



TO: Members, Pharmacy Examining Board

FROM: Jeremy Levin, Director of Advocacy – Rural Wisconsin Health Cooperative
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DATE: January 9, 2018

RE: Clearinghouse Rule 16-085 Relating to Compounding Pharmaceuticals (Phar 15)

On behalf of our organizations and the members we represent throughout Wisconsin, we respectfully request that the Pharmacy Examining Board make the following changes to CR 16-085 in order to better align Wisconsin's state regulation with national best practices, while protecting patients and providing certainty to heavily regulated health care operators in this state:

1. Include a statement at the beginning of the rule stating the purpose of the rule:

“The intent of this regulation, Phar 15, is to create a state regulatory standard that aligns with compounding standards found in the United States Pharmacopeia (USP) general chapters. Every effort will be made by the Pharmacy Examining Board to assure that Phar 15 remains aligned, and not in conflict with, USP general chapters. In the event the requirements in this chapter directly conflict with any federal law or regulation, the federal law or regulation shall supersede the requirements in this chapter.”

2. Strike Section 15.31(3)(g).

3. Modify Section 15.31(3)(m):

- **Current Language:**

A minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.

- **Proposed Language:**

For classified areas physically separated through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02-inch water column is required to separate each classified area. If a pass through is used, only one door shall be opened at a time. A pressure gauge or velocity meter shall be used to monitor the pressure differential or airflow between classified areas with results documented at least daily.

4. Modify Section 15.31 (3)(o)

- **Current Language:**

The ante area and buffer area shall be separate rooms, with walls and doors between them and controls to prevent the flow of lower quality air into the higher ISO class areas. If a pass through is used, only one door shall be opened at a time.

- **Proposed Language:**

For classified areas not physically separated:

- The buffer and ante areas shall be designated with a line of demarcation
- The principle of displacement airflow shall be employed with an air velocity of 40 feet per minute or more from the buffer area across the line of demarcation.

No person shall compound using any ingredient that was at any time non-sterile in a classified area not physically separated.

Thank you for your consideration of these modifications. Please do not hesitate to contact us with any questions.