

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2005

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HOUSE BILL 1374

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

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Sponsors: Representatives Culpepper; and Insko.

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Referred to: Finance.

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April 21, 2005

1 A BILL TO BE ENTITLED  
2 AN ACT TO ESTABLISH THE PHARMACY BENEFITS MANAGER  
3 REGULATION TRANSPARENCY ACT OF 2005 TO ENSURE PROPER  
4 REGULATION OF THOSE INDIVIDUALS OR ENTITIES WHOSE ACTIONS  
5 AFFECT NORTH CAROLINA CITIZENS' ACCESS TO PRESCRIPTION  
6 DRUGS.

7 The General Assembly of North Carolina enacts:

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

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

11 **"§ 58-50-157. Title; intent.**

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

16 **"§ 58-50-158. Definitions.**

17 The following definitions shall apply in this Part:

- 18 (1) Board. – The North Carolina Board of Pharmacy as created in  
19 G.S. 90-85.6.
- 20 (2) Commissioner. – The Commissioner of the North Carolina Department  
21 of Insurance.
- 22 (3) Claims processing services. – Administrative services performed in  
23 connection with the processing and adjudication of a claim for  
24 prescription drug or device benefits provided by or on behalf of a  
25 health benefit plan.
- 26 (4) Covered person. – A member, policyholder, subscriber, enrollee,  
27 beneficiary, dependent, or other individual participating in a health  
28 benefit plan.
- 29 (5) Department. – The North Carolina Department of Insurance.

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

- 1           c.     The dispensing of prescription drugs through the United States  
2                 Postal Service or similar service.
- 3           d.     Prescription drug rebate contracting and administration.
- 4           e.     Patient compliance, therapeutic intervention, and generic  
5                 substitution programs.
- 6           f.     Disease management programs involving prescription drug  
7                 utilization.
- 8           (10) Pharmacy benefits manager. – A person who, or business or other  
9                 entity that, performs pharmacy benefit management. The term includes  
10                a person or entity acting for a pharmacy benefits manager in a  
11                contractual or employment relationship in the performance of  
12                pharmacy benefit management for a health benefit plan and includes  
13                the dispensing of a prescription drug by an out-of-state pharmacy as  
14                permitted under G.S. 90-85.21A.
- 15           (11) Pharmacy provider services. – A pharmacy or pharmacist providing  
16                services regulated by the Board as the practice of pharmacy.
- 17           (12) Practice of pharmacy. – The term as defined in G.S. 90-85.3(r).
- 18           (13) Prescription drug. – The term as defined in G.S. 90-85.3(s).

19 **"§ 58-50-159. Certificate of authority.**

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

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

- 29           (1) All organizational documents of the pharmacy benefits manager,  
30 including any articles of incorporation, articles of association,  
31 partnership agreement, trade name certificate, or trust agreement, any  
32 other applicable documents, and all amendments to these documents.
- 33           (2) The bylaws, rules, regulations, or similar documents regulating the  
34 internal affairs of the pharmacy benefits manager.
- 35           (3) The names, addresses, official positions, and professional  
36 qualifications of the individuals who are responsible for the conduct of  
37 affairs of the pharmacy benefits manager, including all: (i) members  
38 of the board of directors, board of trustees, executive committee, or  
39 other governing board or committee; (ii) the principal officers in the  
40 case of a corporation or the partners or members in the case of a  
41 partnership or association; (iii) all shareholders holding directly or  
42 indirectly ten percent (10%) or more of the voting securities of the  
43 pharmacy benefits manager; and (iv) any other person who exercises  
44 control or influence over the affairs of the pharmacy benefits manager.

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

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

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

7           "**§ 58-50-160. Maintenance records; access; confidentiality; financial examination.**"

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

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

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

24           "**§ 58-50-161. Disclosure.**"

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

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

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

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

42           "**§ 58-50-162. Contracts; approval of agreements required; prohibited provisions.**"

43           (a) A health benefit plan shall not enter into an agreement with a person or entity  
44           to provide pharmacy benefit management unless the person or entity has obtained a

1 pharmacy benefits manager license pursuant to G.S. 58-50-159(a). No pharmacy  
2 benefits manager shall provide pharmacy benefit management for a health benefit plan  
3 without a written agreement between the pharmacy benefits manager and the health  
4 benefit plan. The written agreement shall be retained as part of the official records of  
5 both the health benefit plan and the pharmacy benefits manager for the duration of the  
6 agreement and for five years thereafter. The agreement shall contain a provision that the  
7 pharmacy benefits manager is subject to all provisions of Article 51 of Chapter 58 of the  
8 General Statutes to the extent those requirements apply to access to prescription drugs.

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

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

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

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

41 (2) For each health benefit plan for which the pharmacy benefits manager  
42 provides pharmacy benefit management, the health benefit plan's  
43 formularies, restricted access drugs, or devices as defined in  
44 G.S. 58-3-221, or prior approval requirements for obtaining

1           prescription drugs, whether a particular drug or therapeutic class of  
2           drugs is excluded from its formulary, and the circumstances under  
3           which a nonformulary drug may be covered.

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

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

19           **"§ 58-50-163. Prohibited practices of pharmacy benefits manager.**

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

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

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

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

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

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

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

38           (e) A pharmacy benefits manager shall not discriminate when advertising  
39           pharmacies participating in a pharmacy benefits manager's network of pharmacies under  
40           contract to provide pharmacy benefit management. Any list of participating pharmacies  
41           shall be complete and all inclusive of all pharmacies under written agreement with a  
42           pharmacy benefits manager to provide pharmacy provider services to a person covered  
43           under a specific health benefit plan.

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

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

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

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

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

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

- 26           (1) The pharmacy benefits manager's interpretation of any statistical data  
27 relied upon in determining the processing fee.
- 28           (2) Any descriptions of the methods employed in setting the processing  
29 fee rates.
- 30           (3) The total number and dollar amount of paid claims.
- 31           (4) The cost to the pharmacy benefits manager to process a prescription  
32 drug claim.

33 **"§ 58-50-164. Disclosure to covered persons; authorization for substitutions.**

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

38       (b) The notice shall contain a statement advising the covered person that the  
39 pharmacy benefits manager is regulated by the Department and has the right to file a  
40 complaint, appeal, or grievance with the Department concerning the pharmacy benefits  
41 manager. The notice shall include the toll-free telephone number, mailing address, and  
42 electronic mail address of the Department.



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

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