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## PHARMACY BENEFITS MANAGEMENT INDUSTRY - BACKGROUND MEMORANDUM

Section 3 of House Bill No. 1332 (attached as an appendix) requires a study of the pharmacy benefits management industry. The bill provides that the study is to include:

- The extent of competition in the marketplace for health insurance and prescription drugs.
- Whether protecting the confidentiality of trade secret or proprietary information has a positive or negative impact on prescription drug prices.
- The ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer.
- The impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers.
- The use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs.
- The actual impact of the use of pharmacy benefits management techniques on community pharmacies.
- The impact of mail service pharmacies on consumers and community pharmacies.
- The impact of generic and brand name drugs in formulary development, drug switches, and mail order operations as well as spread pricing, data sales, and manufacturers' rebates and discounts.
- The price consumers actually pay for prescription drugs in North Dakota.
- Consideration of the legality of imposing statutory restrictions on pharmacy benefits managers.

### BACKGROUND

Health care spending has increased dramatically in this country in recent years, and one of the major factors in that growth has been the cost of prescription drugs. The Kaiser Family Foundation has estimated that the cost of prescription drugs will increase by an average of nearly 11 percent per year over the next eight years. One method through which health insurers, businesses, and governments are attempting to reduce prescription drug costs is through the use of pharmacy benefit managers.

#### Pharmacy Benefits Management

A pharmacy benefit manager (PBM) is an entity that manages prescription drug coverage for another

entity, such as an insurance carrier, self-insured employer, or managed care organization. A PBM may operate as an independent stand-alone business or as a subsidiary of an insurance company or a pharmacy chain store. Although PBMs initially were established to administer prescription drug insurance benefits, the scope of service of PBMs has expanded to include clinical services and mail order pharmacies. A PBM may be responsible for the entire management of the health insurance plan pharmacy benefit or may provide any of the following services:

- Processing of claims through which the PBM electronically provides a pharmacy with information regarding member eligibility, benefit coverage, and prescription reimbursement and maintains a data base to provide information for the PBM and the payer with respect to cost, utilization, and benefits management.
- Establishing pharmacy networks for payers through negotiated agreements with retail pharmacies.
- Managing drug formularies for use by members of a health insurance plan or by Medicare recipients.
- Providing reports to the payer to assist in evaluating the cost and utilization of drugs.
- Developing programs to influence members to choose generic drugs.
- Negotiating rebates from pharmaceutical manufacturers for delivering a particular volume of products or for achieving a specified market share for a product.
- Evaluating the necessity, appropriateness, and efficiency of the use of prescription drugs.

The Federal Trade Commission indicates that about 60 PBMs administer nearly 80 percent of the prescription drug expenditures in the United States and administer prescription drug benefits for about 200 million Americans. Other reports suggest that as a result of 2003 federal Medicare legislation, over 75 percent of the population of this country will be under pharmacy benefit management plans.

#### North Dakota Law

In 2005 the Legislative Assembly adopted House Bill No. 1332, which created North Dakota Century Code (NDCC) Chapter 26.1-27.1 and established regulatory measures for the pharmacy benefits management industry. North Dakota Century Code Section 26.1-27.1-01 defines "pharmacy benefits management" as the procurement of prescription drugs at a negotiated rate for dispensation within this

state to covered individuals; the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals; or the providing of any of the following services with regard to the administration of the following pharmacy benefits:

1. Claims processing, retail network management, and payment of claims to a pharmacy for prescription drugs dispensed to a covered individual.
2. Clinical formulary development and management services.
3. Rebate contracting and administration.

Under NDCC Section 26.1-27.1-02, a person is prohibited from acting as a PBM in this state unless the person holds a certificate of registration as an administrator of life or health insurance or annuities under Chapter 26.1-27.

North Dakota Century Code Section 26.1-27.1-03 sets forth disclosure requirements for PBMs. That section requires a PBM to disclose to the Insurance Commissioner any ownership interest of any kind with an insurance company responsible for providing benefits directly or through reinsurance to any plan for which the PBM provides services or any organization that is related to the provision of pharmacy services, the provision of other prescription drug or devices services, or a pharmaceutical manufacturer.

Under NDCC Section 26.1-27.1-04, a PBM is required to comply with other statutory provisions relating to the dispensing and substitution by pharmacists of brand name, generic, and therapeutically equivalent prescription drugs. That section also prohibits a PBM from requiring a pharmacist or pharmacy to participate in one contract in order to participate in another contract. A PBM is also prohibited from excluding an otherwise qualified pharmacist or pharmacy from participation in a particular network if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the PBM's contract.

North Dakota Century Code Section 26.1-27.1-05 establishes required contents of a pharmacy benefits management agreement. That section requires a PBM to offer to a covered entity options for the covered entity to contract for services that must include a transaction fee without a sharing of a payment received by the PBM, a combination of a transaction fee and a sharing of a payment received by the PBM, or a transaction fee based on the covered entity receiving all the benefits of a payment received by the PBM. In addition, that section requires that the agreement between the PBM and the covered entity must include a provision allowing the covered entity to have audited the PBM's books, accounts, and records, including de-identified utilization information, as necessary to confirm that the benefit of a payment received by the PBM is being shared as required by the contract. Under Chapter 26.1-27.1, a payment received by a PBM is defined as

the aggregate amount of a rebate collected by the PBM which is allocated to a covered entity, an administrative fee collected from the manufacturer in consideration of an administrative service provided by the PBM to the manufacturer, a pharmacy network fee, and any other fee or amount collected by the PBM from a manufacturer or labeler for a drug switch program, formulary management program, mail service pharmacy, educational support, data sales related to a covered individual, or any other administrative function.

North Dakota Century Code Section 26.1-27.1-06 requires the Insurance Commissioner during an examination of a health insurer or provider of health coverage to examine any contract between the insurer or provider and a PBM to determine if a payment received by the PBM and which the insurer or provider received from the PBM has been applied toward reducing the insurer's or provider's rates or has been distributed to members or policyholders. To facilitate the examination, the insurer or provider is required to disclose annually to the Insurance Commissioner the benefits of the payment received by the PBM received under any contract with a PBM and describe the manner in which the payment received by the PBM is applied toward reducing rates or is distributed to members or policyholders. The information provided to the Insurance Commissioner is considered a trade secret under the Uniform Trade Secrets Act.

### **PBM Legislation in Other States**

The National Conference of State Legislatures reports that since 2001, legislatures in at least 32 states have considered bills that would regulate PBMs. Among the states that have adopted PBM regulatory legislation are Vermont, Maine, and South Dakota.

#### **Vermont**

In 2002 the Vermont Legislature adopted legislation that established detailed disclosure and financial reporting by PBMs. The legislation also required annual reports that analyze success on cost-savings by PBMs.

#### **Maine**

In 2003 the Maine Legislature adopted legislation that required full disclosure of contracted activities between a PBM and a pharmaceutical manufacturer and required price discounts and rebates to be passed on to the customers. In April 2005 a federal district judge determined that the Maine law was not preempted by federal law regulating employer health plans, the law did not violate the commerce clause of the United States Constitution, and the law was not a "taking" of intellectual property without just compensation in violation of the Fifth Amendment to the United States Constitution.

**South Dakota**

In 2004 the South Dakota Legislature adopted legislation regulating PBMs. The legislation required licensing of PBMs and required a PBM to exercise good-faith and fair dealing toward customers. The legislation also allowed customers to request rebate and revenue information regarding PBMs and to obtain copies of PBM audits.

**PREVIOUS INTERIM STUDIES**

During the 2003-04 interim, the Budget Committee on Health Care studied the value of the medical assistance program use of benefit purchasing pools, preferred drug lists, and other pharmacy benefit management concepts, including the fiscal impact of the appeals and grievance process on existing programs. The committee received information regarding the federal Medicare Prescription Drug, Improvement, and Modernization Act of 2003, including its impact on the state Medicaid program. The committee also received reports from representatives of the Department of Human Services and the Drug Use Review Board regarding the status of implementing the prior authorization program under which certain drugs may not be prescribed until authorization is received from a Medicaid agency or insurer.

The committee made no recommendations with respect to the study.

During the 2001-02 interim, the Budget Committee on Health Care studied the prices of prescription drugs and possible mechanisms to lower costs to consumers and the state and whether the state should establish a program to assist in the purchase of prescription drugs based upon income. The committee reviewed cost-containment strategies and pharmaceutical assistance programs in other states. The committee made no recommendations as a result of its study.

**POSSIBLE STUDY APPROACH**

In conducting this study, the committee may consider seeking additional information from representatives of the PBM industry, pharmacists, consumers, and the Insurance Commissioner while monitoring the impact of the regulation of PBMs under House Bill No. 1332 (2005). The committee should also continue to receive and review information regarding PBM legislation and litigation in other states and decisions and reports issued by the Federal Trade Commission.

ATTACH:1

2. A pharmacy benefits manager shall notify the commissioner in writing within five business days of any material change in the pharmacy benefits manager's ownership.

**26.1-27.1-04. Prohibited practices.**

1. A pharmacy benefits manager shall comply with chapter 19-02.1 regarding the substitution of one prescription drug for another.
2. A pharmacy benefits manager may not require a pharmacist or pharmacy to participate in one contract in order to participate in another contract. The pharmacy benefits manager may not exclude an otherwise qualified pharmacist or pharmacy from participation in a particular network if the pharmacist or pharmacy accepts the terms, conditions, and reimbursement rates of the pharmacy benefits manager's contract.

**26.1-27.1-05. Contents of pharmacy benefits management agreement - Requirements.**

1. A pharmacy benefits manager shall offer to a covered entity options for the covered entity to contract for services that must include:
  - a. A transaction fee without a sharing of a payment received by the pharmacy benefits manager;
  - b. A combination of a transaction fee and a sharing of a payment received by the pharmacy benefits manager; or
  - c. A transaction fee based on the covered entity receiving all the benefits of a payment received by the pharmacy benefits manager.
2. The agreement between the pharmacy benefits manager and the covered entity must include a provision allowing the covered entity to have audited the pharmacy benefits manager's books, accounts, and records, including de-identified utilization information, as necessary to confirm that the benefit of a payment received by the pharmacy benefits manager is being shared as required by the contract.

**26.1-27.1-06. Examination of insurer-covered entity.**

1. During an examination of a covered entity as provided for in chapter 26.1-03, 26.1-17, or 26.1-18.1, the commissioner shall examine any contract between the covered entity and a pharmacy benefits manager and any related record to determine if the payment received by the pharmacy benefits manager which the covered entity received from the pharmacy benefits manager has been applied toward reducing the covered entity's rates or has been distributed to covered individuals.
2. To facilitate the examination, the covered entity shall disclose annually to the commissioner the benefits of the payment received by the pharmacy benefits manager received under any contract with a pharmacy benefits manager and shall describe the manner in which the payment received by the pharmacy benefits manager is applied toward reducing rates or is distributed to covered individuals.
3. Any information disclosed to the commissioner under this section is considered a trade secret under chapter 47-25.1.

**26.1-27.1-07. Rulemaking authority.** The commissioner shall adopt rules as necessary before implementation of this chapter.

**SECTION 3. PHARMACY BENEFITS MANAGEMENT INDUSTRY - LEGISLATIVE COUNCIL STUDY.** The legislative council shall study, during the 2005-06 interim, the pharmacy benefits management industry, including the extent of competition in the marketplace for health insurance and prescription drugs; whether protecting the confidentiality of trade secret or proprietary information has a

positive or negative impact on prescription drug prices; the ownership interest or affiliation between insurance companies and pharmacy benefits management companies and whether such relationships are good for the consumer; the impact of disclosure of information regarding relationships between pharmacy benefits management companies and their customers; the use of various cost-containment methods by pharmacy benefits managers, including the extent to which pharmacy benefits managers promote the use of generic drugs; the actual impact of the use of pharmacy benefits management techniques on community pharmacies; the impact of mail service pharmacies on consumers and community pharmacies; the impact of generic and brand name drugs in formulary development, drug switches and mail order operations, as well as spread pricing, data sales and manufacturers rebates and discounts; the price consumers actually pay for prescription drugs in North Dakota; and consideration of the legality of imposing statutory restrictions on pharmacy benefits managers. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly.