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 Amended by Senate Medical Affairs on January 18, 2024
Author:	Hyde
Subject:	Compounding Pharmacies
Requestor:	Senate Medical Affairs
RFA Analyst(s):	Wren
Impact Date:	February 22, 2024

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 also tasks the Board of Pharmacy with additional regulatory requirements. This bill further permits any person or entity authorized to dispense drugs, including, but not limited to, a pharmacy, institutional pharmacy, or practitioner to purchase or acquire drugs compounded or repackaged by an outsourcing facility directly from the outsourcing facility without an order from a practitioner.

The overall expenditure impact of this bill on the Department of Labor, Licensing and Regulation (LLR) is undetermined. However, the agency previously indicated that expenses for the Board of Pharmacy to update any new regulations relating to the compounding of medications would be minimal and could be managed within existing appropriations. Any expenses for the collection and review of 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 indicated 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. We will update this impact statement if the agency provides a different response.

LLR also indicated on similar legislation that there would be no expenditure impact to the agency or Board of Pharmacy for the regulation of the purchase or acquisition of drugs compounded or repackaged by an outsourcing facility since this portion of the bill does not alter the responsibilities of the agency or the board.

Based on responses from similar legislation, this bill will have no expenditure impact on the Department of Public Health (DPH) (formerly DHEC) or the Department of Alcohol and Other

Drug Abuse Services (DAODAS) since the bill does not operationally or fiscally impact the agencies. The bill will have no expenditure impact on the Department of Mental Health (DMH), the Department of Vocational Rehabilitation (Vocational Rehabilitation), the Department of Veterans' Affairs (Veterans' Affairs), or the Department of Disabilities and Special Needs (DDSN) since the bill does not impose additional requirements on current pharmacy operations. Additionally, the bill will have no expenditure impact on the Medical University of South Carolina (MUSC) since any expenses to implement the provisions of the bill can be managed with existing resources. Further, the South Carolina Public Employee Benefit Authority (PEBA) indicated that the bill will have no expenditure impact on the State Health Plan or its pharmacy reimbursements.

Based on a response on similar legislation, the Department of Health and Human Services (DHHS) indicated that any initial expenses to implement the provisions of the bill can be managed with existing resources, unless there is an unforeseen ramp-up in utilization, since the department has a cost-savings model in place for pharmacy operations. DHHS further indicated that the bill may increase Other Funds and Federal Funds expenses in future years by an undetermined amount depending on the compounded or repacked drug that is acquired, administered, or dispensed without involvement from the practitioner or consistency with regards to drug rebates.

The Board of Pharmacy falls under the Division of Professional and Occupational Licensing. Proviso 81.3 of the FY 2023-24 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

Amended by Senate Medical Affairs on January 18, 2024
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. However, until regulations are promulgated by the Board of Pharmacy, compounding pharmacies must comply with the compounding standards in use on the effective date of this bill as outlined in the Non-Sterile Compounding Pharmacy and Sterile Compounding Pharmacy Inspection Forms as published by the Board of Pharmacy, unless the Pharmacy is held to a higher standard of another body such as an accrediting body. 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. The bill also removes certain requirements for nuclear pharmacy facilities and deletes certain standards for the preparation, labeling, and distribution of sterile products by pharmacies. The bill further permits any person or entity authorized to dispense drugs, including,

but not limited to, a pharmacy, institutional pharmacy, or practitioner to purchase or acquire drugs compounded or repackaged by an outsourcing facility directly from the outsourcing facility without an order from a practitioner. An outsourcing facility is defined as a facility registered with the United States Food and Drug Administration to operate under Section 503B of the Federal Food and Cosmetic Act.

Department of Labor, Licensing and Regulation. LLR previously indicated that the overall expenditure impact of the bill on the agency was 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 collection and review of 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 indicated 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. We will update this impact statement if LLR provides a different response.

LLR also indicated on similar legislation that there would be no expenditure impact to the agency or Board of Pharmacy for the regulation of the purchase or acquisition of drugs compounded or repackaged by an outsourcing facility since this portion of the bill does not alter the responsibilities of the agency or the board.

Department of Public Health. The Department of Health and Environmental Control will become DPH and the Department of Environmental Services beginning July 1, 2024. Based on a response on similar legislation, this bill will have no expenditure impact on DPH since the bill does not operationally or fiscally impact the agency.

Department of Alcohol and Other Drug Abuse Services. Based on a response on similar legislation, the bill will have no expenditure impact on DAODAS since it does not operationally or fiscally impact the agency.

Department of Mental Health. DMH previously indicated that similar legislation would have no expenditure impact on the department since it does not impose additional requirements on the department's pharmacy operations.

Department of Vocational Rehabilitation. Based on a response on similar legislation, this bill will have no expenditure impact on the Vocational Rehabilitation since the agency does not

prescribe or directly purchase medication to be dispensed by staff. The department administers existing medication as prescribed by the individual's physician.

Department of Veterans' Affairs. Based on a response on similar legislation, this bill will have no expenditure impact on Veterans' Affairs since the bill requires the department to perform activities that can be conducted in the normal course of business in oversight of contracted facilities.

Department of Disabilities and Special Needs. DDSN indicated that similar legislation would have no expenditure impact on the department since the legislation requires the department to perform activities that can be conducted in the normal course of business.

Medical University of South Carolina. MUSC anticipates that the bill may have a minimal impact on the agency but expects that any expenses to implement the bill can be managed with existing resources.

Public Employee Benefit Authority. PEBA does not anticipate that this bill will have an expenditure impact on the State Health Plan or its pharmacy reimbursements.

Department of Health and Human Services. DHHS indicated that any initial expenses to implement the provisions of the bill can be managed with existing resources, unless there is an unforeseen ramp-up in utilization, since the department has a cost-savings model in place for pharmacy operations. DHHS further indicated that the bill may increase Other Funds and Federal expenses in future years by an undetermined amount depending on the compounded or repacked drug that is acquired, administered, or dispensed without involvement from the practitioner or consistency with regards to drug rebates.

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 2023-24 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. We will update this impact statement if LLR revises its response regarding the expenditure impact of the bill.

Local Expenditure
N/A

Local Revenue
N/A

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

Frank A. Rainwater, Executive Director