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

SPONSOR Campos **ORIGINAL DATE** 2/7/19 **LAST UPDATED** 2/25/19 **HB**

SHORT TITLE Pharmacy Licensure & Registration Compliance **SB** 271/aSPAC/aSJC

ANALYST Daly

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY19	FY20	FY21	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total		NFI	NFI	NFI		

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From

Regulation & Licensing Department (RLD)
Board of Nursing (BN)
Human Services Department (HSD)
Medical Board (MB)
New Mexico Attorney General (NMAG)

SUMMARY

Synopsis of SJC Amendments

The Senate Judiciary Committee amendments to Senate Bill 271, as amended by SPAC, strike SPAC's amendments 1, 3, 4 and 5, which restore the communication protection contained in Section 6(B) of the original bill, leaving in effect the SPAC amendment removing manufacturers from the definition of wholesale drug distributor. SJC amendment 3 then strikes all of Section 6, removing both the liability and communications protections contained in the original bill. The SJC amendments also strike language in the title to the bill referring to those protections, consistent with its other amendments.

Synopsis of SPAC Amendment

The Senate Public Affairs Committee amendment to Senate Bill 271 strikes the language in Section 6(B) providing that communications to the board relating to disciplinary actions are not

public records. It also removes manufacturers from the definition of wholesale drug distributor.

NMAG comments that as to public records, the net effect of the amendment maintains the status quo: communications and information related to disciplinary matters remain subjection to inspection under the Inspection of Public Records Act.

Synopsis of Original Bill

Senate Bill 271 amends the Pharmacy Act (Act) to authorize three new categories of licenses to:

- Outsourcing facilities, defined as a facility at one location or address that compounds sterile drugs and is currently registered with the United States Food and Drug Administration (USDA);
- Repackagers, defined as a person who repackages a drug, including a medicinal gas, and is registered as a drug establishment by USDA; and
- Third-Party Logistics Providers, defined as a person who 1) provides or coordinates warehousing or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor or dispenser of that product; but 2) does not take ownership of the product and is not responsible for direct sale or distribution of the product.

SB 271 sets the licensing requirements and fees at the same rate as exists for wholesale drug distributors, and provides the same grounds for disciplinary proceedings which could lead to suspension or revocation of a license, as well as adding additional grounds that apply to any person or entity licensed by the board. Surety bonds are required for these new license categories, subject to the existing provision that multiple locations or affiliated companies do not need to provide separate bonds.

SB 271 also replaces the educational requirement for licensure as a pharmacist intern from not less than 30 semester hours in a school or college of pharmacy or its equivalent to whatever educational requirements are established by the board.

In Section 6, this bill provides that communications to the board relating to disciplinary actions are not public records. It also grants civil and criminal immunity to board members, staff, and persons who provide information to the board in good faith.

FISCAL IMPLICATIONS

No fiscal impact is anticipated. The Pharmacy Board historically has licensed and regulated repackagers and third party logistic providers as wholesale drug distributors at the same licensing fee provided in this bill, so no impact in revenue or operating budget should result from the issuance of these two new categories of licenses. Similarly, no estimate for the new category of outsourcing facility licenses has been provided, and RLD has reported no additional revenue or budget impact related to this license category.

SIGNIFICANT ISSUES

RLD advises that this bill allows the board to maintain oversight of these facility types in a manner reflective of facility operation and will harmonize board licensure and regulation of these

license types with recently enacted federal law. It explains that in 2013, a new category of drug compounders, termed "outsourcing facilities," was recognized in the federal Drug Quality and Security Act, Pub.L. No. 113-54 (DQSA). According to RLD, outsourcing facilities engage in a type of manufacturing, and the board has traditionally licensed manufacturers, but given fundamental differences between traditional manufacturers and outsourcing facilities, a separate license class will help the board maintain appropriate oversight.

Further, the board historically licensed and regulated repackagers and third party logistics providers as wholesale drug distributors, but that federal law now preempts a state from regulating a third party logistics provider as a wholesale drug distributor, and excludes repackagers from the definition of wholesale distributor. Updating the Act will avoid conflict with federal law, and enable the board to maintain effective oversight of these types of entities.

The provisions of Section 6 provide for all-encompassing nondisclosure of records. RLD notes that it mirrors that contained in the Medical Practice Act and prevents any release of written and oral communications relating to potential and actual disciplinary action at any time except as necessary to carry out the board's purposes or in a judicial appeal from the board's actions. See Section 61-6-34, NMSA 1978. In contrast, provisions of other health care licensing boards provide that complaint records become public upon an action by the board. Under the Chiropractic Physician Practice Act the records may be disclosed once the board acts on a complaint. See Section 61-4-10(C), NMSA 1978. Under both the Dental Health Care Act and the Osteopathic Medicine Act records may be disclosed when the board either issues a notice of contemplated action (NCA) or reaches a settlement prior to the issuance of the NCA. See Sections 61-5A-25(C) and 61-10-5.1(C), NMSA 1978. Under the Professional Psychologist Act records relating to a disciplinary action may be disclosed at its conclusion. See Section 61-9-5.1(C), NMSA 1978.

NMAG also comments on this nondisclosure provision:

> The bill's proposed IPRA (Inspection of Public Records Act) exception provides that information related to disciplinary matters "shall not be disclosed except *to the extent necessary to carry out the board's purposes* or in a judicial appeal from the board's actions" (emphasis added). (This can be found on page 20, lines 21-23.) This could lead to some ambiguity, as the Board's purposes may be unclear and an individual subject to discipline might seek to prevent the disclosure of disciplinary records by arguing that disclosure is unnecessary. If the intent is to defer to the judgment of the Board, it could instead read as: "shall not be disclosed except to the extent necessary to carry out the board's purposes <u>as determined at the discretion of the board, for purposes of discovery for a disciplinary action of the board,</u> or in a judicial appeal from the board's actions."

Further, NMAG notes that as drafted, SB 271 shields individuals who provide information to the board in good faith from civil and criminal liability. (This is on pages 20-21, lines 24-2.) It advises:

> as drafted it does not appear to limit that immunity, and this language could be misconstrued to allow an individual to avoid disciplinary or criminal responsibility for misconduct by reporting the same to the Board. One way to clarify this would be:
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> > "C. No person or legal entity providing information to the board in good

> faith, whether as a report, a complaint or testimony, shall be subject to civil damages or criminal prosecutions for providing such information to the board."

TECHNICAL ISSUES

On page 6, line 16 the phrase "licensed by the board" appears to be unnecessary.

Additionally, NMAG points out that Section 6(B) provides that certain communications "are not public records for the purposes of [IPRA]." It recommends that this language be clarified to provide that such communication is exempt from inspection under IPRA (as it would fall under IPRA's eighth exception: "otherwise provided by law"), since the communication would still be defined as a public record under IPRA.

OTHER SUBSTANTIVE ISSUES

RLD reports that the University of New Mexico's College of Pharmacy has revised its curriculum to include earlier provision of patient care. The removal of the 30 semester hour prerequisite will allow the board to modify requirements consistent with changing curriculum capabilities.

MD/gb/sb