

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.)

Prepared By: Health Care Committee

BILL: SB 516

INTRODUCER: Health Care Committee

SUBJECT: Open Government Sunset Review of AHCA/Trade Secrets

DATE: December 19, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Garner	Wilson	HE	Favorable
2.	_____	_____	GO	_____
3.	_____	_____	RC	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill reenacts and amends s. 409.91196, Florida Statutes, to continue the public records and meetings exemption for records and meetings related to the supplemental rebate agreements in the Medicaid prescription drug program. The bill removes redundant language, corrects statutory cross references, and specifies that records of confidential portions of a Medicaid Pharmaceutical and Therapeutics (P&T) Committee meeting must be maintained by the agency.

This bill amends s. 409.91196, F. S.

II. Present Situation:

Constitutional Access to Public Records and Meetings

Florida has a long history of providing public access to the records and meetings of governmental and other public entities. The state's Public Records Act, in ch. 119, F.S., and the public meetings law, in ch. 286, F.S., were first enacted in 1967.¹ These statutes have been amended numerous times since their enactment.

In November 1992, the public affirmed the tradition of government-in-the-sunshine by enacting a constitutional amendment, which guaranteed and expanded the practice. Article I, s. 24 of the State Constitution provides every person with the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf. The section specifically includes the legislative, executive and judicial branches of government and each agency or department created under

¹ Chapters 67-125 and 67-356, L.O.F.

them. It also includes counties, municipalities, and districts, as well as constitutional officers, boards, and commissions or entities created pursuant to law or the State Constitution. All meetings of any collegial public body must be open and noticed to the public.

The State Constitution authorizes exemptions to the open government requirements and establishes the means by which these exemptions are to be established. Under Art. I, s. 24(c) of the State Constitution, the Legislature may provide by general law for the exemption of records and meetings. A law enacting an exemption:

- Must state with specificity the public necessity justifying the exemption;
- Must be no broader than necessary to accomplish the stated purpose of the law;
- Must relate to one subject;
- Must contain only exemptions to public records or meetings requirements; and
- May contain provisions governing enforcement.

Exemptions to public records and meetings requirements are strictly construed because the general purpose of open records and meetings requirements is to allow Florida's citizens to discover the actions of their government

The Medicaid Prescription Drug Program and the Need for a Public Records and Meetings Exemption Related to Supplemental Rebate Agreements

The 2001 Florida Legislature significantly expanded its efforts to control pharmaceutical costs in the state's Medicaid program by enacting a program called the preferred drug list (PDL) (ch. 2001-104, Laws of Florida). Under this law, Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or must obtain prior authorization from the Agency for Health Care Administration (AHCA) to prescribe a medication not on the PDL, in order for the prescription to be paid for by Medicaid.

In order for a drug manufacturer to have its medications considered for inclusion on the PDL, it must agree to provide the state both federally-mandated rebates and state-mandated supplemental rebates. Since rebate negotiations 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 by Medicaid agencies from manufacturers that discloses identities of manufacturers or wholesalers, or the prices charged by these manufacturers or wholesalers. The federal prohibition applies to the U.S. Secretary of the Department of Health and Human Services, the U.S. Secretary of Veterans Affairs, or a state agency or contractor.

To address the federal confidentiality requirements and to ensure that this pricing information could be used for negotiating state supplemental rebate agreements, the 2001 Legislature enacted a public records and public meetings exemption related to rebate negotiations (ch. 2001-216, Laws of Florida). This public records and meetings exemption is codified in s. 409.91196, F.S.

The specific records maintained by AHCA that are exempt under the provisions of s. 409.91196, F.S., are bid forms from the manufacturers that are provided to AHCA and Provider Synergies (the company that manages the PDL and negotiates pricing), internal cost sheets developed by

Provider Synergies from these bid forms and provided to AHCA and the P&T Committee, and the final contracts containing supplemental rebate agreements and unit rebate amounts. These contracts are between AHCA and pharmaceutical manufacturers. These contracts contain both the federal rebate amounts and the state-mandated supplemental rebate amounts that are the product of negotiations. Each record is specific to a particular manufacturer or its subsidiary. The Agency for Health Care Administration's Division of Medicaid, Bureau of Pharmacy Services, and Provider Synergies maintain copies of the initial bid forms, internal cost sheets, and contracts. There is no method to access these records other than through the Division of Medicaid or from a manufacturer.

The public meetings exemption contained in s. 409.91196, F.S., is applied in limited circumstances. The exemption pertains only to those portions of the public meetings of the P&T Committee where proprietary pricing information is discussed. The committee usually meets on a quarterly basis. Meetings are noticed in the *Florida Administrative Weekly* and held in locations that are accessible to the public.

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Staff reviewed the provisions and applicable law pursuant to the criteria specified in the Open Government Sunset Review Act of 1995 (2004), to determine if the provisions of s. 409.91196, F.S., making meetings and specified records of Medicaid pharmaceutical rebate negotiations exempt from the Public Meetings Law and Public Records Law, should be continued or modified. Staff consulted with and surveyed AHCA staff and other interested parties in conducting the Open Government Sunset Review of s. 409.91196, F.S. Staff also reviewed legal analyses conducted by the National Conference of State Legislatures (NCSL),² other literature examining federal protection of pharmaceutical pricing information, and the Senate analysis of the bill (CS/SB 904) which created these public records and meetings exemptions. Finally, staff attended a meeting of the Medicaid P&T Committee in July 2005 to observe how the committee addresses confidential issues during its public meetings.

The public necessity originally identified for the public records and meetings exemption created in s. 409.91196, F.S., was "the agency and pharmaceutical manufacturers [through the public records and meetings exemption] will have frank and open communication regarding rebates, causing the number of rebates to increase, thereby benefiting Medicaid recipients and the public." The agency's response to the committee's survey emphasized that the same public necessity still exists and that maintaining the exemption is essential to the effective and efficient administration of the PDL program, as well as to protect proprietary information whose disclosure would allow competitors to use pricing information gained in Florida in negotiations and bids for private health plans or Medicaid programs in other states.

Data suggests that the state supplemental rebate negotiation process has been facilitated by this exemption and has been successful in benefiting the people of Florida. Since its implementation in 2002, the PDL program has generated over \$262 million in state supplemental rebates, with \$292 million in additional cost savings projected for Fiscal Year 2005-06, a significant portion of

² National Conference of State Legislatures. (1999). *Prescription Drug Pricing: Constitutional Boundaries on State Legislation*. <http://www.ncsl.org/programs/health/pricerept-vt.htm>

which will be derived from supplemental rebate negotiations. In its survey response, AHCA representatives repeatedly stressed that without this public records and public meetings exemption these cost savings would not have been achieved, as “manufacturers would be much less willing to negotiate with Florida Medicaid if the results of these negotiations were then made available to competitors.”

Senate staff identified an issue related to the executive sessions during public meetings. No records, written or taped, are maintained of these discussions, possibly in violation of the record keeping requirements of s. 286.011, F.S. This issue was identified in the agency’s survey response, the response from the First Amendment Foundation (FAF), and discussions with agency staff at the public meeting attended by legislative staff.

There are many times when the committee’s policy decisions are modified or even reversed after engaging in these executive sessions. The minutes of the overall meeting reflect, at a high level, the issues discussed during the executive session; however, most of these discussions during an executive session center on the very proprietary pricing information most directly affected by the exemption. The FAF recommends requiring AHCA to produce and maintain a transcript of the discussions that occur during the executive sessions, which would later become available to the public. While the public disclosure aspect of this proposal may be contradictory to the intent of the exemption, the requirement that AHCA and the P&T Committee maintain a record of these discussions and that they should be accessible through the same mechanisms the rebate contracts are available (i.e., auditing purposes) may be appropriate.

Senate Health Care Committee staff found that the exemption meets the requirements for reenactment with some changes. The exemption, viewed against the open government sunset review criteria, does protect information of a proprietary nature that could create a problem for manufacturers as they negotiate with private health plans and other state Medicaid programs. The exemption allows AHCA to effectively and efficiently negotiate pharmaceutical pricing and rebates in such a way that ensures pharmaceutical manufacturers continue to participate in the state’s Medicaid pharmacy program at significant cost savings to the state. The only issue of concern pertains to record keeping of negotiations that occur during executive sessions that are held in private.

Accordingly, staff recommended that the exemption in s. 409.91196, F.S., be reenacted and amended to correct statutory cross references and to require AHCA and the P&T Committee to produce and maintain a record of any discussions during executive session portions of a public meeting that are held in a confidential setting apart from the open meeting.

III. Effect of Proposed Changes:

Section 1. Amends s. 409.91196, F.S., relating to the public records and meetings exemption for records and portions of the meetings of the P&T Committee where rebate amounts, percent of rebates, manufacturer’s pricing, and supplemental rebate amounts are disclosed or discussed, to correct statutory cross references, and to require records to be maintained for certain confidential portions of a P&T Committee meeting. The section is also amended to delete the provision that repeals the exemption.

Section 2. Provides that the bill will take effect October 1, 2006.

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:

In accordance with a review pursuant to the Open Government Sunset Review Act, this bill amends s. 409.91196, F.S., and preserves the public records and meetings exemption in that section. The amendments do not expand the exemption. The bill complies with 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, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The reenactment of this public records and meetings exemption will facilitate pharmaceutical manufacturers continuing to negotiate with the state, producing higher rebates for medications provided through the Medicaid program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.

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