STATE OF NEW HAMPSHIRE
OFFICE OF PROFESSIONAL LICENSURE AND CERTIFICATION
DIVISION OF HEALTH PROFESSIONS
BOARD OF PHARMACY
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OPLC

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Licensing Supervisor

December 19, 2017

To whom it may concern:

On or about November 28, 2017, the New Hampshire Board of Pharmacy ("the Board") sent a notification concerning the compounding of sterile products. Specifically, the Board noted that it had concerns that some compounders may not be complying with USP 797 standards, state law, and board rules when making Compounded Sterile Products ("CSPs"). Such practice creates an unwarranted and significant risk to patient health and safety.

Due to confusion, the Board now writes to clarify that the letter dated November 28, 2017 was not a cease and desist order. Rather, the letter was intended to provide an informational notice to licensees and practitioners to inform them of the Board's interpretation of its statutes and rules.

At an emergency meeting on December 18, 2017, the Board voted to stay enforcement of the Board's interpretation of USP 797 as outlined in the November letter until February 1, 2018. Specifically, the letter dated November 28, 2017 noted that the Board would not seek to enforce the cited provisions of its laws, rules, and the USP 797 standards until January 1, 2018; the Board has stayed this for those affected by the letter until February 1, 2018. The Board has done so to provide time for patients to obtain alternative means to obtain their medication, for providers to develop compliance plans and to allow for additional public comment.

The Board will also hold a public discussion concerning the November 28, 2017 letter at the next regularly scheduled meeting, on January 17, 2018 at 11:00 am. This discussion will run for one hour with a limit of ten minutes per speaker for public comment, at the Board's discretion. Written comment will be accepted up to January 10, 2017 for Board review and can be mailed to the Board office at Philbrook Building, 121South Fruit Street, Suite 401, Concord, N.H. 03301.

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

Regards,

Michael D. Bullek BSP, R.Ph.
Administrator/Chief of Compliance
For the Board

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November , 2017

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 CPSs.

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