

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 578

INTRODUCER: Health Regulation Committee and Senator Gaetz

SUBJECT: State Pharmacy Services

DATE: April 1, 2009 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Bell	Wilson	HR	Fav/CS
2.			HA	
3.			RC	
4.				
5.				
6.				

Please see Section VIII. for Additional Information:

- A. COMMITTEE SUBSTITUTE..... Statement of Substantial Changes
- B. AMENDMENTS..... Technical amendments were recommended
- Amendments were recommended
- Significant amendments were recommended

I. Summary:

The bill creates the Pharmacy and Therapeutic Advisory Council in the Executive Office of the Governor to promote quality, consistency, and efficiency in the state purchasing and administration of pharmaceuticals, including the development of a drug-utilization review process across agencies and the review of agency proposals to maximize the cost-effectiveness of the purchasing of pharmaceuticals.

The bill requires all state agencies to purchase drugs through the statewide purchasing contract administered by the Department of Health (DOH), unless the Council approves a more cost-effective agency plan or the drugs required are not available through the contract. The Department of Veterans' Affairs, the Department of Management Services, and the Agency for Health Care Administration (AHCA) are exempted from the purchasing requirements in the bill. The bill authorizes the DOH to provide pharmacy services to other state agencies including: repackaging, dispensing, purchasing, and dispensing of pharmaceuticals through the DOH central pharmacy.

The bill creates one undesignated section of law.

The bill substantially amends ss. 381.0203, and 499.003, F.S.

II. Present Situation:

Statutory Requirements Relating to Advisory Councils

Section 20.03(7), F.S., defines “advisory council” to mean “an advisory body created by specific statutory enactment and appointed to a function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives.” Section 20.052, F.S., establishes requirements for advisory bodies created by a specific statutory enactment. An advisory body may not be created unless:

- It meets a statutorily defined purpose;
- Its powers and responsibilities conform with the definitions for governmental units in s. 20.03, F.S.;
- Its members, unless expressly provided otherwise in the State Constitution, are appointed for 4-year staggered terms; and
- Its members, unless expressly provided otherwise by specific statutory enactment, serve without additional compensation or honorarium, and are authorized to receive only per diem and reimbursement for travel expenses as provided in s. 112.061, F.S.

OPPAGA Research Memorandum – Consolidating Statewide Pharmaceutical Services

The Office of Program Policy Analysis and Government Accountability (OPPAGA) was required by Chapter 2009-15, Laws of Florida, to assess the feasibility of consolidating statewide pharmaceutical services for state agencies, including the purchasing, repackaging, and dispensing of pharmaceuticals. The OPPAGA research memorandum, released March 3, 2009, found that:

- Five state agencies spent \$232 million on pharmaceuticals for agency clients in FY 2007-08. These five agencies purchase 92 percent of their pharmaceuticals through a bulk purchasing contract through the DOH that lowers the prices for all participating purchasers.
- The state could attain additional cost savings by consolidating drug repackaging under the DOH’s central pharmacy or a private vendor. The OPPAGA compared the unit dose and script dispensing fees paid by the Agency for Persons with Disabilities with the Department of Corrections’ and the Department of Juvenile Justice’ current contracts for repackaging and filling prescriptions with the DOH’s central pharmacy costs and determined that consolidation under the DOH may be the more cost-effective option.
- The DOH may be able to expand its drug purchasing through the federal 340B drug pricing program, which could bring significant savings to the state.

Pharmaceutical Purchasing in Florida

Section 381.0203, F.S., authorizes the DOH to contract on a statewide basis for the purchase of drugs for use by other state agencies and political subdivisions. The DOH’s Bureau of Statewide Pharmaceutical Services is responsible for managing the statewide contract with the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), a group-purchasing organization, and

has contracted with Cardinal Health, Inc., to serve as the wholesale distributor for statewide drug purchasing.¹

The DOH, the Department of Corrections, the Department of Children and Families, the Department of Juvenile Justice, and the Agency for Persons with Disabilities purchase pharmaceuticals and fill prescriptions for their agency clients. These agencies have consolidated most of their pharmaceutical purchasing through the bulk purchasing MMCAP contract administered by the DOH. However, the agencies often need the purchased drugs repacked into unit doses to be dispensed to clients. Most agencies contract with private firms to perform the drug repackaging. Agency staff is responsible for dispensing most of the prescriptions, although some agencies contract with private firms to dispense prescriptions at some state residential and secure facilities.

In order to control costs the five agencies that directly purchase pharmaceuticals have either established a formulary or use the Medicaid formulary. The agencies also require senior staff to approve requests to prescribe drugs not on the agency formulary. Formularies and prescribing policies are set by agency pharmacy and therapeutic committees which review physician prescribing patterns and patient utilization trends to establish appropriate drug preferences for the most cost-effective treatments. There is no statewide formulary, but drug utilization data collected by the DOH, show that the agency drug formularies are similar. The OPPAGA memo suggests that it would be feasible to consolidate formulary management under a statewide pharmacy and therapeutic advisory council. The Governor's Chief Medical Officers' Task Force is currently assessing the possibility of creating a statewide formulary.

The AHCA, the Department of Veterans' Affairs, and the Department of Management Services administer reimbursement or drug benefit plan arrangements for Medicaid recipients, veterans, and state employees, respectively, but do not purchase pharmaceuticals directly, repackage drugs, or fill and dispense prescriptions.

The Minnesota Multistate Contracting Alliance for Pharmacy

The MMCAP was created in 1985, as a free voluntary pharmaceutical group purchasing organization operated and managed by the Materials Management Division of the State of Minnesota's Department of Administration for government health care facilities that includes the participation of at least 45 states and several cities. There are at least four other operating multi-state buying pools but the MMCAP is the largest. Purchasing pharmaceuticals through the MMCAP allows the state to leverage its purchasing volume and obtain lower prices than wholesale distributors traditionally offer.

The MMCAP reports that it achieves an average savings of approximately 23.7 percent below the average wholesale price for brand name pharmaceuticals and 65 percent below the average wholesale price for generic drugs.² Participating states also achieve administrative savings by avoiding the need to establish their own contracts. Florida agencies that purchase through the MMCAP pay no dispensing fees for prescription drugs, unless the agency has a contract for

¹ 64F-15.001, Florida Administrative Code.

² National Conference of State Legislatures, Pharmacy Bulk Purchasing: Multi-state and Inter-agency Plans, 2008. Found at: < <http://www.ncsl.org/programs/health/bulkrx.htm> > (Last visited March 29, 2009).

pharmacy services to fill prescriptions. In April 2008, the MMCAP administration contracted with a consulting firm to evaluate the MMCAP's prices and found them to be lower than prices achieved by the other four multi-state group-purchasing organizations.³

The OPPAGA memo reported that three pharmaceutical procurement methods were more cost-effective than contracting with the MMCAP, but the methods were not generally available to all state agencies. The lowest prices nationally are obtained through the U.S. Department of Veterans Affairs, the Medicaid program, and the federal 340B pricing program.

340B Drug Pricing Program

The 340B Drug Pricing program was established in U.S. Public Law 102-585, of the Veterans Health Care Act of 1992. Section 340B of the law limits the costs of drugs for federal purchasers and for certain federal agency grantees. The program is administered by the federal Office of Pharmacy Affairs. As of April 1, 2007, the 340B program had 12,290 participants including Federally Qualified Health Centers (FQHC), HIV/AIDS clinics (Ryan White Title I-IV), family planning clinics, and certain Disproportionate Share Hospitals.⁴ Participants in the 340B program purchase pharmaceuticals through a wholesaler or directly from the manufacturer. A recent survey found that 340B prices are approximately 24 percent lower than that available to group purchasing organizations.⁵

The DOH is the only state agency that can purchase drugs at the federal 340B prices because the DOH is the recipient of federally awarded programs and responsible for the administration of the FQHC. However, Florida may be able to expand some of its pharmaceutical purchasing through the 340B program. The Department of Corrections is piloting an initiative with the DOH to purchase drugs for patients with HIV/AIDS and sexually transmitted diseases through the 340B program. Physicians employed by the DOH will treat inmates in the pilot, and because of the direct treating relationship, the DOH will be authorized to purchase drugs for inmates in the pilot project.

Department of Health Central Pharmacy

The DOH is authorized to establish and maintain a pharmacy services program under s. 381.0203(2), F.S. The pharmacy services provided by the DOH include a central pharmacy to support pharmaceutical services provided by the county health departments, including pharmaceutical repackaging, dispensing, and the purchase and distribution of immunizations and other pharmaceuticals. The DOH is also the agency responsible for the regulation of drugs, cosmetics, and household products under ch. 499, F.S. According to the OPPAGA memo, the DOH central pharmacy could provide cost-effective pharmaceutical repackaging and prescription

³ MMCAP Pharmacy GPO Pricing Evaluation, The Patterson Dahlgren Group, Inc, 2008. Found at: < http://www.naspo.org/documents/MMCAP_2008_Final.pdf > (Last visited on March 29, 2009).

⁴ See <http://www.ncsl.org/legis/HEALTH/drug340b.htm> (Last visited on March 29, 2009).

⁵ National Conference of State Legislatures, Pharmacy Bulk Purchasing: Multi-state and Inter-agency Plans, 2008. Found at: < <http://www.ncsl.org/programs/health/bulkrx.htm> > (Last visited on March 29, 2009).

filling services to other state agencies. The current agency costs are illustrated in the graph below:⁶

Contract/Agency	Unit Dose Rate or Script Dispensing Fee
Omnicare/Agency for Persons with Disabilities	\$4.23 per prescription
Guardian/Agency for Persons with Disabilities	\$4.23 per prescription
Terry Yon and Associates/ Agency for Persons with Disabilities	\$3.50 per prescription
Terry Yon and Associates/ Department of Corrections	\$1.85 per 30 count card \$3.00 per 100 count strip
Terry Yon and Associates/ Department of Juvenile Justice	\$3.40 per prescription
Department of Health	\$1.57 to \$1.85 per 30 count card \$2.50 per 100 strip \$1.57 mail order fill (plus \$2.00 shipping)

The Medicaid Prescription Drug Program

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) (chapter 2001-104, Laws of Florida). Medicaid prescribing practitioners are required to prescribe the medications on the PDL, or must obtain prior authorization from the AHCA to prescribe a medication not on the PDL, in order for the prescription to be paid for by Medicaid. The Medicaid program spent \$1.1 billion on pharmaceutical reimbursement in FY 2007-08.⁷

The PDL is a listing of the most cost-effective therapeutic options recommended by the Medicaid Pharmacy and Therapeutics (P & T) Committee, codified in s. 409.9115, F.S. The P & T Committee, composed of 11 members appointed by the Governor, meets at least quarterly, reviews all drug classes included on the PDL once a year, and recommends pharmaceuticals for PDL inclusion or removal. The P & T Committee may also make recommendations to the AHCA regarding prior authorization requirements for Medicaid prescribed drugs.

Other Medicaid prescription drug programs and policies include:

- The AHCA contracts with eMPowerX to provide Medicaid prescribing practitioners with a handheld wireless personal digital assistant (PDA) that gives providers access to a comprehensive “real time” clinical drug database, a 90-day prescription history for patients, the Medicaid PDL, and electronic prescribing capabilities.⁸
- The Florida Medicaid Drug Therapy Management Program in s. 409.912(39)(a)10., F.S., that focuses on improving the quality of behavioral health drug prescribing, improving patient adherence, reducing clinical risk, and lowering costs.

⁶ Source: OPPAGA Research Memorandum on the Feasibility of Consolidating Statewide Pharmaceutical Services, March 3, 2009, OPPAGA analysis of contracts with the Agency for Persons with Disabilities, the Department of Corrections, and the Department of Juvenile Justice, and administrative cost reports from the Department of Health.

⁷ OPPAGA Research Memorandum on the Feasibility of Consolidating Statewide Pharmaceutical Services, March 3, 2009.

⁸ AHCA, Medicaid Prescribed Drug Program, Spending Control Initiatives, Quarterly Report, December 31, 2007. Found at: < http://ahca.myflorida.com/Medicaid/Prescribed_Drug/pdf/quarterly_report_12_31_2007.pdf > (Last visited on March 29, 2009).

- The Recipient Lock-in Program requires Medicaid recipients who have been identified as high volume pharmaceutical drug users and potential abusers of prescribed drugs, or who consistently obtain prescriptions from multiple physicians to be enrolled in the lock-in program. A Medicaid recipient enrolled in the lock-in program must obtain all of his or her medications through a single pharmacy for the next 12 months.
- The AHCA received federal funding to for a Generic Prescription GenRx Program to increase the use of generic drugs in the Medicaid program, provide Medicaid recipients with 10-day starter packs of generic medication during a physician office visit, electronically transmit the prescription to the recipient's pharmacy, and provide treatment guideline compliance.
- The Medicaid Drug Utilization Board, required by federal law, reviews and approves drug use criteria and standards for both prospective and retrospective drug use reviews. The Board applies these criteria and standards in the application of drug utilization review activities, reviews and reports the results of the drug use reviews, and recommends and evaluates the educational intervention programs.

III. Effect of Proposed Changes:

Section 1. Creates the Pharmacy and Therapeutic Advisory Council (Council) in the Executive Office of the Governor to advise the DOH and other government agencies. The members of the Council and the chair will be appointed by the Governor to 2-year terms or until their successors are appointed and members may be appointed to more than one term. Council members must be residents of Florida, and must be selected on the basis of specialty, board certification, prior pharmacy and therapeutic experience, experience treating medical assistance recipients, ability to represent a broad base of constituents, and number of years in practice. Council membership must include at least one physician, pharmacist, and nurse licensed under chapters 458, 465, and 464, F.S., respectively.

The Council will include voting and nonvoting members. Voting members will include:

- The Council chair, who must be a pharmacist and employed by a state agency that will be responsible for staffing the Council;
- Representatives from the AHCA, the DOH, the Agency for Persons with Disabilities, the Department of Children and Family Services, the Department of Corrections, the Department of Elderly Affairs, and the Department of Juvenile Justice; and
- The Bureau Chiefs of the AHCA Medicaid Bureau of Pharmacy Services and the DOH Bureau of Statewide Pharmaceutical Services.

The nonvoting members on the Council will include one representative from the AHCA's drug contracting program and one representative from the Executive Office of the Governor. Other nonvoting members will include:

- The contracting officer for the DOH's drug procurement program;
- A clinical pharmacy program manager from the AHCA;
- The chair of the DOH's Pharmacy and Therapeutics Committee;
- The general counsel for the AHCA or his or her designee;
- The general counsel for a state agency or his or her designee; and

- The statewide pharmacy director of the Department of Corrections' Office of Health Services.

The bill prohibits the Council from interfering with the Medicaid Pharmacy and Therapeutics Committee or the Drug Utilization Board, which oversee clinical activities within the Medicaid Bureau of Pharmacy Services, and from interfering with existing mandated Medicaid services and from developing or implementing new Medicaid policies. The Council is specifically prohibited from interfering with the work of the AHCA as it relates to the federal and state requirements to develop a preferred drug list, negotiate rebate agreements for medications included in the preferred drug list, and protecting the confidentiality of rebate agreements.

The Council is directed to use Medicaid's processes as a guide for assisting state agencies in:

- Developing an unbiased clinical perspective on drug evaluations and utilization protocols that are relevant to patient care provided by state agencies;
- Developing drug-utilization-review processes relevant to state agencies;
- Building a formulary structure that enforces formulary compliance or adherence within each agency;
- Performing pharmacoeconomic analyses on formulary management so that the state maximizes the cost effectiveness of the its pharmaceutical purchasing;
- Reviewing new and existing therapies using criteria established for efficacy, safety, and quality in order to maximize cost-effective purchasing; and
- Reviewing state agency proposals to maximize the cost of effectiveness of pharmaceutical purchasing in compliance with s. 381.0203, F.S.

The bill requires the Council to verify the cost-effectiveness and clinical efficacy of any state bulk purchasing contract under s. 381.0203(1), F.S., at least once every two years.

Council members will serve without compensation but will be entitled to travel and per diem expenses under s. 112.061, F.S. The Council is authorized to request the participation of subject-matter experts to address specific drug, therapeutic, or drug procurement issues under review by the Council.

The bill specifies that a majority of the members on the council constitutes a quorum and an affirmative vote of a majority of the members is necessary to take action. The Council will meet quarterly, or at the call of the chair.

Section 2. Amends s. 381.0203, F.S., to require the DOH to contract on a statewide basis for the purchase of pharmaceutical drugs, to be used by state agencies and political subdivisions. The bill requires all state agencies, with the exception of the Agency for Health Care Administration, the Department of Management Services, and the Department of Veterans' Affairs, to purchase drugs through the statewide contract unless:

- The Pharmacy and Therapeutic Advisory Council created in the bill approves a more cost-effective purchasing plan; or
- The drugs required are not available through the statewide purchasing contract.

Of the eight state agencies that provide prescription drugs services to their clients, five already purchase most of their pharmaceuticals through the statewide purchasing contract administered by the DOH.

The DOH currently operates a central pharmacy that repackages, dispenses, and purchases pharmaceuticals and immunizations for county health departments. The bill directs the DOH to provide central pharmacy services to other state agencies and political subdivisions upon written agreement. The bill provides that cost savings realized by the state through the utilization of the central pharmacy may be used by the DOH to offset any additional costs.

Section 3. Amends s. 499.003, F.S., to specify that a “wholesale distribution” of a prescription drug to persons other than a consumer or patient does not include: the sale, purchase, trade, or transfer of a prescription drug among agencies and health care entities of the state to complete the dispensing of a prescription drug to a patient under the care of a state agency or health care entity, or to a patient for whom the state is responsible for providing or arranging health care services. The bill provides that the agency or health care entity that receives the prescription drug on behalf of the patient is deemed the patient’s agent.

This provision will facilitate the purchasing of prescription drugs by the DOH on behalf of other state agencies and the dispensing of the drugs by the DOH.

Section 4. The effective date of the bill is July 1, 2009.

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 Article VII, Section 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 Article I, Section 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 Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Agency for Persons with Disabilities has estimated that by consolidating its purchasing of pharmaceuticals with the DOH, and utilization of the DOH central pharmacy would produce a net savings of \$488,258 to the Agency. The cost saving estimated does not include Medicaid recipients served by the Agency.

The Department of Juvenile Justice and the Department of Corrections estimate cost savings associated with increasing department pharmaceutical purchasing through the MMCAP contract and repackaging and filling prescriptions through the DOH Central Pharmacy.

The DOH will incur additional costs to handle the increased demand of pharmacy central services. However, the bill provides that cost savings realized by other agencies that use the central pharmacy will be transferred to the DOH to offset the additional workload.

The Pharmacy and Therapeutics Advisory Committee created in the bill is directed to meet at least quarterly. The state will incur a cost to provide reimbursement Council member for travel expenses and per diem.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation Committee on April 1, 2009:

The committee substitute substantially changed the bill in the following ways:

- Creates the Pharmacy and Therapeutic Advisory Council in the Executive Office of the Governor to promote quality, consistency, and efficiency in the state purchasing and administration of pharmaceuticals;
- Specifies membership and duties of the Pharmacy and Therapeutic Advisory Council;
- Requires certain state agencies to directly purchase drugs through the statewide purchasing contract administered by the Department of Health, unless the Pharmacy and Therapeutics Council approves a more cost-effective agency plan, or the drugs are not available through the contract; and

- Authorizes the Department of Health central pharmacy to provide pharmacy services to other state agencies, including the repacking, dispensing, purchasing, and dispensing of pharmaceuticals.

B. Amendments:

None.

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