

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2005

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HOUSE DRH50323-LUfqq-110 (4/12)

Short Title: Pharmacy Benefits Manager Regulation Act/Fees. (Public)

Sponsors: Representative Culpepper.

Referred to:

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH THE PHARMACY BENEFITS MANAGER  
REGULATION TRANSPARENCY ACT OF 2005 TO ENSURE PROPER  
REGULATION OF THOSE INDIVIDUALS OR ENTITIES WHOSE ACTIONS  
AFFECT NORTH CAROLINA CITIZENS' ACCESS TO PRESCRIPTION  
DRUGS.

The General Assembly of North Carolina enacts:

**SECTION 1.** Article 50 of Chapter 58 is amended by adding the following  
new Part to read:

"Part 6. Pharmacy Benefits Manager Regulation Transparency Act of 2005.

**"§ 58-50-157. Title; intent.**

This Part shall be known as the 'Pharmacy Benefits Manager Regulation  
Transparency Act of 2005', and is intended to protect the public, safety, and welfare by  
ensuring that individuals and entities whose actions affect North Carolina citizens'  
access to prescription drugs are properly regulated.

**"§ 58-50-158. Definitions.**

The following definitions shall apply in this Part:

- (1) Board. – The North Carolina Board of Pharmacy as created in  
G.S. 90-85.6.
- (2) Commissioner. – The Commissioner of the North Carolina Department  
of Insurance.
- (3) Claims processing services. – Administrative services performed in  
connection with the processing and adjudication of a claim for  
prescription drug or device benefits provided by or on behalf of a  
health benefit plan.

- 1           (4) Covered person. – A member, policyholder, subscriber, enrollee,  
2 beneficiary, dependent, or other individual participating in a health  
3 benefit plan.
- 4           (5) Department. – The North Carolina Department of Insurance.
- 5           (6) Health benefit plan. – An accident and health insurance policy or  
6 certificate; a nonprofit hospital or medical service corporation  
7 contract; a health maintenance organization subscriber contract; a  
8 health program administered by a department or the State in the  
9 capacity of provider of health coverage; a plan provided by a multiple  
10 employer welfare arrangement; or a plan provided by another benefit  
11 arrangement, to the extent permitted by the Employee Retirement  
12 Income Security Act of 1974, as amended, or by any waiver of or other  
13 exception to the Act provided under federal law, federal common law  
14 or regulation. However, 'health benefit plan' does not mean any of the  
15 following kinds of insurance:
- 16           a. Accident.
- 17           b. Credit.
- 18           c. Disability income.
- 19           d. Long-term or nursing home care.
- 20           e. Medicare supplement.
- 21           f. Specified disease.
- 22           g. Dental or vision.
- 23           h. Coverage issued as a supplement to liability insurance.
- 24           i. Workers' compensation.
- 25           j. Medical payments under automobile or homeowners insurance.
- 26           k. Insurance under which benefits are payable with or without  
27 regard to fault and that is statutorily required to be contained in  
28 any liability policy or equivalent self-insurance.
- 29           l. Hospital income or indemnity.
- 30           (7) Pharmaceutical manufacturer. – An entity registered with the United  
31 States Food and Drug Administration as an entity to manufacturer  
32 prescription drugs.
- 33           (8) Pharmacy. – Any place where prescription drugs are dispensed or  
34 compounded under G.S. 90-85.3(q) or G.S. 90-85.21A.
- 35           (9) Pharmacy benefit management. – The procurement of prescription  
36 drugs at a negotiated rate for dispensing within this State to a covered  
37 person, the administration or management of prescription drug benefits  
38 provided by a health benefit plan for the benefit of a covered person,  
39 or any of the following services provided with regard to the  
40 administration of those services:
- 41           a. Claims processing, retail network management and payment of  
42 claims to pharmacies for prescription drugs dispensed to  
43 covered individuals.

- 1           b. The development of a clinical formulary of prescription drugs  
2           to be covered by a health benefit plan, including the  
3           determination of the applicability of co-payments to specific  
4           prescription drugs.  
5           c. The dispensing of prescription drugs through the United States  
6           Postal Service or similar service.  
7           d. Prescription drug rebate contracting and administration.  
8           e. Patient compliance, therapeutic intervention, and generic  
9           substitution programs.  
10          f. Disease management programs involving prescription drug  
11          utilization.

12          (10) Pharmacy benefits manager. – A person who, or business or other  
13          entity that, performs pharmacy benefit management. The term includes  
14          a person or entity acting for a pharmacy benefits manager in a  
15          contractual or employment relationship in the performance of  
16          pharmacy benefit management for a health benefit plan and includes  
17          the dispensing of a prescription drug by an out-of-state pharmacy as  
18          permitted under G.S. 90-85.21A.

19          (11) Pharmacy provider services. – A pharmacy or pharmacist providing  
20          services regulated by the Board as the practice of pharmacy.

21          (12) Practice of pharmacy. – The term as defined in G.S. 90-85.3(r).

22          (13) Prescription drug. – The term as defined in G.S. 90-85.3(s).

23        **"§ 58-50-159. Certificate of authority.**

24          (a) No person shall act, offer to act, or hold himself or herself out as providing  
25          pharmacy benefit management in this State without a valid pharmacy benefits manager  
26          license issued by the Commissioner. Licenses shall be renewed annually.

27          (b) Each application for the issuance or renewal of a license shall be made upon a  
28          form prescribed by the Commissioner and shall be accompanied by a nonrefundable  
29          filing fee of five hundred dollars (\$500.00) along with evidence of maintenance of a  
30          fidelity bond, errors and omissions liability insurance, or other security, of a type and in  
31          an amount to be determined by rules adopted by the Commissioner. Applications for  
32          licensure shall include or be accompanied by the following information and documents:

33               (1) All organizational documents of the pharmacy benefits manager,  
34               including any articles of incorporation, articles of association,  
35               partnership agreement, trade name certificate, or trust agreement, any  
36               other applicable documents, and all amendments to these documents.

37               (2) The bylaws, rules, regulations, or similar documents regulating the  
38               internal affairs of the pharmacy benefits manager.

39               (3) The names, addresses, official positions, and professional  
40               qualifications of the individuals who are responsible for the conduct of  
41               affairs of the pharmacy benefits manager, including all: (i) members  
42               of the board of directors, board of trustees, executive committee, or  
43               other governing board or committee; (ii) the principal officers in the  
44               case of a corporation or the partners or members in the case of a

- 1                    partnership or association; (iii) all shareholders holding directly or  
2                    indirectly ten percent (10%) or more of the voting securities of the  
3                    pharmacy benefits manager; and (iv) any other person who exercises  
4                    control or influence over the affairs of the pharmacy benefits manager.  
5                    (4)                Annual financial statements or reports for the two most recent years  
6                    that prove that the applicant is solvent and any other information the  
7                    Commissioner may require to review the current financial condition of  
8                    the applicant.  
9                    (5)                A general description of the business operations, including information  
10                   on staffing levels and activities proposed in this State and nationwide.  
11                   The description shall provide details setting forth the pharmacy  
12                   benefits manager's capability for providing a sufficient number of  
13                   experienced and qualified personnel in the areas of pharmacy benefits  
14                   manager services.  
15                   (6)                A Certificate of Compliance issued by the Board indicating that the  
16                   pharmacy benefits manager's plan of operation is consistent with the  
17                   Pharmacy Practice Act under Article 4A of Chapter 90 of the General  
18                   Statutes, including G.S. 90-85.21 and G.S. 90-85.21A and any rules  
19                   adopted under that Act.  
20                   (7)                The name and address of the registered agent for service of process in  
21                   this State.  
22                   (8)                A detailed description of the claims processing services, pharmacy  
23                   services, insurance services, other prescription drug or device services,  
24                   audit procedures for network pharmacies, or other administrative  
25                   services to be provided.  
26                   (9)                All incentive arrangements or programs, such as prescription drug  
27                   rebates, discounts, disbursements, or any other similar financial  
28                   program or arrangement relating to income or consideration received  
29                   or negotiated, directly or indirectly, with any pharmaceutical company,  
30                   that relates to prescription drugs, including, at a minimum, information  
31                   on the formula or other method for calculation and amount of the  
32                   incentive arrangements, rebates, or other disbursements, the identity of  
33                   the associated prescription drug, and dates and amounts of those  
34                   disbursements.  
35                   (10)              Any ownership interest or affiliation of any kind with any health  
36                   benefit plan responsible for providing benefits directly or through  
37                   reinsurance to any plan for which the pharmacy benefits manager  
38                   provides services or any parent companies, subsidiaries and other  
39                   entities or businesses relative to the provision of pharmacy service,  
40                   other prescription drug or device services, or a pharmaceutical  
41                   manufacturer or its assignee.  
42                   (11)              Any agreement or practice to bill a health benefit plan for prescription  
43                   drugs at a cost higher than the pharmacy benefits manager pays a  
44                   pharmacy provider for providing pharmacy services.

1           (12) Any agreement to sell prescription drug data, including data  
2           concerning the prescribing practices of the health care providers in this  
3           State.

4           (13) A signed statement that the pharmacy benefits manager shall comply  
5           with the provisions of Chapter 58 of the General Statutes in providing  
6           pharmacy benefits management in this State to the same extent as that  
7           of any health benefit plan.

8           (c) The Commissioner shall have the authority to adopt rules to ensure the  
9           performance of duties under this section.

10 **"§ 58-50-160. Maintenance records; access; confidentiality; financial examination.**

11           (a) Every pharmacy benefits manager shall maintain for the duration of the  
12           written agreement and for two years thereafter books and records of all transactions  
13           between pharmacy benefits managers, health benefit plans, covered persons, and  
14           pharmacies.

15           (b) The Department shall have access to books and records maintained by a  
16           pharmacy benefits manager for the purposes of examination, audit, and inspection. The  
17           information contained in those books and records is not a public record under Chapter  
18           132 of the General Statutes. However, the Department may use this information in any  
19           proceeding instituted against a pharmacy benefits manager or health benefit plan for  
20           violations of this section.

21           (c) The Commissioner shall conduct periodic financial examinations of every  
22           pharmacy benefits manager in this State to ensure an appropriate level of regulatory  
23           oversight necessary to protect the public health, safety, and welfare of consumers of  
24           prescription drugs. The pharmacy benefits manager shall pay a fee for the examination,  
25           which fee shall be deposited in escrow to provide all expenses for the regulation,  
26           supervision, and examination of all entities subject to regulation under this section.

27 **"§ 58-50-161. Disclosure.**

28           (a) A pharmacy benefits manager shall satisfy the following disclosure  
29           requirements to health benefit plans:

30           (1) A pharmacy benefits manager that derives any payment or benefit for  
31           providing pharmacy benefits management from a drug manufacturer,  
32           distributor, or assignee based on volume or any other measurement of  
33           sales, prescribing, or dispensing of certain prescription drugs or classes  
34           or brands of drugs within this State shall fully disclose to the health  
35           benefit plan the amount of those payments and benefits received and  
36           the amount of the payments and benefits retained by the pharmacy  
37           benefits manager.

38           (2) A pharmacy benefits manager shall provide to a health benefit plan all  
39           financial utilization information requested by a health benefit plan  
40           relating to the provision of benefits to participants on behalf of that  
41           health benefit plan relating to services provided to or on behalf of that  
42           health benefit plan.

43           (b) A violation of this section constitutes an unfair method of competition or  
44           unfair and deceptive trade practice under G.S. 58-63-10 and G.S. 75-1.1.

1 **"§ 58-50-162. Contracts; approval of agreements required; prohibited provisions.**

2 (a) A health benefit plan shall not enter into an agreement with a person or entity  
3 to provide pharmacy benefit management unless the person or entity has obtained a  
4 pharmacy benefits manager license pursuant to G.S. 58-50-159(a). No pharmacy  
5 benefits manager shall provide pharmacy benefit management for a health benefit plan  
6 without a written agreement between the pharmacy benefits manager and the health  
7 benefit plan. The written agreement shall be retained as part of the official records of  
8 both the health benefit plan and the pharmacy benefits manager for the duration of the  
9 agreement and for five years thereafter. The agreement shall contain a provision that the  
10 pharmacy benefits manager is subject to all provisions of Article 51 of Chapter 58 of the  
11 General Statutes to the extent those requirements apply to access to prescription drugs.

12 (b) A pharmacy benefits manager shall not require a pharmacy to serve a specific  
13 health benefit plan in order for a pharmacy to serve a separate health benefit plan. A  
14 pharmacy benefits manager shall not discriminate against a pharmacy from participating  
15 in a particular network to serve a specific health benefit plan or plans solely because the  
16 pharmacy declined to participate in another health benefit plan or network managed by  
17 the pharmacy benefits manager.

18 (c) Each pharmacy benefits manager shall file with the Commissioner a copy of  
19 the pharmacy benefits manager's standard contract with a pharmacy to provide  
20 pharmacy provider services in this State before providing pharmacy benefit  
21 management in this State. If the Commissioner notifies, in writing, the pharmacy  
22 benefits manager filing the standard contract that the contract does not comply with the  
23 requirements of law, specifying the reasons for his opinion, it shall be unlawful  
24 thereafter for that pharmacy benefits manager to provide pharmacy benefit management  
25 or contract with a pharmacy to provide pharmacy provider services in this State. The  
26 action of the Commissioner in this regard shall be subject to review by any court of  
27 competent jurisdiction. However, nothing in this Part shall be construed to give  
28 jurisdiction to any court not already having jurisdiction.

29 (d) Each pharmacy benefits manager shall annually, on or before the first day of  
30 March of each year, file in the office of the Commissioner the following information  
31 from the previous calendar year:

- 32 (1) The number of and reasons for grievances received from covered  
33 persons regarding pharmacy benefit management. The report shall  
34 include the number of covered lives, total number of grievances  
35 categorized by reason for the grievance, the number of grievances  
36 referred to the second-level grievance review, the number of  
37 grievances resolved at each level and their resolution, and a description  
38 of the actions that are being taken to correct the problems that have  
39 been identified through grievances received. Every pharmacy benefits  
40 manager shall file with the Commissioner, as part of the pharmacy  
41 benefits manager's annual grievance report, a certificate of compliance  
42 stating that the carrier has established and follows, for each of the lines  
43 of business, grievance procedures that comply with G.S. 58-50-62.

1           (2) For each health benefit plan for which the pharmacy benefits manager  
2 provides pharmacy benefit management, the health benefit plan's  
3 formularies, restricted access drugs, or devices as defined in  
4 G.S. 58-3-221, or prior approval requirements for obtaining  
5 prescription drugs, whether a particular drug or therapeutic class of  
6 drugs is excluded from its formulary, and the circumstances under  
7 which a nonformulary drug may be covered.

8           (e) The written agreement between a health benefit plan and the pharmacy  
9 benefits manager shall not provide that a pharmacy is responsible for the actions of the  
10 health benefit plan or the pharmacy benefits manager. A pharmacy permit holder shall  
11 have a lien against the health benefit plan or pharmacy benefits manager for services  
12 rendered under a contract with a pharmacy to provide pharmacy provider services for  
13 which the covered individuals of the health benefit plan received pharmacy provider  
14 services.

15           (f) In accordance with G.S. 58-51-37, each pharmacy benefits manager shall  
16 make available a valid and enforceable written contract to be signed by an authorized  
17 representative of the pharmacy stating that the pharmacy intends to participate in a  
18 network of pharmacy providers to serve a specific health benefit plan. A pharmacy shall  
19 not be deemed to be under contract with the pharmacy benefits manager to provide  
20 pharmacy provider services absent a contract. The act of a pharmacy submitting a  
21 prescription drug claim to a pharmacy benefits manager shall not be deemed to meet the  
22 requirements of this subsection.

23 **"§ 58-50-163. Prohibited practices of pharmacy benefits manager.**

24           (a) A pharmacy benefits manager shall not intervene in the delivery of  
25 transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the  
26 purpose of:

27               (1) Influencing the prescriber's choice of therapy.

28               (2) Influencing the patient's choice of pharmacist or pharmacy.

29               (3) Altering the prescription information, including switching the  
30 prescribed drug without the express authorization of the prescriber.

31           (b) No agreement shall mandate that a pharmacy permit holder change a covered  
32 person's prescription unless the prescribing physician and the covered person authorize  
33 the pharmacist to make the change.

34           (c) A health benefit plan or a pharmacy benefits manager shall not discriminate  
35 with respect to participation in the network or reimbursement as to any pharmacy that is  
36 acting within the scope of the pharmacy's license or certification.

37           (d) A pharmacy benefits manager shall not discriminate when contracting with a  
38 pharmacy on the basis of co-payments or days of supply. A contract shall apply the  
39 same coinsurance, co-payment, and deductible to covered drug prescriptions filled by  
40 any pharmacy, including a mail-order pharmacy or pharmacist who participates in the  
41 network.

42           (e) A pharmacy benefits manager shall not discriminate when advertising  
43 pharmacies participating in a pharmacy benefits manager's network of pharmacies under  
44 contract to provide pharmacy benefit management. Any list of participating pharmacies

1 shall be complete and all inclusive of all pharmacies under written agreement with a  
2 pharmacy benefits manager to provide pharmacy provider services to a person covered  
3 under a specific health benefit plan.

4 (f) No pharmacy benefits manager shall mandate basic record keeping by any  
5 pharmacist or pharmacy that is more stringent than required by State or federal laws or  
6 regulations.

7 (g) A violation of this section constitutes an unfair method of competition or  
8 unfair and deceptive trade practice under G.S. 58-63-10 and G.S. 75-1.1.

9 (h) For purposes of 29 U.S.C. § 1144(b)(2)(A), it is the intent of this State that  
10 G.S. 58-51-37 regulate insurance.

11 (i) A pharmacy benefits manager shall not reverse payment for pharmacy  
12 services once the claim for those pharmacy services has been approved by the pharmacy  
13 benefits manager unless the pharmacy benefits manager can demonstrate by substantial  
14 evidence that the claim was fraudulently submitted by the pharmacy.

15 (j) A pharmacy benefits manager shall not violate G.S. 58-3-225 in paying a  
16 pharmacy for pharmacy provider services. A pharmacy shall not be required to continue  
17 to provide pharmacy provider services to covered persons of a health benefit plan being  
18 provided pharmacy benefit management when the pharmacy has not received payment  
19 for previously providing those services in accordance with G.S. 58-3-225.

20 (k) Before increasing the amount to a pharmacy permit holder to process a  
21 prescription drug claim, each pharmacy benefits manager shall file with the  
22 Commissioner the amount to be charged for that service. In no event shall the pharmacy  
23 benefits manager increase the fee by an amount to exceed ten percent (10%) in any  
24 calendar year. Each filing shall become effective on the date specified in the filing, but  
25 not earlier than 210 days from the date the filing is received by the Commissioner. A  
26 filing shall be open to public inspection immediately upon submission to the  
27 Commissioner. In ensuring compliance, the Commissioner may require the filing of  
28 supporting data, including:

29 (1) The pharmacy benefits manager's interpretation of any statistical data  
30 relied upon in determining the processing fee.

31 (2) Any descriptions of the methods employed in setting the processing  
32 fee rates.

33 (3) The total number and dollar amount of paid claims.

34 (4) The cost to the pharmacy benefits manager to process a prescription  
35 drug claim.

36 **"§ 58-50-164. Disclosure to covered persons; authorization for substitutions.**

37 (a) When the services of a pharmacy benefits manager are used, the pharmacy  
38 benefits manager shall provide a written notice approved by the health benefit plan and  
39 the Department to covered persons advising them of the identity of, and relationship  
40 among, the pharmacy benefits manager, the covered person, and the health benefit plan.

41 (b) The notice shall contain a statement advising the covered person that the  
42 pharmacy benefits manager is regulated by the Department and has the right to file a  
43 complaint, appeal, or grievance with the Department concerning the pharmacy benefits



1 manager. The notice shall include the toll-free telephone number, mailing address, and  
2 electronic mail address of the Department.

3 (c) The notice shall conform to G.S. 58-35-25, and the pharmacy benefits  
4 manager shall provide a copy of the notice to the Department and each pharmacist or  
5 pharmacy participating in the network."

6 **SECTION 2.** This act is effective when it becomes law.