Pharmacy Examining Board 2/14/2022
C. Public Hearing: Clearinghouse Rule 22-007 (Phar 15), Relating to Compounding Pharmaceuticals

John Long
Director Regulatory Affairs, CVS Health

One CVS Drive
Woonsocket, RI 02895

p 614-572-9008
f 614-766-6957

john.long@cvshealth.com

Via Electronic Mail

February 10, 2022

Nilajah Hardin
Administrative Rules Coordinator
Department of Safety and Professional Services (DSPS)
Division of Policy Development
P.O. Box 8366
Madison, WI 53708-8366
DSPSAdminRules@wisconsin.gov

RE: Chapter Phar 15 Compounding Pharmaceuticals-Sterile Compounding

Dear Nilajah Hardin:

I am writing to you in my capacity as Pharmacy Regulatory Affairs Director for CVS Health and its family of pharmacies located across the country. CVS Health would like to thank the Pharmacy Examining Board ("Board") for their constant vigilance to continuously improve regulations that enhance patient care and guide the practice of pharmacy in Wisconsin. Through our integrated offerings across the spectrum of pharmacy care, we are uniquely positioned to provide greater access to care, engage plan members in behaviors that improve their health, and lower overall costs for health plans and their members. CVS Health provides multiple points of care to patients via our retail, mail, infusion, long-term-care, specialty pharmacies and Minute Clinics.

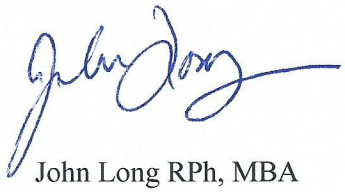
Based on the proposed revisions to Chapter Phar 15 from the Pharmacy Examining Board, CVS Health would like to provide the following comments on the new/amended rules.

While reviewing the Pharmacy Examining Board's draft language, there appears to be some confusion over the objective of the rule change. Specifically, the Board stated that it will not be moving forward with rulemaking to align with the 2019 revisions of the United States Pharmacopeia ("USP") chapter 797 at this time, because due to appeals filed, the 2019 revisions of USP 797 are currently on hold. In fact, the USP had published a newer proposed revision to the standard in 2021, which is still currently in the public comment period. However, the Board has included language specifically from the 2019 revision in contradiction of it's published intent. Specifically, Phar 15.37 uses "Category 1 and 2" as a basis to

establish beyond-use-dates. These "Categories" do not exist in the context of the current version of USP 797, but rather is language borrowed from the 2019 version that was never published. In essence, these Categories, without definition, are yet to become an applicable standard from the USP. Furthermore, if the Board is utilizing proposed/future revisions of the USP as a basis for this proposed rule, the newest revision contains 3 Categories, not 2.

This mix in terminology will create confusion to the pharmacy staff members and therefore, CVS Health requests clarity. CVS Health appreciates the opportunity to submit feedback on these Phar 15 rules in Wisconsin. If you have any questions, please contact me directly at 614-572-9008.

Best regards,



John Long RPh, MBA

cc: Jameson Whitney, Esq.

From: Brian Koenig
To: DSPS Admin Rules
Subject: USP 795, 797, 800, 825 & WI PHARM 15
Date: Monday, February 14, 2022 6:44:24 PM

Dear Board.

Thank you for the opportunity to talk in the public Pharmacy Board meeting as a guest. I do apologize if my selection of time to speak was in the wrong location per your meeting protocols.

As asked by Nilajah Hardin to summarize, my concern was if the WI Pharmacy Board have any plans to add to the current WI PHARM 15 or to adopt what will be federally approved in future months by the USP and FDA. As I read the current PHARM 15, it doesn't reconcile with the current USP 797 v2008 which is enforceable nor any of the proposed versions like 2019 and 2021. The lack of reconciliation can lead pharmacies to invoke standards that are not as stringent as what is currently enforceable on the federal level. For example, I do not believe the current PHARM 15 discusses testing the PEC (cleanbenches, BSC, isolators) nor the SEC (classified cleanrooms) on a semiannual basis, viable sampling protocols, nor HD compounding in details that are already established in the enforceable USP 797 v2008. I read several years back, that for federal monies to be received for pharmacy compounding, the pharmacy compounding facility must adhere to USP documents or similar. This being a document from the CMS and published in the public domain.

Some of the discussion afterwards today in which the public could not participate, was centered on why a blanket statement can not be used for compounding pharmacies to adhere to the most current enforceable version of USP 795, 797, 800, and 825. I would state that like the WI State Regulation SPS 332.24 Ventilation [29 CFR 1910.94} which is basically WI chemical fume hood operational requirements, that you could consider the adoption of the USP compounding documents and then add statements that the WI Pharmacy Board considers essential. These additional requirements could help to resolve concerns of "should" aspects to "shall" aspects as mentioned in today's meeting. One such requirement that is currently in WI PHARM 15 in which I would professionally recommend to remain a part of WI PHARM 15 is the requirement of a CNBT certified or similar technician to test/certify these compounding facilities.

If I can clarify or be of any additional assistance, please contact me.

As the former owner of Wisconsin Air Flow, Inc that worked in this area of test/certification, member on 2 of the CETA application guide taskforces involved in USP compounding protocols and over 30 years of experience in this field I the State of Wisconsin, I would be happy to be of any professional assistance in this endeavor to bring Wisconsin PHARM 15 compounding regulations to reconciling or exceeding the federal standards.

Brian L Koenig, PE, MBA, CNBT
bkoenig@techsafety.com
Technical Safety Services

TO: John Weitekamp, Chairman
Pharmacy Examining Board

FROM: Danielle Womack, Vice President of Public Affairs
Pharmacy Society of Wisconsin

DATE: 14 February 2022

SUBJECT: Clearinghouse Rule 22-007 (Phar 15), Relating to Compounding Pharmaceuticals

On behalf of the Pharmacy Society of Wisconsin's nearly 4,500 members, I would like to thank you for the opportunity to share our thoughts on Phar 15 relating to compounding and for accepting stakeholder input throughout the entire rulemaking process.

The Pharmacy Society of Wisconsin is dedicated to patient safety and recognizes the need for updated regulations on compounding. We appreciate the Board's stance of updating the chapter despite the moving target of USP Standards to ensure Phar 15's alignment with 2008 USP Standards.

Based upon a review of CR 22-007 and consultation with our member experts, we have the following recommendations:

- Phar 15.30 through 15.36 use terminology such as "stored in a refrigerator" and "stored in a freezer" but do not dictate a specific temperature range. Beginning with Phar 15.37, the terminology refers to specific temperatures for refrigerated and frozen products.

  We recommend that the Board consider using consistent terminology to clarify appropriate temperature requirements across the chapter. By streamlining the language, pharmacies will better develop and maintain workflows and create standard operating procedures to ensure medications are stored appropriately.

- The revised Phar 15.34 states that no more than three commercially manufactured "packages" may be used in immediate-use compounding. There are settings in which more than three vials or packages of three or fewer products may be commonly mixed; this would no longer be allowed. The 2019 and 2021 proposed <797> revisions both use language specifying that immediate use compounds must not be prepared using more than three different sterile *products*.

  We recommend that the Board change the word "packages" to "products" to reflect better the requirements of USP <797> and contemporary practice.

Thank you for the opportunity to provide comments on the Phar 15 revisions and your consideration of our recommendations. I am happy to answer any questions you may have.