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I certify that the attached copies are true, full and correct copies of the TEMPORARY Rule(s) adopted on 06/11/2015 by the
Board of Pharmacy 855

Agency and Division

Administrative Rules Chapter Number

Karen MacLean

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Rules Coordinator

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Address

To become effective 07/01/2015 through 12/27/2015.

RULE CAPTION

Amends record keeping requirements in Drug Distribution Agent rules.

Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION

Secure approval of new rule numbers with the Administrative Rules Unit prior to filing.

ADOPT:

AMEND:

855-062-0040

SUSPEND:

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155

RULE SUMMARY

Amendments update record keeping requirements for Drug Distribution Agents. These amendments identify the information that a Drug Distribution Agent who distributes product to a Wholesaler or Pharmacy must contain in their records. Amendments also reflect that a pedigree must be maintained if a Drug Distribution Agent distributes product to another Drug Distribution Agent.

Karen MacLean

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Rules Coordinator Name

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Secretary of State
STATEMENT OF NEED AND JUSTIFICATION
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accompanies this form

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Board of Pharmacy
Agency and Division

855
Administrative Rules Chapter Number

Amends record keeping requirements in Drug Distribution Agent rules.

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of:

Record keeping requirements for Drug Distribution Agents

Statutory Authority:

689.205

Other Authority:

Statutes Implemented:

689.155

Need for the Temporary Rule(s):

The amendments to these rules are needed to coincide with new and amended rules for Drug Distribution Agents, Manufacturers, and Wholesalers that become effective July 1, 2015. These rules identify the information that must be maintained when a Drug Distribution Agent distributes product to a wholesaler or pharmacy. Amendments also direct Drug Distribution Agents to maintain and provide to the recipient of the distribution a pedigree when one Drug Distribution Agent distributes product to another Drug Distribution Agent.

Documents Relied Upon, and where they are available:

Drug Supply Chain Security Act (DSCSA) available at:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm>

Title II of the Drug Quality and Security Act (DQSA) available at:

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>

Justification of Temporary Rule(s):

Without this temporary rule Drug Distribution Agents will not be required to keep adequate records in addition, record keeping requirements and standards will be inconsistent with Wholesalers rules.

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