

HR.HR.03558

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Proposed Committee Substitute by the Committee on Health Regulation

A bill to be entitled

2 An act relating to state pharmacy services; creating 3 the Pharmacy and Therapeutic Advisory Council within 4 the Executive Office of the Governor; providing duties 5 of the council; providing for the appointment and 6 qualification of members; providing for the use of 7 subject-matter experts when necessary; providing 8 requirements for voting and a quorum; providing for 9 quarterly meetings of the council; providing for 10 staffing; providing for reimbursement of per diem and 11 travel expenses for members of the council; amending 12 s. 381.0203, F.S.; requiring certain state agencies to 13 purchase drugs through the statewide purchasing 14 contract administered by the Department of Health; providing an exception; amending s. 499.003, F.S.; 15 excluding from the definition of "wholesale 16 distribution" certain activities of state agencies; 17 18 providing an effective date. 19

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

Section 1. <u>The Pharmacy and Therapeutic Advisory Council.</u>
(1) <u>The Pharmacy and Therapeutic Advisory Council is</u>
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

Page 1 of 6

681994

HR.HR.03558

28	implement new ones. Specifically, the council may not interfere
29	with the work of the Agency for Health Care Administration as it
30	complies with federal and state statutory obligations to develop
31	a preferred drug list, to negotiate rebate agreements for
32	medications included in the preferred drug list, and to protect
33	the confidentiality of rebate agreements. The council may not
34	interfere with the Medicaid Pharmacy and Therapeutics Committee
35	or the Drug Utilization Review Board, which oversee clinical
36	activities within the Medicaid Bureau of Pharmacy Services if
37	such interference would violate any federal or state statutory
38	obligations.
39	(2) The Pharmacy and Therapeutic Advisory Council shall use
40	Medicaid processes within the existing Medicaid structure of the
41	Agency for Health Care Administration as a guide for assisting
42	state agencies in:
43	(a) Developing an unbiased clinical perspective on drug
44	evaluations and utilization protocols that are relevant to
45	patient care provided through programs administered by state
46	agencies.
47	(b) Developing drug-utilization-review processes that are
48	relevant to the agencies and those receiving care through
49	programs administered by the agencies.
50	(c) Building a formulary structure that enforces formulary
51	compliance or adherence within each agency.
52	(d) Performing pharmacoeconomic analyses on formulary
53	management so that the state maximizes the cost-effectiveness of
54	its pharmaceutical purchasing.
55	(e) Reviewing new and existing therapies using criteria
56	established for efficacy, safety, and quality in order to

681994

HR.HR.03558 57 maximize cost-effective purchasing. (e) Reviewing state agency proposals to maximize the cost-58 59 effectiveness of pharmaceutical purchasing in compliance with s. 381.0203. 60 61 (3) The members of the council and the chair shall be 62 appointed by the Governor to 4-year staggered terms or until their successors are appointed. Members may be appointed to more 63 64 than one term. The Governor shall fill any vacancies for the 65 remainder of the unexpired term in the same manner as the 66 original appointment. 67 (4) The council shall include voting and nonvoting members, 68 and the chair, who is a voting member, must be a pharmacist employed by a state agency. 69 70 (a) The voting members shall represent: 71 1. The Agency for Health Care Administration. 2. The Agency for Persons with Disabilities. 72 73 3. The Department of Children and Family Services. 74 4. The Department of Corrections. 75 5. The Department of Elderly Affairs. 76 6. The Department of Health. 77 7. The Department of Juvenile Justice. 78 8. The Bureau of Medicaid Pharmacy Services within the 79 Agency for Health Care Administration, which shall be 80 represented by the bureau chief. 81 9. The Bureau of Statewide Pharmaceutical Services within 82 the Department of Health, which shall be represented by the 83 bureau chief. 84 (b) The nonvoting members shall be: 85 1. A representative from the Agency for Health Care

Page 3 of 6

681994

HR.HR.03558

86	Administration's drug contracting program.
87	2. The contracting officer for the Department of Health's
88	drug procurement program.
89	3. A clinical pharmacy program manager from the Agency for
90	Health Care Administration.
91	4. The chair of the Department of Health's Pharmacy and
92	Therapeutics Committee.
93	5. The general counsel for the Agency for Health Care
94	Administration or his or her designee.
95	6. The general counsel for a state agency in the executive
96	branch of state government, or his or her designee.
97	7. A representative from the Executive Office of the
98	Governor.
99	8. The statewide pharmacy director of the Department of
100	Corrections' Office of Health Services.
101	(5) Members of the council shall consist of at least one
102	physician licensed under chapters 458 or 459, Florida Statutes,
103	at least one pharmacist licensed under chapter 465, Florida
104	Statutes, and at least one registered nurse licensed under
105	chapter 464, Florida Statutes. Each member designated in this
106	subsection must have an active license in his or her profession
107	and may not have been the subject of any agency disciplinary
108	action.
109	(6) Members, who must be residents of this state, shall be
110	selected on the basis of specialty, board certification, prior
111	pharmacy and therapeutic experience, experience treating medical
112	assistance recipients, ability to represent a broad base of
113	constituents, and number of years of practice. Members must not
114	have any conflicts of interest due to their service on the

Page 4 of 6

681994

HR.HR.03558

115 council.

116	(7) The council may request the participation of additional
117	subject-matter experts to address specific drug, therapeutic, or
118	drug-procurement issues under review by the council.
119	(8) A majority of the members of the council constitutes a
120	quorum, and an affirmative vote of a majority of the voting
121	members is necessary to take action.
122	(9) The council shall meet quarterly or at the call of the
123	chair.
124	(10) The council shall be staffed by the chair's department
125	or agency.
126	(11) The council members shall serve without compensation,
127	but are entitled to reimbursement for travel and per diem
128	expenses incurred in the performance of their duties in
129	accordance with s. 112.061, Florida Statutes.
130	Section 2. Subsection (1) and paragraph (a) of subsection
131	(2) of section 381.0203, Florida Statutes, are amended to read:
132	381.0203 Pharmacy services
133	(1) The department <u>must</u> may contract on a statewide basis
134	for the purchase of drugs, as defined in s. 499.003, to be used
135	by state agencies and political subdivisions, and may adopt
136	rules to administer this section. Effective January 1, 2010, all
137	state agencies, except the Agency for Health Care
138	Administration, the Department of Veterans Affairs, and the
139	Department of Management Services, must purchase drugs through
140	the statewide contract unless:
141	(a) The Pharmacy and Therapeutic Advisory Council approves
142	a more cost-effective purchasing plan; or
143	(b) The drugs required are not available through the

681994

HR. HR. 03558

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144	statewide purchasing contract.
145	(2) The department <u>must</u> may establish and maintain a
146	pharmacy services program, <u>that includes</u> including , but <u>is</u> not
147	limited to:
148	(a) A central pharmacy to support pharmaceutical services
149	provided by the county health departments, including
150	pharmaceutical repackaging, dispensing, and the purchase and
151	distribution of immunizations and other pharmaceuticals. Such
152	services shall be provided to other state agencies and political
153	subdivisions of the state upon written agreement. Cost savings
154	realized by the state through utilization of the central
155	pharmacy may be used by the department to offset additional
156	costs.
157	Section 3. Paragraph (g) is added to subsection (53) of
158	section 499.003, Florida Statutes, to read:
159	499.003 Definitions of terms used in this part.—As used in
160	this part, the term:
161	(53) "Wholesale distribution" means distribution of
162	prescription drugs to persons other than a consumer or patient,
163	but does not include:
164	(g) The sale, purchase, trade, or transfer of a
165	prescription drug among agencies and health care entities of the
166	state to complete the dispensing of the prescription drug to a
167	patient under the care of a state agency or health care entity,
168	or to a patient for whom the state is responsible for providing
169	or arranging health care services. The agency or health care
170	entity that received the prescription drug on behalf of the
171	patient is deemed the patient's agent under s. 465.003(6).
172	Section 4. This act shall take effect July 1, 2009.