F I S C A L I M P A C T R E P O R T

SPONSOR Campos **ORIGINAL DATE** 2/8/18 **LAST UPDATED** **HB**

SHORT TITLE Pharmacy Act Licensure & Registration **SB** 258/aSRC

ANALYST Chilton

REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY18	FY19	FY20		
	See Fiscal Implications	See Fiscal Implications	Recurring	Pharmacy Fund

(Parenthesis ( ) Indicate Revenue Decreases) *See Fiscal Impact below

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY18	FY19	FY20	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	NFI	Minimal	Minimal	Minimal	Recurring	Pharmacy Fund

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Response Received From
Regulation and Licensing Department (RLD)

Response Not Received From
Department of Health (DOH)

SUMMARY

Synopsis of SRC Amendment

The Senate Rules Committee amendment strikes the terms “manufacturers” and “manufacturer’s warehouses” from the list of those persons or entities considered in the definition of “wholesale drug distributor.” Remaining behind in the definition section HH are own-label distributors, private-label distributors, jobbers, brokers, distributor's warehouses, chain drug warehouses, wholesale drug warehouses, independent wholesale drug traders and retail pharmacies that conduct wholesale distribution.

Synopsis of Original Bill

Senate Bill 258 amends the Pharmacy Act (Section 61-11-2 NMSA 1978), adding definitions of "outsourcing facility", "repackager," and "third-party logistics provider." The definitions are summarized as follows:

- Outsourcing facility – a single-address facility registered with the federal government to compound sterile drugs. (FDA definition)
- Repackager - perform[s] the operations a formulator would handle if the formulator were packaging the product into consumer-sized containers. (FDA definition)
- Third-party logistics provider - an entity that provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of a product but which entity does not take ownership of the product nor have responsibility to direct the sale or disposition of the product (definition in SB 258)

Outsourcing facilities and repackagers are then added (in Section 61-11-9.1) to the groups requiring surety bonds for initial or renewal licensure. All three types of entities defined above are added to Section 61-11-14 to the list of types of licenses to be issued by the Board of Pharmacy, with a fee set for each license of up to one thousand dollars. The three types of facility are also added to those that might be penalized (in Section 61-11-20) by suspension or revocation of licensure if their state licensure or federal registration is suspended or revoked.

Several changes in syntax are made elsewhere in the Pharmacy Act that do not change the meaning of those passages.

FISCAL IMPLICATIONS

RLD, which includes the Board of Pharmacy, does not indicate a cost to the agency in licensing these new types of provider. In fact, existing repackagers, third-party logistics providers, and outsourcing facilities are licensed currently as wholesale drug distributors. The Board of Pharmacy does not anticipate changing the licensing fees charged to these types of entities, which currently are set at $700 every two years.

SIGNIFICANT ISSUES

RLD indicates the reasoning for adding these definitions as follows:

> This bill will allow the board to maintain oversight of these facility types in a manner reflective of facility operation; it will harmonize board licensure and regulation of these license types with recently enacted federal law.
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> In 2013, the Drug Quality and Security Act, Pub.L. No. 113-54 (DQSA) created a new category of drug compounders, termed "outsourcing facilities". Outsourcing facilities engage in a type of manufacturing. The board licenses manufacturers, but, given the fundamental differences between traditional manufacturers and outsourcing facilities, a separate license class will help the board to maintain appropriate oversight.
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> The DQSA preempts a state from regulating a third party logistics provider as a wholesale drug distributor, and excludes re-packager from the definition of wholesale

distributor. The board historically licensed and regulated re-packagers and third party logistics providers as wholesale drug distributors.

This amendment to the Pharmacy Act is necessary and required to avoid conflict with federal law, and enable the board to maintain effective oversight of these entities.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

RLD states that, if the bill were not passed, "The board [of pharmacy] may face challenges over statutory authority to regulate these facilities, and will face challenges created by inconsistencies with federal law. Regulation of these entities serves to protect the health and safety of the public by preserving drug supply chain integrity; and enforcement of operational standards, including for sterile compounded products.

LAC/al/jle