A bill to be entitled 1 2 An act relating to Medicaid; amending s. 409.908, F.S.; 3 revising reimbursement rates for providers of Medicaid 4 prescribed drugs; amending s. 409.912, F.S.; revising 5 reimbursement rates to pharmacies for Medicaid prescribed 6 drugs; providing an effective date. 7 8 Be It Enacted by the Legislature of the State of Florida: 9 Section 1. Subsection (14) of section 409.908, Florida 10 Statutes, is amended to read: 11 409.908 Reimbursement of Medicaid providers .-- Subject to 12 13 specific appropriations, the agency shall reimburse Medicaid 14 providers, in accordance with state and federal law, according 15 to methodologies set forth in the rules of the agency and in 16 policy manuals and handbooks incorporated by reference therein. 17 These methodologies may include fee schedules, reimbursement methods based on cost reporting, negotiated fees, competitive 18 19 bidding pursuant to s. 287.057, and other mechanisms the agency 20 considers efficient and effective for purchasing services or 21 goods on behalf of recipients. If a provider is reimbursed based 22 on cost reporting and submits a cost report late and that cost 23 report would have been used to set a lower reimbursement rate 24 for a rate semester, then the provider's rate for that semester 25 shall be retroactively calculated using the new cost report, and 26 full payment at the recalculated rate shall be effected 27 retroactively. Medicare-granted extensions for filing cost reports, if applicable, shall also apply to Medicaid cost 28 Page 1 of 17

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29 reports. Payment for Medicaid compensable services made on 30 behalf of Medicaid eligible persons is subject to the 31 availability of moneys and any limitations or directions 32 provided for in the General Appropriations Act or chapter 216. 33 Further, nothing in this section shall be construed to prevent 34 or limit the agency from adjusting fees, reimbursement rates, 35 lengths of stay, number of visits, or number of services, or 36 making any other adjustments necessary to comply with the 37 availability of moneys and any limitations or directions 38 provided for in the General Appropriations Act, provided the 39 adjustment is consistent with legislative intent.

A provider of prescribed drugs shall be reimbursed 40 (14)41 the least of the amount billed by the provider, the provider's 42 usual and customary charge, or the Medicaid maximum allowable 43 fee established by the agency, plus a dispensing fee. The 44 Medicaid maximum allowable fee for ingredient cost will be based on the lower of: average wholesale price (AWP) minus 18.4 16.4 45 percent, wholesaler acquisition cost (WAC) plus 2.75 4.75 46 47 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge 48 49 billed by the provider. Medicaid providers are required to 50 dispense generic drugs if available at lower cost and the agency 51 has not determined that the branded product is more cost-52 effective, unless the prescriber has requested and received 53 approval to require the branded product. The agency is directed 54 to implement a variable dispensing fee for payments for 55 prescribed medicines while ensuring continued access for Medicaid recipients. The variable dispensing fee may be based 56

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57 upon, but not limited to, either or both the volume of 58 prescriptions dispensed by a specific pharmacy provider, the 59 volume of prescriptions dispensed to an individual recipient, 60 and dispensing of preferred-drug-list products. The agency may 61 increase the pharmacy dispensing fee authorized by statute and in the annual General Appropriations Act by \$0.50 for the 62 63 dispensing of a Medicaid preferred-drug-list product and reduce 64 the pharmacy dispensing fee by \$0.50 for the dispensing of a 65 Medicaid product that is not included on the preferred drug 66 list. The agency may establish a supplemental pharmaceutical 67 dispensing fee to be paid to providers returning unused unitdose packaged medications to stock and crediting the Medicaid 68 69 program for the ingredient cost of those medications if the 70 ingredient costs to be credited exceed the value of the 71 supplemental dispensing fee. The agency is authorized to limit 72 reimbursement for prescribed medicine in order to comply with 73 any limitations or directions provided for in the General 74 Appropriations Act, which may include implementing a prospective 75 or concurrent utilization review program.

76 Section 2. Subsection (39) of section 409.912, Florida77 Statutes, is amended to read:

409.912 Cost-effective purchasing of health care.--The agency shall purchase goods and services for Medicaid recipients in the most cost-effective manner consistent with the delivery of quality medical care. To ensure that medical services are effectively utilized, the agency may, in any case, require a confirmation or second physician's opinion of the correct diagnosis for purposes of authorizing future services under the Page 3 of 17

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85 Medicaid program. This section does not restrict access to 86 emergency services or poststabilization care services as defined 87 in 42 C.F.R. part 438.114. Such confirmation or second opinion 88 shall be rendered in a manner approved by the agency. The agency 89 shall maximize the use of prepaid per capita and prepaid 90 aggregate fixed-sum basis services when appropriate and other 91 alternative service delivery and reimbursement methodologies, 92 including competitive bidding pursuant to s. 287.057, designed 93 to facilitate the cost-effective purchase of a case-managed 94 continuum of care. The agency shall also require providers to 95 minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the 96 97 inappropriate or unnecessary use of high-cost services. The 98 agency shall contract with a vendor to monitor and evaluate the 99 clinical practice patterns of providers in order to identify 100 trends that are outside the normal practice patterns of a provider's professional peers or the national quidelines of a 101 102 provider's professional association. The vendor must be able to 103 provide information and counseling to a provider whose practice 104 patterns are outside the norms, in consultation with the agency, 105 to improve patient care and reduce inappropriate utilization. 106 The agency may mandate prior authorization, drug therapy 107 management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or 108 109 particular drugs to prevent fraud, abuse, overuse, and possible 110 dangerous drug interactions. The Pharmaceutical and Therapeutics 111 Committee shall make recommendations to the agency on drugs for which prior authorization is required. The agency shall inform 112 Page 4 of 17

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113 the Pharmaceutical and Therapeutics Committee of its decisions 114 regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as 115 116 Medicaid providers by developing a provider network through 117 provider credentialing. The agency may competitively bid singlesource-provider contracts if procurement of goods or services 118 119 results in demonstrated cost savings to the state without 120 limiting access to care. The agency may limit its network based 121 on the assessment of beneficiary access to care, provider 122 availability, provider quality standards, time and distance 123 standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid 124 125 beneficiaries, practice and provider-to-beneficiary standards, 126 appointment wait times, beneficiary use of services, provider 127 turnover, provider profiling, provider licensure history, 128 previous program integrity investigations and findings, peer 129 review, provider Medicaid policy and billing compliance records, 130 clinical and medical record audits, and other factors. Providers 131 shall not be entitled to enrollment in the Medicaid provider network. The agency shall determine instances in which allowing 132 133 Medicaid beneficiaries to purchase durable medical equipment and 134 other goods is less expensive to the Medicaid program than long-135 term rental of the equipment or goods. The agency may establish rules to facilitate purchases in lieu of long-term rentals in 136 order to protect against fraud and abuse in the Medicaid program 137 138 as defined in s. 409.913. The agency may seek federal waivers 139 necessary to administer these policies.

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(39) (a) The agency shall implement a Medicaid prescribeddrug spending-control program that includes the following components:

143 1. A Medicaid preferred drug list, which shall be a 144 listing of cost-effective therapeutic options recommended by the 145 Medicaid Pharmacy and Therapeutics Committee established 146 pursuant to s. 409.91195 and adopted by the agency for each therapeutic class on the preferred drug list. At the discretion 147 148 of the committee, and when feasible, the preferred drug list 149 should include at least two products in a therapeutic class. The 150 agency may post the preferred drug list and updates to the 151 preferred drug list on an Internet website without following the rulemaking procedures of chapter 120. Antiretroviral agents are 152 153 excluded from the preferred drug list. The agency shall also 154 limit the amount of a prescribed drug dispensed to no more than 155 a 34-day supply unless the drug products' smallest marketed 156 package is greater than a 34-day supply, or the drug is 157 determined by the agency to be a maintenance drug in which case 158 a 100-day maximum supply may be authorized. The agency is 159 authorized to seek any federal waivers necessary to implement 160 these cost-control programs and to continue participation in the 161 federal Medicaid rebate program, or alternatively to negotiate 162 state-only manufacturer rebates. The agency may adopt rules to implement this subparagraph. The agency shall continue to 163 provide unlimited contraceptive drugs and items. The agency must 164 165 establish procedures to ensure that:

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a. There is 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; and

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

2. Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lesser of: the average wholesale price (AWP) minus <u>18.4</u> 16.4 percent, the wholesaler acquisition cost (WAC) plus <u>2.75</u> 4.75 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

The agency shall develop and implement a process for 178 3. 179 managing the drug therapies of Medicaid recipients who are using significant numbers of prescribed drugs each month. The 180 181 management process may include, but is not limited to, 182 comprehensive, physician-directed medical-record reviews, claims 183 analyses, and case evaluations to determine the medical 184 necessity and appropriateness of a patient's treatment plan and 185 drug therapies. The agency may contract with a private 186 organization to provide drug-program-management services. The 187 Medicaid drug benefit management program shall include 188 initiatives to manage drug therapies for HIV/AIDS patients, 189 patients using 20 or more unique prescriptions in a 180-day period, and the top 1,000 patients in annual spending. The 190 agency shall enroll any Medicaid recipient in the drug benefit 191 management program if he or she meets the specifications of this 192

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193 provision and is not enrolled in a Medicaid health maintenance 194 organization.

195 The agency may limit the size of its pharmacy network 4. 196 based on need, competitive bidding, price negotiations, 197 credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and 198 199 location of pharmacies included in the Medicaid pharmacy 200 network. A pharmacy credentialing process may include criteria 201 such as a pharmacy's full-service status, location, size, 202 patient educational programs, patient consultation, disease 203 management services, and other characteristics. The agency may 204 impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-205 206 participating providers. The agency must allow dispensing 207 practitioners to participate as a part of the Medicaid pharmacy 208 network regardless of the practitioner's proximity to any other 209 entity that is dispensing prescription drugs under the Medicaid 210 program. A dispensing practitioner must meet all credentialing 211 requirements applicable to his or her practice, as determined by 212 the agency.

213 5. The agency shall develop and implement a program that 214 requires Medicaid practitioners who prescribe drugs to use a 215 counterfeit-proof prescription pad for Medicaid prescriptions. 216 The agency shall require the use of standardized counterfeitproof prescription pads by Medicaid-participating prescribers or 217 prescribers who write prescriptions for Medicaid recipients. The 218 219 agency may implement the program in targeted geographic areas or statewide. 220

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221 6. The agency may enter into arrangements that require 222 manufacturers of generic drugs prescribed to Medicaid recipients 223 to provide rebates of at least 15.1 percent of the average 224 manufacturer price for the manufacturer's generic products. 225 These arrangements shall require that if a generic-drug 226 manufacturer pays federal rebates for Medicaid-reimbursed drugs 227 at a level below 15.1 percent, the manufacturer must provide a 228 supplemental rebate to the state in an amount necessary to 229 achieve a 15.1-percent rebate level.

230 The agency may establish a preferred drug list as 7. 231 described in this subsection, and, pursuant to the establishment 232 of such preferred drug list, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to 233 234 those required by Title XIX of the Social Security Act and at no 235 less than 14 percent of the average manufacturer price as 236 defined in 42 U.S.C. s. 1936 on the last day of a quarter unless 237 the federal or supplemental rebate, or both, equals or exceeds 238 29 percent. There is no upper limit on the supplemental rebates 239 the agency may negotiate. The agency may determine that specific 240 products, brand-name or generic, are competitive at lower rebate 241 percentages. Agreement to pay the minimum supplemental rebate 242 percentage will guarantee a manufacturer that the Medicaid 243 Pharmaceutical and Therapeutics Committee will consider a 244 product for inclusion on the preferred drug list. However, a pharmaceutical manufacturer is not guaranteed placement on the 245 preferred drug list by simply paying the minimum supplemental 246 rebate. Agency decisions will be made on the clinical efficacy 247 248 of a drug and recommendations of the Medicaid Pharmaceutical and

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249 Therapeutics Committee, as well as the price of competing 250 products minus federal and state rebates. The agency is 251 authorized to contract with an outside agency or contractor to 252 conduct negotiations for supplemental rebates. For the purposes 253 of this section, the term "supplemental rebates" means cash 254 rebates. Effective July 1, 2004, value-added programs as a 255 substitution for supplemental rebates are prohibited. The agency 256 is authorized to seek any federal waivers to implement this 257 initiative.

8. 258 The Agency for Health Care Administration shall expand 259 home delivery of pharmacy products. To assist Medicaid patients 260 in securing their prescriptions and reduce program costs, the 261 agency shall expand its current mail-order-pharmacy diabetes-262 supply program to include all generic and brand-name drugs used by Medicaid patients with diabetes. Medicaid recipients in the 263 264 current program may obtain nondiabetes drugs on a voluntary 265 basis. This initiative is limited to the geographic area covered 266 by the current contract. The agency may seek and implement any 267 federal waivers necessary to implement this subparagraph.

268 9. The agency shall limit to one dose per month any drug269 prescribed to treat erectile dysfunction.

10.a. The agency may implement a Medicaid behavioral drug management system. The agency may contract with a vendor that has experience in operating behavioral drug management systems to implement this program. The agency is authorized to seek federal waivers to implement this program.

b. The agency, in conjunction with the Department ofChildren and Family Services, may implement the Medicaid

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277 behavioral drug management system that is designed to improve 278 the quality of care and behavioral health prescribing practices 279 based on best practice guidelines, improve patient adherence to 280 medication plans, reduce clinical risk, and lower prescribed 281 drug costs and the rate of inappropriate spending on Medicaid 282 behavioral drugs. The program may include the following 283 elements:

284 Provide for the development and adoption of best (I) 285 practice guidelines for behavioral health-related drugs such as 286 antipsychotics, antidepressants, and medications for treating 287 bipolar disorders and other behavioral conditions; translate 288 them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators 289 290 that are based on national standards; and determine deviations from best practice guidelines. 291

(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.

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304 Track spending trends for behavioral health drugs and (V) 305 deviation from best practice guidelines.

306 (VI) Use educational and technological approaches to 307 promote best practices, educate consumers, and train prescribers 308 in the use of practice guidelines.

309

Disseminate electronic and published materials. (VII)

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(VIII) Hold statewide and regional conferences.

311

Implement a disease management program with a model (IX) 312 quality-based medication component for severely mentally ill individuals and emotionally disturbed children who are high 313 314 users of care.

315 The agency shall implement a Medicaid prescription 11.a. 316 drug management system. The agency may contract with a vendor 317 that has experience in operating prescription drug management systems in order to implement this system. Any management system 318 319 that is implemented in accordance with this subparagraph must 320 rely on cooperation between physicians and pharmacists to 321 determine appropriate practice patterns and clinical quidelines 322 to improve the prescribing, dispensing, and use of drugs in the 323 Medicaid program. The agency may seek federal waivers to 324 implement this program.

325 The drug management system must be designed to improve b. 326 the quality of care and prescribing practices based on best 327 practice quidelines, improve patient adherence to medication plans, reduce clinical risk, and lower prescribed drug costs and 328 the rate of inappropriate spending on Medicaid prescription 329 330 drugs. The program must:

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331 Provide for the development and adoption of best (I) 332 practice guidelines for the prescribing and use of drugs in the 333 Medicaid program, including translating best practice guidelines 334 into practice; reviewing prescriber patterns and comparing them 335 to indicators that are based on national standards and practice 336 patterns of clinical peers in their community, statewide, and 337 nationally; and determine deviations from best practice 338 guidelines.

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

(III) Assess Medicaid recipients who are outliers in their use of a single or multiple prescription drugs with regard to the numbers and types of drugs taken, drug dosages, combination drug therapies, and other indicators of improper use of prescription drugs.

(IV) Alert prescribers to patients who fail to refill prescriptions in a timely fashion, are prescribed multiple drugs that may be redundant or contraindicated, or may have other potential medication problems.

351 (V) Track spending trends for prescription drugs and352 deviation from best practice guidelines.

353 (VI) Use educational and technological approaches to 354 promote best practices, educate consumers, and train prescribers 355 in the use of practice guidelines.

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(VII) Disseminate electronic and published materials.

(VIII) Hold statewide and regional conferences.

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(IX) Implement disease management programs in cooperation with physicians and pharmacists, along with a model qualitybased medication component for individuals having chronic medical conditions.

362 12. The agency is authorized to contract for drug rebate 363 administration, including, but not limited to, calculating 364 rebate amounts, invoicing manufacturers, negotiating disputes 365 with manufacturers, and maintaining a database of rebate 366 collections.

367 13. The agency may specify the preferred daily dosing form 368 or strength for the purpose of promoting best practices with 369 regard to the prescribing of certain drugs as specified in the 370 General Appropriations Act and ensuring cost-effective 371 prescribing practices.

372 14. The agency may require prior authorization for 373 Medicaid-covered prescribed drugs. The agency may, but is not 374 required to, prior-authorize the use of a product:

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a. For an indication not approved in labeling;

b. To comply with certain clinical guidelines; or

377 c. If the product has the potential for overuse, misuse,378 or abuse.

380 The agency may require the prescribing professional to provide 381 information about the rationale and supporting medical evidence 382 for the use of a drug. The agency may post prior authorization 383 criteria and protocol and updates to the list of drugs that are 384 subject to prior authorization on an Internet website without 385 amending its rule or engaging in additional rulemaking.

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386 15. The agency, in conjunction with the Pharmaceutical and 387 Therapeutics Committee, may require age-related prior 388 authorizations for certain prescribed drugs. The agency may preauthorize the use of a drug for a recipient who may not meet 389 390 the age requirement or may exceed the length of therapy for use 391 of this product as recommended by the manufacturer and approved 392 by the Food and Drug Administration. Prior authorization may 393 require the prescribing professional to provide information 394 about the rationale and supporting medical evidence for the use 395 of a drug.

396 16. The agency shall implement a step-therapy prior 397 authorization approval process for medications excluded from the 398 preferred drug list. Medications listed on the preferred drug 399 list must be used within the previous 12 months prior to the 400 alternative medications that are not listed. The step-therapy 401 prior authorization may require the prescriber to use the 402 medications of a similar drug class or for a similar medical 403 indication unless contraindicated in the Food and Drug 404 Administration labeling. The trial period between the specified 405 steps may vary according to the medical indication. The step-406 therapy approval process shall be developed in accordance with 407 the committee as stated in s. 409.91195(7) and (8). A drug 408 product may be approved without meeting the step-therapy prior 409 authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation 410 411 that the product is medically necessary because:

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a. There is not a drug on the preferred drug list to treat
the disease or medical condition which is an acceptable clinical
alternative;

b. The alternatives have been ineffective in the treatmentof the beneficiary's disease; or

c. Based on historic evidence and known characteristics of
the patient and the drug, the drug is likely to be ineffective,
or the number of doses have been ineffective.

421 The agency shall work with the physician to determine the best 422 alternative for the patient. The agency may adopt rules waiving 423 the requirements for written clinical documentation for specific 424 drugs in limited clinical situations.

425 17. The agency shall implement a return and reuse program 426 for drugs dispensed by pharmacies to institutional recipients, 427 which includes payment of a \$5 restocking fee for the 428 implementation and operation of the program. The return and 429 reuse program shall be implemented electronically and in a 430 manner that promotes efficiency. The program must permit a 431 pharmacy to exclude drugs from the program if it is not 432 practical or cost-effective for the drug to be included and must 433 provide for the return to inventory of drugs that cannot be 434 credited or returned in a cost-effective manner. The agency 435 shall determine if the program has reduced the amount of Medicaid prescription drugs which are destroyed on an annual 436 basis and if there are additional ways to ensure more 437 438 prescription drugs are not destroyed which could safely be

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439 reused. The agency's conclusion and recommendations shall be 440 reported to the Legislature by December 1, 2005.

441 The agency shall implement this subsection to the (b) 442 extent that funds are appropriated to administer the Medicaid 443 prescribed-drug spending-control program. The agency may contract all or any part of this program to private 444 445 organizations.

446 The agency shall submit quarterly reports to the (C) Governor, the President of the Senate, and the Speaker of the 447 House of Representatives which must include, but need not be 448 449 limited to, the progress made in implementing this subsection 450 and its effect on Medicaid prescribed-drug expenditures. 451

Section 3. This act shall take effect March 1, 2009.

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