

## State of Idaho Division Of Occupational and Professional Licenses Board of Pharmacy

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RE: Compounding Drugs in Shortage

The Board has received many inquiries regarding the compounding of commercially available products while those products' statuses on the FDA's drug shortage list is contested. The Rules of the Board of Pharmacy provide that "[a] drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if ... [t]he commercial product is not reasonably available in the market in time to meet the patient's needs."

The FDA's drug shortage list provides a clear benchmark for when commercially available products are not reasonably available in the supply chain. But the Board's rule is not limited to that list. The Board recognizes that commercially available products may not be reasonably available in the supply chain for a host of reasons. So long as the product is not reasonably available in the supply chain to timely meet the patient's need and the pharmacy is not regularly compounding the product as part of its business but rather only in response to the need to make the product reasonably available, compounding the product would not run afoul of the rule.

For further information, please review the Board's pending rule, <u>IDAPA 24.36.01</u>.700.04: 04. Limited Compounding.

- a. Triad Relationship. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order.
- b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if:
- i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or
- ii. The commercial product is not reasonably available in the market in time to meet the patient's needs.