MISSOURI MOU REVIEW

Missouri Considered:

- Regulatory Applicability/Jurisdiction
  (Do we have legal authority?)
- Regulatory Feasibility (Can we do it?)
- Regulatory Resources (Can we afford it?)

Regulatory Applicability/ Jurisdiction

- Investigation Collaboration [Section III.a(1)]:
  - [Pharmacy Board and Medical Board] "*will cooperate in investigating any complaints involving overlapping jurisdiction.*"
  - **REC: "To the extent authorized by state law…."**

Regulatory Applicability/ Jurisdiction

- Investigations [Section III.a.(3)]:
  - **Determination** of whether there is a potential public health risk. Is this an official state finding?
  - Do we have legal authority?
  - **REC: Delete/Require investigation to "consider or review" public health risk.**

Regulatory Applicability/ Jurisdiction

- Complaint Resolution [Section III.a(4)]:
  - If the complaint is found to be valid…the State will take appropriate action to ensure that the pharmacist/pharmacy/physician determines the "**root cause of the problem**" and "**undertakes sufficient corrective action**."
  - Limited jurisdiction for BOP, DHSS & physicians (DHSS/MDs cannot seize drugs, test compounds, etc.)
  - **REC: "To the extent authorized by law…."; Retain discretion**

Regulatory Feasibility (Remedial Actions)

- Investigations [Section III.a.(3)]:
  - **Determination** of whether there is a potential public health risk. Is this an official state finding?
  - **Confirm** that public risk is **adequately contained**.
  - What does that mean/do we have the resources?
  - **REC: Delete/Require investigation to "consider or review" public health risk.**

Regulatory Feasibility (Inordinate Amounts)

- "The state of [Missouri] will review compounding records during inspections of compounding pharmacies to identify whether the compounding pharmacy**, or the compounding pharmacist** or physician is distributing inordinate amounts of compounded human drug products interstate."

Inordinate Amount Definition

- "A **pharmacist, pharmacy or physician** has distributed an inordinate amount of compounded human drug products interstate if the number **of units of compounded human drug products** distributed interstate during **any calendar month** is equal to or greater than 30 percent of the number of units of compounded and non-compounded products distributed or dispensed both intrastate and interstate by **such pharmacist, pharmacy or physician** during **that month**."

Regulatory Feasibility (Inordinate Amounts)

- Delivery/distribution method not required to be documented. **REC: Remove mandatory inspection requirement; Only require reporting/action if discovered.**
- Does this require an individual pharmacist determination? **REC: Limit language just to pharmacy.**

Inordinate Amount Definition

- Definition of units?
- 30% limit may be inadequate for pharmacies dispensing to neighboring states. **REC: ??? but higher than 30%.**
- What is the review period/expectation? **REC: "During THAT calendar month, reference calendar year or give designated time period.**
- Shared services arrangements
  - Rx exemption may not be helpful here

Inter-governmental Working Meeting on Drug Compounding and DSCSA

U.S. Food and Drug Administration
Silver Spring, Maryland

November 16-17, 2015