

THE STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY

57 Regional Drive
Concord, N.H. 03301-8518



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October 20, 1998

Jane Axelrad
Associate Director For Policy
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fisher Lane, HFD-005
Rockville, MD 20857

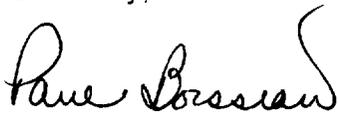
Dear **Ms. Axelrad:**

On behalf of the New Hampshire Board of Pharmacy, I am submitting the enclosed Memorandum of Understanding (MOU) for acceptance, as an exhibit, by the Food and Drug Administration. We believe this MOU satisfies the requirements of Section 127, "Pharmacy Compounding" of the Food and Drug Modernization Act of 1997 relative to the compounding and distribution of certain drugs prepared by pharmacists.

It is our understanding that the FDA is currently working with the National Association of Boards of Pharmacy in the development of a standardized MOU for use by the various states. When that prototype is finalized, the NHBOP will then negotiate that MOU with FDA.

Thank you for your attention to this matter and we look forward to your reply.

Sincerely,


Paul G. Boisseau, R.Ph.
Executive Secretary
FOR THE BOARD

cc: Carmen Catizone, NABP
Elizabeth Hiner, FDA

98D-0272

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**THE STATE OF NEW HAMPSHIRE
BOARD OF PHARMACY**

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**Memorandum of Understanding
(Exhibit)**

Between

New Hampshire Board of Pharmacy

And

The Food and Drug Administration

I. INTRODUCTION

Pursuant to Section 127, "Pharmacy Compounding" of the Food and Drug Modernization Act of 1997, the New Hampshire Board of Pharmacy (NHBOP) has developed this memorandum of understanding (MOU) to address specific issues related to compounded drugs. The purpose of this MOU is to provide specific guidelines on the dispensing of compounded drug products.

II. INVESTIGATION OF COMPLAINTS OF COMPOUNDED DRUGS SENT OUT-OF-STATE

In general, the board of pharmacy in the state in which the compounding pharmacy is located will investigate complaints about compounded drugs that are shipped out of state. That Board of Pharmacy (in the state where the compounding pharmacy is located) may obtain the assistance of the board of pharmacy that is located in the state where the compounded drug was shipped.

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If the complaint involves a death or serious injury to the patient, either board of pharmacy (in the state where the drug was shipped or the state where the compounding pharmacy is located) may initiate the investigation. A serious injury is defined as any experience that is fatal, life threatening, permanently disabling, requires inpatient hospitalization, or overdose due to formulation. In a case involving a death or serious injury, the boards of pharmacy will coordinate to determine which board will investigate the complaint. The result of any investigation of a complaint may be shared with the other board.

III. INORDINATE DISTRIBUTION OF COMPOUNDED DRUGS OUT-OF-STATE

A pharmacy may dispense compounded drugs interstate in an amount greater than 5% of its total drugs dispensed or distributed, provided that the pharmacy notifies the state board of pharmacy with which it is licensed or registered and provides additional information that may be required by that state board of pharmacy. The NHBOP shall develop procedures to implement this notification requirement. This notification shall not be instead of any other registration or licensure requirements that may be applicable to the pharmacy in the state into which it ships compounded drug products.

In addition, pharmacies that dispense a majority of their total compounded prescriptions interstate, must provide counseling to patients and a toll free telephone number, which is affixed to the label of the patient's medication. The pharmacy must be available at least 40 hours and 5 days a week, unless state rules require greater access to counseling services from nonresident or mail order pharmacies.

IV. COMPOUNDED DRUGS FOR OFFICE USE

A Pharmacy may compound drugs for the use of a licensed prescriber who administers or dispenses the drugs, in accordance with state law, to patients in the prescriber's office. However, a pharmacy may not dispense compounded drugs to a prescriber's office for the purpose of resale. Compounded medication for office use must be prepared pursuant to an order by a prescriber.