**Department of State Health Services**
**Council Agenda Memo for State Health Services Council**
**August 17-18, 2016**

**Agenda Item Title:** Amendments to rules concerning the Texas HIV State Pharmacy Assistance Program.

**Agenda Number:** 4.e.

**Recommended Council Action:**

_____For Discussion Only

___X__For Discussion and Action by the Council

**Background:**

The Texas HIV Medication Program (THMP) is a part of the HIV/STD Prevention and Care Branch, which is located within the TB/HIV/STD/Viral Hepatitis Unit in the Infectious Disease Prevention Section within the Division for Disease Control and Prevention Services.

The HIV State Pharmacy Assistance Program (SPAP) is a part of THMP, which provides medications for the treatment of HIV and its related complications for low-income Texans. SPAP provides medication copayments on behalf of eligible clients with Medicare Part D prescription drug coverage.

In fiscal year 2014, the THMP served 19,594 clients of which 2,203 were receiving insurance assistance through SPAP. The THMP is funded by federal revenue through the Ryan White Act and totaled $112,066,858 in fiscal year 2014.

**Summary:**

The proposed rule amendments to SPAP will align the THMP with new federal guidance. that requires states to pay prescription medication insurance premiums in addition to copayments and coinsurance in order to be eligible to claim a rebate. Rebates are available to the THMP as a result of changes in federal law in 2011 that allowed Ryan White Part B participants (states) to invoice drug manufacturers for rebates on medication copayments paid on behalf of clients with prescription drug coverage, either through Medicare Part D or an insurance plan. These rebates are calculated as if the SPAP were paying the full price for the drugs, not just the copayment. These rebates have ranged from $19.1 to $34.6 million in the last four years. Rebate projections for state fiscal year 2017 are in excess of $30 million.

The proposed amendments will add language to allow the SPAP to pay Medicare Part D insurance premiums in addition to copayments and coinsurance in order to be eligible to claim a rebate. In the current rules, premium payments are prohibited. If unchanged, this prohibition would mean that DSHS would be unable to file for rebates for medications. Failure to amend these rules would result in a loss of this revenue for DSHS.

**Key Health Measures:**

Outcomes will be monitored through stakeholder feedback that is routinely received and evaluated through their participation in regularly scheduled meetings of the Texas HIV Medication Advisory Committee (MAC). The MAC advises the Executive Commissioner for the Health and Human Services Commission (HHSC) and DSHS in the development of procedures and guidelines for the THMP. The MAC is charged with reviewing the THMP goals and aims, evaluating ongoing efforts, recommending both short-range and long-range goals and objectives for medication needs, and performing other tasks as assigned by the HHSC Executive Commissioner.

HIV/STD Prevention and Care Branch staff monitor the number of clients served; client demographics (race, age, ethnicity, gender, and zip code in which clients reside); the number of participating pharmacies; and the cost of prescriptions including the average annual cost per client. Staff do not anticipate any changes to these numbers as a result of the rule changes; however, they will review the data quarterly for any unintended consequences.

TB/HIV/STD Epidemiology and Surveillance staff collect general data such as the number of persons diagnosed, number and demographic information about persons living with disease, number of persons who died with the disease, and infection rates.

**Summary of Input from Stakeholder Groups:**

The following organizations attend meetings of the DSHS MAC: Legacy Community Health Services, Parkland Health System, Peabody Clinic, AIDS Arms Dallas, Bluitt Flowers Clinic, St. Hope Foundation, Tarrant County Health Department, FFACTS University Hospital Clinic, Valley AIDS Coalition, Thomas Street Clinic, David Powell Clinic, Travis County Health Department, Harris County Hospital District, and the HIV Advocacy Work Group. These organizations serve clients who receive prescription medications through ADAP and SPAP.

The MAC and attending stakeholder organizations formally reviewed the proposed rule amendments at their June 17, 2016, meeting. They discussed the amendments and only one member stated that the wording was confusing but an alternative wording choice was not proposed. Other MAC members did not agree with the comment and therefore the proposed rule text was not changed.

**Proposed Motion:**

Motion to recommend HHSC approval for publication of rules contained in agenda item # 4.e.

**Approved by Assistant Commissioner/Director:** Janna Zumbrun **Date:** 7-21-16

**Presenter:** Rachel Sanor **Program:** Texas HIV Medication Program Group Manager, TB/HIV/STD/Viral Hepatitis Unit **Phone No.:** 512-533-3002

**Approved by CPEA:** Carolyn Bivens **Date:** 7-21-16

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 98. Texas HIV Medication Program
Subchapter A. Texas HIV State Pharmacy Assistance Program
Amendments §98.3, §98.6 and §98.10

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §98.2, §98.6, and §98.10, concerning the Texas HIV State Pharmacy Assistance Program (SPAP).

BACKGROUND AND PURPOSE

The SPAP is a part of the Texas HIV Medication Program (THMP), which provides medications for the treatment of HIV and its related complication for low-income Texans. SPAP provides medication copayments on behalf of eligible clients with Medicare Part D prescription drug coverage. The amendments are proposed to align the rules with new federal funding guidance. Rebates are available to the THMP as a result of changes in federal law in 2011 that allowed Ryan White Part B participants (states) to invoice drug manufacturers for rebates on medication copayments paid on behalf of clients with prescription drug coverage, either through Medicare Part D or an insurance plan. The proposed amendments will add language to allow the SPAP to pay prescription drug coverage insurance premiums in addition to copayments and coinsurance in order to be eligible to claim a rebate. The proposed amendments, if enacted, will have an added public health benefit by adding a new method to allow the THMP to assist HIV infected individuals with their prescription medications.

SECTION-BY-SECTION SUMMARY

Amendments to §98.2, Definitions, would add “premium” to the definition of “Out-of-Pocket Costs” to clarify that this expense would be allowed.

Amendments to §98.6, Denial, Non-Renewal, and Termination of Benefits, would delete paragraph "(7) failure to continue premium payments under Medicare" as a reason for terminating enrollment in the program. This language would no longer be needed if the program is paying premiums. As a result, the remaining paragraphs are renumbered.

Amendments to §98.10, Limitations and Benefits Provided, would add “Medicare Part D premium payments” as a benefit that the program is allowed to pay for those clients enrolled in the program.

FISCAL NOTE

Ms. Imelda Garcia, Director, Infectious Disease Prevention Section, has determined that for each year of the first five years that the sections will be in effect, there will be fiscal implications to state government as a result of enforcing and administering the sections as proposed. The SPAP program currently serves approximately 2,200 clients; with an average monthly premium cost of $18.80, expanding SPAP to cover the cost of premiums would cost the State approximately $500,000 per year. However, this cost will be recouped via the rebates garnered from medication copayments. Rebate projections for Fiscal Year 2017 are in excess of $30 million. This revenue would be from drug manufacturer rebates that have ranged in previous years from $19.1 to $34.6 million. Ms. Garcia, has determined that for each year of the first five years that the sections will be in effect, there will be no fiscal implications to local governments as a result of enforcing and administering the sections as proposed.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Ms. Garcia has also determined that there will be no adverse impact on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections.

ECONOMIC COSTS TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Ms. Garcia has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated will be the improvement of public health programs for HIV infected individuals by adding a new method to allow the program to pay for prescription medications. In addition there will be improved efficiency that comes from improving the clarity and readability of these rules.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Juanita Salinas, Department of State Health Services, TB/HIV/STD/VH Unit, Mail Code 7909, P.O. Box 149347, Austin, Texas 78714-9347, or by email to juanita.salinas@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The amendments are authorized by Texas Health and Safety Code, §85.003, which requires the department to act as lead agency and primary resource for AIDS and HIV policy; Health and Safety Code, §85.016, which allows for the adoption of rules; Health and Safety Code, §85.061, which establishes the Texas HIV Medication Program; Health and Safety Code, §85.063, which requires the department to establish procedures and eligibility guidelines for the HIV Medication Program; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The amendments affect the Health and Safety Code, Chapters 85 and 1001; and Government Code, Chapter 531.

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 98. Texas HIV Medication Program
Subchapter A. Texas HIV State Pharmacy Assistance Program

Legend: (Proposed Amendment(s))
Single Underline = Proposed new language
**[Bold, Print, and Brackets]** = Current language proposed for deletion
Regular Print = Current language
(No change.) = No changes are being considered for the designated subdivision

§98.2. Definitions.

The terms, when used in this subchapter, are defined as follows:

(1) – (9) (No change.)

(10) Out-of-pocket costs--The premium, co-pay, coinsurance and deductible amounts that an individual would be expected to pay when enrolled in a Medicare prescription drug plan.

(11) – (12) (No change.)

§98.6. Denial, Non-Renewal, and Termination of Benefits.

A person may be denied enrollment in the program, be denied renewal in the program, and/or have enrollment in the program terminated for any of the following reasons:

(1) – (6) (No change.)

**[(7) failure to continue premium payments under Medicare;]**

(7) **[(8)]** failure to enroll in Medicare prescription drug plan and apply for the Low Income Subsidy under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (information on Medicare enrollment and applying for the Low Income Subsidy can be found at http://www.medicare.gov);

(8) **[(9)]** failure to notify the program of changes to permanent home address or insurance coverage;

(9) **[(10)]** the recipient notifies the program in writing that they no longer want to receive program benefits;

(10) **[(11)]** the recipient has not requested or used services during any period of six consecutive months; and/or

(11) **[(12)]** program funds are exhausted.

§98.10. Limitations and Benefits Provided.

(a) Benefits payable by the program to recipients are as follows:

(1) – (2) (No change.)

(3) Medicare Part D premium payments.

(b) – (c) (No change.)