



July 31, 2020

Philip J. Trapskin
[redacted]
[redacted]

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

Dear Mr. Trapskin,

On April 15, 2020, the Wisconsin Pharmacy Examining Board granted a variance of Wis. Stat. § 450.07(1) and Wis. Admin. Code § 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 was to mirror similar actions taken by the federal government to allow manufacturers of other goods to manufacture masks during the COVID-19 emergency. The Board later extended this variance to August 1, 2020. The Board considered whether to extend this variance on July 23, 2020, and determined that the requirements of Wis. Stat. § 450.02(3m)(b) have been met. The Board **modifies** the variance as follows:

The variance of Wis. Stat. § 450.07(1) now reads 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 or following a period of declared emergency ~~and for 90 days following the end of the 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 of Phar 12.03(1) now reads 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 or following a period of declared emergency ~~and for 90 days following the end of the 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.

The Board reminds any persons who are engaged in manufacturing in reliance on this variance that the Board is only relaxing requirements pertaining to federal regulations referenced in Phar 12.04 and 12.05 to the extent that the appropriate federal agencies relax or waive such regulations. This variance is hereby **extended 90 days**, unless modified, rescinded, or extended by further action of the Pharmacy Examining Board pursuant to Wis. Stat. § 450.02(3m)(b).

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

Sincerely,


Jameson R. Whitney

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