



# DEA DISTRIBUTOR'S CONFERENCE 2015



**Mike Burleson, R.Ph.  
Executive Director  
Board of Pharmacy**

# Educational Purposes Only

- This presentation does not constitute legal advice. Issues of pharmacy law are fact specific. As such, specific questions should be referred to your legal counsel.
- The opinions expressed are those of the presenter and should be confirmed and/or researched by those utilizing them in their pharmacy practice.



# Disclosure Statement

I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of the above stated continued education program.



# Board of Pharmacy Purpose

- The purpose of the Board is to promote, preserve, and protect public health, welfare, and safety by and through effective control and regulation of the practice of pharmacy.



# Board of Pharmacy

WHOLESALE DISTRIBUTORS

MANUFACTURES

THIRD PARTY LOGISTIC PROVIDERS

AS PHARMACISTS AND PHARMACIES ALL  
HAVE A RESPONSIBILITY TO BE SURE THAT  
DRUGS ARE SAFE!



# Wholesale Distributor

KRS 315.400: Definitions:ADR, End User, NDC, TPLs (will discuss later), Exemptions,

Wholesale Distributor: means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, wholesale distributors, 3PLs, third-party return processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.

<http://www.lrc.ky.gov/statutes/statute.aspx?id=31042>



# Wholesale Distributor

KRS 315.402:

Licensure of Wholesale Distributors of prescription drugs

Record Retention (must be kept five years)

Administrative Regulations (201 KAR 2:320)

Confidentiality (SS numbers of owners/officers): 201 KAR  
2:105 Section 4

<http://www.lrc.ky.gov/statutes/statute.aspx?id=31043>



# Wholesale Distributor

KRS 315.404: Return or exchanges of prescription drugs

- (1) (a) A Wholesale Distributor may receive prescription drugs returns or exchanges from a pharmacy, pharmacy warehouse, or other person authorized to distribute a prescription drug to an end user under the terms and conditions of an agreement between the parties.
- (2) Shall supply prescription drugs only to a person or entity licensed to possess or distribute prescription drugs to an end user.
- (3) Only delivered to the business address



# Wholesale Distributor

KRS 315.404: Return or exchanges of prescription drugs

(4) A licensed Wholesale Distributor, pharmacy, or other person authorized by law to furnish prescription drugs to an end user shall be accountable for their return process and shall ensure that all aspects of their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.



# Wholesale Distributor

KRS 315.406: Prescription Drug Pedigree for drugs leaving normal distribution channel

<http://www.lrc.ky.gov/statutes/statute.aspx?id=31045>



# Wholesale Distributor

KRS 315.408: Electronic Track and Trace System

<http://www.lrc.ky.gov/statutes/statute.aspx?id=31046>



# Wholesale Distributor

KRS 315.410: Order to cease distribution of prescription drugs; hearing.

1. The Board can issue an order to cease distribution of prescription drugs if: in violation of KRS 315.406, if prescription drug is accompanied by a falsified pedigree in violation of KRS 315.406, or the prescription drug is a counterfeit prescription drug.
2. Right for administrative hearing within 10 days after the date of the order.



# Wholesale Distributor

KRS 315.412: Penalties for violation of KRS 315.400 to  
KRS 315.410

1. Unknowingly violates: \$5,000
2. Acts with gross negligence and violates: \$15,000
3. Knowingly violates: \$100,000

<http://www.lrc.ky.gov/statutes/statute.aspx?id=31048>



# Wholesale Distributor

If shipping controlled substance drugs within or into Kentucky must also be licensed with the Office of Drug Enforcement and Professional Practices of the Kentucky Cabinet for Health and Family Services.

<http://chfs.ky.gov/NR/rdonlyres/DE6BB40F-51D1-425E-9B04-7444814CE03E/0/DEPPBNewCSLicenseApplicationForm012215.pdf>



# Wholesale Distributor

If located in Kentucky must submit application and must be inspected by a Pharmacy and Drug Inspector of the Board prior to opening/storing drugs.



# Wholesale Distributor

<http://www.lrc.state.ky.us/kar/201/002/105.htm>

1. Definition
2. Requirements
3. Qualifications for License
4. Application, Fees, Renewals
5. Standards: facilities; security; recordkeeping; written policies and procedures; returned, damaged and outdated; handling recalls; visual examination



# Wholesale Distributor

## ISSUES:

Pharmacies are not receiving their controlled substance orders due to going over threshold quantity set by Wholesale Distributors.

DEA has set quotas or thresholds:

Individuals from Wholesale Distributor go to pharmacy and ask how many prescriptions have been refused.



# Wholesale Distributor

Question: Could a Wholesale Distributor be disciplined by a Board of Pharmacy for not fulfilling an order submitted to the Wholesale Distributor and the reason be because of a reason of over threshold and/or quotas?

Board of Pharmacy Purpose:

KRS 315.121(3)



# Wholesale Distributor

Wholesale Distributors have contacted Boards about suspicious orders by pharmacies.



# Third Party Logistic (3PLs)

Drug Quality and Security Act prohibits states from licensing as Wholesale Distributors.

1. Legislation has been introduced and passed in some states regarding new licensing of 3PLs.
2. Some states will be introducing legislation
3. Some states may not require licensure



# MANUFACTURER

KRS 315.036

Board only requires licensure of Manufacturer located in Kentucky. If Manufacturer is located outside of Kentucky, it is not required to be licensed unless shipping prescription drugs into Kentucky, then licensed as a Wholesale Distributor.

<http://www.lrc.ky.gov/statutes/statute.aspx?id=30994>



# MANUFACTURER

201 KAR 2:320. Permit requirements

1. Requirements
2. Qualifications for Permit
3. Application, Fees, Renewals
4. Standards: facilities; security; recordkeeping; written p & p; returned, damaged, and outdated; handling recalls; visual inspection
5. Pharmacist-in-charge

<http://www.lrc.state.ky.us/kar/201/002/320.htm>



# QUESTIONS



# CONTACT INFORMATION

MICHAEL BURLESON, R.Ph.

EXECUTIVE DIRECTOR

KENTUCKY BOARD OF PHARMACY  
STATE OFFICE BLDG ANNEX, STE 302

125 HOLMES STREET

FRANKFORT KY 40601

502-564-7910

502-696-3806 FAX

WEBSITE: [pharmacy.ky.gov](http://pharmacy.ky.gov)

EMAIL: [pharmacy.board@ky.gov](mailto:pharmacy.board@ky.gov)

[mike.burleson@ky.gov](mailto:mike.burleson@ky.gov)

