

Prescription requirements

Iowa Board of Pharmacy
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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

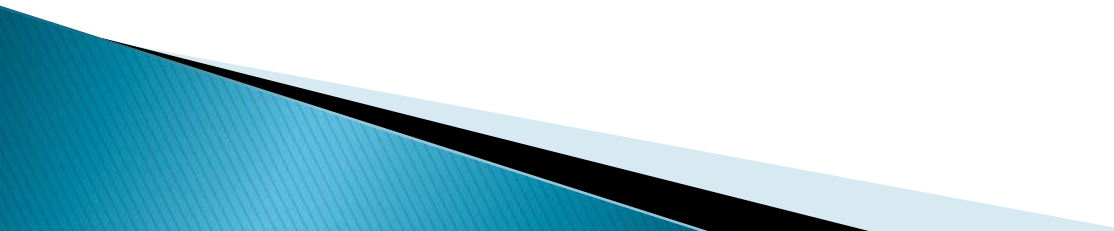
Administrative rules

- ▶ *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
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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
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