

STATE OF NEW HAMPSHIRE
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION

DIVISION OF HEALTH PROFESSIONS

BOARD OF PHARMACY

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To Whom It May Concern:

The New Hampshire Board of Pharmacy (“the Board”) has recently become aware that certain providers and dispensers in our state are engaged in compounding sterile products (“CSPs”) in a manner not in compliance with the NH State statutes and the Board’s rules. Specifically, the Board has concerns that some compounders may not be complying with USP 797 standards when compounding sterile intravenous (“IV”) products, and the Board is concerned this could pose a significant risk to patient health and safety. Thus, the Board is writing this letter to notify all those engaged in compounding of CSPs of the State and Board’s requirements for compliance to USP 797. The Board reminds those engaging in this activity that it is unlawful to compound sterile products without complying with the following requirements.

RSA 318:42, II allows various providers — physicians, dentists, optometrists, podiatrists, veterinarians, advanced practice registered nurses, naturopathic doctors, and physician assistants — to compound drugs to meet the immediate needs of their patients, so long as they do so in accordance with RSA 318:14-a.¹ RSA 318:14-a, I states, in relevant part, that “[a]ll compounding shall be done in accordance with the United State Pharmacopeia as defined by board of pharmacy rules.” Subsection V further states that the board of pharmacy shall adopt rules governing the regulation of compounding.

The Board’s rules governing compounding can be found at Chapter 404 of the Board’s rules. Ph 404.01(b) states:

The board shall require all compounders engaging in compounding in all situations to adhere to and comply with the current edition of the United States Pharmacopeia including but not limited to Chapters 795 (USP 795) and 797 (USP 797), following those guidelines that apply to their practice setting. These chapters shall be reviewed in full and followed by compounders prior to non-sterile or sterile pharmaceutical compounding. These regulations shall apply to non-sterile and sterile compounding of medications.

¹ Nurses and physician assistants are further limited in the types of compounding they can perform by RSA 318:42, VIII.

The United States Pharmacopeia Chapter 797 (“USP 797”) governs the compounding of all sterile products. Thus, all those engaged in sterile compounding in all situations are required to adhere to and comply with the requirements of USP 797.

USP 797 does have an Immediate-Use provision which is intended for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for Low-Risk CSPs subjects the patient to additional risk due to delays in therapy. Preparations that are Medium-risk level or High-risk level CSPs shall not be prepared as immediate-use CSPs.

USP 797, the compounding of certain IV products, such as Remicade®, is considered a Medium Risk Level compounded sterile preparation (“CSPs”) because it involves more than three manipulations in transferring the product from the manufactured sterile package to the sterile IV bag. Medium Risk CSPs must be compounded per USP 797 standards which require that the compounding be done in a compliant segregated compounding area restricted to sterile compounding activities, to reduce the risk of contamination of the product.

The Board understands that some entities or individuals may not be complying with USP 797 standards when compounding CSPs such as Remicade® in either clinics or in patients’ homes. Use of Compounded Sterile Products compounded outside USP 797 standards — as required by state statute and Board adopted rules — may pose a significant risk to patient health and safety.

Any entity or individual engaged in this practice must cease doing so no later than January 1st, 2018. This is meant to allow practices and other entities to make the necessary arrangements to procure or compound these medications for patients properly, without an interruption in patient care.

Any questions please contact the Board office at 603-271-2350.

Sincerely,



Michael Bullek, BSP, R.Ph.
Administrator/Chief of Compliance
New Hampshire Board of Pharmacy