



April 15, 2020

Philip Trapskin
[redacted]
[redacted]

RE: Variance Request per Wis. Stat. § 450.02(3m)

Dear Mr. Trapskin,

On April 14, 2020, the Wisconsin Pharmacy Examining Board reviewed your variance request. You requested a variance of Wis. Stat. § 450.07(1) and Phar 12.03(1) to **temporarily allow the manufacturing of needed personal protective equipment (PPE) without a license, an inspection, or compliance with FDA regulations**. The stated purpose of the request is to mirror similar actions taken by the federal government to allow manufacturers of other goods to manufacture masks during the COVID-19 emergency.

The effect of the variance would modify Wis. Stat. § 450.07(1) to read as follows:

(1) Except as provided under sub. (1m), no person may engage in manufacturing in this state unless the person obtains a manufacturer's license from the board, except that a person may engage in the manufacturing of personal protective equipment without a license during a period of declared emergency under Wis. Stat. § 323.10. For the issuance of a license under this subsection, the applicant shall pay the initial credential fee determined by the department under s. 440.03 (9) (a).

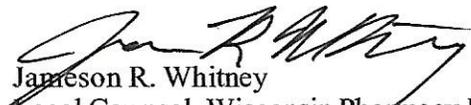
The variance would also modify Phar 12.03(1) to read as follows:

(1) No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter except that a person may engage in the manufacturing of personal protective equipment without a license during a period of declared emergency under Wis. Stat. § 323.10. The board shall not require any such person to comply with the federal regulations referenced in Phar 12.04 and 12.05 insofar as such regulations are relaxed or waived by the appropriate federal agencies during the declared emergency.

The Board considered the evidence presented and determined that the requirements of Wis. Stat. § 450.02(3m)(a) have been met. **Your variance, as requested, has been granted.** This variance shall apply to all persons seeking to manufacture PPE on a temporary basis in the state of Wisconsin, and shall remain in effect for 90 days from today's date pursuant to Wis. Stat. § 450.02(3m)(b), unless modified or extended by further action of the Pharmacy Examining Board.

Please feel free to contact me if you have any questions.

Sincerely,


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