By Senator Wilson

33-767-05

A bill to be entitled

An act relating to the Medicaid program; amending s. 409.91195, F.S.; requiring that the Medicaid Pharmaceutical and Therapeutics Committee recommend medications used to relieve the symptoms of the influenza virus to the Agency for Health Care Administration; providing that prior authorization for such medications is not required during certain months; amending s. 409.912, F.S.; authorizing the agency to remove the prior-authorization requirement for influenza drugs recommended by the committee; requiring that the agency reimburse a maximum supply of one medication used to treat the influenza virus; providing an effective date.

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

Section 1. Present subsection (11) of section 409.91195, Florida Statutes, is redesignated as subsection (12), and a new subsection (11) is added to that section, to read:

409.91195 Medicaid Pharmaceutical and Therapeutics Committee.--There is created a Medicaid Pharmaceutical and Therapeutics Committee within the Agency for Health Care Administration for the purpose of developing a preferred drug formulary pursuant to 42 U.S.C. s. 1396r-8.

(11) The Medicaid Pharmaceutical and Therapeutics Committee shall recommend to the agency at least two medications that diminish the effects of the influenza virus,

and these medications will not require prior authorization between the months of October and May of any year.

Section 2. Paragraph (a) of subsection (39) of section 409.912, Florida 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 Medicaid program. This section does not restrict access to emergency services or poststabilization care services as defined in 42 C.F.R. part 438.114. Such confirmation or second opinion shall be rendered in a manner approved by the agency. The agency shall maximize the use of prepaid per capita and prepaid aggregate fixed-sum basis services when appropriate and other alternative service delivery and reimbursement methodologies, including competitive bidding pursuant to s. 287.057, designed to facilitate the cost-effective purchase of a case-managed continuum of care. The agency shall also require providers to minimize the exposure of recipients to the need for acute inpatient, custodial, and other institutional care and the inappropriate or unnecessary use of high-cost services. The agency may mandate prior authorization, drug therapy management, or disease management participation for certain populations of Medicaid beneficiaries, certain drug classes, or particular drugs to prevent fraud, abuse, overuse, and possible dangerous drug interactions. The Pharmaceutical and Therapeutics Committee shall make recommendations to the

agency on drugs for which prior authorization is required. The agency shall inform the Pharmaceutical and Therapeutics Committee of its decisions regarding drugs subject to prior authorization. The agency is authorized to limit the entities it contracts with or enrolls as Medicaid providers by developing a provider network through provider credentialing. The agency may limit its network based on the assessment of beneficiary access to care, provider availability, provider quality standards, time and distance standards for access to care, the cultural competence of the provider network, demographic characteristics of Medicaid beneficiaries, practice and provider-to-beneficiary standards, appointment wait times, beneficiary use of services, provider turnover, provider profiling, provider licensure history, previous program integrity investigations and findings, peer review, provider Medicaid policy and billing compliance records, clinical and medical record audits, and other factors. Providers shall not be entitled to enrollment in the Medicaid provider network. The agency is authorized to seek federal waivers necessary to implement this policy.

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

1. Medicaid prescribed-drug coverage for brand-name drugs for adult Medicaid recipients is limited to the dispensing of four brand-name drugs per month per recipient. Children are exempt from this restriction. Antiretroviral agents are excluded from this limitation. No requirements for prior authorization or other restrictions on medications used to treat mental illnesses such as schizophrenia, severe depression, or bipolar disorder may be imposed on Medicaid

recipients. Medications that will be available without restriction for persons with mental illnesses include atypical antipsychotic medications, conventional antipsychotic medications, selective serotonin reuptake inhibitors, and other medications used for the treatment of serious mental illnesses. The agency shall also limit the amount of a prescribed drug dispensed to no more than a 34-day supply. The agency shall continue to provide unlimited generic drugs, contraceptive drugs and items, and diabetic supplies. Although a drug may be included on the preferred drug formulary, it would not be exempt from the four-brand limit. The agency may authorize exceptions to the brand-name-drug restriction based upon the treatment needs of the patients, only when such exceptions are based on prior consultation provided by the agency or an agency contractor, but the agency must establish 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

c. Except for the exception for nursing home residents and other institutionalized adults and except for drugs on the restricted formulary for which prior authorization may be sought by an institutional or community pharmacy, prior authorization for an exception to the brand-name-drug restriction is sought by the prescriber and not by the pharmacy. When prior authorization is granted for a patient in

an institutional setting beyond the brand-name-drug restriction, such approval is authorized for 12 months and monthly prior authorization is not required for that patient.

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

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

4. The agency may limit the size of its pharmacy network based on need, competitive bidding, price negotiations, credentialing, or similar criteria. The agency shall give special consideration to rural areas in determining the size and location of pharmacies included in the Medicaid

pharmacy network. A pharmacy credentialing process may include criteria such as a pharmacy's full-service status, location, size, patient educational programs, patient consultation, disease-management services, and other characteristics. The agency may impose a moratorium on Medicaid pharmacy enrollment when it is determined that it has a sufficient number of Medicaid-participating providers.

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

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

7. The agency may establish a preferred drug formulary in accordance with 42 U.S.C. s. 1396r-8, and, pursuant to the establishment of such formulary, it is authorized to negotiate supplemental rebates from manufacturers that are in addition to those required by Title XIX of the Social Security Act and at no less than 14 percent of the average manufacturer price

as defined in 42 U.S.C. s. 1936 on the last day of a quarter unless the federal or supplemental rebate, or both, equals or exceeds 29 percent. There is no upper limit on the supplemental rebates the agency may negotiate. The agency may determine that specific products, brand-name or generic, are competitive at lower rebate percentages. Agreement to pay the minimum supplemental rebate percentage will guarantee a manufacturer that the Medicaid Pharmaceutical and Therapeutics Committee will consider a product for inclusion on the preferred drug formulary. However, a pharmaceutical manufacturer is not guaranteed placement on the formulary by simply paying the minimum supplemental rebate. Agency decisions will be made on the clinical efficacy of a drug and recommendations of the Medicaid Pharmaceutical and Therapeutics Committee, as well as the price of competing products minus federal and state rebates. The agency is authorized to contract with an outside agency or contractor to conduct negotiations for supplemental rebates. For the purposes of this section, the term "supplemental rebates" means cash rebates. Effective July 1, 2004, value-added programs as a substitution for supplemental rebates are prohibited. The agency is authorized to seek any federal waivers to implement this initiative.

8. The agency shall establish an advisory committee for the purposes of studying the feasibility of using a restricted drug formulary for nursing home residents and other institutionalized adults. The committee shall be comprised of seven members appointed by the Secretary of Health Care Administration. The committee members shall include two physicians licensed under chapter 458 or chapter 459; three pharmacists licensed under chapter 465 and appointed from a

list of recommendations provided by the Florida Long-Term Care Pharmacy Alliance; and two pharmacists licensed under chapter 465.

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

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

11.a. The agency shall 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 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 behavioral drugs. The program shall include the following elements:

(I) Provide for the development and adoption of best practice guidelines for behavioral health-related drugs such as antipsychotics, antidepressants, and medications for treating bipolar disorders and other behavioral conditions; translate them into practice; review behavioral health prescribers and compare their prescribing patterns to a number of indicators that are based on national standards; and determine deviations 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 same-class behavioral health drugs, and may have other potential medication problems.

(V) Track spending trends for behavioral health drugs and deviation 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.

(VII) Disseminate electronic and published materials.

(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.

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

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

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

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

15. The agency shall implement a return and reuse program for drugs dispensed by pharmacies to institutional recipients, which includes payment of a $5 restocking fee for the implementation and operation of the program. The return and reuse program shall be implemented electronically and in a

manner that promotes efficiency. The program must permit a pharmacy to exclude drugs from the program if it is not practical or cost-effective for the drug to be included and must provide for the return to inventory of drugs that cannot be credited or returned in a cost-effective manner.

16. The agency may remove the requirement for prior authorization for the drugs recommended by the Medicaid Pharmaceutical and Therapeutics Committee, as prescribed by s. 409.91195(11), as treatment for the influenza virus. The agency shall reimburse up to a 14-day supply of one of the medications for any recipient having a prescription in order to avoid hospitalizations and complications from the influenza virus.

Section 3. This act shall take effect upon becoming a law.

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SENATE SUMMARY

Requires the Medicaid Pharmaceutical and Therapeutics Committee to make recommendations for medications used to relieve the symptoms of the influenza virus to the Agency for Health Care Administration. Provides that prior authorization for such medications is not required during certain months. Authorizes the agency to remove the prior-authorization requirement for influenza drugs recommended by the committee. Requires the agency to reimburse a maximum supply of one medication used to treat the influenza virus.