By the Committee on Health Regulation; and Senators Gaetz, Peaden, and Rich

588-04075-09 2009578c1

A bill to be entitled

An act relating to state pharmacy services; creating the Pharmacy and Therapeutic Advisory Council within the Executive Office of the Governor; providing duties of the council; providing for the appointment and qualification of members; providing for the use of subject-matter experts when necessary; providing requirements for voting and a quorum; providing for quarterly meetings of the council; providing for staffing; providing for reimbursement of per diem and travel expenses for members of the council; amending s. 381.0203, F.S.; requiring certain state agencies to purchase drugs through the statewide purchasing contract administered by the Department of Health; providing an exception; amending s. 499.003, F.S.; excluding from the definition of "wholesale distribution" certain activities of state agencies; providing an effective date.

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Be It Enacted by the Legislature of the State of Florida:

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Section 1. The Pharmacy and Therapeutic Advisory Council.—
(1) The Pharmacy and Therapeutic Advisory Council is
created within the Executive Office of the Governor to serve in
an advisory capacity to the Department of Health and other
governmental agencies. The council may not interfere with
existing mandated Medicaid services and may not develop or
implement new ones. Specifically, the council may not interfere
with the work of the Agency for Health Care Administration as it

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complies with federal and state statutory obligations to develop a preferred drug list, to negotiate rebate agreements for medications included in the preferred drug list, and to protect the confidentiality of rebate agreements. The council may not interfere with the Medicaid Pharmacy and Therapeutics Committee or the Drug Utilization Review Board, which oversee clinical activities within the Medicaid Bureau of Pharmacy Services if such interference would violate any federal or state statutory obligations.

- (2) The Pharmacy and Therapeutic Advisory Council shall use Medicaid processes within the existing Medicaid structure of the Agency for Health Care Administration as a guide for assisting state agencies in:
- (a) Developing an unbiased clinical perspective on drug evaluations and utilization protocols that are relevant to patient care provided through programs administered by state agencies.
- (b) Developing drug-utilization-review processes that are relevant to the agencies and those receiving care through programs administered by the agencies.
- (c) Building a formulary structure that enforces formulary compliance or adherence within each agency.
- (d) Performing pharmacoeconomic analyses on formulary management so that the state maximizes the cost-effectiveness of its pharmaceutical purchasing.
- (e) Reviewing new and existing therapies using criteria established for efficacy, safety, and quality in order to maximize cost-effective purchasing.
 - (f) Reviewing state agency proposals to maximize the cost-

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effectiveness of pharmaceutical purchasing in compliance with s. 381.0203.

- (3) The council shall verify the cost-effectiveness and clinical efficacy of any state contracts under s. 381.0203(1), Florida Statutes, no less than once every 2 years.
- (4) The members of the council and the chair shall be appointed by the Governor to 4-year staggered terms or until their successors are appointed. Members may be appointed to more than one term. The Governor shall fill any vacancies for the remainder of the unexpired term in the same manner as the original appointment.
- (5) The council shall include voting and nonvoting members, and the chair, who is a voting member, must be a pharmacist employed by a state agency.
 - (a) The voting members shall represent:
 - 1. The Agency for Health Care Administration.
 - 2. The Agency for Persons with Disabilities.
 - 3. The Department of Children and Family Services.
 - 4. The Department of Corrections.
 - 5. The Department of Elderly Affairs.
 - 6. The Department of Health.
 - 7. The Department of Juvenile Justice.
- 8. The Bureau of Medicaid Pharmacy Services within the Agency for Health Care Administration, which shall be represented by the bureau chief.
- 9. The Bureau of Statewide Pharmaceutical Services within the Department of Health, which shall be represented by the bureau chief.
 - (b) The nonvoting members shall be:

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1. A representative from the Agency for Health Care Administration's drug contracting program.

- 2. The contracting officer for the Department of Health's drug procurement program.
- 3. A clinical pharmacy program manager from the Agency for Health Care Administration.
- $\underline{\text{4. The chair of the Department of Health's Pharmacy and}}$ Therapeutics Committee.
- 5. The general counsel for the Agency for Health Care Administration or his or her designee.
- 6. The general counsel for a state agency in the executive branch of state government, or his or her designee.
- $\underline{\text{7. A representative from the Executive Office of the}}$ Governor.
- 8. The statewide pharmacy director of the Department of Corrections' Office of Health Services.
- (6) Members of the council shall consist of at least one physician licensed under chapters 458 or 459, Florida Statutes, at least one pharmacist licensed under chapter 465, Florida Statutes, and at least one registered nurse licensed under chapter 464, Florida Statutes. Each member designated in this subsection must have an active license in his or her profession and may not have been the subject of any agency disciplinary action.
- (7) Members, who must be residents of this state, shall 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 of practice. Members must not

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have any conflicts of interest due to their service on the council.

- (8) The council may request the participation of additional subject-matter experts to address specific drug, therapeutic, or drug-procurement issues under review by the council.
- (9) A majority of the members of the council constitutes a quorum, and an affirmative vote of a majority of the voting members is necessary to take action.
- (10) The council shall meet quarterly or at the call of the chair.
- (11) The council shall be staffed by the chair's department or agency.
- (12) The council members shall serve without compensation, but are entitled to reimbursement for travel and per diem expenses incurred in the performance of their duties in accordance with s. 112.061, Florida Statutes.
- Section 2. Subsection (1) and paragraph (a) of subsection (2) of section 381.0203, Florida Statutes, are amended to read: 381.0203 Pharmacy services.—
- (1) The department <u>must</u> <u>may</u> contract on a statewide basis for the purchase of drugs, as defined in s. 499.003, to be used by state agencies and political subdivisions, and may adopt rules to administer this section. <u>Effective January 1, 2010, all state agencies</u>, except the Agency for Health Care

 <u>Administration</u>, the Department of Veterans' Affairs, and the <u>Department of Management Services</u>, must purchase drugs through the statewide contract unless:
- (a) The Pharmacy and Therapeutic Advisory Council approves a more cost-effective purchasing plan; or

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(b) The drugs required are not available through the statewide purchasing contract.

- (2) The department <u>must</u> <u>may</u> establish and maintain a pharmacy services program <u>that includes</u>, <u>including</u>, but <u>is</u> not limited to:
- (a) 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. Such services shall be provided to other state agencies and political subdivisions of the state upon written agreement. Cost savings realized by the state through utilization of the central pharmacy may be used by the department to offset additional costs.

Section 3. Paragraph (g) is added to subsection (53) of section 499.003, Florida Statutes, to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

- (53) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
- go The sale, purchase, trade, or transfer of a prescription drug among agencies and health care entities of the state to complete the dispensing of the 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 agency or health care entity that received the prescription drug on behalf of the patient is deemed the patient's agent under s. 465.003(6).

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175		Section	4.	This	act	shall	take	effect	July	1,	2009	•	