ONE HUNDRED AND SEVENTH LEGISLATURE

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E. LOUISE LINCOLN, Clerk

Presented by Mr. Silverman of Calais.

STATE OF MAINE

IN THE YEAR OF OUR LORD NINETEEN HUNDRED SEVENTY-FIVE

AN ACT to Establish a Drug Formulary Commission and to Require the Use of Generic Names in Prescriptions for Certain Drugs.

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

Sec. 1. 22 **MRSA**, § 2204-D is enacted to read:

§ 2204-D. Generic name required

Every physician who prescribes by brand name a drug listed in the formulary prepared by the Drug Formulary Commission pursuant to chapter 552 shall, in each such prescription, oral or written, also include the generic or the chemical name of such drug, if any.

Sec. 2. 22 **MRSA**, c. 552 is enacted to read:

CHAPTER 552

DRUG FORMULARY COMMISSION

§ 2221. Definitions

1. Commission. "Commission" means the Drug Formulary Commission in the department established under section 2222.

2. Commissioner. "Commissioner" means the Commissioner of the Department of Health and Welfare.

3. Department. "Department" means the Department of Health and Welfare.

§ 2222. Drug Formulary Commission

There is created within the Department of Health and Welfare the Drug Formulary Commission. The commission shall be the sole agency of State Government responsible for administration of this chapter. It shall be a separate, distinct organizational unit, the functions of which shall not be integrated in any way as a part of the function of any other organizational unit of State Government. For purposes of administrative support, the commissioner of the department may determine the appropriate location of the commission within the department's organizational structure. The department shall provide the commission any administrative or financial support, including staff, office space, equipment, materials and supplies, which from time to time may be reasonably required to carry out its activities. The commission shall make full use of existing support services available in State Government to assist with carrying out the responsibilities set by this chapter. Any reasonable and proper expenses of the commission shall be borne out of currently available state or federal funds.

§ 2223. Powers and duties of commission

1. Preparation of formulary. The commission shall prepare a formulary of generic or chemical, and brand names of drugs and pharmaceuticals considered by the commission as therapeutically equivalent. The sources for such a document shall include a list of drugs most frequently prescribed by licensed physicians in the State, the formularies of various hospitals in the State, and any additional formularies available from any agency or department of the United States and of other states, but shall not include drugs which are the subject matter of patent rights issued by the United States Patent Office.

2. Revision of formulary. The formulary shall be revised from time to time, but in no event less frequently than once a year, so as to include new pertinent information on drugs approved for inclusion or drugs to be deleted and to reflect current information as to the therapeutic efficacy of drugs and pharmaceuticals.

3. Distribution of formulary. The commission shall provide for distribution of copies of the formulary and revisions thereto to physicians licensed to practice within the State and to other appropriate individuals and shall supply a copy to any individual.

4. Transfer of duties prohibited. The commission shall possess full authority and responsibility for administering all the powers and duties of the commission. It shall not in any case assign to another agency of State Government any power or duty granted to the commission by statute, or by rules, regulations or procedures adopted pursuant to this chapter.

5. Duties relating to generic names of drugs. Relating to generic or chemical and brand names of drugs and pharmaceuticals, or a formulary thereof, the commission shall have the power and duty to:

A. Develop and maintain an up-to-date information system. The information shall be available for use by the people of Maine, public and

private agencies, political subdivisions and the State. Educational materials shall be prepared, published and disseminated. Objective sources and valid research methodologies shall be continuously employed. Existing sources of information shall be used to the fullest extent possible, while maintaining safeguards of state and federal law. Information may be requested and shall be received from any state government or public or private organization.

Functions of the drug information system shall include, but not be limited to:

(1) Conducting research on the equivalency of generic or chemical name drugs and brand name drugs;

(2) Collecting, maintaining and disseminating such knowledge, data and statistics related to drugs; and the therapeutic equivalency of generic or chemical name and brand name drugs; as will enable the commission to fulfill its responsibilities;

(3) Determining the extent of the use of drugs including generic or chemical name and brand name drugs and pharmaceuticals and the needs and priorities for the use of drugs in the State and political subdivisions. Included may be a survey of health facilities and practitioners such as hospitals, nursing homes, boarding homes, clinics, state, county and municipal institutions, pharmacies, doctors and pharmacists.

(4) Maintaining an inventory of the type and sources of drugs available or provided under public and private auspices;

(5) Conducting a continuous evaluation of the quality, equivalency and costs (production, wholesale or retail) of drugs;

B. Help individual citizens, health facilities and health practitioners with the use, administration and prescription of drugs, whether generic or chemical name or brand names. The commission shall provide, or coordinate the provision of, information, technical assistance and consultation to people, public and private organizations who use, administer or prescribe drugs.

C. Seek and receive funds from the Federal Government and private sources to further its activities. Included in this function is authority to solicit, accept, administer, disburse and coordinate for the State in accordance with the intent, objectives and purposes of this chapter and within any limitation which may apply from the sources of such funds, the commission has authority to seek and obtain the use of any funds from any source to carry out activities of the commission. Any gift of money or property made by will or otherwise, and any grant or other funds appropriated, services or property available from the Federal Government, the State or any political subdivision thereof and from all other sources, public or private, may be accepted and administered. The office may do all things necessary to cooperate with the Federal Government or any of its agencies in making application for any funds. Included in this duty is authority to coordinate the disbursement of all state funds, or funds administered through agencies of State Government, appropriated or made avaliable.

D. Enter into agreements necessary or incidental to the performance of its duties. Included is the power to make agreements with qualified community, regional and state level, private nonprofit and public agencies, organizations and individuals in this and other states. The commission may engage expert advisors and assistants who may serve without compensation, or to the extent funds may be available by appropriation, grant, gift or allocation from a state department, the office may pay for such expert advisors or assistants;

E. Prepare, adopt, amend, rescind and administer policies, priorities, procedures, rules and regulations to govern its affairs and services. The commission may adopt rules to carry out the powers and duties conducted under the authority in accordance with the purpose and objectives of this chapter. It shall especially adopt such rules and regulations as may be necessary to define contractual terms, conditions of agreements and all other rules as are necessary for the proper administration of this chapter. Such adoption, amendment and rescission shall be made as provided under Title 5, chapters 301 to 307, Administrative Code;

F. Develop and implement an educational program. Convene and conduct conferences of public and private nonprofit organizations concerned with the use and prescription of generic and brand name drugs. Included shall be the power to encourage health facilities and practitioners to use, administer and prescribe generic and brand name drugs. Also included is the power to encourage all health and disability insurance programs to encourage use of therapeutically equivalent generic or chemical name drugs.

G. Foster, develop, organize, conduct or provide for the conduct of training programs for all persons concerned with the use of generic or chemical name and brand name drugs or pharmaceuticals considered by the commission to be therapeutically equivalent.

H. Coordinate activities and cooperate with programs in this and other states.

I. Establish and maintain a principal office at the department's general headquarters.

J. Do other acts and exercise such other powers necessary or convenient to execute and carry out the purposes and authority expressly granted in this chapter.

§ 2224. Membership

The commission shall consist of 5 members who shall be appointed by the Governor.

1. Qualifications. To be qualified to serve, members shall have education, training, experience, knowledge, expertise and interest in assuring that there is readily available to all citizens of the State drugs and pharmaceuticals which are therapeutically adequate and are offered at prices consistent with the actual cost of manufacture and merchandising regardless of whether the drug is produced and sold as a brand name or generic or chemical name

drug. Members shall be residents of different geographical areas of the State and reflect a diversity of the characteristics enumerated above. They shall be selected from outstanding people who have demonstrated by active participation and unselfish and dedicated personal interest in the fields of consumer protection and affairs, health, elderly and low income citizen movements, medicine and pharmacology. Members shall be individuals possessing recognized competence in the rendering of professional services under, or the administration of, state health programs and a majority of the members shall be practicing members of the professions authorized to render health services under state-financed health programs; provided, however, that not more than one member of the commission shall be a professional subject to the provisions of Title 32, chapter 41. Each member shall serve at the pleasure of the Governor.

2. Appointment and terms. Members shall be appointed for a term of 3 years, except that of the members first appointed, 2 shall be appointed for a term of 3 years, 2 shall be appointed for a term of 2 years and one shall be appointed for a term of one year, as designated by the Governor at the time of appointment, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. Any vacancy in the commission shall not affect its powers, but shall be filled in the same manner in which the original appointment was made.

Members shall be eligible for reappointment for not more than one consecutive term and may serve after the expiration of their term until their successors have been appointed, qualified and taken office. The appointing authority may terminate the appointment of any member of the commission for good and just cause and the reason for the termination of each appointment shall be communicated to each member so terminated. The appointment of any member of the commission shall be terminated if a member is absent from 3 consecutive meetings without good and just cause that is communicated to the chairman. An official, employee, consultant or any other individual employed, retained or otherwise compensated by or representative of the Executive Branch of the Government of the State of Maine shall not be a member of the commission; but shall assist the commission if so requested.

3. Commission; chairman and officers. The Governor shall designate the chairman from among the members appointed to the commission. The commission may elect such other officers from its members as it deems appropriate.

§ 2225. Meetings; compensation; quorum

1. Meetings. The commission shall meet at the call of the chairman or at the call of 2 of the members appointed and currently holding office. The commission shall keep minutes of all meetings, including a list of people in attendance. Minutes of all meetings shall be sent forthwith to the Governor and leadership of the Legislature who shall provide for their appropriate distribution and retention in a place of safekeeping.

2. **Expenses and travel.** Members of the commission shall serve without compensation, but they may be reimbursed on the same basis as employees of state departments for actual travel and other necessary expenses incurred in the performance of their duties.

3. **Quorum.** A majority of the commission members shall constitute a quorum for the purpose of conducting the business of the commission and exercising all the powers of the commission. A vote of the majority of the members present shall be sufficient for all actions of the commission.

Sec. 3. Effective date. The effective date of section 1 of this Act shall be January 1, 1976.

Sec. 4. Appropriation. There is appropriated from the General Fund to the Department of Health and Welfare the sum of $5,000 to carry out the purposes of this Act. The breakdown shall be as follows:

	1975-76
HEALTH AND WELFARE, DEPARTMENT OF	
Drug Formulary Commission	
All Other	$5,000

STATEMENT OF FACT

The intent of this legislation is to provide residents of the State of Maine the opportunity to purchase prescription drugs by generic name at less expense and with the safety factor of a professionally tested equivalent meeting pharmaceutical and medical standards.