pharmacy for (3) 21 prescription medications dispensed to covered individuals; 22 (4) formulary development and management, 23 including utilization management and quality assurance 24 25 programs; .194751.2 - 3 -

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1 rebate contracting and administration; (5) 2 (6) audit of contracted pharmacies; establishment of pharmacy reimbursement 3 (7) pricing and methodology; and 4 determination of single- and multiple-5 (8) source drugs; 6 7 I. "pharmacy benefit manager" means a person that: contracts with a retail pharmacy on behalf (1) 8 9 of a covered entity to provide for the provision of pharmacy services to the covered entity by the retail pharmacy; and 10 provides pharmacy benefit management (2) 11 12 services; "pharmacy discount card" means any form of proof J. 13 that allows the holder to obtain a discount on a prescription 14 drug when paying for the prescription at the prescription's 15 point of sale; 16 "retail pharmacy" means a place of business 17 Κ. licensed pursuant to the Pharmacy Act where drugs are 18 compounded or dispensed and pharmaceutical care is provided; 19 "superintendent" means the superintendent of 20 L. insurance of the office of superintendent of insurance; and 21 М. "therapeutically equivalent drug" means a drug 22 that has the same amount of active ingredients in the same 23 dosage form as another drug and that, when administered, can be 24 expected to provide the same therapeutic effect as the other 25 .194751.2 - 4 -

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SECTION 3. [NEW MATERIAL] PHARMACY BENEFIT MANAGERS--LICENSURE--APPLICATION--FEES--DURATION.--

Α. A person shall not act as or hold oneself out as a pharmacy benefit manager unless the person holds a current license issued by the office of the superintendent.

A person seeking licensure by the office of the B. superintendent shall submit an application to the office of the superintendent in a form and in accordance with procedures that conform to rules that the superintendent has promulgated. At a minimum, the application shall include the following information:

13 a copy of the applicant's organizational (1)14 documents, including the applicant's articles of incorporation, articles of association, partnership agreement, trust 15 agreement, bylaws or other documents applicable to the 16 17 applicant's organization;

(2) any amendment to the applicant's organizational documents;

(3)a financial statement for each of the two years preceding the date of application, including: (a) projected financial statements

relating to the person's initial period of licensure as a pharmacy benefit manager;

a balance sheet that reflects the (b) .194751.2

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1 condition of the applicant on the date that operations as a 2 pharmacy benefit manager are projected to start; (c) a statement of revenue and expenses 3 indicating expected member months; and 4 (d) a cash flow statement that lists any 5 capital expenditures, purchase and sale of investments and 6 7 deposits with the state; and the names, addresses and official 8 (4) 9 positions of the individuals responsible for the conduct of the applicant's affairs, including: 10 (a) each member of the board of 11 12 directors, board of trustees, executive committee or other governing body or committee; 13 14 (b) the principal officer, if the applicant is a corporation; 15 (c) each partner or member, if the 16 applicant is a partnership or association; and 17 any other information that the 18 (d) superintendent requires. 19 20 C. An applicant for the issuance or renewal of a license pursuant to this section shall pay a fee in an amount 21 set by the superintendent. 22 D. The superintendent may assess a fee against 23 pharmacy benefit managers to cover the costs of administering 24 the regulation of pharmacy benefit managers in the state. 25 .194751.2 - 6 -

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1 Ε. The superintendent may suspend, cancel or revoke 2 a pharmacy benefit manager's license if the pharmacy benefit manager has failed to comply with the provisions of the 3 Pharmacy Benefit Manager Act or with rules the superintendent 4 has adopted and promulgated pursuant to that act. 5 F. A pharmacy benefit manager license shall be 6 7 effective until the earlier of: one year from the date that application 8 (1)for the licensure is approved or renewed, as applicable; or 9 the date the license is suspended, 10 (2) canceled or revoked. 11 12 SECTION 4. [NEW MATERIAL] MAXIMUM ALLOWABLE COST PRICE--13 ESTABLISHMENT.--A pharmacy benefit manager shall: 14 Α. establish a maximum allowable cost price for a drug only if the drug is: 15 (1) a multiple-source generic drug prescribed 16 after expiration of its generic exclusivity period as provided 17 18 in federal law; 19 (2)a drug with not fewer than three "A-rated" 20 therapeutically equivalent drugs, as listed in the most recent edition or supplement of the United States food and drug 21 administration's Approved Drug Products with Therapeutic 22 Equivalence Evaluations, with a significant cost difference 23 between the generic drug being considered and its originator 24 brand drug; and 25 .194751.2 - 7 -

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(3) not obsolete or temporarily unavailable;

B. base a maximum allowable cost price pursuant to Subsection A of this section on comparable drug prices obtained from multiple nationally recognized comprehensive data sources, including wholesalers, drug file vendors and pharmaceutical manufacturers of drugs that are nationally available and available for purchase locally by pharmacies in the state; and

C. modify a maximum allowable cost price established pursuant to Subsection A of this section not less than every seven days to reflect updated information from data sources described in Subsection B of this section.

SECTION 5. [NEW MATERIAL] PRICING CHALLENGE PROCESS .--

A. A contract between a pharmacy benefit manager and a retail pharmacy shall establish a process by which a retail pharmacy or its representative may challenge a maximum allowable cost price established pursuant to Section 4 of the Pharmacy Benefit Manager Act. The contract shall provide that the pharmacy benefit manager will respond to a challenge no later than the seventh business day after the date on which the retail pharmacy makes the challenge.

B. If a retail pharmacy successfully challenges a maximum allowable cost price pursuant to procedures established under Subsection A of this section, the pharmacy benefit manager shall make an adjustment in the drug price retroactive to the date the challenge was made and make the adjustment

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1 applicable to all network pharmacy providers.

2 C. If a challenge made pursuant to Subsection A of this section is not successful, the pharmacy benefit manager 3 shall: 4

(1) provide the reason that the challenge was unsuccessful and notify the retail pharmacy that it may appeal 7 the challenge decision; and

allow a retail pharmacy to appeal the 8 (2) challenge to the office of the superintendent according to 9 rules adopted and promulgated by the superintendent. 10

SECTION 6. [NEW MATERIAL] REQUIRED DISCLOSURE AND NOTICE PROVISIONS .--

A pharmacy benefit manager shall disclose in a Α. contract with a retail pharmacy the data sources from which, and the methodologies pursuant to which, the pharmacy benefit manager obtains pricing data used when it established a maximum allowable cost price pursuant to Section 4 of the Pharmacy Benefit Manager Act.

B. A contract between a pharmacy benefit manager and a retail pharmacy shall include a provision that the pharmacy benefit manager will notify the retail pharmacy or its representative within seven business days of a substitution, addition or deletion of a data source from which the pharmacy benefit manager obtains pricing data it uses in establishing a maximum allowable cost price pursuant to Section 4 of the

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1 Pharmacy Benefit Manager Act.

2 C. A pharmacy benefit manager shall notify a retail 3 pharmacy when it modifies a maximum allowable cost price on the date the pharmacy benefit manager modifies the maximum 4 5 allowable cost price. SECTION 7. [NEW MATERIAL] GENERIC REIMBURSEMENT RATE.--6 7 In establishing its average reimbursement rate Α. 8 for generic drugs, a pharmacy benefit manager shall: 9 (1) not base its calculation of the rate 10 solely on the amount allowed by the covered entity for generic 11 drugs; and 12 (2) base its calculation on an average of prices for all generic drugs dispensed, including drugs not 13 14 subject to a maximum allowable cost price pursuant to Section 4 of the Pharmacy Benefit Manager Act. 15 A pharmacy benefit manager shall pay to a retail 16 Β. pharmacy an average reimbursement rate for a generic drug based 17 18 on an average of the actual amount, excluding any dispensing 19 fee, that the retail pharmacy charges for the drug. 20 C. A pharmacy benefit manager shall disclose in its contract with a retail pharmacy the average reimbursement rate 21 for generic drugs established pursuant to Subsection A of this 22 section and the details of how the pharmacy benefit manager 23 calculates the average reimbursement rate for generic drugs. 24 [NEW MATERIAL] PROHIBITED ACTIONS--RETAIL 25 SECTION 8. .194751.2

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1 PHARMACIES--NETWORK ADEQUACY .-- A pharmacy benefit manager 2 shall: 3 not, without prior written agreement from the Α. 4 retail pharmacy: change a term of a contract with a retail 5 (1)pharmacy; or 6 7 (2) automatically enroll or disenroll a retail pharmacy from a pharmacy benefit network; 8 not charge a transaction fee for a claim that a 9 Β. retail pharmacy submits electronically to the pharmacy benefit 10 11 manager; 12 C. not require that a retail pharmacy be a member of a network managed by the pharmacy benefit manager as a 13 condition for the retail pharmacy to participate in another 14 pharmacy network managed by the pharmacy benefit manager; 15 not exclude a retail pharmacy from participation D. 16 bracketed material] = delete 17 in a pharmacy network if the retail pharmacy: (1) accepts the terms, conditions and 18 reimbursement rates of the pharmacy benefit manager; 19 20 (2)meets all applicable federal and state licensure and permit requirements; and 21 (3) has not been excluded from participation 22 as a provider in any federal or state program; and 23 establish a pharmacy network that includes Ε. 24 sufficient retail pharmacies to ensure network adequacy in 25 .194751.2 - 11 -

1 accordance with rules that the superintendent has adopted and 2 promulgated. [NEW MATERIAL] COVERED INDIVIDUALS--3 SECTION 9. RELATIONSHIPS.--A pharmacy benefit manager shall not: 4 require that a covered individual use a retail 5 Α. pharmacy, mail-order pharmacy, specialty pharmacy or other 6 7 entity providing pharmacy services: 8 in which the pharmacy benefit manager has (1)9 an ownership interest; or that has an ownership interest in the 10 (2) 11 pharmacy benefit manager; or 12 Β. provide an incentive to a covered individual to 13 encourage that covered individual to use a retail pharmacy, 14 mail-order pharmacy, specialty pharmacy or other entity providing pharmacy services: 15 in which the pharmacy benefit manager has 16 (1)an ownership interest; or 17 that has an ownership interest in the 18 (2) 19 pharmacy benefit manager. SECTION 10. 20 [NEW MATERIAL] RULEMAKING.--The superintendent shall adopt and promulgate rules to carry out 21 the provisions of the Pharmacy Benefit Manager Act. 22 - 12 -23 24 25 .194751.2

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