

# **Memorandum of Understanding (MOU) Discussion**

**FDA Meeting  
November 16, 2015**

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Minnesota Board of Pharmacy**

# MOU Agreement

- **“MOU establishes an agreement between the State and the U.S. FDA regarding the distribution of inordinate amounts of compounded human drug products interstate ...**
- **Authority of the Board of Pharmacy to:**
  - **Sign on behalf of the state**
  - **Inspect or investigate physicians who are compounding**

# MOU Definitions

- **MN definition: Practitioner means a licensed practitioner in the course of professional practice only, may prescribe, administer, and dispense a legend drug**
- **Would a separate MOU be required for each regulatory Board for licensees allowed to dispense under state law?**

# MOU Definitions

- **Dispensing versus distribution**
- **MN definition:**  
**Pharmacy means a place of business in which prescription drugs are prepared, compounded, or dispensed**
- **Under 503a, all compounded drug products need to be dispensed pursuant to a prescription**

# MOU Definitions

- **Distribution of inordinate amounts of compounded drug products interstate**
- **Definition of inordinate amounts**
  - **Units versus prescription orders**
  - **Inclusion of compounded & non-compounded units**

# MOU Agreement

- **“...the number distributed interstate is equal to or greater than 30 percent of the number of units of compounded and non-compounded drug products distributed or dispensed intrastate and interstate...”**

# MOU Agreement

- **“The state will notify the FDA...within 72 hours of receiving any complaint relating to a compounded human drug product distributed outside the State...**
- **Ability to meet time requirement**
- **Authority to require the entity to determine the root cause of the problem**
- **Current statues regarding sharing of information about complaints**

# MOU Agreement

- **“...review compounding records during inspection of compounding pharmacies...”**
- **Need a consistent approach**
  - **Required records & time periods**
  - **Frequency of inspections**
  - **Authority to audit physicians**

# MOU Agreement

- **“By signing this MOU, the State...affirms that is now possesses and will maintain...the legal authority...and the resources necessary to effectively carry out all aspects of this MOU.”**

# Contact Information

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