ATTACHMENT 1

DEPARTMENT OF CONSUMER AFFAIRS

REGULATORY REQUEST QUESTIONNAIRE

Instructions for completing this questionnaire

- Responses to this questionnaire should be typed and dated. Each question should be answered within a single main document, which is limited to 50 pages. Supporting evidence for your responses may be included as an *Appendix*, but all essential information should be included within the main document.

- Each question from the questionnaire should be stated in upper case (capital) letters. The response should follow in lower case letters.

- Each part of every question must be addressed. If there is no information available to answer the question, state this as your response and describe what you did to attempt to find information that would answer the question. If you think the question is not applicable, state this and explain your response.

- When supporting documentation is appropriate, include it as an *Appendix*. Appendices would be labeled as follows: Each document appended should be lettered in alphabetical order. Pages within each appendix should be numbered sequentially. For example, the third page of the first appendix will be labeled A3, and the fifth page of the second appendix will be labeled B5. References within the main document to information contained in Appendices should use these page labels.

- Please read the entire questionnaire before answering any questions so that you will understand what information is being requested and how questions relate to each other.

Section A: Applicant Group Identification

This section of the questionnaire is designed to help identify the group seeking regulation and to determine if the applicant group adequately represents the occupation.

1. What occupational group is seeking regulation? Identify by name, address and associational affiliation the individuals who should be contacted when communicating with this group regarding this application.

2. List all titles currently used by California practitioners of this occupation. Estimate the total number of practitioners now in California and the number using each title.

3. Identify each occupational association or similar organization representing current practitioners in California, and estimate its membership. For each, list the name of any associated national group.

4. Estimate the percentage of practitioners who support this request for regulation. Document the source of this estimate.

5. Name the applicant group representing the practitioners in this effort to seek regulation. How was this group selected to represent practitioners?

6. Are all practitioner groups listed in response to question 2 represented in the organization seeking regulation? If not, why not?

Section B: Consumer Group Identification

This section of the questionnaire is designed to identify consumers who typically seek practitioner services and to identify nonapplicant groups with an interest in the proposed regulation.

7. Do practitioners typically deal with a specific consumer population? Are clients generally individuals or organizations? Document.

8. Identify any advocacy groups representing California consumers of this service. List also the name of applicable national advocacy groups.

9. Identify any consumer populations not now using practitioner services likely to do so if regulation is approved.

10. Does the applicant group include consumer advocate representation? If so, document. If not, why not?

11. Name any non-applicant groups opposed to or with an interest in the proposed regulation. If none, indicate efforts made to identify them.

Section C: Sunrise Criteria

This part of the questionnaire is intended to provide a uniform method for obtaining information regarding the merits of a request for governmental regulation of an occupation. The information you provide will be used to rate arguments in favor of imposing new regulations (such as educational standards, experience requirements, or examinations) to assure occupational competence.

Part C1 – Sunrise Criteria and Questions

The following questions have been designed to allow presentation of data in support of application for regulation. Provide concise and accurate information in the form indicated in the *Instructions* portion of this questionnaire.

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE

12. Is there or has there been significant public demand for a regulatory standard? Document. If not, what is the basis for this application?

13. What is the nature and severity of the harm? Document the physical, social, intellectual, financial or other consequences to the consumer resulting from incompetent practice.

14. How likely is it that harm will occur? Cite cases or instances of consumer injury. If none, how is harm currently avoided?

15. What provisions of the proposed regulation would preclude consumer injury?

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT

16. To what extent do consumers currently control their exposure to risk? How do clients locate and select practitioners?

17. Are clients frequently referred to practitioners for services? Give examples of referral patterns.

18. Are clients frequently referred elsewhere by practitioners? Give examples of referral patterns.

19. What sources exist to inform consumers of the risk inherent in incompetent practice and of what practitioner behaviors constitute competent performance?

20. What administrative or legal remedies are currently available to redress consumer injury and abuse in this field?

21. Are the currently available remedies insufficient or ineffective? If so, explain why.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC

22. Explain why marketplace factors will not be as effective as governmental regulation in ensuring public welfare. Document specific instances in which market controls have broken down or proven ineffective in assuring consumer protection.

23. Are there other states in which this occupation is regulated? If so, identify the states and indicate the manner in which consumer protection is ensured in those states. Provide, as an appendix, copies of the regulatory provisions from these states.

24. What means other than governmental regulation have been employed in California to ensure consumer health and safety. Show why the following would be inadequate:
    a. code of ethics
    b. codes of practice enforced by professional associations
    c. dispute-resolution mechanisms such as mediation or arbitration
    d. recourse to current applicable law
    e. regulation of those who employ or supervise practitioners
    f. other measures attempted

25. If a "grandfather" clause (in which current practitioners are exempted from compliance with proposed entry standards) has been included in the regulation proposed by the applicant group, how is that clause justified? What safeguards will be provided consumers regarding this group?

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS

26. What specific benefits will the public realize if this occupation is regulated? Indicate clearly how the proposed regulation will correct or preclude consumer injury. Do these benefits go beyond freedom from harm? If so, in what way?

27. Which consumers of practitioner services are most in need of protection? Which require least protection? Which consumers will benefit most and least from regulation?

28. Provide evidence of "net" benefit when the following possible effects of regulation are considered:
    a. restriction of opportunity to practice
    b. restricted supply of practitioners
    c. increased costs of service to consumer
    d. increased governmental intervention in the marketplace.

V. PRACTITIONERS OPERATE INDEPENDENTLY, MAKING DECISIONS OF CONSEQUENCE

29. To what extent do individual practitioners make professional judgments of consequence? What are these judgments? How frequently do they occur? What are the consequences? Document.

30. To what extent do practitioners work independently (as opposed to working under the auspices of an organization, an employer or a supervisor)?

31. To what extent do decisions made by the practitioner require a high degree of skill or knowledge to avoid harm?

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED

32. Does the proposed regulatory scheme define a scope of activity which requires licensure, or merely prevent the use of a designated job title or occupational description without a license?

33. Describe the important functions, tasks and duties performed by practitioners. Identify the services and/or products provided.

34. Is there a consensus on what activities constitute competent practice of the occupation? If so, state and document. If not, what is the basis for assessing competence?

35. Are indicators of competent practice listed in response to *Question 34* measurable by objective standards such as peer review? Give examples.

36. Specify activities or practices that would suggest that a practitioner is incompetent. To what extent is public harm caused by personal factors such as dishonesty? Document.

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED

37. What similar occupations have been regulated in California?

38. Describe functions performed by practitioners that differ form those performed by occupations listed in *Question 37*.

39. Indicate the relationships among the groups listed in response to *Question 37* and practitioners. Can practitioners be considered a branch of currently regulated occupations?

40. What impact will the requested regulation have upon the authority and scopes of practice of currently regulated groups?

41. Are there unregulated occupations performing services similar to those of the group to be regulated? If so, identify.

42. Describe the similarities and differences between practitioners and the groups identified in *Question 41*.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGES, SKILLS AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE

43. Is there a generally accepted core set of knowledges, skills and abilities without which a practitioner may cause public harm? Describe and document.

44. What methods are currently used to define the requisite knowledges, skills and abilities? Who is responsible for defining these knowledges, skills and abilities?

45. Are these knowledges, skills and abilities testable? Is the work of the group sufficiently defined that competence could be evaluated by some standard (such as ratings of education, experience or exam performance)?

46. List institutions and program titles offering accredited and nonaccredited preparatory programs in California. Estimate the annual number of graduates from each. If no such preparatory programs exist within California, list programs found elsewhere.

47. Apart from the programs listed in *Question 46*, indicate various methods of acquiring requisite knowledge, skill and ability. Examples may include apprenticeships, internships, on-the-job training, individual study, etc.

48. Estimate the percentage of current practitioners trained by each of the routes described in *Questions 46-47*.

49. Does any examination or other measure currently exist to test for functional competence? If so, indicate how and by whom each was constructed and by whom it is currently administered. If not, indicate search efforts to locate such measures.

50. Describe the format and content of each examination listed in *Question 49*. Describe the sections of each examination. What competencies is each designed to measure? How do these relate to the knowledges, skills and abilities listed in *Question 43*?

51. If more than one examination is listed above, which standard do you intend to support? Why? If none of the above, why not, and what do you propose as an alternative?

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED

52. How many people are exposed annually to this occupation? Will regulation of the occupation affect this figure? If so, in what way?

53. What is the current cost of the service provided? Estimate the amount of money spent annually in California for the services of this group. How will regulation affect these costs? Provide documentation for your answers.

54. Outline the major governmental activities you believe will be necessary to appropriately regulate practitioners. Examples may include such program elements as: qualifications evaluation, examination development or administration, enforcement, school accreditation, etc.

55. Provide a cost analysis supporting regulatory services to this occupation. Include costs to provide adequate regulatory functions during the first three years following implementation of this regulation. Assure that at least the following have been included:
    a. costs of program administration, including staffing
    b. costs of developing and/or administering examinations
    c. costs of effective enforcement programs

56. How many practitioners are likely to apply each year for certification if this regulation is adopted? If small numbers will apply, how are costs justified?

57. Does adoption of the requested regulation represent the most cost-effective form of regulation? Indicate alternatives considered and costs associated with each.

Part C2 – Rating on Sunrise Criteria

Assign each Criterion a numeric rating of 0–5 in the space provided. The rating should be supported by the answers provided to the questions in *Part C1*. Scale descriptions are intended to give examples of characteristics indicative of ratings.

0_____1_____2_____3_____4_____5

(*Little Need for Regulation*) LOW HIGH (*Great Need for Regulation*)

I. UNREGULATED PRACTICE OF THIS OCCUPATION WILL HARM OR ENDANGER THE PUBLIC HEALTH SAFETY AND WELFARE _____

low: Regulation sought only by practitioners. Evidence of harm lacking or remote. Most effects secondary or tertiary. Little evidence that regulation would correct inequities.

high: Significant public demand. Patterns of repeated and severe harm, caused directly by incompetent practice. Suggested regulatory pattern deals effectively with inequity. Elements of protection from fraudulent activity and deceptive practice are included.

II. EXISTING PROTECTIONS AVAILABLE TO THE CONSUMER ARE INSUFFICIENT _____

low: Other regulated groups control access to practitioners. Existing remedies are in place and effective. Clients are generally groups or organizations with adequate resources to seek protection.

high: Individual clients access practitioners directly. Current remedies are ineffective or nonexistent.

III. NO ALTERNATIVES TO REGULATION WILL ADEQUATELY PROTECT THE PUBLIC _____

low: No alternatives considered. Practice unregulated in most other states. Current system for handling abuses adequate.

high: Exhaustive search of alternatives finds them lacking. Practice regulated elsewhere. Current system ineffective or nonexistent.

IV. REGULATION WILL MITIGATE EXISTING PROBLEMS ____

low: Little or no evidence of public benefit from regulation. Case not demonstrated that regulation precludes harm. Net benefit does not indicate need for regulation.

high: Little or no doubt that regulation will ensure consumer protection. Greatest protection provided to those who are least able to protect themselves. Regulation likely to eliminate currently existing problems.

V. PRACTITIONERS OPERATE INDEPENDENTLY, MAKING DECISIONS OF CONSEQUENCE ____

low: Practitioners operate under the supervision of another regulated profession or under the auspices of an organization which may be held responsible for services provided. Decisions made by practitioners are of little consequence.

high: Practitioners have little or no supervision. Decisions made by practitioners are of consequence, directly affecting important consumer concerns.

VI. FUNCTIONS AND TASKS OF THE OCCUPATION ARE CLEARLY DEFINED ____

low: Definition of competent practice unclear or very subjective. Consensus does not exist regarding appropriate functions and measures of competence.

high: Important occupational functions are clearly defined, with quantifiable measures of successful practice. High degree of agreement regarding appropriate functions and measures of competence.

VII. THE OCCUPATION IS CLEARLY DISTINGUISHABLE FROM OTHER OCCUPATIONS THAT ARE ALREADY REGULATED ____

low: High degree of overlap with currently regulated occupations. Little information given regarding the relationships among similar occupations.

high: Important occupational functions clearly different from those of currently regulated occupations. Similar non-regulated groups do not perform critical functions included in this occupation's practice.

VIII. THE OCCUPATION REQUIRES POSSESSION OF KNOWLEDGES, SKILLS AND ABILITIES THAT ARE BOTH TEACHABLE AND TESTABLE ____

low: Required knowledge undefined. Preparatory programs limited in scope and availability. Low degree of required knowledge or training. Current standard sufficient to measure competence without regulation. Required skill subjectively determined; not teachable and/or not testable.

high: Required knowledges clearly defined. Measures of competence both objective and testable. Incompetent practice defined by lack of knowledge, skill or ability. No current standard effectively used to protect public interest.

IX. ECONOMIC IMPACT OF REGULATION IS JUSTIFIED _____

low: Economic impact not fully considered. Dollar and staffing cost estimates inaccurate or poorly done.

high: Full analysis of all costs indicate net benefit of regulation is in the public interest.

ATTACHMENT 2

State of California Department of Consumer Affairs

Memorandum

To: Ad-hoc Committee on PBM Regulation Date: July 31, 2003

From: Paul Riches
Legislative Analyst

Subject: Possible Elements of PBM Regulation In California

This memo will lay out possible elements of pharmacy benefit manager (PBM) regulation in California. These elements have been derived from three principal documents [NCPA Model Law on PBMs, NAIC Draft Model Law on Formulary Development, and a recently enacted Maine statute that imposes disclosure requirements on PBMs]. In addition, these elements draw on testimony and comment provided at the meetings of the Ad-hoc Committee (committee) on PBM Regulation and during discussions in board meetings.

The existing model statutes are difficult to apply directly to California for a number of reasons. First, California is unique in establishing a separate state agency (the Department of Managed Healthcare) for regulating health maintenance organizations (HMOs). Other states generally vest this authority with the state insurance commissioner. Because some limited number of lives are covered through insurance plans regulated by the Department of Insurance, drafting a statute for PBMs, which serve both HMOs and insurers, presents knotty jurisdictional questions. Second, health benefits provided by HMOs are subject to a detailed statutory scheme of regulation (the Knox-Keene Act) which is more extensive than that in other states. Accordingly, any proposal to regulate PBMs in California will require the development of a unique legislative proposal. Such a proposal may well draw conceptual support from these other documents, but the details of how to draft and implement such a proposal will necessarily be specific to California's existing law and the harm that regulation will prevent or ameliorate.

The committee continues to seek a clear definition of the purpose of a proposed regulation, but a number of issues have been raised that permit a rough sketch of potential regulatory proposals. This memo is intended to help focus the committee's discussion on potential regulation. The inclusion of any element in this memo should not be construed as a recommendation from staff for its inclusion in any final proposal. By the same token, the exclusion of any element from this memo should not be taken as a recommendation from staff to exclude it from consideration by the committee for inclusion in a final proposal. Each element should be considered individually, and the committee should demonstrate a clear connection between that element and a real or reasonably probable future harm that it can prevent or ameliorate before including the element in any final proposal.

The committee still faces the threshold question of whether the regulation of PBMs is necessary to protect the public which should be addressed by the responses to the Sunrise questionnaire. This memo assumes, for the purposes of discussion, an affirmative answer to that threshold question.

Possible Elements

1. Jurisdiction – A key aspect of any regulatory proposal is determining which agency (either existing or newly created for the purpose) should assume the responsibility for administering and enforcing the new regulatory scheme. A number of existing agencies come to mind as possibilities for regulating PBMs. However, the ultimate determination will likely be tightly linked to nature of the regulatory scheme (licensure, disclosure, business practice controls, etc.) and the missions of the relevant agencies. The following are potential agencies and a brief description of their regulatory purpose:

Department of Managed Health Care
Mission Statement:

The people of the Department of Managed Health Care work toward an accountable and viable managed care delivery system that promotes healthier Californians. Through leadership and partnership the department shares responsibility with everyone in managed care to ensure aggressive prevention and high quality health care as well as improved overall efficiency, including the reduction of "papeleo" (burdensome paperwork).

Department of Insurance
Description of DOI:

Insurance is a $80 billion-a-year industry in California. Overseeing the industry and protecting the state's insurance consumers is the responsibility of the California Department of Insurance (CDI). The CDI regulates, investigates and audits insurance business to ensure that companies remain solvent and meet their obligations to insurance policyholders. As administrator, the Commissioner enforces the laws of the California Insurance Code and promulgates regulations to implement these laws. The Commissioner issues certificates of authority to insurance and title companies seeking admittance into the California market; and licenses agents, brokers, solicitors and bail bonds agents domiciled in the state. CDI's statewide toll-free hotline, serves as an information clearinghouse for consumers with insurance-related questions or problems. The unit, staffed by insurance experts, provides immediate assistance to callers whenever possible. The CDI responds to thousands of consumer request for assistance complaints received each month. Acting on these requests, the department protects consumers by investigating and prosecuting companies and licensees accused of insurance code violations, including fraud.

Department of Consumer Affairs
Mission Statement:

To promote and protect the interests of California consumers by:
• Serving as guardian and advocate for their health, safety, privacy, and economic well being.
• Enhancing public participation in regulatory decision-making.
• Promoting legal and ethical standards of professional conduct.
• Identifying marketplace trends so that the Department's programs and policies are contemporary, relevant, and responsive.
• Partnering with business and consumer groups in California and the nation.
• Working with law enforcement to combat fraud and enforce consumer protection laws vigorously and fairly.

Board of Pharmacy
Mission Statement:

The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care through education, communication, licensing, legislation, regulation, and enforcement.

Department of Health Services
Mission Statement:

The mission of the California Department of Health Services (CDHS) is to protect and improve the health of all Californians.

Medical Board of California
Mission Statement:

The mission of the Medical Board of California is to protect healthcare consumers through proper licensing and regulation of physicians and surgeons and certain allied healthcare professions and through the vigorous, objective enforcement of the Medical Practice Act.

Managed Risk Medical Insurance Board
Mission Statement:

MRMIB is dedicated to improving the health of Californians by increasing access to affordable, comprehensive and quality health care coverage

2. Nature of Regulation – Depending on the nature of the harm that regulation seeks to prevent or ameliorate, the particular nature of such regulation may take a number of different forms. For instance, the board regulates principally through its program of licensure and enforcement actions related to that licensure program. Other avenues include: mandated disclosure (i.e., sunshine laws), direct regulation (inspection and enforcement), creation of a private right of action for violations, or any blend of the above or other approaches.

3. Formulary Development – A key aspect of PBM practice is the development, maintenance, and implementation of drug formularies. One potential avenue of

regulation is to specify who may participate in this activity, define the process such activity must follow, and specify the criteria by which formulary decisions must be judged. The NAIC draft model law provides an extensive framework for the regulation of this aspect of PBM practice.

4. Patient Protections – Patient protection could take many forms from mandated disclosure of formulary information, reimbursement requirements to establishing rights of appeal or appeal processes. Again, the nature of the protections provided should be narrowly tailored to address problem once it is defined.

5. Disclosure – Much time and attention has been devoted to potential financial conflicts of interest that PBMs may encounter. Establishing a program of financial disclosure to either or both the contracting health plan or the patient has been proposed. In fact, such a scheme of regulation was recently enacted by Maine.

6. Funding – Proposed regulation of PBMs would require the creation of a funding source to support the administration and enforcement of any new requirements. The committee should identify a funding source sufficient to provide meaningful administration and enforcement of any scheme of regulation it proposes.

ATTACHMENT 3

NCPA PHARMACY BENEFIT MANAGER MODEL ACT

OVERVIEW

The starting point for the NCPA Pharmacy Benefit Manager Model Act (04/09/03 draft) ("PBM Model") is the regulatory framework designed for third party administrators. Sections 1 – 6, 9 and 19-26 are basically standard provisions found in regulations of this nature with minor variations to address matters relative to the pharmacy profession. However, Sections 7,8 and 10-18 are designed to address the concerns expressed by the pharmacy profession based on their years of experiences with pharmacy benefit managers.

The PBM Model places the primary responsibility for regulation with the state insurance department; however, the Board of Pharmacy also has an important role. The PBM is required to obtain a certificate of authority (COA) to do business in a state. The PBM must obtain a certificate of compliance from the Board to include with its COA application. The PBM Model relies upon the existing regulatory scheme of insurance regulation that includes reviewing COA applications (Section 5), conducting financial examinations (Section 9), reviewing annual financial statements (Section 10) approving contracts (Section 11) and using administrative powers to handle the suspension or revocation of the COA (Sections 19-22).

The Board of Pharmacy is charged with reviewing the PBM's plan of operation to ensure that it is consistent with the Pharmacy Practice Act (Section 7), to review the audit process when there is an unresolved dispute between the PBM and the pharmacy/pharmacist and to handle complaints involving a professional or patient health or safety issue. The audit function will allow the Board to review the operation of the PBM as it relates to the plan of operation filed.

This Model provides a framework for consideration on a state-by-state basis. It must be reviewed in the context of your state regulatory system and appropriate revisions/additions made to address state specific needs.

BRIEF OVERVIEW OF MAJOR PROVISIONS

Section 5 – Certificate of Authority to act as a Pharmacy Benefit Manager.

- PBM is required to obtain a certificate of compliance from the Board of Pharmacy in order to file a certificate of authority application with the insurance department.
- PBM must provide a detailed description of its claims processing services, pharmacy services, audit functions and insurance services.
- PBM must provide information on all incentive arrangements including rebates and discounts.

Section 8 – Disclosure of ownership or affiliation and certain agreements.

- PBM is required to disclose any ownership interest or affiliation of any kind with an insurance company or a company providing pharmacy services or prescription drugs.
- PBM must disclose agreements to favor one manufacturer over another, to share manufacturer rebates, to sell drug data, and to share revenue with a mail order or internet pharmacy manager.

Section 9 – Maintenance of records by Pharmacy Benefit Manager; access; confidentiality; financial examination.

- The books and records of the PBM must be open to examination by the Department and must be maintained for 5 years.

- The cost of the financial examination must be paid by the PBM and the funds collected are placed in a special fund that can be used to cover the expenses incurred during the examination.

Section 11 – Contracts must be approved; Prohibited Provisions

- Written agreement required and contracts must be filed with the Insurance Department for prior approval.

- PBM may not discriminate against any pharmacist/pharmacy that is willing to participate in the network.

- PBM cannot exclude a pharmacist/pharmacy from a contract because it is not willing to participate in all contracts offered by the PBM.

- PBM must act as the fiduciary on behalf of the pharmacist/pharmacy for funds received for services provided by the pharmacist/pharmacy.

Section 12 –Pharmacy Benefit Manager prohibited practices.

- PBM cannot switch a prescription without the consent of the patient and the prescriber

- A pharmacist/pharmacy cannot be terminated because it filed a complaint against the PBM or because it expresses disagreement with PBM actions regarding a specific covered person.

- PBM may not discriminate when contracting with pharmacies on the basis of co-payments or days of supply.

- All participating pharmacies must be included in the advertising.

- PBMs cannot mandate basic record keeping that is more stringent than that required by state or federal laws or regulations.

Section 13 – Termination of Agreements between PBM and the Pharmacist/Pharmacy

- Pharmacist/pharmacy cannot be terminated because it filed a complaint against the PBM or because it expresses disagreement with pbm actions regarding a specific covered person.

- PBM must give a pharmacist/pharmacy written notice of termination and at least 30 days prior notice.

- Termination does not relieve the PBM of the responsibility to make any payment due for services rendered.

Section 14 – Medication Reimbursement Costs: Use of Index Required.

PBM must use a nationally recognized benchmark for reimbursement.

Section 15 – Timely payments to Pharmacists/Pharmacies; Audits.

- Within 7 calendar days of electronic claims processing, the PBM is required to pay the pharmacist/pharmacy.

- Claims cannot be retroactively denied or adjusted after 7 days except in certain limited cases including fraud.

- Extrapolation audits may not be required.

- An audit must be performed and the pharmacist/pharmacy must be allowed to review the audit and concur prior to the PBM attempting to recoup monies paid.

- Within 24 hours of a price increase, a PBM must adjust its payments

- If the parties cannot agree with the audit results, then the Board of Pharmacy shall review the audit.

Section 24 – Applicability of other laws and regulations.
In lieu of repeating provisions already set forth in most state statutes, this section would provide that PBMs are subject to existing requirements prohibiting unfair trade practices and provisions designed to protect patient confidentiality.

NCPA

Pharmacy Benefit Manager Model Act

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Section 1. Title.

This Act shall be known and cited as the Pharmacy Benefit Manager Act.

Section 2. Purpose and Intent.

The purpose of this Act is to establish standards and criteria for the regulation and licensing of Pharmacy Benefit Managers. This Act is designed to promote, preserve,

and protect the public health, safety, and welfare by and through effective regulation and licensing of Pharmacy Benefit Managers.

Section 3. Definitions.

For purposes of this Act:

A. "Board of Pharmacy" or "Board" means the State Board of Pharmacy.

B. "Commissioner" means the Commissioner of Insurance.

C. "Covered Person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

D. "Department" means Department of Insurance.

E. "Health Benefit Plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the cost of health care services including prescription drug benefits.

F. "Maintenance drug" means a drug prescribed by a practitioner who is licensed to prescribe drugs and used to treat a medical condition for a period greater than 30 days.

G. "Multi-source drug" means a drug that is stocked and is available from three or more suppliers.

H. "Pharmacist" means any individual properly licensed as a pharmacist by the State Board of Pharmacy.

I. "Pharmacist Services" includes drug therapy and other patient care services provided by a licensed pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the Rules of the Board.

DRAFTING NOTE: You may define it as "the practice of pharmacy as defined in (provide state code cite)."

J. "Pharmacy" means any appropriately licensed place within this state where drugs are dispensed and pharmacist services are provided.

DRAFTING NOTE: You may define it by referencing to the appropriate cite in the state code.

K. "Pharmacy Benefit Management Plan" means an arrangement for the delivery of

pharmacist services in which a Pharmacy Benefit Manager undertakes to, pay for, or reimburse any of the costs of pharmacist services for a covered person on a prepaid or insured basis which (i) contains one or more incentive arrangements intended to influence the cost or level of pharmacist services between the health benefit plan sponsor and one or more pharmacies with respect to the delivery of pharmacist services and (ii) requires or creates benefit payment differential incentives for covered persons to use under contract with the Pharmacy Benefit Manager.

L. "Pharmacy Benefits Manager" or "PBM" means a person, business or other entity and any wholly or partially owned or controlled subsidiary of such entity, that administers the prescription drug/device portion of health benefit plans on behalf of a third party including plan sponsors, insurance companies, unions, and health maintenance organizations in accordance with a pharmacy benefit management plan.

M. "Usual and Customary Price" means the price the pharmacist 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. Applicability and Scope.

This Act shall apply to a Pharmacy Benefit Manager that provides claims processing services, other prescription drug or device services, or both to covered persons who are residents of this state.

Section 5. Certificate of Authority to act as a Pharmacy Benefit Manager.

A. No person or organization shall act or operate as a Pharmacy Benefit Manager in this state without a valid certificate of authority issued by the Department. The failure of any person to hold such a certificate while acting as a Pharmacy Benefit Manager shall subject such person to a fine of not less than $5,000 or more than $10,000 for each violation.

B. Each person seeking a certificate of authority to act as a Pharmacy Benefit Manager shall file with the Department an application for a certificate of authority upon a form to be furnished by the Department, which application shall include or have attached the following information and documents:

(1) All basic organizational documents of the Pharmacy Benefit Manager, such as the articles of incorporation, articles of association, partnership agreement, trade name certificate, trust agreement, shareholder agreement and other applicable documents and all amendments to those documents.

(2) The bylaws, rules and regulations or similar documents regulating the conduct or

the internal affairs of the Pharmacy Benefit Manager.

(3) The names, addresses, official positions and professional qualifications of the individuals who are responsible for the conduct of the affairs of the Pharmacy Benefit Manager, including all members of the board of directors, board of trustees, executive committee, other governing board or committee, the principal officers in the case of a corporation, the partners or members in the case of a partnership or association and any other person who exercises control or influence over the affairs of the Pharmacy Benefit Manager.

(4) A Certificate of Compliance issued by the State Board of Pharmacy indicating that the Pharmacy Benefit Manager's plan of operation is consistent with the Pharmacy Practice Act and any regulations promulgated thereunder.

(5) Annual statements or reports for the 3 most recent years, or such other information as the Department may require in order to review the current financial condition of the applicant.

(6) If the applicant is not currently acting as a Pharmacy Benefit Manager, a statement of the amounts and sources of funds available for organization expenses and the proposed arrangements for reimbursement and compensation of incorporators or other principals.

(7) The name and address of the agent for service of process in the state.

(8) A detailed description of the claims processing services, pharmacy services, insurance services, other prescription drug or device services, audit procedures for network pharmacies or other administrative services to be provided.

(9) All incentive arrangements or programs such as rebates, discounts, disbursements, or any other similar financial program or arrangement relating to income or consideration received or negotiated, directly or indirectly, with any pharmaceutical company, that relates to prescription drug or device services, including at a minimum information on the formula or other method for calculation and amount of the incentive arrangements, rebates or other disbursements, the identity of the associated drug or device and the dates and amounts of such disbursements.

(10) A copy of the Fidelity Bond required in Section 6.

(11) Such other information as the Commissioner may require.

(12) A filing fee of $5,000.

C. The applicant shall make available for inspection by the Department copies of all

contracts with insurers or other persons utilizing the services of the Pharmacy Benefit Manager. Certain contracts are subject to prior approval as provided in Section 11.

D. The Department shall not issue a certificate of authority if it determines that the Pharmacy Benefit Manager or any principal thereof is not competent, trustworthy, financially responsible, or of good personal and business reputation or has had an insurance license or pharmacy license denied for cause by any state.

E. A certificate of authority issued under this section shall remain valid, unless suspended or revoked by the Department, so long as the Pharmacy Benefit Manager continues to do business in this state.

Section 6. Fidelity Bond.

A Pharmacy Benefit Manager shall have and keep in full force and effect a fidelity bond equal to at least 10 percent of the amount of the funds handled or managed annually by the Pharmacy Benefit Manager. However, the Department, after due notice to all interested parties and an opportunity for hearing and after consideration of the record, may require an amount in excess of $500,000 but not more than 10 percent of the amount of the funds handled or managed annually by the Pharmacy Benefit Manager.

Section 7. Certificate of Compliance issued by Board of Pharmacy.

A. Each Pharmacy Benefit Manager seeking to become licensed in the state must submit its plan of operation for review in a format to be furnished by the Board of Pharmacy.
B. The Board will review the submission in order to determine if it complies with the Pharmacy Practice Act. The Board shall promulgate rules and regulations concerning, but not limited to, the format required, the fee to accompany the filing, the requirements for annual filings for re-certification and any other information that it may require to complete its review.
C. If the Pharmacy Benefit Manager's filing meets with the Board 's approval, it shall be issued a Certificate of Compliance. Subsequent changes in the plan of operation must be filed with the Board.
D. The Pharmacy Benefit Manager must update its filing on an annual basis.
E. The fees collected shall be used solely for the purpose of regulating Pharmacy Benefit Managers.

Section 8. Disclosure of ownership or affiliation and certain agreements.

A. Each Pharmacy Benefit Manager shall identify to the Department any ownership interest or affiliation of any kind with:

1. Any insurance company responsible for providing benefits directly or through

reinsurance to any plan for which the Pharmacy Benefit Manager provides services; or

2. Any parent companies, subsidiaries and other entities or businesses relative to the provision of pharmacy services, other prescription drug or device services or a pharmaceutical manufacturer.

B. Every Pharmacy Benefit Manager shall disclose the following agreements:

1.any agreement with a pharmaceutical manufacturer to favor the manufacturer's products over a competitor's products or to place the manufacturer's drug on the Pharmacy Benefit Manager's preferred list or formulary, or to switch the drug prescribed by the patient's health care provider with a drug agreed to by the Pharmacy Benefit Manager and the manufacturer;

2.any agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the Pharmacy Benefit Manager or to pay money or other economic benefits to the Pharmacy Benefit Manager,

3.any agreement or practice to bill the health plan for prescription drugs at a cost higher than the Pharmacy Benefit Manager pays the pharmacy and

4. any agreement to share revenue with a mail order or internet pharmacy company.

5.any agreement to sell prescription drug data including data concerning the prescribing practices of the health care providers in the state.

Section 9. Maintenance of records by Pharmacy Benefit Manager; access; confidentiality; financial examination.

A. Every Pharmacy Benefit Manager shall maintain for the duration of the written agreement and for 5 years thereafter books and records of all transactions between the Pharmacy Benefit Manager, insurers, covered persons and pharmacies.

B. The Department shall have access to books and records maintained by the Pharmacy Benefit Manager for the purposes of examination, audit and inspection. The information contained in such books and records is confidential. However, the Department may use such information in any proceeding instituted against the Pharmacy Benefit Manager or insurer.

C. The Commissioner shall conduct periodic financial examinations of every Pharmacy Benefit Manager in this state to ensure an appropriate level of regulatory oversight. The Pharmacy Benefit Manager shall pay the cost of the examination. The cost of the examination shall be deposited in a special fund to provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this Act.

Section 10. Annual financial statement and filing fee; notice of change of ownership.

A. Each authorized Pharmacy Benefit Manager shall file with the Department a full and true statement of its financial condition, transactions and affairs. The statement shall be filed annually on or before March 1 or within such extension of time therefore as the Department for cause may have granted. The statement shall be in such form and contain such matters as the Department prescribes and it must include the total number of persons subject to management by the Pharmacy Benefit Manager during the year, number of persons terminated during the year, the number of persons covered at the end of the year and the dollar value of claims processed.

B. The annual financial statement shall be verified by at least two officers of the Pharmacy Benefit Manager.

C. At the time of the filing its annual statement, the Pharmacy Benefit Manager shall pay a filing fee of $1000.00.

D. The Pharmacy Benefit Manager must notify the Department in writing within 5 calendar days of any material change in its ownership.

Section 11. Contracts; Agreements must be Approved; Prohibited Provisions.

A. No person may act as a Pharmacy Benefit Manager without a written agreement between such person and the Pharmacy Benefit Manager.

B. A Pharmacy Benefit Manager shall not require a pharmacist/pharmacy to participate in one contract in order to participate in another contract. The Pharmacy Benefit Manager shall not exclude an otherwise qualified pharmacist/pharmacy from participation in a particular network solely because the pharmacist/pharmacy declined to participate in another plan or network managed by the Pharmacy Benefit Manager.

C. The Pharmacy Benefit Manager must file a copy with the Department of all contracts/agreements with pharmacies for approval not less than thirty (30) days before the execution of the contract/agreement. The contract shall be deemed approved unless the Department disapproves the contract/agreement within thirty (30) days after it is filed.

D. The written agreement between the insurer and the Pharmacy Benefit Manager shall not provide that the pharmacist/pharmacy is responsible for the actions of the insurer or the Pharmacy Benefit Manager.

E. All agreements shall provide that when the Pharmacy Benefits Manager receives payment for the services of the pharmacist/pharmacy that the Pharmacy Benefit

Manager shall act as a fiduciary of the pharmacy/pharmacist who provided the services. The Pharmacy Benefit Manager shall distribute said funds in accordance with the time frames provided in this Act.

F. In addition to the requirements set forth in this Section and Sections 12 and 13, the Department shall develop formal criteria for the approval and disapproval of such contracts/agreements.

G. Such written agreements shall be retained as part of the official records of both the Pharmacy Benefit Manager and the insurer for the duration of the agreement and for 5 years thereafter.

H. The Department shall consult with the Board on the criteria prior to promulgation.

Section 12. Pharmacy Benefit Manager Prohibited Practices

A. A Pharmacy Benefit Manager shall not intervene in the delivery or transmission of prescriptions from the prescriber to the pharmacist or pharmacy for the purpose of: influencing the prescriber's choice of therapy; influencing the patient's choice of pharmacist or pharmacy; or altering the prescription information, including but not limited to, switching the prescribed drug without the express written authorization of the prescriber.

B. No agreement shall mandate that a pharmacist/pharmacy change a covered person's prescription unless the prescribing physician and the covered person authorize the pharmacist to make the change.

C. The insurer and the Pharmacy Benefit Manager may not discriminate with respect to participation in the network or reimbursement as to any pharmacist/pharmacy that is acting within the scope of his or her license or certification.

D. The Pharmacy Benefit Manager may not transfer a health benefit plan to another payment network unless it receives written authorization from the insurer.

E. No Pharmacy Benefit Manager may discriminate when contracting with pharmacies on the basis of co-payments or days of supply. A contract shall apply the same coinsurance, co-payment and deductible to covered drug prescriptions filled by any pharmacy or pharmacist who participates in the network.

F. No Pharmacy Benefit Manager may discriminate when advertising with pharmacies are participating pharmacies. Any list of participating pharmacies shall be complete and all inclusive.

G. No Pharmacy Benefits Manager may mandate basic record keeping by any pharmacist or pharmacy that is more stringent than required by state or federal

laws or regulations.

Section 13. Termination of Agreements between Pharmacy Benefit Manager and the Pharmacist/Pharmacy.

A. A pharmacist/pharmacy may not be terminated or penalized by a Pharmacy Benefit Manager solely because of filing a complaint, grievance or appeal as permitted under this Act.

B. A pharmacist/pharmacy may not be terminated or penalized because it expresses disagreement with the Pharmacy Benefit Manager's decision to deny or limit benefits to a Covered Person or because the pharmacist/pharmacy assists such Covered Person to seek reconsideration of the Pharmacy Benefit Manager's decision or because the pharmacist/pharmacy discusses alternative medications.

C. Prior to the terminating a pharmacy from the network, the Pharmacy Benefit Manager must give the pharmacy/pharmacist a written explanation of the reason for the termination at least 30 days prior to the termination date unless the termination is based on the (i) loss of the pharmacy's license to practice pharmacy or cancellation of professional liability insurance or (ii) conviction of fraud.

D. Termination of a contract between a pharmacy benefits manager and a pharmacy or pharmacist, or termination of a pharmacy or pharmacist from a pharmacy benefits manager's provider network shall not release the pharmacy benefits manager from the obligation to make any payment due to the pharmacy or pharmacist for pharmacist's services rendered.

Section 14. Medication Reimbursement Costs; Use of Index Required.

Pharmacy Benefit Managers shall use a current and nationally recognized benchmark to base the reimbursement paid to network pharmacies for medications and products. The reimbursement must be determined as follows:

A. For brand (single source) products the Average Wholesale Price (AWP) as listed in First Data Bank (Hearst publications) or Facts & Comparisons (formerly Medispan) correct and current on the date of service provided shall be used as an index.

B. For generic drug (multi-source) products, Maximum Allowable Cost (MAC) shall be established by referencing First Data Bank/Facts & Comparisons Baseline Price (BLP). Only products that are compliant with pharmacy laws as equivalent and generically interchangeable with a Federal FDA Orange Book rating of "A-B" will be reimbursed from a MAC price methodology. If a multi-source product has no BLP price, then it shall be treated as a single source branded drug for the purpose of determining reimbursement.

Section 15. Timely Payments to Pharmacists/Pharmacies; Audits.

A. If a Pharmacy Benefit Manager processes claims via electronic review then it shall electronically transmit payment within seven calendar days of said claims transmission to the pharmacist/pharmacy. Specific time limits for the Pharmacy Benefit Manager to pay the pharmacist for all other services rendered must be set forth in the Agreement.

B. Within 24 hours of a price increase notification by a manufacturer or supplier, the PBM must adjust its payments to the pharmacist/pharmacy consistent with the price increase.

C. Claims paid by the PBM shall not be retroactively denied or adjusted after seven days from adjudication of such claims except as provided in paragraph C below. In no case shall acknowledgement of eligibility be retroactively reversed.

D. The PBM may retroactively deny or adjust in the event (i) the original claim was submitted fraudulently; (ii) the original claim payment was incorrect because the provider was already paid for services rendered, or (iii) the services were not rendered by the pharmacist/pharmacy.

E. The PBM may not require extrapolation audits as a condition of participating in the contract, network or program.

F. The PBM shall not recoup any monies that it believes are due as a result of the audit by set off until the pharmacist/pharmacy has the opportunity to review the PBM's findings and concurs with the results. If the parties cannot then the audit shall be subject to review by the Board.

Section 16. Notice to Covered Person.

A. When the services of a Pharmacy Benefit Manager are utilized, the Pharmacy Benefit Manager must provide a written notice approved by the insurer to covered persons advising them of the identity of, and relationship between, the Pharmacy Benefit Manager, the insured and the covered person.

B. The notice must contain a statement advising the covered person that the Pharmacy Benefit Manager is regulated by the Insurance Department and that the consumer has the right to file a complaint, appeal or grievance with the Insurance Department concerning the Pharmacy Benefit Manager. The notice shall provide the toll-free telephone number, mailing address and electronic mail address of the Insurance Department.

C. The notice must be written in plain English, using terms that will be generally understood by the prudent layperson.

D. A copy of the notice shall be provided to the Insurance Department and each pharmacist/pharmacy participating in the network.

Section 17. Complaint Process.

A. The Department and the Board shall each adopt procedures for formal investigation of complaints concerning the failure of a pharmacy benefits manager to comply with this Act.

B. The Department shall refer a complaint received under this Act to the Board if the complaint involves a professional or patient health or safety issue.

C. The Board shall refer a complaint received under this chapter to the Department if the complaint involves a business or financial issue.

Section 18. Adjustment or settlement of claims; compensation of Pharmacy Benefit Manager.

Compensation to a Pharmacy Benefit Manager for any claims that the Pharmacy Benefit Manager adjusts or settles on behalf of an insurer shall in no way be contingent on claims experience. This section does not prohibit the compensation of a Pharmacy Benefit Manager based on total number of claims paid or processed.

Section 19. Grounds for suspension or revocation of certificate of authority.

A. The certificate of authority of a Pharmacy Benefit Manager shall be suspended or revoked if the Department determines that the Pharmacy Benefit Manager:

1. Is in an unsound financial condition;
2. Has used or is using such methods or practices in the conduct of its business so as to render its further transaction of business in this state hazardous or injurious to insured persons or the public; or
3. Has failed to pay any judgment rendered against it in this state within 60 days after the judgment is final.

B. The Department may, in its discretion, suspend or revoke the certificate of authority of a Pharmacy Benefit Manager if it finds that the Pharmacy Benefit Manager:

1. Has violated any lawful rule or order of the Department or any provision of this chapter;
2. Has refused to be examined or to produce its accounts, records, and files for examination, or if any of its officers has refused to give information with, respect to its affairs or has refused to perform any other legal obligation as to such examination, when required by the Department;
3. Has, without just cause, refused to pay proper claims or perform services arising under its contracts or has, without just cause, compelled covered persons to accept less than the amount due them or to employ attorneys or

bring suit against the Pharmacy Benefit Manager to secure full payment or settlement of such claims;

4. Has failed to reimburse pharmacists/pharmacies in a timely manner as required by this Act;
5. Has failed to pay any fees or other financial requirements levied by the Department;
6. Is or was affiliated with and under the same general management or interlocking directorate or ownership as another Pharmacy Benefit Manager which transacts business in this state without having a certificate of authority;
7. At any time fails to meet any qualification for which issuance of the certificate could have been refused had such failure then existed and had been known to the Department;
8. Has, or any person on its behalf, has advertised or merchandised its services in an untrue, misrepresentative, misleading, deceptive or unfair manner.
9. Has been convicted of, or has entered a plea of guilty or nolo contendere to, a felony relating to the business of insurance or insurance administration in this state or in any other state without regard to whether adjudication was withheld; or
10. Is under suspension or revocation in another state.

C. The Department may, in its discretion and without advance notice or hearing thereon, immediately suspend the certificate of any Pharmacy Benefit Manager. If it finds that one or more of the following circumstances exist:

1. The Pharmacy Benefit Manager is insolvent or impaired.
2. The fidelity bond required by Section 6 is not maintained.
3. A proceeding for receivership, conservatorship, rehabilitation, or other delinquency proceeding regarding the Pharmacy Benefit Manager has been commenced in any state
4. The financial condition or business practices of the Pharmacy Benefit Manager otherwise poses an imminent threat to the public health, safety, or welfare of the residents of this state.

Section 20. Order of suspension or revocation of certificate of authority; notice.

A. The suspension or revocation of a certificate of authority of a Pharmacy Benefit Manager shall be affected by order of the Department mailed to the Pharmacy Benefit Manager by registered, certified or overnight mail.

B. In its discretion, the Department may cause notice of any such revocation or suspension to be published in one or more newspapers of general circulation published in this state.

Section 21. Period of suspension; obligations during suspension; reinstatement.

A. A certificate of authority of a Pharmacy Benefit Manager shall be suspended for such period, not to exceed 1 year, as is fixed in the order of suspension, unless such suspension or the order upon which the suspension is based is modified, rescinded, or reversed.

B. During the period of suspension, the Pharmacy Benefit Manager shall file its annual statement and pay fees as required under this part as if the certificate had continued in full force.

C. Upon expiration of the suspension period, if within such period the certificate has not otherwise terminated, the certificate shall automatically be reinstated, unless the causes of the suspension have not been removed or the Pharmacy Benefit Manager is otherwise not in compliance with the requirements of this Act.

Section 22. Administrative fine in lieu of suspension or revocation.

A. If the Department finds that one or more grounds exist for the suspension or revocation of a certificate of authority issued under this part, the Department may, in lieu of such suspension or revocation, impose a fine upon the Pharmacy Benefit Manager.

B. With respect to any nonwillful violation, such fine may not exceed $1,000 per violation. In no event may such fine exceed an aggregate amount of $5,000 for all nonwillful violations arising out of the same action. When a Pharmacy Benefit Manager discovers a nonwillful violation, the Pharmacy Benefit Manager shall correct the violation and, if restitution is due, the restitution shall include interest at the rate of 12 percent per year from either the date of the violation or the date of inception of the policy of the affected person, at the option of the Pharmacy Benefit Manager.

C. With respect to any knowing and willful violation of a lawful order or rule of the Department or a provision of this part, the Department may impose a fine upon the Pharmacy Benefit Manager in an amount not to exceed $5,000 for each such violation. In no event may such fine exceed an aggregate amount of $25,000 for all knowing and willful violations arising out of the same action. In addition to such fine, the Pharmacy Benefit Manager shall make restitution when due in accordance with the provisions of subsection (b).

D. The failure of a Pharmacy Benefit Manager to make restitution when due as required under this section constitutes a willful violation of this Act. However, if a Pharmacy Benefit Manager in good faith is uncertain as to whether any restitution is due or as to the amount of restitution due, it shall promptly notify the Department of the circumstances; and the failure to make restitution pending a determination of whether restitution is due or the amount of restitution due will not constitute a violation of this Act.

Section 23. Regulations.

The Commissioner and the Board may promulgate regulations to carry out the provisions of this Act. The regulations shall be subject to review in accordance with general rules of administrative rulemaking and review of regulations.

Section 24. Applicability of other laws and regulations.

(Drafting Note: If the State has an unfair trade practices act and a privacy/confidentiality act then the Pharmacy Benefit Manager Act should be subject to those provisions. If not then this Act needs to be revised to include prohibitions against discrimination, false and misleading advertising and protections for privacy/confidentiality of covered person information.)

Section 25. Separability.

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the Act, and the application of the provision to persons or circumstances other than those to which it is held invalid, shall not be affected.

Section 26. Effective Date.

This Act shall be effective (insert date). In order to continue to do business in this state, a Pharmacy Benefit Manager must obtain a Certificate of Authority from the Insurance Department within ninety (90) days after the effective date of this Act.

Section __ Assessment; Creation of Pharmacy Benefit Managers Licensing Fund **(Optional)**

A. The expense of administering this Act, including the cost incurred by the Commissioner, shall be assessed annually by the Commissioner against all Pharmacy Benefit Managers operating in this state. The assessment shall be in proportion to the business done in this state.

B. All fees assessed under this Act and paid to the Commissioner shall be deposited in the Pharmacy Benefit Managers Licensing Fund that shall provide all expenses for the regulation, supervision and examination of all entities subject to regulation under this Act.

C. The Commissioner shall give each Pharmacy Benefit Manager notice of the assessment, which shall be paid to the Commissioner on or before April 1 of each year.

D. If an assessment is not paid by the prescribed date, the amount of any assessment, plus a penalty, the license of the defaulting pharmacy benefits manger may be revoked or suspended by the Commissioner until the assessment and any penalty has been paid.

Draft: 12/8/02
A new model
Adopted by the Regulatory Framework (B) Task Force

The NAIC solicits comments on this draft. Comments should be sent by email to Jolie H. Matthews at jmatthew@naic.org.

HEALTH CARRIER PRESCRIPTION DRUG BENEFIT MANAGEMENT MODEL ACT

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Section 1. Title

This Act shall be known and may be cited as the Health Carrier Prescription Drug Benefit Management Act.

Drafting Note: In some states existing statutes may provide the commissioner with sufficient authority to promulgate the provisions of this Act in a regulation format. States should review existing authority and determine whether to adopt this model as an act or adapt it to promulgate as a regulation.

Section 2. Purpose and Intent

The purpose of this Act is to provide standards for the establishment, maintenance and management of prescription drug formularies and other pharmaceutical benefit management procedures used by health carriers that provide prescription drug benefits.

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Drafting Note: This Act is not intended to address the off-label use of prescription drugs. The "off-label use" of a prescription drug occurs when a prescription drug that has been approved by the federal Food and Drug Administration (FDA) for one or more indications, but the prescription drug is used for indications or in doses other than those stated in the labeling approved by the FDA. Many states have enacted "off-label use" laws or regulations to address this situation. States that have enacted "off-label use" laws or regulations should review the provisions of this Act to determine whether any provisions of this Act should be modified or clarified in light of those laws or regulations.

Section 3. Definitions

For purposes of this Act:

A. "Authorized representative" means:

(1) A person to whom a covered person has given express written consent to represent the covered person for the purpose of filing a medical exceptions request under Section 7 of this Act;

(2) A person authorized by law to provide substituted consent for a covered person;

(3) A family member of the covered person or the covered person's treating health care professional when the covered person is unable to provide consent; or

(4) For the purpose of filing a medical exceptions request under Section 7 of this Act on behalf of a covered person, the covered person's prescribing, treating or dispensing provider.

B. "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocol and practice guidelines used by the health carrier to determine the medical necessity and appropriateness of health care services.

C. "Commissioner" means the Commissioner of Insurance.

Drafting Note: Use of the title of the chief insurance regulatory official wherever the term "commissioner" appears. If the jurisdiction of certain health carriers, such as health maintenance organizations, lies with some state agency other than the insurance department, or if there is dual regulation, a state should add language referencing that agency to ensure the appropriate coordination of responsibilities.

D. "Covered benefits" or "benefits" means those health care services to which a covered person is entitled under the terms of the health benefit plan.

E. "Covered person" means a policyholder, subscriber, enrollee or other individual participating in a health benefit plan.

F. (1) "Dose restriction" means imposing a restriction on the number of doses of a prescription drug that will be covered during a specific time period.

(2) "Dose restriction" does not include:

(a) A restriction set forth in the terms of coverage under a health carrier's health benefit plan for prescription drug benefits that limits the number of doses of a prescription drug that will be covered during a specific time period; or

(b) A restriction on the number of doses when the prescription drug that is subject to the restriction cannot be supplied by or has been withdrawn from the market by the drug's manufacturer.

G. "Facility" means an institutional provider of health care services or a health care setting, including but not limited to hospitals and other licensed inpatient centers, ambulatory surgical or treatment centers, skilled nursing centers, residential treatment centers, diagnostic, laboratory and imaging centers, and rehabilitation and other therapeutic health settings.

H. "Formulary" means a list of prescription drugs that has been developed by a health carrier or its designee, which the health carrier or its designee references in determining applicable coverage and benefit levels.

I. "Generic substitution" means the substitution of a generic version of a brand name prescription drug that has the same active ingredients, strength and intended use as the brand name prescription drug.

Drafting Note: Subsection I defines the term "generic substitution" for use in Section 6C of this Act. States should review the language of this definition and the use of this defined term in Section 6C of this Act to determine whether the language of this definition needs to be modified or clarified in light of any other existing state law regulating generic substitution.

J. "Grievance" means a complaint submitted by or on behalf of a covered person regarding:

(1) The availability, delivery or quality of health care services, including a complaint regarding an adverse determination made pursuant to utilization review;

(2) Claims payment, handling or reimbursement for health care services; or

(3) Matters pertaining to the contractual relationship between a covered person and a health carrier.

K. "Health benefit plan" means a policy, contract, certificate or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services.

L. "Health care professional" means a physician, pharmacist or other health care practitioner who is licensed, accredited or certified to perform specified health care services consistent with state law.

Drafting Note: States may wish to specify the health care professionals to whom this definition may apply (e.g. physicians, pharmacists, psychologists, nurse practitioners, etc.). This definition applies to individual health care professionals, not corporate "persons."

M. "Health care provider" or "provider" means a health care professional or a facility.

N. "Health care services" means services for the diagnosis, prevention, treatment, cure or relief of a health condition, illness, injury or disease.

O. "Health carrier" means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the commissioner, that contracts or offers to contract to provide, deliver, arrange for, pay for or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services.

Drafting Note: States that license health maintenance organizations pursuant to statutes other than the insurance statutes and regulations, such as the public health laws, will want to reference the applicable statutes instead of, or in addition to, the insurance laws and regulations.

P. "Health maintenance organization" means a person that undertakes to provide or arrange for the delivery of health care services to covered persons on a prepaid basis, except for covered person's responsibility for copayments, coinsurance or deductibles.

Q. "Medical and scientific evidence" means evidence found in the following sources:

(1) Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff;

(2) Peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline), and Elsevier Science Ltd. for indexing in Excerpta Medicus (EMBASE);

(3) Medical journals recognized by the Secretary of Health and Human Services under Section 1861(t)(2) of the federal Social Security Act;

(4) The following standard reference compendia:

(a) The American Hospital Formulary Service–Drug Information;

(b) Drug Facts and Comparisons;

(c) The American Dental Association Accepted Dental Therapeutics; and

(d) The United States Pharmacopoeia–Drug Information;

(5) Findings, studies or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes, including:

(a) The federal Agency for Healthcare Research and Quality;

(b) The National Institutes of Health;

(c) The National Cancer Institute;

(d) The National Academy of Sciences;

(e) The Centers for Medicare & Medicaid Services;

(f) The federal Food and Drug Administration; and

(g) Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health care services; or

(6) Any other relevant data that is comparable to the sources listed in Paragraphs (1) through (5).

R. "Participating provider" means a provider that, under contract with the health carrier or with its contractor or subcontractor, has agreed to provide health care

services to covered persons with an expectation of receiving payment, other than coinsurance, copayments or deductibles, directly or indirectly from the health carrier.

S. "Person" means an individual, a corporation, a partnership, an association, a joint venture, a joint stock company, a trust, an unincorporated organization, and any entity or any combination of the foregoing.

T. "Pharmaceutical benefit management procedure" or "PBMP" includes any of the following that is used to manage prescription drug benefits:

(1) A formulary;

(2) Dose restrictions;

(3) Prior authorization requirements; or

(4) Step therapy requirements.

U. "Pharmacy and Therapeutics (P&T) committee" means an advisory committee or committees or equivalent body or bodies that is comprised of individuals who are either employed by or under contract with the health carrier or its designee, a majority of whose membership includes health care professionals, such as physicians and pharmacists, who, collectively, have current knowledge and expertise in:

(1) Clinically appropriate prescribing, dispensing and monitoring of outpatient prescription drugs; and

(2) Drug use review, evaluation and intervention.

Drafting Note: The definition of "Pharmacy and Therapeutics (P&T) committee" is intentionally broad in order to permit health carriers to establish, or have established, one or more advisory committees or equivalent bodies to carry out one or more of the functions a P&T committee or committees are to perform, as described under Section 5 of this Act, related to development and maintenance of a formulary or other pharmaceutical benefit management procedure (PBMP). For example, a health carrier may choose to use one advisory committee or equivalent body to develop a formulary and another advisory committee or equivalent body to develop other PBMPs. The definition also is intentionally broad in order to provide health carriers with the flexibility to choose individuals for membership on an advisory committee or equivalent body who are employees of the health carrier or its designee and those who are not employees of the health carrier or its designee.

V. "Prescriber" means any licensed, certified or otherwise legally authorized health care professional authorized by law to prescribe a prescription drug.

W. "Prescription drug" means a drug that has been approved or is regulated and for which full marketing is otherwise permitted by the federal Food and Drug Administration and that can, under federal and state law, be dispensed only pursuant to a prescription drug order from a licensed, certified or otherwise legally authorized prescriber.

Drafting Note: States with laws that mandate coverage for patient costs associated with clinical trials and laws that mandate coverage for the off-label use of prescription drugs should review those laws to determine what impact, if any, this definition of "prescription drug" has on those laws. In particular, states should assess its impact in light of the definition's reference to "full marketing." This reference was included in order to exclude coverage under this Act for treatment investigational new drugs (INDs).

X. "Prescription drug order" means an order from a prescriber or the prescriber's designated agent to a pharmacist for a prescription drug to be dispensed.

Y. "Prior authorization" means the process of obtaining prior approval for coverage of a prescription drug.

Z. "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition are to be prescribed.

Section 4. Applicability and Scope

A. This Act shall apply to health carriers that provide benefits for outpatient prescription drugs under a health benefit plan issued by the health carrier where the health carrier or its designee administers coverage for this benefit through the use of a formulary or through the application of any other pharmaceutical benefit management procedure.

B. Nothing in this Act shall be construed to apply to prescription drugs that are categorically or contractually excluded from a covered person's health benefit plan. A provision in the benefit contract that purports to exclude all nonformulary prescription drugs shall not be considered a categorical exclusion for purposes of this Act.

Section 5. Requirements for the Development and Maintenance of Prescription Drug Formularies and Other Pharmaceutical Benefit Management Procedures

A. (1) Each health carrier that provides benefits for prescription drugs and manages this benefit through the use of a formulary or other PBMP shall establish, or have established, one or more P&T committees that the health carrier considers appropriate to develop and maintain formularies or any other PBMP in accordance with the requirements of this section.

(2) The health carrier shall ensure that any P&T committee established pursuant to this subsection has policies and disclosure requirements in place that address potential conflicts of interest that members of a P&T committee may have with developers or manufacturers of prescription drugs.

B. (1) The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process to:

(a) Evaluate medical and scientific evidence concerning the safety and effectiveness of prescription drugs, including available comparative information on clinically similar prescription drugs, when deciding what prescription drugs to include on a formulary; and

(b) Evaluate applicable medical and scientific evidence concerning the safety and effectiveness of prescription drugs when developing any other PBMP.

(2) The health carrier shall ensure that any P&T committee maintains documentation of the process required under Paragraph (1) and makes any records and documents relating to the process available, upon request, to the health carrier for record keeping purposes under Section 8 of this Act.

C. The health carrier shall ensure that any P&T committee established in accordance with Subsection A has and uses a process to enable it, in a timely manner, but at least annually, to consider the need for and implement appropriate updates and changes to the formulary or other PBMPs based on:

(1) Newly available scientific and medical evidence or other information concerning prescription drugs currently listed on the formulary or subject to any other PBMP and scientific and medical evidence or other information on newly approved prescription drugs and other prescription drugs not currently listed on the formulary or subject to any other PBMP to determine whether a change to the formulary or PBMP should be made;

(2) If applicable, information received from the health carrier with respect to medical exception requests made under Section 7 of this Act to enable the P&T committee to evaluate whether the prescription drugs currently listed on the formulary or subject to any other PBMP are meeting the health care service needs of covered persons; and

(3) Information relating to the safety and effectiveness of a prescription drug currently listed on the formulary or subject to any other PBMP or relating to clinically similar prescription drugs not currently listed on the

formulary or subject to any other PBMP from the health carrier's quality assurance activities or claims data that was received since the date of the P&T committee's most recent review of that prescription drug.

D. Subject to Section 9 of this Act, a health carrier may contract with another person to perform the functions of a P&T committee as described in this section.

Section 6. Information to Prescribers, Pharmacies, Covered Persons and Prospective Covered Persons

A. (1) Each health carrier or its designee shall maintain and make available to prescribers and pharmacies that are either participating in the health carrier's network or providing health care services to covered persons, by electronic means or, upon the request of a prescriber or pharmacy, in writing, the following:

(a) Its current formulary list by major therapeutic category;

(b) Information indicating which prescription drugs, if any, are subject to a PBMP that has been developed and maintained pursuant to Section 5 of this Act; and

(c) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, information on how and what written documentation is required to be submitted in order for covered persons or their authorized representatives to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.

(2) Whenever the health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a new or revised dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a new or revised step therapy or prior authorization requirement that causes a particular prescription drug not to be covered until the requirements of that PBMP have been met, unless the change is being made for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer, the health carrier or its designee shall provide notice of that change to:

(a) Prescribers at least sixty (60) days prior to the effective date of the change, unless the health carrier will provide coverage for up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person;

(b) Pharmacies participating in the health carrier's network by the effective date of the change; and

(c) Prescribers, who did not receive advance notice of the change because of the exception allowed under Subparagraph (a) of this paragraph, by the effective date of the change.

B. (1) Each health carrier or its designee shall make available to covered persons and prospective covered persons electronically and, upon request, in writing in a manner calculated to be understood by a layperson:

(a) Its current formulary list and any updates and changes to that list;

(b) Information indicating which prescription drugs, if any, are subject to a PBMP that has been developed and maintained pursuant to Section 5 of this Act; and

(c) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, information on how and what written documentation is required to be submitted in order for a covered person or the covered person's authorized representative to file a request under the health carrier's medical exceptions process established pursuant to Section 7 of this Act.

(2) In addition to the information to be provided under Paragraph (1), a health carrier or its designee electronically or in writing, upon request, shall explain the following in a manner calculated to be understood by a layperson that:

(a) The amount that the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time;

(b) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and

(c) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider

to determine whether continuation of that particular prescription drug is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.

C. (1) Whenever a health carrier makes or approves a change in a formulary that causes a particular prescription drug not to be covered, applies a dose restriction that causes a prescription for a particular prescription drug not to be covered for the number of doses prescribed, or applies a prior authorization or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met, the health carrier or its designee shall do one of the following:

(a) At least sixty (60) days prior to its effective date, the health carrier or its designee shall notify covered persons, who are currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of the new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, of the change, in writing or, if the covered person has agreed to receive information in this manner, by electronic means; or

(b) Whenever a covered person, who is currently receiving benefits for the drug that is being discontinued from coverage or that is the subject of a new or revised PBMP that results in no coverage until the requirements of the PBMP have been met, requests a refill of the drug, the health carrier or its designee shall cover up to a 60-day supply of the drug on the same terms as covered previously so long as the drug continues to be prescribed for the covered person during that time period and inform the covered person or the covered person's authorized representative of the change, unless:

(i) The covered person's prescribing provider agrees to a request from the health carrier or pharmacist to change the prescription in accordance with the formulary change or new or revised PBMP; or

(ii) For a formulary change or a new or revised PBMP pertaining to generic substitution, the prescription drug order does not prohibit generic substitution, the covered person agrees at the pharmacy to generic substitution, or generic substitution is required by state law.

(2) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, the notice provided pursuant to Paragraph (1)(a) or as part of the information to be provided pursuant to Paragraph (1)(b) shall

include information on how and what written documentation is required to be submitted for the covered person or the covered person's authorized representative to file a medical exceptions request in accordance with the health carrier's medical exceptions process set forth in Section 7 of this Act.

(3) A health carrier or its designee shall not be required to provide the notice required pursuant to Paragraph (1)(a) or cover up to a 60-day supply of a prescription drug pursuant to Paragraph (1)(b) whenever:

(a) The prescription drug is being discontinued from coverage on the formulary for safety reasons or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; or

(b) The change in or a new PBMP for the prescription drug is for safety reasons.

Section 7. Medical Exceptions Approval Process Requirements and Procedures

A. Each health carrier that provides prescription drug benefits and manages this benefit through the use of a formulary or through the application of a dose restriction that causes a prescription for a particular drug not to be covered for the number of doses prescribed or step therapy requirement that causes a particular drug not be covered until the requirements of that PBMP have been met shall establish and maintain a medical exceptions process that allows covered persons or covered persons' authorized representatives to request approval for:

(1) Coverage of a prescription drug that is not covered based on the health carrier's formulary;

(2) Continued coverage of a particular prescription drug that the health carrier is discontinuing coverage on the formulary for reasons other than safety or because the prescription drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; or

(3) An exception to a PBMP that causes a prescription drug to not be covered until the step therapy requirement is satisfied or not be covered at the prescribed number of doses.

Drafting Note: This section is not intended to apply to requests for an exception to a pharmaceutical benefit management procedure (PBMP) involving a prior authorization requirement. Those types of requests for benefits for which a health carrier requires prior authorization are to be resolved under a health carrier's utilization review process.

B. (1) A covered person or the covered person's authorized representative may file a request under Subsection A only if the covered person's prescribing

provider has determined that the requested prescription drug is medically necessary to treat the covered person's disease or medical condition because:

(a) There is not a prescription drug listed on the formulary to treat the covered person's disease or medical condition that is an acceptable clinical alternative;

(b) The prescription drug alternative listed on the formulary or required to be used in accordance with step therapy requirements:

(i) Has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or

(ii) Has caused or based on sound clinical evidence and medical and scientific evidence is likely to cause an adverse reaction or other harm to the covered person; or

(c) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the covered person's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the covered person and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

(2) (a) A health carrier may require the covered person or the covered person's authorized representative upon request to provide a written certification from the covered person's prescribing provider of the determination made under Paragraph (1).

(b) The health carrier may require the written certification to include any of, but no more than, the following information:

(i) The patient's name, group or contract number, subscriber number or other information necessary to identify the covered person;

(ii) Patient history;

(iii) The primary diagnosis related to the requested prescription drug that is the subject of the medical exceptions request;

(iv) Based on Paragraph (1)(a), (b) or (c), the reason:

(I) Why the formulary drug is not acceptable for the individual patient;

(II) If the medical exceptions request involves a step therapy requirement, why the prescription drug required to be used is not acceptable for the individual patient; or

(III) If the medical exceptions request involves a dose restriction, why the available number of doses for the prescription drug is not acceptable for the individual patient;

(v) The reason why the prescription drug that is the subject of the medical exceptions request is needed for the individual patient or, if the medical exceptions request involves a dose restriction, why an exception to the dose restriction is needed for the individual patient; and

(vi) Any other information reasonably necessary to evaluate the medical necessity of the medical exceptions request.

(3) Participation by a provider on behalf of a covered person in the medical exceptions process established under this section shall be construed as being the same as a provider's advocating on behalf of a covered person within the utilization review process established by the health carrier for purposes of [insert reference to state law equivalent to Section 6J of the Managed Care Plan Network Adequacy Model Act].

Drafting Note: Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act provides that a health carrier may not prohibit a participating provider from advocating on behalf of covered persons within the utilization review or grievance processes established by the carrier or a person contracting with the carrier. The medical exceptions process established under this section for the review of requests for approval for exceptions to a formulary or being subject to a dose restriction or step therapy requirement is similar to the expedited utilization review process that health carriers may be required to establish for the review of health care service benefit requests. Paragraph (3) is intended to ensure that providers participating in the medical exceptions process established under this section have the same protections given to participating providers under Section 6J of the NAIC Managed Care Plan Network Adequacy Model Act.

C. (1) Upon receipt of a request made pursuant to Subsection A, the health carrier shall ensure that the request is reviewed by appropriate health care professionals who, in reaching a decision on the request, shall take into account the specific facts and circumstances that apply to the covered person for whom the request has been made using documented clinical review criteria that:

(a) Are based on sound clinical evidence and medical and scientific evidence; and

(b) If available, appropriate practice guidelines, which may include generally accepted practice guidelines, evidence-based practice guidelines, practice guidelines developed by the health carrier's P&T committee or any other practice guidelines developed by the federal government, national or professional medical or pharmacist societies, boards and associations.

(2) The health care professional or professionals designated by the health carrier to review the request under Paragraph (1) shall ensure that the decision reached on the request is consistent with the benefits and exclusions under the covered person's health benefit plan with the health carrier.

D. (1) The medical exceptions process under this section shall require the health carrier to make a decision on a request made pursuant to Subsection A and provide notice of the decision to the covered person or the covered person's authorized representative as quickly as the covered person's particular medical condition requires, but in no event later than seventy-two (72) hours after the later of the date of receipt of the request or, if required by the health carrier, the date of receipt of the certification under Subsection B(2).

(2) (a) If the health carrier fails to make a decision on the request and provide notice of the decision within the time frame required under Paragraph (1):

(i) The covered person shall be entitled to have coverage for, up to one month's supply of the prescription drug that is the subject of the request; and

(ii) The health carrier shall make a decision on the request prior to the covered person's completion of the supply provided in Item (i).

(b) If the health carrier fails to make a decision on the request and provide notice of the decision prior to the covered person's

completion of the supply provided for in Subparagraph (a) of this paragraph, the health carrier shall maintain coverage, as specified in Subparagraph (a) of this paragraph, on the same terms on an ongoing basis, as long as the prescription drug continues to be prescribed for that covered person and is considered safe for the treatment of the covered person's disease or medical condition until a decision is made on the request and notice of that decision is provided, unless there is a material change in the covered person's terms of coverage or the applicable benefit limits have been exhausted.

E. (1) Whenever a request made under this section is approved, the health carrier shall not require the covered person to request approval under this section for a refill, or a new prescription to continue using the prescription drug after the refills for the initial prescription have been exhausted, for the same prescription drug that was previously approved under this section for coverage or continued coverage or that was previously approved under this section as an exception to the health carrier's PBMP for that drug, subject to the terms of coverage under the health carrier's health benefit plan for prescription drug benefits as long as:

(a) The covered person's prescribing provider continues to prescribe the prescription drug to treat the same disease or medical condition of the covered person; and

(b) The prescription drug continues to be considered safe for treating the covered person's disease or medical condition.

(2) In addition to Paragraph (1), whenever a request made under this section is approved, the health carrier shall provide coverage for the approved prescription drug.

(3) A health carrier shall not establish a special formulary tier or co-payment or other cost-sharing requirement that is applicable only to prescription drugs approved for coverage under this section.

Drafting Note: A state that requires health carriers to establish specific formulary tiers with specific cost-sharing requirements for each tier should modify the language in Paragraph (3) to take into account the requirements of its law.

F. (1) Any denial by a health carrier of a request made under Subsection A:

(a) Shall be provided to the covered person or, if applicable, the covered person's authorized representative in writing or, if the covered person has agreed to receive information in this manner, electronically;

(b) Shall be provided electronically to the covered person's prescribing provider or, upon request, in writing; and

(c) May be appealed by filing a grievance pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act].

(2) The denial shall, in a manner calculated to be understood by the covered person or, if applicable, the covered person's authorized representative, set forth:

(a) The specific reason or reasons for the denial;

(b) A reference to the evidence or documentation, including the clinical review criteria, including practice guidelines, and clinical evidence and medical and scientific evidence considered in reaching the decision to deny the request;

(c) Instructions for requesting, a written statement of the clinical and medical or scientific rationale for the denial; and

(d) A description of the process and procedures that must be followed for filing a grievance to appeal the denial pursuant to [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act], including any time limits applicable to those procedures.

G. A health carrier that permits a covered person's prescribing participating provider to make formulary and other PBMP exceptions without having to obtain authorization from the carrier and that maintains on an ongoing basis in its administrative systems information about the exception status of a particular prescription drug for a particular covered person shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F with respect to the prescription drug orders of these prescribing participating providers.

H. A health carrier shall not be required to establish a medical exceptions process in accordance with Subsection A or required to comply with the provisions of Subsections B, C, D, E(1) and (2) and F if the health carrier:

(1) Has an expedited utilization review process as set forth in [insert reference in state law equivalent to Section 10 of the Utilization Review and Benefit Determination Model Act]; and

(2) Allows covered persons or their authorized representatives to use this process to seek approval for coverage of a prescription drug that is not otherwise covered because of the health carrier's formulary or because of any other PBMP requirement that restricts coverage of the prescription drug until the PBMP requirement has been met.

I. Nothing in this section shall be construed to allow a covered person to use the medical exceptions process set out in this section to request coverage for a prescription drug that is categorically or contractually excluded from coverage under the covered person's health benefit plan.

Section 8. Record Keeping and Reporting Requirements

A. (1) Each health carrier shall maintain written or electronic records sufficient to demonstrate compliance with this Act, including records documenting the application of a process for making decisions on formularies and other PBMPs that is required under Section 5 of this Act and, except for a health carrier that satisfies the requirements of Section 7G or H of this Act, records documenting the application of the medical exceptions process that is required under Section 7 of this Act.

(2) The records shall be maintained for period of three (3) years or until the completion of the health carrier's next market conduct examination, whichever is later, and shall be made available to the commissioner upon request by the commissioner.

B. Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, each health carrier shall maintain data on and, upon request, make available to the commissioner the following information with respect to medical exceptions requests made under Section 7 of this Act:

(1) The total number of medical exceptions requests;

(2) From the total number of medical exceptions requests provided under Paragraph (1):

(a) The number of requests made for coverage of a nonformulary prescription drug;

(b) The number of requests made for continuing coverage of a prescription drug that the health carrier was discontinuing from coverage on the formulary for reasons other than safety or because the drug cannot be supplied by or has been withdrawn from the market by the drug's manufacturer; and

(c) The number of requests made for an exception to being subject to a PBMP that subjects a prescription drug to dose restrictions or step therapy requirements;

(3) The number of medical exceptions requests approved and denied; and

(4) Any other information the commissioner may request.

Section 9. Oversight and Contracting Responsibilities

A. A health carrier shall be responsible for monitoring all activities carried out by, or on behalf, of the health carrier under this Act and for ensuring that all requirements of this Act and applicable regulations are met.

B. Whenever a health carrier contracts with another person to perform activities required under this Act or applicable regulations, the commissioner shall hold the health carrier responsible for monitoring the activities of that person with which the health carrier contracts and for ensuring that the requirements of this Act and applicable regulations with respect to that activity are met.

Section 10. Disclosure Requirements

A. Each health carrier that uses a formulary or any other PBMP shall in the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons:

(1) Disclose the existence of the formulary and any other PBMP and that there may be other plan restrictions or requirements that may affect the specific prescription drugs that will be covered;

(2) Except for a health carrier that satisfies the requirements of Section 7G or H of this Act, describe the medical exceptions process that may be used to request coverage of nonformulary prescription drugs or to obtain an exception to being subject to a dose restriction or step therapy requirement; and

(3) If applicable, describe the process for filing a grievance as set forth in [insert reference in state law equivalent to the Health Carrier Grievance Procedure Model Act] to appeal a denial of a medical exceptions request.

B. (1) In addition to Subsection A, the policy, certificate, membership booklet, outline of coverage or other evidence of coverage provided to covered persons shall explain in layperson's terms information on the health carrier's formulary and other PBMPs, including what a formulary and each PBMP that that health carrier uses is, and state that a copy of the formulary list and information about which prescription drugs are subject

to a PBMP will be provided to a covered person by the health carrier or its designee on request.

(2) In addition to the information explained under Paragraph (1), a health carrier shall explain in layman's terms in a separate document or other attachment to the policy, certificate, membership booklet, outline of coverage or other evidence of coverage that:

(a) The amount that the covered person may be required to pay out-of-pocket for a particular prescription drug may change from time-to-time;

(b) The covered person should check with the health carrier or its designee before obtaining a refill for a particular prescription drug the covered person is currently using to learn whether there has been any change in the requirements for obtaining coverage for the drug or whether there has been a change in the amount that the covered person is required to pay out-of-pocket for the drug; and

(c) If there has been a change in the requirements for obtaining coverage for a particular prescription drug that the covered person is currently using or an increase in the amount that the covered person is required to pay out-of-pocket for the drug, the covered person should consider contacting his or her prescribing provider to determine whether continuation of that particular prescription drug is appropriate or whether there is an acceptable alternative prescription drug that can be used to treat the covered person's disease or medical condition.

Section 11. Regulations

The commissioner may promulgate regulations to carry out the provisions of this Act. The regulations shall be subject to review in accordance with [insert statutory citation providing for administrative rulemaking and review of regulations].

Section 12. Penalties

A violation of this Act shall [insert appropriate administrative penalty from state law].

Section 13. Separability

If any provision of this Act, or the application of the provision to any person or circumstance shall be held invalid, the remainder of the Act, and the application of the provision to persons or circumstances other that those to which it is held invalid, shall not be affected.

Section 14. Effective Date

This Act shall be effective [insert date].

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Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA c. 603, sub-c. 4 is enacted to read:

SUBCHAPTER 4

PRESCRIPTION DRUG PRACTICES

§2699. Prescription drug practices

Pharmacy benefits managers shall and contracts for pharmacy benefits management must comply with the requirements of this section.

1. Definitions. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings.

A. "Covered entity" means a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization licensed pursuant to Title 24 or 24-A; a health program administered by the department or the State in the capacity of provider of health coverage; or an employer, labor union or other group of persons organized in the State that provides health coverage to covered individuals who are employed or reside in the State. "Covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income or other long-term care.

B. "Covered individual" means a member, participant, enrollee, contract holder or policy holder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a policy, contract or plan for a covered individual.

C. "ERISA" means the Employee Retirement Income Security Act of 1974, 29 United States Code, Sections 1001 to 1461 (1988).

D. "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

E. "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a

labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 270.20 (1999).

F. "Pharmacy benefits management" means 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 any of the following services provided with regard to the administration of pharmacy benefits:

(1) Mail service pharmacy;

(2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(3) Clinical management formulary development and management services;

(4) Rebate contracting and administration;

(5) Certain patient compliance, therapeutic intervention and generic substitution programs; and

(6) Disease management programs.

G. "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity and includes mail service pharmacy.

2. Required practices. A pharmacy benefits manager owes a fiduciary duty to a covered entity and covered individuals and shall discharge that duty in accordance with the provisions of ERISA, state and federal law and this section.

A. A pharmacy benefits manager shall perform its duties with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.

B. A pharmacy benefits manager shall discharge its duties with respect to the covered entity and covered individuals solely in the interests of the covered individuals and for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses of administering health plans.

C. A pharmacy benefits manager shall notify the covered

entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subsection.

D. A pharmacy benefits manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices Act or when authorized by that Act or ordered by a court of this State for good cause shown.

E. With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual the following provisions apply.

(1) The pharmacy benefits manager may substitute a lower-priced generic drug for a higher-priced prescribed drug.

(2) The pharmacy benefits manager may not substitute a higher-priced generic drug for a lower-priced prescribed drug.

(3) The pharmacy benefits manager shall consult with the prescribing health professional or that person's authorized representative and shall:

(a) Disclose the costs of both drugs to the covered individual and the covered entity and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution; and

(b) Obtain the approval of the prescribing health professional or that person's authorized representative for the substitution.

(4) The pharmacy benefits manager shall transfer in full to the covered entity or covered individuals any benefit or payment received in any form by the pharmacy

benefits manager as a result of the prescription drug substitution.

F. A pharmacy benefits manager that derives any payment or benefit for the dispensation of prescription drugs within the State based on volume of sales for certain prescription drugs or classes or brands of drugs within the State shall pass that payment or benefit on in full to the covered entity or covered individuals.

G. A pharmacy benefits manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

3. Prohibition. A pharmacy benefits manager may not in a contract with a covered entity or a prescription drug manufacturer or labeler accept or agree to an obligation that is inconsistent with the fiduciary duties imposed by subsection 2, ERISA or other state or federal law.

4. Waiver prohibited. Any agreement to waive the provisions of this section is against public policy and void.

5. Enforcement. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Compliance with this section may be enforced through private action or action by the Attorney General.

A. A covered entity, covered individual or other person injured as a result of a violation of this section is eligible to bring a private action as a person pursuant to the Unfair Trade Practices Act.

B. An action by the Attorney General pursuant to this subsection is subject to the provisions of this paragraph and the Maine Unfair Trade Practices Act. Each violation of this section is a civil violation for which the Attorney General may obtain, in addition to other remedies, injunctive relief and a fine in an amount not to exceed $10,000 per violation, plus the costs of suit, including necessary and reasonable investigative costs, reasonable expert fees and reasonable attorney's fees.

SUMMARY

This bill specifies the fiduciary duties of pharmacy benefits managers and the obligation to serve the covered entities with whom they contract and the covered individuals provided health care benefits by the covered entities. The bill prohibits contractual terms that are inconsistent with the pharmacy benefits manager's fiduciary duties. The bill requires payment to a pharmacy benefits manager based on volume of certain drugs or as a result of substitution of drugs to be passed on to the covered entity or covered individuals. The bill requires disclosure of financial terms that apply between a pharmacy benefits manager and a manufacturer or labeler. The bill requires consultation with and agreement of the prescribing health professional or a representative of that professional before a pharmacy benefits manager may switch a prescription drug to be dispensed to a covered individual. The bill prohibits agreements to waive provisions of the law. Violations of the law are violations of the Maine Unfair Trade Practices Act and are enforceable by private action or the Attorney General.