Prescription requirements

Iowa Board of Pharmacy
Sue Mears, RPh, Compliance officer

Implementation of DQSA

- *Legislative Action*
  - Senate File 453 approved through legislature, signed into law, effective July 1, 2016
    - Identifies Outsourcing facility as a licensure category
    - Identifies FDA warning letter as conclusive evidence of a violation of federal law (Outsourcing facility and pharmacy)
    - Provides more specific authority for IA BOP re: inspections of NR pharmacies
- *Rule making*
  - Comprehensive update of compounding rules completed
    - Effective November, 2015

Administrative rules

- *Requires compliance with USP 795/797*
  - Delayed enforcement until May 2016
- *Identifies Outsourcing facility*
  - Requires licensure in Iowa
- *Updates exception for compounding essentially a copy of an approved product*
  - Only allowed when creating a “clinically significant” change to meet a “medical” need
- *Addresses office stock compounding*
  - Directs that only Outsourcing facilities can provide non-patient-specific compounded products for office stock
  - Exception provided for veterinary office stock

Future rule updates

- *Rule making to incorporate SF 453 action*
  - Will provide detail on application and licensure requirements for Outsourcing facilities
  - Will require Outsourcing facilities also be licensed as a pharmacy in Iowa if dispensing pt-specific prescriptions
- *Incorporate language from draft FDA guidance*
  - Will propose to rules committee inclusion of criteria to determine if a compounded product is essentially a copy of an approved drug

Comments to rule making

- Proposed rule making offers comments be submitted by:
  - Governor's office
  - Public (public, pharmacies, practitioners, etc.)
  - Administrative Rules Review Committee
- Comments received re: office stock / prescription requirements for pharmacies
- Board response to comments
- Continued questions

Enforcement / Education

- Office stock prohibition communicated via:
  - Board meeting discussions
  - Rule making notification
  - Newsletter article
  - BOP's FAQ page / Facebook / Twitter
  - CO visits
- Routine inspections continue as normal
  - No evidence that pharmacies are providing office stock
- Inspection process to review compounding records
  - Review of compounding logs for all elements (ingredient information, staff involved, BUD, prescription number) as well as volumes of products
  - Batch compounding records must include documentation for each disbursement (prescription information)
- Retail pharmacies, in general, compounding very low volume of non-sterile, pt-specific compounds