The Florida Senate

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Committee on Health Care Senator Durell Peaden, Jr., Chair

OPEN GOVERNMENT SUNSET REVIEW OF S. 409.91196, F.S., AGENCY FOR HEALTH CARE ADMINISTRATION/TRADE SECRETS

SUMMARY

Section 409.91196, F.S., specifies that trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates which are contained in records of the Agency for Health Care Administration (AHCA) and its agents with respect to supplemental rebate negotiations and which are prepared pursuant to a supplemental rebate agreement under the Medicaid prescribed-drug spending-control program are confidential and exempt from s. 119.07, F.S., and s. 24(a), Art. I of the State Constitution. This statute also specifies that those portions of meetings of the Medicaid Pharmaceutical and Therapeutics Committee at which trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates are disclosed for discussion or negotiation of a supplemental rebate agreement are exempt from s. 286.011, F.S., and s. 24(b), Art. I of the State Constitution. This statute specifies that these exemptions are subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, F.S., and shall stand repealed on October 2, 2006, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 119.15(2), F.S. (2004), provides that an exemption may be maintained only if the exemption: protects information of a sensitive, personal nature concerning individuals; allows the state or its political subdivisions to effectively and efficiently administer a governmental program; or protects confidential information concerning an entity. The Open Government Sunset Review Act of 1995 also specifies criteria for the Legislature to consider in its review of an exemption from the Public Records Law or Public Meetings Law.

Staff has reviewed the exemptions in s. 409.91196, F.S., pursuant to the Open Government Sunset Review Act of 1995 (2004), and finds that the exemptions meet the requirements for reenactment with some changes. The exemptions, viewed against the open government sunset review criteria, do 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 (over $262 million in supplemental rebates over the last three years). The only issue of concern pertains to record keeping of negotiations that occur during executive sessions during public meetings. No records or transcripts of the discussions during the executive sessions are kept by the agency or the Pharmaceutical and Therapeutics Committee, possibly in violation of the record keeping requirements of s. 286.011, F.S.

Accordingly, staff recommends that the exemptions in s. 409.91196, F.S., be revived and readopted and amended to correct statutory cross references and to require AHCA and the Pharmaceutical and Therapeutics 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.

BACKGROUND

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). Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or

must obtain prior authorization from 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, the 2001 Legislature also enacted a public records and public meetings exemption related to these rebate negotiations (ch. 2001-216, Laws of Florida). At that time, the Legislature found that "it is a public necessity that trade secrets, rebate amount, percent of rebate, manufacturer's pricing, supplemental rebates that are contained in records, as well as meetings of the Medicaid Pharmaceutical and Therapeutics Committee (P&T Committee) at which this information is negotiated or discussed, pursuant to a supplemental rebate agreement under section 409.91195, Florida Statutes, are confidential and exempt from sections 119.07 and 286.011, Florida Statutes, and Section 24(a) and (b) of Article I of the State Constitution. Information pertaining to similar agreements negotiated by pharmaceutical manufacturers and the Federal Government is confidential under 42 U.S.C. s.1396r-8. A supplemental rebate as a percentage of average manufacture price is confidential under federal law and the federal rebate could be made known if not protected in Florida. Because of the protection afforded by federal law, if this information is not protected in Florida, manufacturers would not be willing to offer a rebate in Florida. Further, the Legislature finds that the number and value of supplemental rebates obtained by the agency will increase, to the benefit of Medicaid recipients, if information related to state supplemental rebates is protected in the records received by the agency and if the meetings at which this information is discussed or negotiated are closed because manufacturers will be assured that they will not be placed at a competitive disadvantage by the exposure of this information. As a result, the agency and pharmaceutical manufacturers will have frank and open communication regarding rebates, causing the number of rebates to increase, thereby benefiting Medicaid recipients, and the public."

The public records and public meetings exemptions are codified in s. 409.91196, F.S. This section specifies that trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates which are contained in records of AHCA and its agents with respect to supplemental rebate negotiations and which are prepared pursuant to a supplemental rebate agreement under s. 409.912(40)(a)7., F.S., are confidential and exempt from s. 119.07, F.S., and s. 24(a), Art. I of the State Constitution.[1]

This section also specifies that those portions of meetings of the P&T Committee at which trade secrets, rebate amount, percent of rebate, manufacturer's pricing, and supplemental rebates are disclosed for discussion or negotiation of a supplemental rebate agreement under s. 409.912(40)(a)7., F.S., are exempt from s. 286.011, F.S., and s. 24(b), Art. I of the State Constitution.[2]

Finally, the section specifies that these exemptions are subject to the Open Government Sunset Review Act of 1995 in accordance with s. 119.15, F.S., and shall stand repealed on October 2, 2006, unless reviewed and saved from repeal through reenactment by the Legislature.

Constitutional Access to Public Records and Meetings

Florida has a history of providing public access to the records and meetings of governmental and other public entities. The tradition began in 1909 with the enactment of a law that guaranteed access to the records of public agencies.[3] Over the following decades, a significant body of statutory and judicial law developed that greatly enhanced the original law. 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.[4] These statutes have been amended numerous

[1] Section 409.912(40)(a)7., Florida Statutes, was redesignated as s. 409.912(39)(a)7., F.S., to conform to the repeal of former subsection (38) by s. 55, ch. 2004-5, L.O.F.

[2] Section 409.912(40)(a)7., Florida Statutes, was redesignated as s. 409.912(39)(a)7., F.S., to conform to the repeal of former subsection (38) by s. 55, ch. 2004-5, L.O.F.

[3] Section 1, ch. 5945, 1909; RGS 424; CGL 490.

[4] Chapters 67-125 and 67-356, L.O.F.

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 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 term "public records" has been defined by the Legislature in s. 119.011(11), F.S., to include:

> . . . all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency.

This definition of public records has been interpreted by the Florida Supreme Court to include all materials made or received by an agency in connection with official business, which are used to perpetuate, communicate or formalize knowledge.[5] Unless these materials have been made exempt by the Legislature, they are open for public inspection, regardless of whether they are in final form.[6]

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.[7] The Public Records Act is liberally construed in favor of open government, and exemptions from disclosure are to be narrowly construed so they are limited to their stated purpose.[8]

There is a difference between records that the Legislature has made exempt from public inspection and those that are exempt and confidential. If the Legislature makes a record confidential, with no provision for its release such that its confidential status will be maintained, such information may not be released by an agency to anyone other than to the persons or entities designated in the statute.[9] If a record is not made confidential but is simply exempt from mandatory disclosure requirements, an agency has discretion to release the record in all circumstances.[10]

Under s. 119.10, F.S., any public officer violating any provision of this chapter is guilty of a noncriminal infraction, punishable by a fine not exceeding $500. In addition, any person willfully and knowingly violating any provision of the chapter is guilty of a first-degree misdemeanor, punishable by potential imprisonment not exceeding one year and a fine not exceeding $1,000. Section 119.10, F.S., also provides a first-degree misdemeanor penalty for public officers who knowingly violate the provisions of s. 119.07(1), F.S., relating to the right to inspect public records, as well as suspension and removal or impeachment from office.

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[5] *Shevin v. Bryon, Harless, Schaffer, Reid and Associates, Inc.,* 379 So.2d 633, 640 (Fla. 1980).
[6] *Wait v. Florida Power & Light Company,* 372 So.2d 420 (Fla. 1979).
[7] *Christy v. Palm Beach County Sheriff's Office*, 698 So.2d 1365, 1366 (Fla. 4th DCA 1997).
[8] *Krischer v. D'Amato*, 674 So.2d 909, 911 (Fla. 4th DCA 1996); *Seminole County v. Wood*, 512 So.2d 1000, 1002 (Fla. 5th DCA 1987), review denied, 520 So.2d 586 (Fla. 1988); *Tribune Company v. Public Records*, 493 So.2d 480, 483 (Fla. 2d DCA 1986), review denied sub nom., *Gillum v. Tribune Company*, 503 So.2d 327 (Fla. 1987).
[9] Attorney General Opinion 85-62.
[10] *Williams v. City of Minneola*, 575 So.2d 683, 687 (Fla. 5th DCA), review denied, 589 So.2d 289 (Fla. 1991).
[10] *Department of Professional Regulation v. Spiva*, 478 So.2d 382 (Fla. 1st DCA 1985).

Under s. 286.011(3), F.S., any public officer violating any provision of the Public Meetings Law is guilty of a noncriminal infraction, punishable by a fine not exceeding $500. In addition, any person who is a member of a board or commission who knowingly violates any provision of the Public Meetings Law is guilty of a second-degree misdemeanor, punishable by potential imprisonment not exceeding 60 days and a fine not exceeding $500. Section 286.011, F.S., also provides a second-degree misdemeanor penalty for conduct, which occurs outside the state, which would constitute a knowing violation of the Public Meetings Law.

An exemption from disclosure requirements does not render a record automatically privileged for discovery purposes under the Florida Rules of Civil Procedure. For example, the Fourth District Court of Appeal has found that an exemption for active criminal investigative information did not override discovery authorized by the Rules of Juvenile Procedure and permitted a mother who was a party to a dependency proceeding involving her daughter to inspect the criminal investigative records relating to the death of her infant.[11] The Second District Court of Appeal also has held that records that are exempt from public inspection may be subject to discovery in a civil action upon a showing of exceptional circumstances and if the trial court takes all precautions to ensure the confidentiality of the records.[12]

The Open Government Sunset Review Act of 1995

Section 119.15, F.S. (2004), the Open Government Sunset Review Act of 1995, establishes a review and repeal process for exemptions to public records or meetings requirements. Under s. 119.15(3)(a), F.S. (2004), a law that enacts a new exemption or substantially amends an existing exemption must state that the exemption is repealed at the end of 5 years. Further, a law that enacts or substantially amends an exemption must state that the exemption must be reviewed by the Legislature before the scheduled repeal date. An exemption is substantially amended if the amendment expands the scope of the exemption to include more records or information or to include meetings as well as records. An exemption is not substantially amended if the amendment narrows the scope of the exemption. In the fifth year after enactment of a new exemption or the substantial amendment of an existing exemption, the exemption is repealed on October 2nd, unless the Legislature acts to reenact the exemption.

In the year before the scheduled repeal of an exemption, the Division of Statutory Revision is required to certify to the President of the Senate and the Speaker of the House of Representatives each exemption scheduled for repeal the following year which meets the criteria of an exemption as defined in s. 119.15, F.S. An exemption that is not identified and certified is not subject to legislative review and repeal. If the division fails to certify an exemption that it subsequently determines should have been certified, it shall include the exemption in the following year's certification after that determination.

Under the requirements of the Open Government Sunset Review Act of 1995 (2004), an exemption is to be maintained only if:

- The exempted record or meeting is of a sensitive, personal nature concerning individuals;
- The exemption is necessary for the effective and efficient administration of a governmental program; or
- The exemption affects confidential information concerning an entity.

As part of the review process, s. 119.15(4)(a), F.S. (2004), requires the consideration of the following specific questions:

- What specific records or meetings are affected by the exemption?
- Whom does the exemption uniquely affect, as opposed to the general public?
- What is the identifiable public purpose or goal of the exemption?
- Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how?

Further, under the Open Government Sunset Review Act of 1995 (2004), an exemption may be created or maintained only if it serves an identifiable public purpose. An identifiable public purpose is served if the exemption:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, the administration of

[11] *B.B. v. Department of Children and Family Services*, 731 So.2d 30 (Fla. 4th DCA 1999).

[12] *Department of Highway Safety and Motor Vehicles v. Krejci Company Inc.,* 570 So.2d 1322 (Fla. 2d DCA 1990).

which would be significantly impaired without the exemption;

- Protects information of a sensitive personal nature concerning individuals, the release of which information would be defamatory to such individuals or cause unwarranted damage to the good name or reputation of such individuals or would jeopardize the safety of such individuals; or
- Protects information of a confidential nature concerning entities, including, but not limited to, a formula, pattern, device, combination of devices, or compilation of information which is used to protect or further a business advantage over those who do not know or use it, the disclosure of which information would injure the affected entity in the marketplace.

Further, the exemption must be no broader than is necessary to meet the public purpose it serves.[13] In addition, the Legislature must find that the purpose is sufficiently compelling to override the strong public policy of open government and cannot be accomplished without the exemption.

METHODOLOGY

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),[14] other literature examining federal protection of pharmaceutical pricing information, and the Senate analysis of the bill (CS/SB 904) creating 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.

FINDINGS

The public interest originally identified for justifying the public records and meetings exemptions created in s. 409.91196, F.S., was that "the agency and pharmaceutical manufacturers [through the public records and meetings exemptions] will have frank and open communication regarding rebates, causing the number of rebates to increase, thereby benefiting Medicaid recipients and the public."[15] The agency's response to the Committee's survey states that this same public interest still exists and that maintaining the exemptions are 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 negotiation process has been facilitated by these exemptions and has been successful in benefiting the people of Florida. Since its implementation in 2002, the PDL program has generated over $262 million in supplemental rebates, with $292 million in additional cost savings projected for Fiscal Year 2005-06, a significant portion of which will be derived from supplemental rebate negotiations. In its survey response, AHCA representatives repeatedly stressed that without these public records and public meetings exemptions 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."[16]

The specific records maintained by the agency 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 the agency 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. Copies of the initial bid forms, internal

[13] *Memorial Hospital–West Volusia, Inc. v. News-Journal Corporation,* 2002WL 390687 (Fla. Cir. Ct.).

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

[15] Chapter 2001-216, Laws of Florida.

[16] AHCA response to Open Government Sunset Review Questionnaire, July 22, 2005.

cost sheets, and contracts are maintained by AHCA's Division of Medicaid, Bureau of Pharmacy Services and Provider Synergies. There is no method to access these records other than through the Division of Medicaid or from a manufacturer.

The public meeting 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. On most occasions, few individuals attend the public meetings other than representatives of pharmaceutical manufacturers who request to testify on the inclusion of a particular medication on the PDL. During these meetings, if an issue needs to be discussed that may contain proprietary information and the public audience is limited in number, the Committee chair will announce that the Committee will go into an "executive session" for a specified period of time. During an executive session, the public attendees are asked to leave the meeting room and the Committee members and agency staff discuss the particular issue. Once discussions are concluded, the public is invited to reenter the meeting room and Committee activities continue.

However, there are times when particularly controversial issues are discussed by the Committee and the public meeting draws a large attendance, as was the case of the July 2005 meeting attended by legislative staff. In this instance, the chair declared the need for an executive session and the P&T Committee members left the main conference room and went to a private, adjoining room. Once negotiations were completed, the Committee members reentered the main conference room and continued public discussions. The agency's survey response indicates that the discussions during the executive sessions relate exclusively to proprietary pricing information, which is protected under the current public meetings exemption. They also report that these exempt discussions occur only occasionally.

Staff has 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 so the information in the minutes is limited. The FAF recommends requiring the agency 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 the agency 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.

RECOMMENDATIONS

Staff has reviewed the exemptions in s. 409.91196, F.S., pursuant to the Open Government Sunset Review Act of 1995 (2004), and finds that the exemptions meet the requirements for reenactment with some changes. The exemptions, viewed against the open government sunset review criteria, do 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 recommends that the exemptions in s. 409.91196, F.S., be revived and readopted 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.