HB5529

LRB09720442CELb

97TH GENERAL ASSEMBLY

State of Illinois

2011 and 2012

HB5529

by Rep. Randy Ramey, Jr.

SYNOPSIS AS INTRODUCED:

225 ILCS 120/57.5 new

Amends the Wholesale Drug Distribution Licensing Act. Creates a provision concerning general pedigree requirements. Provides that each prescription drug manufactured in each stage shall have a drug identification number that is assigned by the manufacturer to initiate pedigree tracking. Sets forth the general requirements of assigning, labeling, and transferring documents containing a drug identification number with each prescription drug manufactured. Effective immediately.

LRB097 20442 CEL 65941 b

A BILL FOR

AN ACT concerning regulation.

Be it enacted by the People of the State of Illinois, represented in the General Assembly:

Section 5. The Wholesale Drug Distribution Licensing Act is amended by adding Section 57.5 as follows:

(225 ILCS 120/57.5 new)

Sec. 57.5. General pedigree requirements.

(a) For the purposes of this Section:

"Drug identification number" or "DIN" means a series of Arabic numbers and Roman letters that is assigned to a prescription drug for pedigree transaction identification purposes.

(b) Each prescription drug manufactured in each stage shall have a DIN that is assigned by the manufacturer to initiate pedigree tracking. Each drug manufactured in more than one stage shall have a DIN assigned by the incomplete drug manufacturer. Drug ingredient manufacturers, manufacturers, wholesalers retailers, and providers shall maintain an original assigned DIN with the documentation as specified in subsection (c) of Section 57 of this Act and shall utilize the DIN assigned by the original manufacturer of the drug.

(c) Each DIN shall consist of the components of the National Directory Code number as defined by the FDA, such as

an identification of the drug, strength, size of package, and manufacturer, followed by an Employer Identification Number (EIN), the date of receipt, and a transfer to each party handling the inventory.

(d) The DIN shall be appended and modified with the EIN and data in progression on the drug packaging or record of movement and on any transfer documents containing the updated DIN prepared by the manufacturer and documented by each party as it is given from one party to the next.

(e) The DINs of any 2 drug lots manufactured within a 30-year period shall not be identical.

(f) The DIN of each drug package shall appear clearly and indelibly upon either a part of the drug packaging or container that is not designed to be removed except for repair or upon a separate plate or label that is permanently affixed to such a part.

Section 99. Effective date. This Act takes effect upon becoming law.