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: | | CS/SB 904 | | | |
|----------|------|---|----------------|-----------|--------------|
| SPONSOR: | | Health, Aging and Long-Term Care Committee and Senators Garcia and Silver | | | |
| SUBJECT: | | Public Records and Meetings | | | |
| DATE: | | April 10, 2001 | REVISED: | | |
| | A | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
| 1. L | Liem | | Wilson | НС | Favorable/CS |
| 2. | | | | GO | |
| 3. | | | | RC | |
| 4. | | | | | |
| 5. | | | | | |
| 6. | | | | | |
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I. Summary:

The Committee Substitute for Senate Bill 904 makes information regarding supplemental rebates from pharmaceutical manufacturers under the Florida Medicaid Program confidential and exempt from public disclosure. Portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee at which this information is disclosed for discussion or negotiation are made exempt from Florida's open meetings requirements. The bill provides legislative findings that these exemptions are a public necessity in that disclosure of similar information is prohibited under federal law, and that the exemptions will enable the state to negotiate supplemental pharmaceutical manufacturer rebates for the ultimate benefit of Medicaid recipients. The exemptions are subject to the Open Government Sunset Review Act of 1995 and will be repealed on October 2, 2006, unless reenacted by the Legislature.

The bill creates four undesignated sections of law.

II. Present Situation:

Supplemental Pharmacy Rebates Under Medicaid

The Florida Medicaid Program is the single largest purchaser of prescription drugs in the state. The program currently has a voluntary preferred drug list of medications with net pricing favorable to Medicaid. There is currently a four-brand-name drug per month limit and prior authorization requirements for a few specific drugs, but there are no formulary restrictions.

Large purchasers of pharmaceuticals negotiate a variety of offsets to wholesale prices of these products. The terms of these privately negotiated discounts are not subject to public scrutiny. Rebates and manufacturer pricing are considered by insurers, along with drug efficacy, in the

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adoption of drug formularies to aid in controlling insurer costs. In the instance of Medicaid, federal law requires a minimum 15.1 percent rebate from pharmaceutical manufacturers. States are allowed to negotiate supplemental rebates; California reports that it generally receives rebates averaging 25 percent.

The Committee Substitute for Senate Bill 792 contains the Medicaid-related substantive provisions of the Appropriations Implementing Bill (SB 2002). CS/SB 792 amends s. 409.91195, F.S., to modify the purpose of the Medicaid Pharmaceutical and Therapeutics Committee to require that the committee develop a restricted-drug formulary as permitted by federal law. The committee may recommend additions and deletions to the formulary so that the formulary achieves cost savings while providing medically appropriate drug therapies. The committee is to recommend for inclusion in the formulary drugs that have clinical advantages over other drugs in the formulary, *drugs for which the agency has negotiated supplemental rebates* and any drug presented to the committee by the agency. The bill authorizes the agency to negotiate (either directly or via a contractor) supplemental rebates, which are in addition to the federally-negotiated rebate amount, from pharmaceutical manufacturers The supplemental rebates may be in cash, disease management programs, drug donation programs, drug utilization control programs or other services or investments which guarantee savings to the Medicaid program.

Since rebate negotiations often involve disclosure by pharmaceutical manufacturers of proprietary and trade secret information regarding the elements of their wholesale pricing, federal law (42 U.S.C. 1396r-8) prohibits disclosure of information received from manufacturers that disclosed identities of manufacturers or wholesalers, or the prices charged by these manufacturers or wholesalers. The prohibition applies to the Secretary of the Department of Health and Human Services, the Secretary of Veterans Affairs, or a state agency or contractor.

Public Records in Florida

Florida has a long history of providing public access to the records of governmental and other public entities. The first law affording access to public records was enacted by the Florida Legislature in 1909. In 1992, Floridians voted to adopt an amendment to the Florida Constitution that raised the statutory right of public access to public records to a constitutional level.

The Public Records Law, chapter 119, F.S., specifies the conditions under which public access must be provided to governmental records of the executive branch and other governmental agencies. While the state constitution provides that records of public bodies are to be open to the public, it also provides that the Legislature may create exemptions to these requirements by general law if a public need exists and certain procedural requirements are met. Article I, s. 24, Fla. Const. governs the creation and expansion of exemptions to provide, in effect, that any legislation that creates a new exemption or that substantially amends an existing exemption must also contain a statement of the public necessity that justifies the exemption. Article I, s. 24, Fla. Const. provides that any bill that contains an exemption may not contain other substantive provisions, although it may contain multiple exemptions.

Chapter 95-217, Laws of Florida, repealed the Open Government Sunset Review Act, contained in s. 119.14, F. S., and enacted in its place s. 119.15, F.S., the Open Government Sunset Review Act of 1995. The Open Government Sunset Review Act of 1995 provides for the repeal and prior

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review of any public records exemptions that are created or substantially amended in 1996 and subsequently. The review cycle begins in 2001. The chapter defines the term "substantial amendment" for purposes of triggering a repeal and prior review of an exemption to include an amendment that expands the scope of the exemption to include more records or information or to include meetings as well as records. The law clarifies that an exemption is not substantially amended if an amendment limits or narrows the scope of an existing exemption.

III. Effect of Proposed Changes:

Section 1. Makes trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates, contained in records of the Agency for Health Care Administration and its agents prepared pursuant to a supplemental rebate agreement prepared under s. 409.91195, F.S., confidential and exempt from s. 119.07, F.S., and s. 24(a), Art. I of the State Constitution.

Section 2. Makes portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee in which the information in section 1 of the bill is disclosed for discussion or negotiation exempt from s. 286.011, F.S., and s. 24(b), Art. I of the State Constitution.

Section 3. Provides legislative findings that the exemptions and closure are a public necessity in that similar information is prohibited from disclosure under federal law, and that without the exemption and closure manufacturers would not be willing to offer a rebate in Florida. The bill provides legislative findings that the number and value of rebates obtained by the agency will increase, to the benefit of Medicaid recipients and the public, if documents are exempt and meetings at which this information is discussed are closed because manufacturers will be assured that they will not be placed at a competitive disadvantage by exposure of this information.

Section 4. Provides that the section is subject to the Open Government Sunset Review Act of 1995 and will be repealed on October 2, 2006, unless reviewed and saved from repeal by the Legislature.

Section 5. Provides a contingent effective date linked to the effective date of CS/SB 792, which establishes the substantive provisions relating to Medicaid pharmaceutical rebates.

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 bill creates a public records exemption for information regarding supplemental rebates from pharmaceutical manufacturers and exempts portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee in which certain information is disclosed for discussion or negotiation from Florida's open meetings requirements. The bill provides legislative findings that these exemptions are a public necessity and subjects the exemptions to the Open Government Sunset Review Act of 1995.

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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:

The bill will enable the Medicaid program to negotiate supplemental rebates from pharmaceutical manufacturers, which will reduce the Medicaid price these manufacturers charge for their products.

C. Government Sector Impact:

The bill will reduce costs to the Medicaid program.

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.