	Amendment No. (for drafter's use only)
	CHAMBER ACTION
	<u>Senate</u> <u>House</u>
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1	The Rules & Calendar Council offered the following:
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3	Technical Amendment
4	Remove line(s) 2176-2262 and insert:
5	(34) (35) All entities providing health care services to
6	Medicaid recipients shall make available, and encourage all
7	pregnant women and mothers with infants to receive, and provide
8	documentation in the medical records to reflect, the following:
9	(a) Healthy Start prenatal or infant screening.
10	(b) Healthy Start care coordination, when screening or
11	other factors indicate need.
12	(c) Healthy Start enhanced services in accordance with the
13	prenatal or infant screening results.
14	(d) Immunizations in accordance with recommendations of
15	the Advisory Committee on Immunization Practices of the United
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States Public Health Service and the American Academy of Pediatrics, as appropriate.

(e) Counseling and services for family planning to allwomen and their partners.

20 (f) A scheduled postpartum visit for the purpose of
21 voluntary family planning, to include discussion of all methods
22 of contraception, as appropriate.

(g) Referral to the Special Supplemental Nutrition Programfor Women, Infants, and Children (WIC).

25 (35)(36) Any entity that provides Medicaid prepaid health 26 plan services shall ensure the appropriate coordination of 27 health care services with an assisted living facility in cases where a Medicaid recipient is both a member of the entity's 28 29 prepaid health plan and a resident of the assisted living 30 facility. If the entity is at risk for Medicaid targeted case 31 management and behavioral health services, the entity shall inform the assisted living facility of the procedures to follow 32 33 should an emergent condition arise.

34 (36) (37) The agency may seek and implement federal waivers 35 necessary to provide for cost-effective purchasing of home health services, private duty nursing services, transportation, 36 37 independent laboratory services, and durable medical equipment and supplies through competitive bidding pursuant to s. 287.057. 38 39 The agency may request appropriate waivers from the federal 40 Health Care Financing Administration in order to competitively 41 bid such services. The agency may exclude providers not selected 42 through the bidding process from the Medicaid provider network.

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43 (37)(38) The agency shall enter into agreements with not44 for-profit organizations based in this state for the purpose of
45 providing vision screening.

46 <u>(38)(39)(a)</u> The agency shall implement a Medicaid 47 prescribed-drug spending-control program that includes the 48 following components:

49 Medicaid prescribed-drug coverage for brand-name drugs 1. for adult Medicaid recipients is limited to the dispensing of 50 51 four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded 52 53 from this limitation. No requirements for prior authorization or 54 other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder 55 may be imposed on Medicaid recipients. Medications that will be 56 57 available without restriction for persons with mental illnesses 58 include atypical antipsychotic medications, conventional 59 antipsychotic medications, selective serotonin reuptake 60 inhibitors, and other medications used for the treatment of 61 serious mental illnesses. The agency shall also limit the amount 62 of a prescribed drug dispensed to no more than a 34-day supply. 63 The agency shall continue to provide unlimited generic drugs, 64 contraceptive drugs and items, and diabetic supplies. Although a 65 drug may be included on the preferred drug formulary, it would 66 not be exempt from the four-brand limit. The agency may 67 authorize exceptions to the brand-name-drug restriction based 68 upon the treatment needs of the patients, only when such 69 exceptions are based on prior consultation provided by the

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70 agency or an agency contractor, but the agency must establish 71 procedures to ensure that:

a. There will be a response to a request for prior
consultation by telephone or other telecommunication device
within 24 hours after receipt of a request for prior
consultation;

b. A 72-hour supply of the drug prescribed will be
provided in an emergency or when the agency does not provide a
response within 24 hours as required by sub-subparagraph a.; and

Except for the exception for nursing home residents and 79 c. 80 other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought 81 82 by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by 83 84 the prescriber and not by the pharmacy. When prior authorization 85 is granted for a patient in an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 86 87 months and monthly prior authorization is not required for that patient. 88

89 2. Reimbursement to pharmacies for Medicaid prescribed 90 drugs shall be set at the lesser of: the average wholesale price 91 (AWP) minus 15.4 percent, the wholesaler acquisition cost (WAC) 92 plus 5.75 percent, the federal upper limit (FUL), the state 93 maximum allowable cost (SMAC), or the usual and customary (UAC) 94 charge billed by the provider.

3. The agency shall develop and implement a process formanaging the drug therapies of Medicaid recipients who are using

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Amendment No. (for drafter's use only) 97 significant numbers of prescribed drugs each month. The 98 management process may include, but is not limited to, comprehensive, physician-directed medical-record reviews, claims 99 100 analyses, and case evaluations to determine the medical 101 necessity and appropriateness of a patient's treatment plan and drug therapies. The agency may contract with a private 102 103 organization to provide drug-program-management services. The 104 Medicaid drug benefit management program shall include 105 initiatives to manage drug therapies for HIV/AIDS patients, 106 patients using 20 or more unique prescriptions in a 180-day 107 period, and the top 1,000 patients in annual spending. The 108 agency shall enroll any Medicaid recipient in the drug benefit 109 management program if he or she meets the specifications of this provision and is not enrolled in a Medicaid health maintenance 110 111 organization.

112 4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, 113 114 credentialing, or similar criteria. The agency shall give 115 special consideration to rural areas in determining the size and 116 location of pharmacies included in the Medicaid pharmacy 117 network. A pharmacy credentialing process may include criteria 118 such as a pharmacy's full-service status, location, size, 119 patient educational programs, patient consultation, disease-120 management services, and other characteristics. The agency may 121 impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-122 123 participating providers.

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124 5. The agency shall develop and implement a program that 125 requires Medicaid practitioners who prescribe drugs to use a counterfeit-proof prescription pad for Medicaid prescriptions. 126 The agency shall require the use of standardized counterfeit-127 proof prescription pads by Medicaid-participating prescribers or 128 129 prescribers who write prescriptions for Medicaid recipients. The 130 agency may implement the program in targeted geographic areas or 131 statewide.

132 6. The agency may enter into arrangements that require manufacturers of generic drugs prescribed to Medicaid recipients 133 134 to provide rebates of at least 15.1 percent of the average 135 manufacturer price for the manufacturer's generic products. 136 These arrangements shall require that if a generic-drug manufacturer pays federal rebates for Medicaid-reimbursed drugs 137 138 at a level below 15.1 percent, the manufacturer must provide a 139 supplemental rebate to the state in an amount necessary to 140 achieve a 15.1-percent rebate level.

141 7. The agency may establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the 142 establishment of such formulary, it is authorized to negotiate 143 144 supplemental rebates from manufacturers that are in addition to 145 those required by Title XIX of the Social Security Act and at no 146 less than 14 percent of the average manufacturer price as 147 defined in 42 U.S.C. s. 1936 on the last day of a quarter unless 148 the federal or supplemental rebate, or both, equals or exceeds 149 29 percent. There is no upper limit on the supplemental rebates 150 the agency may negotiate. The agency may determine that specific

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Amendment No. (for drafter's use only) 151 products, brand-name or generic, are competitive at lower rebate 152 percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid 153 154 Pharmaceutical and Therapeutics Committee will consider a 155 product for inclusion on the preferred drug formulary. However, 156 a pharmaceutical manufacturer is not guaranteed placement on the 157 formulary by simply paying the minimum supplemental rebate. 158 Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and 159 Therapeutics Committee, as well as the price of competing 160 161 products minus federal and state rebates. The agency is 162 authorized to contract with an outside agency or contractor to 163 conduct negotiations for supplemental rebates. For the purposes 164 of this section, the term "supplemental rebates" means cash 165 rebates. Effective July 1, 2004, value-added programs as a 166 substitution for supplemental rebates are prohibited. The agency 167 is authorized to seek any federal waivers to implement this 168 initiative.

169 8. The agency shall establish an advisory committee for 170 the purposes of studying the feasibility of using a restricted 171 drug formulary for nursing home residents and other 172 institutionalized adults. The committee shall be comprised of 173 seven members appointed by the Secretary of Health Care 174 Administration. The committee members shall include two 175 physicians licensed under chapter 458 or chapter 459; three 176 pharmacists licensed under chapter 465 and appointed from a list 177 of recommendations provided by the Florida Long-Term Care

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The Agency for Health Care Administration shall expand 9. 180 home delivery of pharmacy products. To assist Medicaid patients 181 182 in securing their prescriptions and reduce program costs, the 183 agency shall expand its current mail-order-pharmacy diabetes-184 supply program to include all generic and brand-name drugs used 185 by Medicaid patients with diabetes. Medicaid recipients in the 186 current program may obtain nondiabetes drugs on a voluntary basis. This initiative is limited to the geographic area covered 187 188 by the current contract. The agency may seek and implement any 189 federal waivers necessary to implement this subparagraph.

190 10. The agency shall limit to one dose per month any drug191 prescribed to treat erectile dysfunction.

192 11.a. The agency shall implement a Medicaid behavioral 193 drug management system. The agency may contract with a vendor 194 that has experience in operating behavioral drug management 195 systems to implement this program. The agency is authorized to 196 seek federal waivers to implement this program.

b. The agency, in conjunction with the Department of Children and Family Services, may implement the Medicaid behavioral drug management system that is designed to improve the quality of care and behavioral health prescribing practices based on best practice guidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and the rate of inappropriate spending on Medicaid

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Amendment No. (for drafter's use only) 204 behavioral drugs. The program shall include the following 205 elements:

206 Provide for the development and adoption of best (I) 207 practice guidelines for behavioral health-related drugs such as 208 antipsychotics, antidepressants, and medications for treating 209 bipolar disorders and other behavioral conditions; translate 210 them into practice; review behavioral health prescribers and 211 compare their prescribing patterns to a number of indicators 212 that are based on national standards; and determine deviations 213 from best practice guidelines.

(II) Implement processes for providing feedback to and educating prescribers using best practice educational materials and peer-to-peer consultation.

(III) Assess Medicaid beneficiaries who are outliers in their use of behavioral health drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of behavioral health drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple sameclass behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs anddeviation from best practice guidelines.

(VI) Use educational and technological approaches to promote best practices, educate consumers, and train prescribers in the use of practice guidelines.

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(VII) Disseminate electronic and published materials.

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(VIII) Hold statewide and regional conferences.

(IX) Implement a disease management program with a model quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high users of care.

237 с. If the agency is unable to negotiate a contract with 238 one or more manufacturers to finance and guarantee savings 239 associated with a behavioral drug management program by September 1, 2004, the four-brand drug limit and preferred drug 240 241 list prior-authorization requirements shall apply to mental 242 health-related drugs, notwithstanding any provision in 243 subparagraph 1. The agency is authorized to seek federal waivers 244 to implement this policy.

245 12.a. The agency shall implement a Medicaid prescription-246 drug-management system. The agency may contract with a vendor that has experience in operating prescription-drug-management 247 248 systems in order to implement this system. Any management system that is implemented in accordance with this subparagraph must 249 rely on cooperation between physicians and pharmacists to 250 251 determine appropriate practice patterns and clinical guidelines 252 to improve the prescribing, dispensing, and use of drugs in the 253 Medicaid program. The agency may seek federal waivers to 254 implement this program.

255 b. The drug-management system must be designed to improve
 256 the quality of care and prescribing practices based on best 257 practice guidelines, improve patient adherence to medication

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258	plans, reduce clinical risk, and lower prescribed drug costs and
259	the rate of inappropriate spending on Medicaid prescription
260	drugs. The program must:
261	(I) Provide for the development and adoption of best-
262	practice guidelines for the prescribing and use of drugs in the
263	Medicaid program, including translating best-practice guidelines
264	into practice; reviewing prescriber patterns and comparing them
265	to indicators that are based on national standards and practice
266	patterns of clinical peers in their community, statewide, and
267	nationally; and determine deviations from best-practice
268	guidelines.
269	(II) Implement processes for providing feedback to and
270	educating prescribers using best-practice educational materials
271	and peer-to-peer consultation.
272	(III) Assess Medicaid recipients who are outliers in their
273	use of a single or multiple prescription drugs with regard to
274	the numbers and types of drugs taken, drug dosages, combination
275	drug therapies, and other indicators of improper use of
276	prescription drugs.
277	(IV) Alert prescribers to patients who fail to refill
278	prescriptions in a timely fashion, are prescribed multiple drugs
279	that may be redundant or contraindicated, or may have other
280	potential medication problems.
281	(V) Track spending trends for prescription drugs and
282	deviation from best practice guidelines.

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283 (VI) Use educational and technological approaches to 284 promote best practices, educate consumers, and train prescribers in the use of practice quidelines. 285 286 (VII) Disseminate electronic and published materials. 287 (VIII) Hold statewide and regional conferences. 288 (IX) Implement disease-management programs in cooperation 289 with physicians and pharmacists, along with a model quality-290 based medication component for individuals having chronic 291 medical conditions. 292 13.12. The agency is authorized to contract for drug

293 rebate administration, including, but not limited to, 294 calculating rebate amounts, invoicing manufacturers, negotiating 295 disputes with manufacturers, and maintaining a database of 296 rebate collections.

297 <u>14.13.</u> The agency may specify the preferred daily dosing 298 form or strength for the purpose of promoting best practices 299 with regard to the prescribing of certain drugs as specified in 300 the General Appropriations Act and ensuring cost-effective 301 prescribing practices.

302 15.14. The agency may require prior authorization for the off-label use of Medicaid-covered prescribed drugs as specified 303 304 in the General Appropriations Act. The agency may, but is not 305 required to, preauthorize the use of a product for an indication 306 not in the approved labeling. Prior authorization may require 307 the prescribing professional to provide information about the 308 rationale and supporting medical evidence for the off-label use 309 of a drug.

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<u>16.15.</u> The agency shall implement a return and reuse

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