

# Texas HIV Medication Advisory Committee Meeting Minutes

January 29, 2021

1:30 p.m.

**Location: Microsoft Teams Live Event**

Member Name	Attended
Adjei, Margaret	Yes
Alozie, Ogechika Karl, M.D.	Yes
Heresi, Gloria, M.D.	Yes
Hillard, Lionel	Yes
Lazarte, Susana, M.D.	Yes
Miertschin, Nancy, M.P.H.	Yes
Rodriguez-Escobar, Yolanda, Ph.D.	Yes
Rosas, Frank (Vice-Chair)	Yes
Vanek, Natalie, M.D. (Chair)	Yes

## **Agenda Item 1: Call Meeting to Order, Welcome and Opening Remarks**

Dr. Natalie Vanek, Chair, called the meeting to order at 1:30 pm and welcomed members, staff, presenters and public in attendance.

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## **Agenda Item 2: Logistical Announcement and Roll Call**

Ms. Sallie Allen, Facilitator, Advisory Committee Coordination Office, HHSC provided logistics announcement, called roll and asked members to introduce themselves, and determined a quorum was present.

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## **Agenda Item 3: Review and approval of the October 16, 2020 meeting minutes**

Ms. Allen requested a motion to approve the October 16, 2020 meeting minutes.

### **Motion:**

Mr. Lionel Hillard motioned to approve the October 16, 2020 meeting minutes with the edit to Agenda Item 5, to change it to read, "program overall growth was 34% due to COVID". Dr. Yolanda Rodriguez-Escobar seconded the motion. Ms. Allen conducted a roll call vote, and the motion passed unanimously with seven approves, no disapproves, and no abstentions.

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## **Agenda Item 4: Laboratory and Infectious Diseases Section Updates – Felipe Rocha, MSSW Director TB/HIV/STD Section**

Dr. Vanek introduced Mr. Felipe Rocha, MSSW Director TB/HIV/STD Section, DSHS, and he provided the committee with an update and referenced handout, *DSHS HIV AIDS Drug Assistance Program, FY21 Deficit*.

Highlights and committee member discussion included:

- Mr. Felipe Rocha explained a temporary organizational change for the TB/HIV/STD Section that became effective December 15, 2020. The Section was moved to the Division of Community Health Improvement (CHI) under Associate Commissioner, Dr. Manda Hall.
- The HIV AIDS Drug Assistance Program (ADAP) is experiencing a significant deficit of \$52 million in Fiscal Year 2021. The program will be operating at a shortfall beginning in March. Additionally, THMP experienced a \$34.4 million increase in medication costs from March 2020 – December 2020.
- Factors impacting the anticipated financial gap, which have been exacerbated by the increase of program demand due to COVID-19 job loss include:
  - Growth in program enrollment when comparing March to December 2020 to March to December 2019.
  - DSHS has taken internal measures to decrease the deficit and is working with federal partners to seek additional funds
  - DSHS implemented two policies to encourage participants to continue to receive medications:
    - Increased 30-day medication fills to 60-day fills. This practice was discontinued October 12, 2020, and
    - A No-contact emergency eligibility process which included an eligibility extension for those participants in need of recertification. This was discontinued on December 31, 2020.
  - Medications increased in cost by over \$1,000 per person annually, due in part to an increased usage in four high-cost single tablet regimens. The number of enrollees prescribed one of these medications increased from 68% to 80%.
- Solutions the THMP will be working to implement to mitigate deficit include:
  - Internal Agency Transfers - In January 2021, and currently on-going, DSHS initiated multiple internal transfers, including allocating funds that may lapse from other programs, identifying expenditures that are eligible to be paid

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with Title V funds, and temporarily removing the cost of the agency's overhead from this program. These funds will be used to cover cost of medications.

- Coronavirus Relief Funds (CRF) - DSHS is requesting \$34.4 million in CRF. This request is not guaranteed and requires Governor office and federal approval that it is an allowable expense.
- Federal Supplemental Request - HRSA is likely to respond with the award in late February 2021. DSHS requested \$51 million in supplemental funds. This request is not guaranteed and requires federal approval.
- Request to move forward \$3 million in federal funds from previous grant years to the current grant year. HRSA is likely to respond in late February. This request requires federal approval.
- Internal THMP strategies to mitigate the deficit include:
  - Remove the Premium Cap for Medicare Recipients. This will increase revenue through medication rebates by encouraging more enrollees.
  - Eliminate the Hepatitis C (HCV) Medication Program for ADAP participants. New enrollments will cease by January 31st. Existing enrollees will complete treatment medications by April 30th.
  - Elimination of 90-day medication fills. These will be discontinued with new enrollees by January 31st, and for existing enrollees by February 28th.
  - Discontinue the spenddown calculation when determining eligibility. THMP currently applies a "spend down" equal to the cost of each participant's yearly THMP medications as an income adjustment for those persons who are over the program's 200% federal poverty level (FPL) requirement. Elimination of the spend down began in the ADAP program the end of December. HRSA informed the program in 2019 that the spenddown would need to be eliminated due to lack of transparency and equity of the practice.
- Potential cost containment rules allowed through the Texas Administrative Code (TAC) that may be considered by the program include:
  - Initiate medical criteria to meet at minimum the most recent federal Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents
  - Discontinue using the formula for adjusting the applicant's gross annual income described in §98.109(b) of this title (relating to Financial Eligibility Criteria).
  - Lower the financial eligibility criteria described in §98.109(a)(4) of this title to a level that is not lower than 125% of federal poverty level.
  - Cease enrollment of new applicants.

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- The THMP has been communicating mitigation strategies with stakeholders. Groups THMP has been meeting with include: the DSHS HRSA project officer; Ryan White Part A partners; MAC sub-committees; ADAP Liaisons and all ADAP providers via All Regions Calls.

MAC members expressed concern regarding lack of communication about budget issues and the financial impact to the program, lack of transparency, and omission of stakeholder involvement with development of mitigation strategies.

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## **Agenda Item 5: THMP Update**

Dr. Vanek introduced Ms. Rachel Sanor, and she provided the committee with an update and referenced powerpoint handout, *THMP Update and COVID-19 Response*.

Highlights and committee member discussion include:

- Reviewed the MAC Appointment process and advised that the THMP released an application for recruitment for open seats on the MAC. Deadline for application submission has been extended to February 14, 2021. A total of five positions need to be filled: three consumers and two physicians.
- THMP observed a 34% growth in new clients from March–December 2020 compared to the same time in 2019. There has been a 24% increase in new enrollees who are not employed during March-December 2020 compared to the same time in 2019. Additionally, the Program has seen a 41% growth in participants who are not employed compared to the same time in 2019. In 2020, current approvals (clients reapplying/re-certifications) have increased by 18% compared to the previous year. From those current approvals, 33% of the increase is from those who are not employed, and 4% of the growth is from those who report being employed.
- HRSA conducted a site visit in 2019 which resulted in a finding that the implementation of the THMP spenddown was not equally applied to all participants. THMP uses the client's personal cost of medications, which can vary, to calculate the spenddown amount and HRSA determined this practice not equitable or transparent.
- As a result of the discontinuation of the spenddown, THMP estimates that 1,300 ADAP participants (estimated to be 7% of total clients) who would have been approved with the spenddown will no longer be eligible. THMP is not retroactively analyzing clients who were previously approved with the spenddown. Instead, when these participants are due for re-certification their application will be reviewed without applying the spenddown.
- The Program continues to see growth in applicants who are lower income and clients not employed. Additionally, the Federal Poverty Level guidance (FPL) has been revised so some clients who may not have qualified previously may now be eligible. Both of these factors contribute to rising program costs.

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- Clients determined not eligible will receive a denial letter from THMP and resources for patient assistance programs like Harbor Path and Gilead to assist with medications.
  - SPAP and TIAP spenddown is projected to be eliminated in May 2021. This delay will allow transition to another insurance plan.

MAC members raised concerns with timing of notification to the community about HRSA finding of the spenddown and potential mitigation strategies. Members also inquired about use of State emergency funds to help off-set the deficit.

- THMP Pharmacy Warehouse is now operating on a "just in time" purchasing system to better manage inventory and distribution of medications.
- Program has seen a change in the mix of ADAP, SPAP, and TIAP clients. SPAP and TIAP clients have remained stable. The most significant growth has been in ADAP. The majority of ADAP enrollees comprise 90% of all clients. During the same quarter last year, ADAP enrollees made up 86% of clients.

THMP has noted significant growth (29% increase) in the use of Biktarvy, a high-cost single tablet regimen that also coincides with increased program enrollment.

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## **Agenda Item 6: Sub-committee Reports (Governance/Data, Eligibility, Formulary)**

Governance and Data sub-committee – Ms. Nancy Miertschin, Chair – advised there was no sub-committee report available.

Eligibility sub-committee – Mr. Frank Rosas, Chair – advised there was no update to provide.

Formulary sub-committee - Dr. Natalie Vanek, Chair – provided following update.

- November meeting - Dr. Roberto Arduino, Houston who is involved in clinical trials for Long Acting Cabotegravir/Rilpivirine. Advised of possible work-flow strategies for distribution of medication to the State and eligible pharmacies.
- December meeting - Focused on Long Acting Cabotegravir/Rilpivirine and unique challenges to rural pharmacies.
- January meeting - Also focused on Long Acting Cabotegravir/Rilpivirine. Dr. Wari Allison spoke to the committee about potential education/training models for the administration of the medication; especially for rural areas. Committee was updated on the eligibility spenddown by THMP.
- Dr. Margaret Adjei recommended that THMP communication guidelines be shared with pharmacists who are often the first point of contact for many rural clients who may need resources for patient assistance programs if they are deemed ineligible in the future.

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## **Agenda Item 7: Public Comment**

- The following individuals provided public oral comment at the meeting regarding changes to the THMP spenddown process:
  - Scott Bertani – Health HIV; oppose changes
  - Helen Zimba – The Afiya Center; oppose changes
  - Tana Pradia – Positive Women’s Network/Co-Chair, Houston Planning Council; oppose changes
  - Allen Murray – Chair, Houston Planning Council; oppose changes
  - Elias Cantu – Valley AIDS Council; oppose changes
  - Isaiah Madrigal – Consumer; oppose changes
  - Alex Moses – Positive Organizing Network; oppose changes
  - Januari Fox – Prism Health North Texas; oppose changes
  - Ruston Taylor – Legacy Community Health; oppose changes
  - Evany Turk – Positive Women’s Network; oppose changes
  - Deneen Robinson – The Afyia Center; consumer/advocate; oppose changes
  - Josh Mica – consumer/advocate; oppose changes
  - Andrew Edmondson – citizen; oppose changes
- The following individuals provided written public comment at the meeting regarding elimination of the THMP spenddown process:
  - Steven Vargas – consumer; oppose changes
  - Greg Casillas – Thrive Youth Center; consumer; oppose changes
  - Aleia Elgabrownny– University Health System; oppose changes
  - Carlos Carmona – oppose changes

Dr. Vanek thanked these individuals for their public comment.

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## **Agenda Item 8: Action Items and agenda topics for next scheduled meeting, April 30, 2021**

Dr. Vanek, Chair, led the discussion on the action items and agenda topics for the next meeting.

MAC members requested that the following items be discussed at the next meeting.

- Identify cost savings for each cost containment strategy proposed by THMP
- Identify the number of clients that will be dropped from the program based on the elimination of the eligibility spenddown

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- Include breakout to capture urban vs rural areas
  - Provide budget update for transparency
  - MAC members requested THMP host an emergency meeting before next scheduled MAC meeting
  - Identify how long it takes THMP to send denial letters to clients – clients need this to apply for patient assistant programs
  - Develop frequently asked questions (FAQ) document with clear communication guidelines pharmacies can share with clients
  - Cabenuva injectable medication (cabotegravir/rilpivirine)
  - Comprehensive THMP data reports (demographics in detail in addition to Dr. Vanek’s breakdown of affected urban/rural)
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## **Agenda Item 9: Adjournment**

Dr. Vanek, Chair, thanked the members and the public and advised next meeting is scheduled for April 30, 2021, and she adjourned the meeting at 4:34pm.

To view and listen to the archived video of the January 29, 2021 Texas HIV Medication Advisory Committee meeting in its’ entirety, click on the link below.

<https://texashhsc.swagit.com/play/01302021-502>