This fiscal impact statement is produced in compliance with the South Carolina Code of Laws and House and Senate rules. The focus of the analysis is on governmental expenditure and revenue impacts and may not provide a comprehensive summary of the legislation.

Bill Number:	H. 3592 Introduced on January 10, 2023
Author:	Hyde
Subject:	Compounding Pharmacies
Requestor:	House Medical, Military, Public, and Municipal Affairs
RFA Analyst(s):	Wren
Impact Date:	January 18, 2023

Fiscal Impact Summary

This bill makes changes to the Pharmacy Practice Act by removing certain definitions related to the compounding of medications and revises requirements for compounding pharmacies, nuclear pharmacy facilities, and for the preparation, labeling, and distribution of sterile products by pharmacies. The bill further tasks the Board of Pharmacy with additional regulatory requirements.

The overall expenditure impact of this bill on the Department of Labor, Licensing and Regulation (LLR) is undetermined. However, the agency indicates that expenses for the Board of Pharmacy to update any new regulations relating to the compounding of medications will be minimal and can be managed within existing appropriations. Any expenses for the statistical reporting by compounding pharmacies to the Board of Pharmacy for statutory and regulatory requirements are undetermined since these reporting requirements may relate to requirements from the U.S. Food and Drug Administration (FDA) as part of the Drug Supply Chain Security Act. Since the requirements of the act are pending, LLR is unable to determine the expenditure impact that may result from the act. Further, LLR indicates that 1.0 FTE may be needed, depending on regulations promulgated by the Board of Pharmacy, but due to the uncertainty of the extent of the regulations, the agency is not requesting funding for the new position at this time. Further, LLR expressed a concern that pending FDA requirements may have an impact on the implementation of this bill.

The Board of Pharmacy falls under the Division of Professional and Occupational Licensing. Proviso 81.3 of the FY 2022-23 Appropriations Act requires LLR to remit 10 percent of the board's expenditures to the General Fund annually unless the board has an overall negative ending cash balance. Since the board's total expenditures are undetermined, the revenue impact on the General Fund is also undetermined.

Explanation of Fiscal Impact

Introduced on January 10, 2023
State Expenditure
This bill makes changes to the Pharmacy Practice Act by removing specified definitions related to the compounding of medications and revises requirements for compounding pharmacies. The

bill also requires the Board of Pharmacy to develop regulations for the compounding of drugs and to promulgate the regulations within eighteen months after the effective date of the bill. Additionally, the bill provides that statistical reports related to compounded prescription records may be required to be reported to the Board of Pharmacy periodically to enable the board to meet various statutory and regulatory requirements. Further, the bill removes certain requirements for nuclear pharmacy facilities and deletes certain standards for the preparation, labeling, and distribution of sterile products by pharmacies.

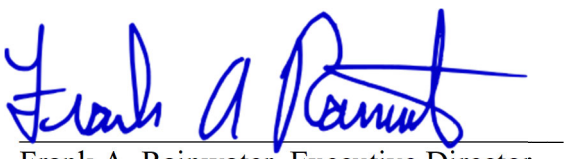
LLR indicates that the overall expenditure impact of this bill on the agency is undetermined. However, expenses for the Board of Pharmacy to update any new regulations relating to compounding of medications are expected to be minimal and can be managed within existing appropriations. Any expenses for the statistical reporting by compounding pharmacies to the Board of Pharmacy for statutory and regulatory requirements are undetermined since these reporting requirements may relate to pending FDA requirements as part of the Drug Supply Chain Security Act. Since the FDA is currently in the rulemaking process for this act, LLR is unable to determine any potential increase in expenses that may result from the act. Final recommendations of the act, which may include a requirement for state boards to report specific compounding and shipping data to the FDA, are expected later this year. Further, LLR indicates that 1.0 FTE for inspections and investigations may be needed, depending on regulations promulgated by the Board of Pharmacy, but due to the uncertainty of the extent of the regulations, the agency is not requesting funding for the new position at this time. Further, LLR expressed a concern that pending FDA requirements may have an impact on the implementation of this bill.

State Revenue
This bill makes changes to the Pharmacy Practice Act by removing certain definitions related to the compounding of medications and revises requirements for compounding pharmacies, nuclear pharmacy facilities, and for the preparation, labeling, and distribution of sterile products by pharmacies. The bill further tasks the Board of Pharmacy with additional regulatory requirements.

The Board of Pharmacy falls under the Division of Professional and Occupational Licensing. Proviso 81.3 of the FY 2022-23 Appropriations Act requires LLR to remit 10 percent of the board's expenditures to the General Fund annually unless the board has an overall negative ending cash balance. Since the board's total expenditures are undetermined, the revenue impact on the General Fund is also undetermined.

Local Expenditure
N/A

Local Revenue
N/A



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