TO: The Professional Practice Committee

FROM: Douglas E. Lentivech

SUBJECT: Discussion of Pharmacy Prescription Labeling

DATE: March 1, 2018

AUTHORIZATION(S):

SUMMARY

Issue for Discussion

The Board of Regents oversees the practice of pharmacy, which includes the dispensing and compounding of various pharmaceuticals. However, the pharmaceuticals themselves are generally regulated at a federal level by the Food and Drug Administration (FDA). This discussion will explain the crossover which can, at times, be confusing, and pose certain issues for both the regulated pharmacist/pharmacy and the public in general.

Reason for Consideration

The Department and the BOR play a critical role in the oversight of the practice of pharmacy. and in ensuring that pharmaceuticals are properly maintained, dispensed and labeled.

Proposed Handling

This discussion will come before the Professional Practice Committee at its public session meeting in March 2018.

Background Information

The Board of Regents has jurisdiction over the licensed practice of pharmacy, which includes individual licensees, as well as business entities including pharmacy establishments. However, the prescription drugs that pharmacists dispense are regulated

by the FDA. The FDA, in regulating pharmaceuticals, considers a variety of factors, and the licensed pharmacist must be aware of those factors and the FDA's determinations.

In order to ensure patient safety and the appropriate prescription of drugs, every FDA-approved prescription drug is required to have approved labelling, often referred to as the package-insert or prescriber information. This labelling contains the clinical information essential to ensuring proper prescribing. Additionally, prescriptions dispensed to a patient are labeled with concise information that ensures the patient takes the medication properly, at the prescribed dose and at the appropriate intervals.

Initially, prior to introduction into the marketplace, drugs must be shown to be both safe and effective. The FDA uses an evidence-based system of drug approval that is essential to ensuring that drugs are both safe and effective. As part of the drug approval process, the FDA reviews the prescription drug labeling to ensure that health professionals have the information required to understand the drug product risks and safe usage.

The FDA approved prescription drug labeling contains a summary for the safe and effective use of the drug. The information provided is required to be informative and accurate; it cannot contain any false or misleading content or suggestions for use when evidence of safety or efficacy are lacking. The prescription drug labeling information is whenever possible based on data derived from human experience.

The FDA approved prescription drug labeling often contains detailed clinical information outlined by section which may include: clinical pharmacology, approved indications and usage, contraindications, warnings and precautions, adverse reactions, overdosage, dosage and administration and clinical study information. The labeling may also contain strengthened or black box warnings. Additionally, the FDA proactively assesses drug safety after it enters the marketplace, and postmarketing information can result in modifications to the approved prescription drug labeling.

Over the years, prescription drug labeling has been modified and changed to meet the needs of health care practitioners, and to facilitate the use of approved labeling to make prescribing decisions. For example, prescription drug labeling now contains a Highlights section, which a high-level summary of the drug information.

Dailymed is an online source of information about marketed prescription drugs and is the official provider of FDA prescription drug labeling information. The National Library of Medicine (NLM) provides this as a public service and does not accept advertisements. The drug labeling information on this site is the most recent submitted to the Food and Drug Administration (FDA).

Although patients may obtain useful information from FDA approved prescription drug labeling, its primary purpose is to give healthcare professionals the information they need to prescribe drugs appropriately. Failure to consider these healthcare considerations could result in professional misconduct issues for the licensed practitioner.

New York State requires that all prescription medications that are prepared and dispensed by a pharmacist to a patient, based upon a patient specific prescription written by a person legally authorized to prescribe, have a prescription label affixed to the immediate medication container. Patient specific medication labels must contain the following information: the pharmacy name and address, the date prepared, the prescription serial number, the name of the prescriber, the name and address of the patient, the drug name, strength, and the directions for the use of the drug by the patient as given upon the prescription.

The 2012 New York State budget contained an initiative named the "SafeRx statute." Education Law §6830 required the development of regulations for the use of standardized patient-centered data elements on all prescription medication labels. This labeling is intended to increase patient understanding and compliance with medication regimens. At that time, the Boards of Pharmacy and Medicine reviewed studies conducted by the United States Pharmacopeia and by the National Association of Boards of Pharmacy in the development of patient centric prescription labeling. The result was regulation that outlined both critical and important elements required to be on all prescription labels.

The critical elements of a prescription label are: patient name, directions for use by the patient, which directions shall be structured in full sentences, and drug name and strength. The critical elements must be emphasized by being highlighted in color, in bold type or both and must be printed in a minimum of 12-point font.

The important elements on the prescription label includes the following: name, address and telephone of the pharmacy, patient's address, prescriber name, date of preparation, and prescription serial number. Important elements of each prescription label and any other information contained on the label cannot be highlighted in color or in bold type and shall not be presented in a manner that undermines the emphasis on the critical elements.

Prescription labeling and drug safety are evolving issues and the State Education Department and the health care boards all remain up to date as circumstances change.