SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

| BILL: | | SB 604 | | | |
|---------------------|--------------|------------------|--------------------------|---------------------|---------------------|
| SPONSOR: | | Senator Saunders | | | |
| SUBJECT: | | Pharmacy | | | |
| DATE: | | January 21, 2002 | 2 REVISED: | | |
| 1. <u>-</u> 2. – 3. | AN Munroe | ALYST | STAFF DIRECTOR Wilson | REFERENCE HC AHS AP | ACTION Favorable |
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I. Summary:

The bill creates a mechanism for Florida-licensed pharmacies that have the same owner, or that have a written contract specifying the services to be performed, to share pharmacy duties. The bill defines "centralized prescription filling," requires each pharmacy performing or contracting for the performance of centralized prescription filling to maintain a policy and procedure manual containing specified information and clarifies that the filling of a prescription by one pharmacy for another pharmacy is not the filling of a transferred prescription. The bill requires the Board of Pharmacy to adopt rules to implement the requirements for centralized prescription filling by Florida-licensed pharmacies.

This bill amends section 465.003, Florida Statutes.

This bill creates s. 465.0265, Florida Statutes.

II. Present Situation:

Chapter 465, Florida Statutes, authorizes the Board of Pharmacy to regulate the practice of pharmacy in Florida. The chapter provides definitions for purposes of the regulation of pharmacy. Section 465.003, F.S., defines "dispense" to mean the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As part of dispensing, the pharmacist must before actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist must certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist must also provide counseling on proper drug usage, if in her or his professional judgment

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counseling is necessary. The actual sales transaction and delivery of such drug is not to be considered dispensing. The administration in not to be considered dispensing.

Section 465.026, F.S., provides that nothing in ch. 465, F.S., shall prohibit a Florida-licensed pharmacist from filling or refilling a valid prescription which is on file in a pharmacy located in Florida or in another state and that has been transferred from one pharmacy to another by any means, if before dispensing the transferred prescription, the dispensing pharmacist, either verbally or by any electronic means, does all of the following: advises the patient that the prescription on file at the other pharmacy must be cancelled before it may be filled or refilled; determines that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed in the prescription; notifies the pharmacy or pharmacist where the prescription is on file that the prescription must be canceled; records in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription is on file, the prescription number, the name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills; and obtains the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, requires so.

Upon receipt of a prescription transfer request, the pharmacist must take specified actions outlined in s. 465.026(2), F.S., which include accurately and completely transferring specified information, recording the requesting pharmacy and pharmacist and the date of the request on the prescription, and cancel the prescription on file by electronic means or by recording the word "void" on the prescription record. If a transferred prescription is not dispensed within a reasonable time, the pharmacist must notify the transferring pharmacy. This notice will revalidate the cancelled prescription and the pharmacist who provided the notice must then cancel the transferred prescription. The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in ch. 893, F.S., for the purpose of refill dispensing is permitted, subject to the requirements of s. 465.026, F.S., and federal law. Compliance with federal law is deemed compliance with s. 465.026, F.S.

Chapter 499, F.S., provides for the regulation of the wholesale distribution of drugs by the Department of Health.

III. Effect of Proposed Changes:

The bill amends s. 465.003, F.S., to define "centralized prescription filling" to mean the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

The bill creates s. 465.0265, F.S., to provide requirements for centralized prescription filling. A Florida-licensed pharmacy is authorized to perform centralized prescription filling for another pharmacy, if the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations. Each

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pharmacy performing or contracting for the performance of centralized prescription filling under this section must maintain a policy and procedures manual, which must be made available to the Board of Pharmacy or its agent upon request. The bill specifies information that must be included in the policies and procedures manual which includes: a description of how each pharmacy will comply with federal and state laws, rules, and regulations; the procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient; the procedure for tracking the prescription label and all pharmacies involved in filling and dispensing the prescription; the policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and the procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

The bill provides that the filling of a prescription by one pharmacy for another pharmacy under the bill may not be construed as the filling of a transferred prescription as provided in s. 465.026, F.S. The Board of Pharmacy must adopt rules to implement the bill's requirements to provide for the centralized filling of prescriptions.

The bill provides an effective date of July 1, 2002.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Art. III, s. 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Some Florida-licensed pharmacies may reduce their business costs to the extent they may share pharmacy duties as provided in the bill.

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C. Government Sector Impact:

The Department of Health will incur costs for the Board of Pharmacy's requirement to adopt rules to implement the bill's provisions for centralized filling of prescriptions.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.