Report of the Department of Professional and Financial Regulation

To the Joint Standing Committee on Business, Research and Economic Development

On

Resolve Chapter 138
(L.D. 1827)

"Resolve, Directing the Department of Professional and Financial Regulation to Study Prescription Drug Labeling Requirements"

January 12, 2007

John Elias Baldacci
Governor

Anne L. Head
Acting Commissioner

I. Introduction

Through a Board of Pharmacy, the State of Maine licenses and regulates the activities of pharmacists, pharmacy technicians, drug outlets (pharmacies), manufacturers and wholesalers in the distribution, delivery and dispensing of prescription drugs. The purpose of the Board and all licensing entities established by the Maine Legislature is to protect the health, safety and welfare of Maine citizens. The board meets its public protection mandate through examination and licensing of applicants who meet minimum licensing standards and by imposing discipline on licensees who fail to meet licensing, and state and federally recognized practice and safety standards.

II. Intent of LD 1827

During the 122nd Maine Legislature, Representative Judd Thompson submitted a bill, L.D. 1827, entitled "An Act to Clarify Prescription Drug Labels," which became Resolve Chapter 138 entitled "Resolve, Directing the Department of Professional and Financial Regulation to Study Prescription Drug Labeling Requirements." This resolve was signed by the Governor on March 17, 2006 and took effect on August 23, 2006.

III. Charge from the Legislature

The resolve called on the Department of Professional and Financial Regulation ("the Department") to consider:

> *A. …current statutory requirements for prescription drug labeling; and*
> *B. …pharmacy practices in the area of prescription drug labeling and the methods used by pharmacists to inform consumers about their prescription drugs and any substitutions made to prescriptions; …*

IV. Study Process

Following the enactment of L.D. 1827, the Department developed a working group with expertise in the areas of pharmacist regulation and retail pharmacy operations. Participating members of the working group were:

Paul Chace, R.Ph.
Pharmacist Member of the Board of Pharmacy and the Board's Complaint Officer
John Harris
Public Member of the Board of Pharmacy
Ken Fasulo
Representative from Hannaford Bros. Co. – Chain Pharmacies
Douglas Carr, Esq.,
Rite Aid Pharmacies – Participation through report preparation review
Robert Morrissette, R.Ph.
Executive Director, Maine Pharmacy Association – Due to scheduling conflicts declined invitation to participate

Anne L. Head
Director, Office of Licensing and Registration
Geraldine L. Betts
Board Administrator, Office of Licensing and Registration

The working group met at the Department's offices in Gardiner, Maine on August 21, 2006 and completed its final report review via email communications.

Preparing and dispensing prescription drugs is regulated by laws enacted by the Maine Legislature, rules adopted by the Maine Board of Pharmacy and Title 21 of the Code of Federal Regulations ("CFR") on drug enforcement.

The work group studied applicable laws and regulations on prescription drug labeling. See Appendix A for a comparison of federal and state prescription drug labeling requirements.

V. Issues Raised

1) Overlapping directives regarding labeling requirements

The work group agreed that the needs and demands for information on a prescription label are difficult, if not impossible, to satisfy. The size of containers and labels, coupled with current federal and state requirements for information on prescription labels, limits customization.

The group recognized the need to provide factual and reliable information to consumers for safe and appropriate administration of prescribed medication.

Ken Fasulo manages the technical aspects of periodically updating pharmacy labeling and printing needs for Hannaford pharmacies. Mr. Fasulo reported that Hannaford is currently reviewing its labeling information to insure that federal and state labeling mandates are met and required information is current. Mr. Fasulo also pointed out that Hannaford has pharmacies in eleven states and tries to customize the requirement of each state to the extent possible. Currently, the following information is listed on Hannaford labels:

Rx number
PH address/phone
Dr Name
Patient name
Dispensing date – fill date
Patient address – optional privacy issue (6 font- confirmation/identification)
Drug name –
Manufacturer
Prescriber – phone
Discard after date
NDC number
Pharmacist full name (initials at a minimum)

At times, the font size on a label is extremely small in order to fit all required information on a single label *(note Ariel 6 point font above)*. In many instances, the font is so small that consumers report having difficulty reading the information. Cautionary stickers regarding the appropriate use and storage of medication take up additional space on labels and containers. These stickers are required by the federal Food and Drug Administration (FDA) and are critical to patient safety.

2) Patient fact sheet

In addition to information on a prescription label, each dispensed medication must include a ***prescription information fact sheet***. The information on the fact sheet is comprehensive and intended to educate the patient. At a minimum, it contains all required label information, a listing of common uses of the medication, instructions for its use and a description of possible side effects.

> **32 MRSA § 13784. Patient information regulation**
> **1. Explanation by pharmacist.** With each new prescription dispensed, the pharmacist, in addition to labeling the prescription in accordance with the requirements of the State, must orally explain to the patient or the patient's agent the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. This section does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

Acting Commissioner Head conveyed to the working group that Representative Thompson, sponsor of the bill, was responding to a constituent's need to have the "common name" listed on the container label to help the patient or the caregiver identify what medication the patient is taking. The patient had been prescribed several medications.

The pharmacist member of the group could not support listing 'common names' on the label. He expressed concern that adding another drug name to the label could create confusion and jeopardize the information currently required on labels. In addition, the word 'common' is not a universally known or defined term in the practice of pharmacy and, in some instances, could constitute mis-branding of the prescription when the proprietary product is being dispensed.

Working group members indicated that patients and caregivers are typically more familiar with brand names than generic names, such as Diazepam, which is also known as Valium. The same theory would apply to potassium, which would be difficult to describe given the limited space on a container or label. It was agreed that the appropriate place to fully describe the medication is on the patient information "fact sheet," which is an insert required by FDA for all prescription medication dispensed. A prescriber may verbally communicate to a patient that "potassium" is being prescribed, but medication dispensed is in accordance with the prescription drug order. The brand or generic name appears on the label.

3) Cost of reconfiguring pharmacy computer systems

A universally recognized computer system is not used among all pharmacies. For example, some independent pharmacies may use the QS1 system, Hannaford and Wal-Mart use the PDX system, and Rite Aid uses its own specialized system. Requiring

another label change would lead to programming and operating cost increases that would be likely be passed on to the purchaser. Another label change in this situation is unnecessary.

4) Role of the prescribing practitioner and the pharmacist

The working group agreed on the importance for the patient or caregiver to talk with the prescribing practitioner. It is the responsibility of the prescribing practitioner to evaluate medical conditions, determine medical treatment, and provide information on treatment plans to the patient. A prescribing practitioner may be knowledgeable about 20-40 drugs, while a pharmacist is generally knowledgeable of up to 870 drugs on pharmacy shelves.

The pharmacist is prepared to educate and counsel the patient on the pharmacology of the dispensed drug. For each new prescription drug dispensed, the pharmacist must counsel the patient on the medication, how to store the medication, and on the frequency and proper way to take the medication. The label includes the *initials* of the pharmacist responsible for the dispensed drug. Although this may make it difficult for a patient to identify the pharmacist who filled the prescription, the pharmacist on duty is always prepared to respond to questions.

The pharmacist cannot respond to questions about a doctor's method on medically related treatment and refers the patient to his or her health care provider. According to working group members, a perception exists that people cannot call on a pharmacist for information about the prescription drug dispensed. During normal business hours, all pharmacies have a pharmacist on duty to supervise pharmacy activities and to answer questions about prescription drugs. A pharmacy technician cannot respond to pharmacology questions for lack of appropriate education and training on pharmacology, patient counseling, and drug utilization, but generally can assist with insurance questions. The patient or caregiver can and should ask questions of the pharmacist when needed.

VI. Conclusion

a) Both state and federal regulations identify information that is required on prescription bottles and labels.

b) Currently, the space on prescription bottles and labels is extremely limited. Any additional information will further reduce the font size making it even more difficult for a patient to read critical information. Patients already criticize the font size of current information.

c) Reprogramming various computer systems used by pharmacies to meet additional information needs would create a cost increase, which would likely be passed on to the consumer.

c) The working group agrees that communication with patients and caregivers is important for successful medical treatment. As required by law *(32 MRSA §13784)* for all new prescriptions, the pharmacist accomplishes this task by orally explaining to the patient or

the caregiver the directions for use and any additional information to assure the proper utilization of the medication or device prescribed.

d) Pharmacists respond to pharmacology questions from patients and caregivers regardless of the severe shortage of pharmacists in Maine. Placing additional and unnecessary burdens on pharmacists could reduce the efficacy of services currently provided.

e) The working group reached consensus that it is impossible to respond to each individual request as it applies to printed information on labels. It is also noteworthy that prescription medication dispensed by an authorized prescriber from his or her office does not carry the labeling requirements mandated for prescription medication dispensed from a pharmacy.

Based on these factors, the working group is confident that current pharmacology services are sufficient to meet patient needs. The group does not recommend additions or deletions on prescription labels from the currently applied standards of practice.

VII. Recommendation for Best Practice

The working group agrees that communication among patients, prescribers and pharmacists is critical to educating the patient and the caregiver on prescribed and over-the-counter medication. However, legislating communication methods is not always the best approach. A patient or caregiver should be encouraged by health care practitioners to ask questions. Many patients currently ask questions of the pharmacist. Even mandating pharmacies to post signage to encourage a patient or caregiver to contact his or her health care provider on questions about treatment, or the pharmacist on pharmacology questions, is not a guarantee that the issue at hand would be resolved. Such action is considered unnecessary by the working group.

The working group does recommend that the Board of Pharmacy remind licensed pharmacists about the mandatory patient counseling requirements and emphasize the importance of encouraging communication to assist patients and caregivers to the extent possible and legally allowed.

APPENDIX A

CURRENT LABELING REQUIREMENTS
Code of Federal Regulations and *Maine Pharmacy Law and Board Rules*

Title 21 Code of Federal Regulations ("CFR") Labeling Requirements[1]

Code of Federal Regulations (1306.14) Minimum required information on the prescription label for a **controlled substance** listed in ***Schedule II***: **Exception:** These requirements do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized under certain provision, see CFR 1306.14 (c)(1-4)	✓ Date of filling; ✓ Pharmacy name; ✓ Pharmacy address; ✓ Serial number of the prescription; ✓ Name of the patient; ✓ Name of the prescribing practitioner; ✓ Directions for use; and ✓ Cautionary statements, if any.
If filled at a **central fill pharmacy:**	In addition to the above – ✓ Retail pharmacy name and address; and ✓ Unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central pharmacy.
Code of Federal Regulations (1306.24) Minimum required information on the prescription label for a **controlled substance** listed in ***Schedule III, IV, or V***: **Exception:** These requirements do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized under certain provisions, see CFR 1306.14 (c)(1-4)	✓ Date of initial filling; ✓ Pharmacy name; ✓ Pharmacy address; ✓ Serial number of the prescription; ✓ Name of the patient; ✓ Name of the prescribing practitioner issuing the prescription; ✓ Directions for use; and ✓ Cautionary statements, if any.
If filled at a **central fill pharmacy:**	In addition to the above – ✓ Retail pharmacy name and address; and ✓ Unique identifier, (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central pharmacy.

[1] The labeling requirement in Title 21 § 1306.14 is specific to Schedule II controlled substances only and 1306.24 is specific to Schedule III, IV and V controlled substances. With the exception of minor wording variations, requirements between the two are relatively the same.

Maine Pharmacy Practice Act *(32 MRSA C.117)* **32 MRSA 13702 (12) Labeling.** "Labeling" means the process of preparing and affixing a label to the outside of any drug container, exclusive of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal law or regulation and state law or rule.	*Key: Blue print denotes overlap from CFR requirements.*
§13794. Labeling of prescriptions Every drug dispensed pursuant to prescription, whether for a legend drug or not, must carry on the label….	✓ Prescription number ✓ Date of filling ✓ Patient name ✓ Directions for use ✓ Name and strength of the drug ✓ Amount dispensed, including either the brand name of the drug or, if a *generic and therapeutically equivalent drug is dispensed it must be in accordance with 32 MRSA, § 13781* ✓ Beyond use date of the drug *("beyond use date" means a date beyond which the contents of the prescription are not recommended to be used)* ✓ Name, address and telephone number of the pharmacy where the prescription was compounded or dispensed.
Board of Pharmacy Rules *(Chapter 21, Section 4 Labeling)* In addition to the information required by 32 MRSA § 13794, the prescription container (label) must clearly show….	✓ The name and address of the originating drug outlet; ✓ The name and address or the unique identifier of the central fill drug outlet (bar code or symbol acceptable); ✓ Identifying information of the originating drug outlet, such as the tracking number (bar code or symbol acceptable); and ✓ Patient information.