120th MAINE LEGISLATURE

FIRST REGULAR SESSION-2001

Legislative Document **No. 1744**

S.P. 572 In Senate, March 27, 2001

An Act to Ensure Patient Access to Medicines.

Reference to the Committee on Health and Human Services suggested and ordered printed.

JOY J. O'BRIEN
Secretary of the Senate

Presented by Senator MITCHELL of Penobscot.
Cosponsored by Representative TESSIER of Fairfield and
Senators: CARPENTER of York, FERGUSON of Oxford, TURNER of Cumberland,
Representatives: FULLER of Manchester, LOVETT of Scarborough, NASS of Acton,
NUTTING of Oakland, WINSOR of Norway.

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

Sec. 1. 5 MRSA §12004-G, sub-§14-D is enacted to read:

14-D. Human Services	Drug Utilization Review Board	Expenses Only	22 MRSA §400-C

Sec. 2. 22 MRSA c. 108 is enacted to read:

CHAPTER 108

MEDICAID DRUG UTILIZATION AND PRIOR AUTHORIZATION

§400-A. General

The Legislature recognizes that outpatient prescription drugs are an essential component of patient care. A formulary, prior authorization process or treatment protocol pertaining to a state Medicaid program, chapter 855, the elderly low-cost drug program, section 254 or any other state medical assistance program may not be used to make coverage and payment decisions relating to a practitioner's lawful use of prescription drugs unless it meets the requirements of this chapter. Any rules adopted before or after the effective date of this chapter by the Department of Human Services are void to the extent that they are inconsistent with this chapter.

§400-B. Definitions

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

1. Board. "Board" means the Drug Utilization Review Board established under section 400-C.

2. Committee. "Committee" means the Pharmacy and Therapeutics Committee established under section 400-E.

3. Compendia. "Compendia" for a drug means the "American Hospital Formulary Services Drug Information," or its successor, the "United States Pharmacopeia - Drug Information," or its successor, peer-reviewed medical literature and clinical information submitted to a state Medicaid agency by the pharmaceutical research company that developed the drug and that is registered with the Federal Food and Drug Administration as the drug distributor.

4. Drug utilization review program or DUR program. "Drug utilization review program" or "DUR program" means a system that includes both retrospective and prospective drug utilization reviews and is designed to ensure that drug utilization is medically appropriate, medically necessary and not likely to have adverse medical results.

5. Drug utilization review criteria or DUR criteria. "Drug utilization review criteria" or "DUR criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate and medically necessary and unlikely to result in adverse medical outcomes.

6. Prior authorization. "Prior authorization" means verification to a prescriber or a dispenser or its contractor that the proposed medical use of an outpatient prescription medicine for a patient meets predetermined criteria for coverage by the medical assistance programs as referenced in section 400-A.

7. Prospective drug utilization review or prospective DUR. "Prospective drug utilization review" or "prospective DUR" means that part of a drug utilization review program that occurs before a drug is dispensed and that uses the DUR criteria to screen for potential drug therapy problems pursuant to section 400-D, subsection 3.

8. Retrospective drug utilization review or retrospective DUR. "Retrospective drug utilization review" or "retrospective DUR" means that part of a drug utilization review program that is an historical review of drug utilization data using DUR criteria to examine pharmacy claims data and other information pursuant to section 400-D, subsection 4, paragraph B.

§400-C. Establishment of Drug Utilization Review Board

The Drug Utilization Review Board is established within the Department of Human Services, Bureau of Medical Services for the implementation of a drug utilization review program.

1. Board; membership. The board consists of 11 members appointed by the Director of the Bureau of Medical Services:

A. Four physicians licensed in this State and actively engaged in the practice of medicine, chosen from a list of nominees provided by the Maine Medical Association;

B. Five pharmacists licensed in this State and actively engaged in the practice of pharmacy, chosen from a list of nominees provided by the Maine Board of Pharmacy;

C. One person who is a resident of this State, chosen to represent beneficiaries of the medical assistance programs as referenced in section 400-A in this State; and

D. One person representing the pharmaceutical industry, chosen from a list of nominees provided by a nation association of pharmaceutical researchers and manufacturers.

2. Terms. Board members serve staggered 3-year terms. Of the initial appointees, one physician, one pharmacist and the beneficiary representative must be appointed for 2-year terms and one physician, 2 pharmacists and the industry representative must be appointed for one-year terms. A member may be reappointed 3 times. A vacancy on the board must be filled for the balance of the unexpired term by a nominee with the same qualifications as the nominee's predecessor chosen from the list for the appropriate member category described in subsection 1.

3. Chair. Board members shall select a chair and a vice-chair on an annual basis from the board membership.

4. Meetings. The board shall meet at least 4 times per year and may meet at other times at the discretion of the chair. Notice of any meeting of the board must be published at least 30 days before a meeting and must comply with the Maine Administrative Procedure Act. Board meetings must comply with the provisions of the freedom of access laws under Title 1, chapter 13, subchapter I and are subject to the provisions of the Maine Administrative Procedure Act.

5. Duties of board. The board shall:

A. Advise and make recommendations regarding rules to be adopted by the department to implement the provisions of state and federal law related to drug utilization review;

B. Oversee the implementation of a DUR program for the medical assistance programs as referenced in section 400-A, including having the responsibility for recommending criteria for selection of contractors and reviewing contracts between the medical assistance programs and any other entity that processes and reviews drug claims and profiles for the DUR program in accordance with this chapter.

C. Develop and apply the DUR criteria for the DUR program under paragraph B, as long as the DUR criteria are consistent with the indications supported or rejected by the compendia and FDA-approved labeling for a drug. The board also shall consider outside information provided by interested parties, including prescribers who treat

significant numbers of patients under the medical assistance programs as referenced in section 400-A;

D. Establish a process to reassess on a periodic basis the DUR criteria and, as necessary, modify the DUR programs; and

E. Provide a period for public comment during each board meeting. Notice of proposed changes to the DUR criteria and modification of the DUR program must be furnished 30 days prior to the consideration or recommendation of any proposed changes to the DUR program.

§400-D. Drug Utilization Review Program

1. Create DUR program. The board, in cooperation with the department, shall create and implement a DUR program for outpatient prescription drugs under the medical assistance programs as referenced in section 400-A using DUR criteria.

2. Drug claims. The department may contract with an entity to process and review drug claims and profiles for the DUR program under subsection 1 as long as the department uses a competitive bidding process as required under Title 5, section 1825-B.

3. Review conducted. The prospective DUR under the DUR program in subsection 1 must be based on DUR criteria established by the board and must require that, before a prescription is filled or delivered, a prospective DUR review must be conducted by a pharmacist at the point of sale to screen for potential drug therapy problems. In conducting the prospective DUR, a pharmacist may not alter the prescribed outpatient drug therapy without a new prescription order by the prescribing physician and approval by the patient. The prospective DUR review must screen for:

A. Therapeutic duplication;

B. Drug-disease contraindications;

C. Drug-drug interactions;

D. Incorrect drug dosage or duration of drug treatment;

E. Drug-allergy interactions; and

F. Clinical abuse or misuse.

4. Retrieval system. The retrospective DUR under the DUR program in subsection 1 must be based on DUR criteria and use the department's mechanized drug claims processing and information retrieval system to analyze medical assistance claims to allow the board to:

A. Identify patterns of fraud, abuse, gross overuse or underuse and inappropriate or medically unnecessary care;

B. Assess data on drug use by applying and reviewing criteria consistent with section 400-C, subsection 5, paragraph C to evaluate:

(1) Therapeutic appropriateness;

(2) Overutilization or underutilization;

(3) Appropriate use of generic products;

(4) Therapeutic duplication;

(5) Drug-disease contraindications;

(6) Drug-drug interactions;

(7) Incorrect drug dosage or duration of drug treatment; and

(8) Clinical abuse or misuse; and

C. Propose remedial strategies to improve the quality of drug care and to promote effective use of funds of medical assistance programs as referenced in section 400-A or expenditures for beneficiaries of the medical assistance program.

§400-E. Establishment of Pharmacy and Therapeutics Committee

1. Prior authorization system. The department has the authority to implement a prior authorization system for outpatient prescription drugs under the medical assistance programs as referenced in section 400-A only as provided in this section.

2. Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee is established within the Department of Human Services, Bureau of Medical Services for the purpose of implementing a prior authorization system for outpatient prescription drugs under the medical assistance programs as referenced in section 400-A.

3. Membership. The committee consists of 11 members as appointed by the commissioner of the state Medicaid agency:

A. Five physicians licensed in this State and actively engaged in the practice of medicine, chosen from a list of nominees provided by the Maine Medical Association;

B. Four pharmacists licensed in this State and actively engaged in the practice of pharmacy, chosen from a list of nominees provided by the Maine Board of Pharmacy;

C. One person representing beneficiaries of the medical assistance programs as referenced in section 400-A in this State; and

D. One person representing the pharmaceutical industry who is a resident of this State, chosen from a list of nominees provided by a national association of pharmaceutical researchers and manufacturers.

4. Terms. Committee members serve staggered 3-year terms. Of the initial appointees, two physicians, one pharmacist and the beneficiary representative must be appointed for 2-year terms and one physician, one pharmacist and the industry representative must be appointed for one-year terms. A member may be reappointed 3 times. A vacancy on the committee must be filled for the balance of the unexpired term by a nominee with the same qualifications as the nominee's predecessor chosen from the list for the appropriate member category as described in subsection 3.

5. Chair. Committee members shall select a chair and a vice-chair on an annual basis from the committee membership.

6. Meetings. The committee shall meet a least 4 times per year and may meet at other times at the discretion of the chair. Notice of any meeting of the committee must be published in a manner consistent with the provisions for notice of public hearings contained in Title 5, sections 8052, 8053 and 8053-A, except that notice must be given at least 30 days before a meeting. Committee meetings must comply with the provisions of the freedom of access laws under Title 1, chapter 13, subchapter I and are subject to the provisions of the Maine Administrative Procedure Act.

7. Duties of Pharmacy and Therapeutics Committee. The committee shall:

A. Advise and make recommendations regarding rules to be adopted by the department regarding outpatient prescription drug prior authorization;

B. Oversee the implementation of an outpatient prescription drug prior authorization system for the medical assistance programs as referenced in section 400-A;

C. Establish the outpatient prescription drug prior authorization review process in compliance with section 400-F;

D. Make formal recommendations to the department regarding any outpatient prescription drug covered by the medical assistance programs as referenced in section 400-A that is to receive prior authorization;

E. Review on a semiannual basis whether an outpatient prescription drug that has prior authorization status should continue to have that status; and

F. Modify the prior authorization review process as necessary to achieve the objectives of this chapter.

§400-F. Drug prior authorization system; review process

1. Drug prior authorization system. A drug prior authorization system must include the following:

A. Telephone, fax or other electronically transmitted approval or denial of prior authorization of an outpatient prescription drug must be provided within 24 hours after receipt of a prior authorization request;

B. In an emergency situation, including a situation in which a response to a prior authorization request is unavailable within the 24-hour period under paragraph A, a 72-hour supply of the prescribed drug, or, at the discretion of the committee, a supply greater than 72-hours worth that ensures a minimum effective duration of therapy for an acute intervention must be dispensed and paid for by the medical assistance programs as referenced in section 400-A;

C. Authorization must be granted if a drug is prescribed for a medically accepted use supported by either the compendia or approved product labeling unless there is a therapeutically equivalent generic drug that is available without having prior authorization; and

D. The system must consult with prescribers to develop a streamlined process for the prescriber to furnish any documentation required to support a prior authorization request. Documentation may include the name, title, address

and telephone number of the prescriber making the request; the date of the request; the product name of the requested drug; a description of the circumstances and basis for the request; and whether the request is an emergency. The process must result directly from patient care interaction and not a separate set of tasks required of the prescriber by the State.

2. Conditions for selection for prior authorization. A drug may not be recommended for prior authorization by the committee and given prior authorization by the department unless a review process is followed under which:

A. The committee analyzes the retrospective DUR data using the DUR criteria to identify a drug whose use is likely to be medically inappropriate or unmedically necessary or likely to result in adverse medical outcomes;

B. The committee considers the potential impact on patient care and the potential fiscal impact that may result from giving the drug prior authorization;

C. Any consideration of the cost of the drug by the committee reflects the total cost of treating the conditions for which the drug is prescribed, including nonpharmaceutical costs and costs incurred by other sectors of the medical assistance programs as referenced in section 400-A that may be affected by the drug's availability for use in treating beneficiaries of the medical assistance programs;

D. The committee provides 30 days' public notice prior to a meeting developing recommendations concerning whether the drug should be given prior authorization. An interested party may request an opportunity to make an oral presentation to the committee related to the prior authorization of the drug. The committee shall also consider any information provided by interested parties, including, but not limited to, physicians, pharmacists, beneficiaries and manufacturers or distributors of the drug;

E. The committee makes a formal written recommendation to the department that the drug be given prior authorization. The recommendation must be supported by an analysis of prospective DUR and retrospective DUR data demonstrating:

(1) The expected impact of the decision on the clinical care likely to be received by beneficiaries for whom the drug is medically necessary;

(2) The expected impact on physicians whose patients require the drug; and

(3) The expected fiscal impact on the medical assistance programs as referenced in section 400-A;

F. The department accepts or rejects the recommendation of the committee and in a written decision determines whether the drug should be granted prior authorization status. The department may consider any additional and clarifying information provided by an interested party in making its decision; and

G. The department's decision is published for public comment in accordance with the Maine Administrative Procedure Act for a period of no less than 30 days. The effective date of the decision may not be prior to the close of the comment period, and effective notice of the decision's finality must be available to prescribers.

3. Drugs approved by Federal Food and Drug Administration under priority review classification. A drug may not be recommended for prior authorization by the committee and granted prior authorization status by the department that has been approved or had any of its particular uses approved by the Federal Food and Drug Administration under a priority review classification.

4. Grievance mechanism. The committee shall develop a grievance mechanism for interested parties to appeal the department's decision to grant a drug prior authorization status. After participating in the grievance mechanism developed by the committee, an interested party aggrieved by the placement of a drug on prior authorization is entitled to an administrative hearing before the department pursuant to the provisions of the Maine Administrative Procedure Act.

5. Review. The committee shall review the prior authorization status of a drug every 6 months.

6. Public notice. The committee shall provide 30 days' public notice in accordance with the Maine Administrative Procedure Act prior to a meeting determining whether changes should be made to the drug prior authorization review process.

SUMMARY

This bill establishes standards and criteria governing the establishment and operation of a prescription drug prior authorization system instituted by the Department of Human Services.