



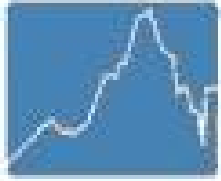
Department of Health Professions

Virginia Board of Pharmacy

FDA Inter-governmental Meeting on
Compounding

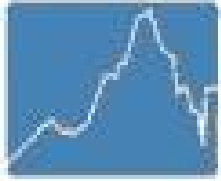
September 21, 2016

Caroline Juran, Executive Director



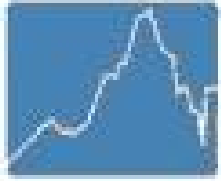
Licensing of Outsourcing Facilities

- HB 1737; effective July 1, 2015
- Created new licensing categories for outsourcing facility permits and nonresident outsourcing facility registrations
- Required pharmacy permit also when dispensing patient-specifically
- All compounding must comply with cGMPs
- Must obtain FDA registration



Licensing of Outsourcing Facilities

- Emergency regulations effective 12/7/15 through 6/6/17
- Board currently working on permanent replacement regulations



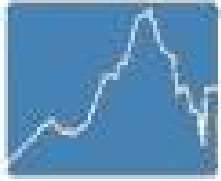
Licensing of Outsourcing Facilities

- Must submit “current” FDA inspection with initial application and annually for renewal
- “Current”
 - Performed within 1 year of submission of initial board application;
 - Performed within 2 years of annual renewal of board licensure.



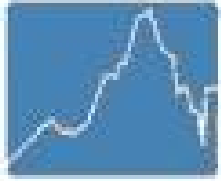
Licensing of Outsourcing Facilities

- If no FDA inspection within required timeframe, may:
 - accept inspection report or other documentation from another entity satisfactory to Board; or
 - Cause inspection to be conducted by Board's duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection



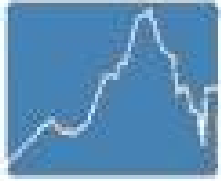
Licensing of Outsourcing Facilities

- Approximately 30 nonresident outsourcing facility applications received in 2016
- Approximately 10 could satisfy current inspection requirement
- Request for Board to accept inspection report from a compliance auditing company for licensure purposes
- Approved concept September 7th, but not implemented as of yet



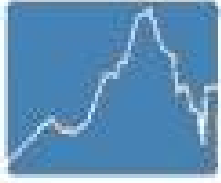
Licensing of Outsourcing Facilities

- FDA inspection must still be submitted if performed within required timeframe
- Outside entity will directly charge facility for inspection



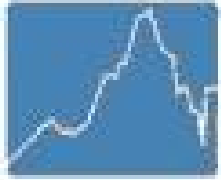
Licensing of Outsourcing Facilities

- Criteria used when considering outside entity:
 - Significant experience performing inspections or assisting companies in complying with cGMPs;
 - Inspector resumes – diversification in education (pharmacists, former FDA inspectors, device engineering, etc.)
 - Policies and procedures for performing inspections
 - Modeling FDA process for performing inspections



Licensing of Outsourcing Facilities

- Criteria used when considering outside entity:
 - Requirement for entity to share inspection report with board, facility's written corrective action, and summary review regarding appropriateness of submitted corrective action



Department of Health Professions

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