

Enforcement of USP 800 and USP 825

To address operational concerns raised by pharmacies and due to the continued community spread of COVID-19, the Board hereby adopts the following <u>resolution</u> on the enforcement of USP 800 and USP 825 as required by the Ohio Administrative Code:

The Board will be inspecting licensees to the standards set forth in OAC 4729:7-2 and 4729:5-6 beginning February 1, 2022. Board staff will be issuing written warnings to all licensees that are not yet compliant with these standards until August 1, 2022, after which time additional administrative action may occur. In addition to addressing or remediating any other noted violations in the written warning, licensees that are issued written warnings will be required to provide a written corrective action plan in accordance with rule 4729:5-3-03 that details the licensee's efforts to become compliant with these standards by the August 1, 2022, deadline.

Nothing in this resolution shall limit the Board from taking administrative action against a licensee that is engaged in the preparation of hazardous drugs or radiopharmaceuticals in a manner that presents a danger of immediate and serious harm to others.

For more information regarding the Board's hazardous compounding or nuclear pharmacy rules, please refer to the following resources:

Pharmacy Compounding: www.pharmacy.ohio.gov/pharmcompound

Radiopharmaceuticals: www.pharmacy.ohio.gov/nuclear

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