Texas HIV Medication Advisory Committee (MAC) Meeting Minutes April 12, 2024 1:30 p.m.

Hybrid Meeting:

Microsoft Teams Virtual Meeting and Physical Location: Moreton Building, Room M-100, 1100 West 49th Street, Austin, Texas 78756

Agenda Item 1: Call to Order, Welcome, Logistical Announcements, and Opening Remarks

Mr. Frank Rosas, Chair, opened the meeting by introducing himself and welcoming members, agency staff, and members of the public who were in attendance. Mr. Rosas called the meeting to order at 1:30 p.m., then introduced and turned the floor to Ms. Jessica Arevalo, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC). She proceeded with the logistical announcement, called roll, asked members to introduce themselves, and certified a quorum with a count of ten members at roll call.

Table 1: The Texas HIV Medication Advisory Committee member attendance at the Friday, April 12, 2024, meeting.

Member Name	Attended
Adjei, Margaret, M.D.	Yes
Heresi, Gloria, M.D.	Yes
Hillard, Lionel	Yes
Lazarte, Susana, M.D. (Vice Chair)	Yes
Lyon, Cordella	Yes
Perez, Rolando, M.D.	Yes
Rodriguez-Escobar, Yolanda, Ph.D.	No
Rosas, Frank (Chair)	Yes
Stefanowicz, Michael, D.O.	Yes
Turner, Helen	Yes
Vargas, Steven	Yes

[&]quot;Yes" indicates attended meeting

Mr. Frank Rosas, Chair, acknowledged the Texas Department of State Health Services (DSHS) staff: Ms. Rachel Sanor, HIV Care and Medications Unit Director. Ms. Sanor introduced DSHS staff in attendance: Mr. Josh Hutchison, Associate Commissioner of Infection Disease Prevention Division (IDP); Ms. Aelia Khan Akhtar, Deputy Associate Commissioner for IDP; Ms. D'Andra Luna, HIV/STD Section Director; Ms. Sylvia Jimenez, Texas HIV Medications Program (THMP) Manager; Ms. Kati Kieffer, Finance Manager; Ms. Ethel Garcia, Medication Data and Analysis Group Manager; Mr. Gil Flores, Communication and Policy Group Manager; Ms. Khuyen Tina Nguyen, Program Specialist, Communications and Policy Group; Ms. Jasmine King, Program Liaison, THMP Program Specialist; Ms. Terri Lemuel, THMP Public Health Specialist.

Agenda Item 2: MAC appointment update

Mr. Rosas introduced Ms. Tina Nguyen, who provided an update on the MAC appointments. Ms. Nguyen confirmed that THMP filled the eleven voting seats of the MAC for 2024. She thanked Dr. Ogechika Alozie, a former MAC member, for his work and service over the past five years of serving on the MAC. Ms. Nguyen welcomed new MAC members: Ms. Cordella Lyon, Dr. Rolando

[&]quot;No" indicates did not attend meeting

Perez, and Dr. Michael Stefanowicz.

Agenda Item 3: Consideration of January 12, 2024, Draft Meeting Minutes

Mr. Rosas referred members to the draft minutes emailed by the program liaison and called for any edits. Hearing none, Mr. Rosas called for a motion to approve the minutes of the January 12, 2024, meeting.

MOTION

Ms. Helen Turner motioned to approve the January 12, 2024, draft minutes as presented. Mr. Lionel Hillard seconded the motion. Ms. Arevalo conducted a roll call vote, and the motion passed by a majority vote with nine yeas (Adjei, Hillard, Lazarte, Lyon, Perez, Rosas, Stefanowicz, Turner, and Vargas), no nays, and two absences (Heresi and Rodriguez-Escobar).

Agenda Item 4: Public Comment

The following individuals sent a written public comment:

- Januari Fox, M.S.W., Director of Policy, Advocacy, and Community Engagement, Prism Health North Texas.
 - Ms. Fox's letter requested DSHS fast-track the proposed timeline for adding Cabenuva to the THMP formulary to help bridge the gap of inequitable access for historically underserved populations.
- Ida Starks, Ambassador, ViiV Healthcare.
 Ms. Starks' letter supported inclusion and affirmed that people living with HIV deserved equitable access to care, including long-acting HIV treatment.
- Matthew Cates, D.O., M.P.H., AAHIVS, Alamo Area Resource Center.
 Dr. Cates' letter encouraged the adoption of Cabenuva under the AIDS Drug Assistance Program (ADAP) formulary to have a stronger, more equipped HIV community in Texas and help the community get closer to an HIV-free future.
- Harmony Garges, M.D., M.P.H., Chief Medical Officer, ViiV Healthcare.
 Dr. Garges' letter requested DSHS include Cabenuva in the THMP formulary for the benefit of people with HIV in the state of Texas.
- Kimberly Smith, M.D., M.P.H., Head of R&D, ViiV Healthcare. Dr. Smith's letter requested DSHS add Cabenuva to the THMP formulary so people living with HIV can access the latest scientific innovations in HIV treatment.
- Dr. Jose Zuniga, President and CEO, International Association of Providers of AIDS Care.
 Dr. Zuniga's letter encouraged making long-acting injectable antiretroviral therapy
 available to eligible people living with HIV across Texas; doing so would not only honor
 patient choice and autonomy but also contribute to the progress toward ending the HIV
 epidemic.

The following individuals provided an onsite public comment:

- Ida Starks, Ambassador, ViiV Healthcare.
 Ms. Starks supported inclusion and advocated for equitable access to care, including longacting HIV treatments.
- Nazley Mohammadi, Pharmacy Manager, CommUnityCare: David Powell Health Center.
 Ms. Mohammadi gave kudos to the THMP team and everyone else who helped make and conduct the TCT pharmacy portal rollout. She also requested Texas add Cabenuva to the formulary and hoped THMP would remove the six-month recertification requirement.
- Dora Martinez, M.D., represented herself.

Dr. Martinez requested Texas provide access and ensure fairness to Texans living with HIV by adding the long-acting injectable, Cabenuva, to the ADAP formulary.

• Lindsay Lanagan, Vice President of Government Relations, Legacy Community Health. Ms. Lanagan advocated adding Cabenuva to the ADAP formulary.

The following individuals provided a virtual oral public comment:

- Michael Elizabeth, Public Health Policy Strategist, Equality Federation.
 Mr. Elizabeth urged DSHS to add Cabenuva to the THMP formulary; doing so would improve health outcomes and equity for the Texas community.
- Harmony Garges, M.D., M.P.H., Chief Medical Officer, ViiV Healthcare.
 Dr. Garges urged THMP to ensure people living with HIV in Texas can access the latest HIV treatments, including Cabenuva.

Agenda Item 5: DSHS Updates

Mr. Rosas introduced Mr. Josh Hutchison, Ms. D'Andra Luna, and Ms. Rachel Sanor to provide DSHS updates.

Highlights included:

a. Agency update

Mr. Hutchison welcomed Ms. Aelia Akhtar, Deputy Associate Commissioner, to IDP. He also acknowledged the public comments. Mr. Hutchison confirmed DSHS is currently reviewing the analysis. DSHS wants to ensure the program does not repeat the same mistakes that caused the \$30 million shortfall a few years prior.

b. HIV/STD Section update
Ms. Luna announced the Operations Unit Director position is vacant as of March 2024.

c. Medication cost analysis

Ms. Sanor provided a brief background on Policy Clarification Notice (PCN) 21-02. She explained PCN 21-02 provides eligibility guidance for the ADAP program. The Texas ADAP program looked at two items within PCN 21-02: eliminating the self-attestation and giving a one-month grace period for recertification. The HIV Care and Medication Unit estimated the cost of eliminating self-attestation during fiscal years 2024 and 2025 at \$40.3 million. The estimated cost of adding a one-month grace period during recertification is \$10.4 million. The overall updated estimated cost is \$52.9 million.

Ms. Sanor shared activities that THMP implemented to reduce the number of people not receiving their medication or failing to renew. THMP increased outreach to those who missed their self-attestation or recertification. The program also reached out to the clients who are currently eligible but have not filled out their medication recently.

d. Formulary

Ms. Luna presented the 90-day fill data. THMP implemented the 90-day fill in August 2023. The percentage of total client utilization was two percent, the percentage of total script utilization was 1.7 percent at that time, and the total cost toward a 90-day supply was 1.9 percent. In February 2024, the total client utilization increased to five percent, and the total script utilization increased to 4.5 percent. The total cost of the 90-day supply was 8.8 percent. Ms. Luna shared THMP's estimated cost of adding Cabenuva to the formulary could be up to \$6.4 million per year.

e. Budget report

Ms. Luna mentioned the state fiscal year (FY) starts on September 1 and runs through August 31. She explained due to additional medication expenditures, the current amount

THMP would roll over to FY24 is \$17.5 million. THMP received \$24.1 million in rebates for FY24.

Discussion

- Mr. Steven Vargas asked about the PCN summary slide and wondered if this meant that it would not be feasible for THMP to remove the six-month attestation.
- Mr. Hutchison clarified DSHS interpreted specific guidance from the Texas legislature to not move forward with implementing PCN 21-02.
- Mr. Vargas questioned the rationale behind this decision.
- Mr. Hutchison replied DSHS cannot provide a rationale for the Texas legislature's decisions.
- Mr. Vargas stated that the MAC needs a rationale for why THMP is not moving forward with this. Mr. Vargas then asked about the analysis. He wondered if THMP is counting in the people who are virally suppressed or if the program is not counting in these people.
- Ms. Sanor explained this analysis looked at the people who currently participate in ADAP and are virally suppressed, and then applied it as if these people were to change over to Cabenuva. The analysis counted those who were virally suppressed. It counted out those who were not virally suppressed.
- Mr. Vargas stressed Cabenuva could help those who are not virally suppressed reach viral suppression, and the program should add them to this analysis.
- Dr. Lazarte requested clarifications on the \$6 million cost of implementation. She asked if the analysis took into consideration subtracting the cost of other regimes when these clients move from one treatment to another.
- Ms. Sanor explained the analysis looked at all the single tablet regimens the enrollees are currently taking, created a weighted average based on each medication and how much it was being used, and then applied it as if everyone were to switch to Cabenuva, who were also virally suppressed. The pricing of different medications was slightly higher than Cabenuva, which was why we had the cost associated with the switch.
- Dr. Lazarte did not believe it could cost \$6 million; not everyone would switch over to the long-acting injectable. She asked about the new actuarial firm evaluation report and analysis.
- Mr. Hutchison stated DSHS does not want to make any decisions that may potentially
 have long-lasting negative implications for the program and the people on it. DSHS is still
 reviewing the long-term analysis of the cost and will share this information the moment
 the program completes the review.
- Ms. Helen Turner expressed her disappointment in the lack of access to care for people living with HIV. She affirmed we need to do more to give these clients better care.
- Mr. Lionel Hillard commented the program analyzed this based on the assumption that
 everyone would move to Cabenuva at the same time. He did not believe this number was
 realistic. Half of this population would not move over to use Cabenuva. The funds needed
 would only be half or a third of the projection.
- Ms. Sanor agreed the program would continue to review the data. The program would look at staggered rates for the projected cost.
- Dr. Gloria Heresi wondered how many patients were virally suppressed and used to determine the \$6 million projected cost for Cabenuva.
- Ms. Sanor explained the cost of Cabenuva for state purchase is confidential. Providing the number of patients used to determine this analysis could compromise this information, so she could not share it.
- Dr. Heresi stated her patients continued to ask for Cabenuva and agreed with her fellow committee members' statements on this topic.
- Dr. Michael Stefanowicz believed long-acting injectables were the future of HIV
 medications. The client could choose the best option for them based on the variety of
 medications available to them. Dr. Stefanowicz wondered if DSHS knew ADAP referential
 data from other states regarding their clients' blended medication uptake. He agreed not

all clients will choose long-acting injectables. Dr. Stefanowicz emphasized the importance of health system literacy for clients. Navigating the health system, especially the sixmonth recertification, is a heavy burden for these clients. Dr. Stefanowicz asked what efforts THMP made to inform clients they could request a 90-day refill from their providers.

- Ms. Sanor replied THMP shared the 90-day fills with ADAP enrollment workers and liaisons from local agencies. These individuals then shared this information and provided outreach to their clients. THMP looked to local agencies and partners to provide direct outreach.
- Mr. Hutchison answered Dr. Stefanowicz's question regarding data points. DSHS recently requested other states' ADAP data from other partners and would review this information.
- Mr. Rosas pointed out that according to Health Resources and Services Administration (HRSA) guidelines, the ADAP formulary must meet baseline standards. This included providing coverage for all core antiretroviral therapies as a funding recipient. Mr. Rosas believed Cabenuva falls into one of the core classes of antiretroviral therapy and should be on the formulary.
- Mr. Rosas acknowledged DSHS's efforts. He proposed to consider Cabenuva and once-ayear eligibility implementation separately due to cost. With Cabenuva costing less than the once-a-year eligibility determination, it might be better to consider adding Cabenuva to the formulary first before implementing the other changes.
- Mr. Vargas remembered there were differences in the interpretation of HRSA standard deduction guidelines and findings. DSHS eventually adopted the recommended standard deduction guidelines from the community advocates. Due to this, Mr. Vargas wondered if there could be a difference in interpretations of the legislative comments and called for a motion to review these comments.

MOTION

Mr. Steven Vargas motioned that the HIV Medication Advisory Committee see the response and written comment, if necessary, from the legislative body advising adding Cabenuva to the formulary for ADAP and the response for not purchasing health coverage using ADAP funds. Mr. Lionel Hillard seconded the motion. Ms. Arevalo conducted a roll call vote. The motion passed by a majority vote with eight "for" (Adjei, Heresi, Hillard, Lyon, Rosas, Stefanowicz, Turner, and Vargas), two "against" (Lazarte and Perez), and one "absence" (Rodriguez-Escobar).

Agenda Item 6: Texas HIV Medication Program (THMP) Updates

Mr. Rosas yielded the floor to Ms. Rachel Sanor and Ms. Sylvia Jimenez.

Highlights included:

- a. TakeChargeTexas (TCT)
 - Quarterly TCT Applications Submitted from December 1, 2023, to February 29, 2024
 - Client Portal
 - ♦ TCT received 536 applications.
 - ♦ Of the 536 applications, 494 were for THMP.
 - ♦ The total number of applications for both care services and THMP was 310.
 - ▶ Agency Portal
 - ♦ TCT received 15,436 applications.
 - ♦ Of the 15,436 applications, 11,219 were for THMP.
 - ♦ The total number of applications for both care services and THMP was 7,095.
 - ♦ The total number of pharmacy order batches was 1,556.

- ♦ The total number of medication orders was 37,145.
- ♦ THMP approved a total of 8,462 clients during this period.
- Quarterly TCT Helpdesk Support Issues from December 1, 2023, to February 29, 2024.
 - ► Issues in the TCT system increased in December due to enhancements. These issues decreased significantly in January and February.
 - ► Issues in the other category increased in February due to the Ryan White Service Report (RSR).
 - ► The other category included issues not related to THMP, such as importing and other items related to contract agencies needed for the RSR.
- Annual TCT Applications Submitted from March 1, 2023, to February 29, 2024
 - ▶ Client Portal
 - ♦ TCT received 2,325 applications.
 - ♦ Of the 2,325 applications, 2,116 were for THMP.
 - ♦ The total number of applications for both care services and THMP was 1,545.
 - Agency Portal
 - ♦ TCT received 62,077 applications.
 - ♦ Of the 62,077 applications, 45,880 were for THMP.
 - ♦ The total number of applications for both care services and THMP was 32,024.
 - ♦ The total number of pharmacy order batches was 5,692.
 - ♦ The total number of medication orders was 144,644.
 - ♦ THMP approved a total of 20,069 clients during this period.
- Annual TCT Helpdesk Support Issues from March 1, 2023, to February 29, 2024
 - ▶ The number of support issues decreased over time.
- b. Projections and demographic information
 - Most of the top ten medications ordered remained in the same spot.
 - Biktarvy 90-day fill appeared in the top ten medications for the first time.
 - The number of ADAP clients in this quarter was slightly higher compared to the last two quarters.
 - ADAP demographics stayed stable.
 - Small amount of growth for the State Pharmacy Assistance Program (SPAP)
 - The Texas Insurance Assistance Program (TIAP) had a slight uptick in the number of clients with medications filled.
 - TIAP demographics overall remained stable.
 - ADAP utilization expected a little growth but not too significant.
 - SPAP utilization increased in January and February due to the donut hole. SPAP utilization decreased once clients met out of pocket. SPAP utilization is stable overall.
 - TIAP utilization has not shown significant changes in projections.
- c. Staffing
 - There are two vacancies for the Program Specialist III position.
 - THMP filled two Program Specialist I positions.
 - There are three vacancies for the Temporary Program Specialist I position.
- d. Application processing
 - THMP remained out of the backlog and up-to-date with processing.

e. Standard deduction

- THMP recalculated the standard deduction amount each year based on the previous state fiscal year expended amount to determine the average amount spent on each client.
- The standard deduction amount decreased from \$12,240 to \$11,177.
- New clients and annual recertifications will use the new standard deduction amount on April 16, 2024.

Discussion

- Mr. Rosas appreciated the TCT portal's efficiency and security.
- Ms. Turner thanked THMP for the great improvements, especially with return mail issues.
 She said some of the pharmacies were still waiting on access to the pharmacy portal and asked THMP to fix the pharmacy portal bugs. This would cause a delay for some of the clients receiving medications.
- Mr. Vargas also gave kudos to THMP for the pharmacy portal rollout and for making it easier for consumers.
- Mr. Vargas asked if THMP could find ways to stop the common issues caused by the RSR and make sure that they would not come up again next year.
- Ms. Sanor mentioned there were enhancements planned to improve the data import process for the RSR and make this process a bit smoother next year.
- Mr. Vargas wondered about the reason for the decrease in standard deduction. He asked about how many people are using ADAP due to Medicaid disenrollment.
- Ms. Sanor explained the medication cost per person decreased, resulting in a decrease in
 the standard deduction. For those impacted by the new standard deduction, THMP would
 refer them to other programs for assistance. Ms. Sanor also clarified THMP had provided
 outreach for clients that Medicaid might have disenrolled. Most individuals were dualeligible and Medicaid would not disenroll them. For the small number of individuals
 impacted by this, we provided outreach to those we could contact and made sure they
 were getting care.
- Dr. Lazarte appreciated the lack of delay in the application processing. She asked how the implementation of the pharmacy portal rollout was going.
- Ms. Sanor responded that the rollout was on March 11, 2024. There was an issue with
 the new system, IAMOnline, which rolled out on March 26, 2024. There are now 16
 pharmacy users using the pharmacy portal. THMP is working on getting reports added to
 the pharmacy portal to obtain more data. Overall, things are going smoothly with the
 pharmacy portal rollout.
- Ms. Helen Turner brought up an issue regarding pharmacies that were unable to access the system. These pharmacies expected an email with further instructions on how to get into the system but have not received anything.
- Ms. Sanor has not heard of this issue at all; she planned to follow up with the team regarding this pharmacy portal access issue.
- Ms. Turner asked if THMP sends medication to a client, and if that client does not use the medication, would THMP take this medication back?
- Mr. Hutchison responded no; THMP would not take the medication once the program dispensed it to the client. However, if a client never picks up their medication from the pharmacy, then the pharmacy would return that unused medication to THMP. However, there are regulations and rules regarding this process.

Agenda Item 7: Sub-Committee Reports

a. Eligibility: Mr. Frank Rosas

• The Eligibility Subcommittee met on February 27, 2024.

- The subcommittee discussion focused on the standard deductions and items Ms. Sanor and Ms. Jimenez just shared.
- Mr. Rosas recognized the four ADAP liaisons from different regions of the state who
 participated in this subcommittee. He acknowledged they are a big asset to the
 program.

b. Governance and Data: Mr. Steven Vargas

- The Governance and Data Subcommittee met on March 12, 2024.
- The subcommittee reviewed the bylaws and members' attendance.
- Ms. Fox requested data on the dual diagnosis of syphilis and HIV.

c. Formulary: Dr. Susana Lazarte

- The Formulary Subcommittee met on February 13, 2024.
- The subcommittee voted against adding Lasix (furosemide) to the formulary since it is cheap and not many clients are on it.
- Dr. Lazarte encouraged providers to utilize 90-day refills.

Discussion

- Mr. Hillard asked for a description of furosemide.
- Dr. Lazarte answered Lasix, or furosemide, is a diuretic given to those with resistance hypertension.
- Mr. Rosas asked the Formulary Subcommittee to discuss the lack of coverage for the onepill regimen from the insurance provider in Harris County.
- Mr. Rosas followed up on the status of reinstating pitavastatin back to the formulary.
- Dr. Lazarte confirmed the Formulary Subcommittee voted and approved adding pitavastatin back to the formulary.
- Ms. Sanor agreed the formulary approved adding both zypitamag and pitavastatin. However, THMP held off adding them back to the formulary because the program needed to review the impact of the 90-day fill on the budget.
- Ms.Turner clarified LPAP stands for Local Pharmacy Assistance Program.
- Mr. Rosas planned to reach out to new MAC members and ask them to join subcommittees.
- Mr. Vargas wondered if THMP could use the drug rebate fund to get Cabenuva added to the formulary.
- Mr. Hutchison explained TIAP and SPAP generate the drug rebate fund. ADAP does not generate the rebates. THMP already planned to use these funds for the medications on the ADAP program.
- Mr. Vargas mentioned the budget slide showed there was still \$7.4 million available in rebate funding.

Agenda Item 8: Review of Action Items and Agenda Topics for the Next Meeting

Highlights included:

Mr. Rosas asked Ms. Nguyen to recap the action items. Ms. Nguyen confirmed there are currently two items on the agenda. Mr. Rosas requested members provide additional topics and action items to consider for the next meeting. He also confirmed the next meeting is scheduled for July 12, 2024.

Agenda items for the next committee meeting included:

• Cabenuva and long-acting injectables.

Action items:

- Response and written comment from the legislative body advising adding Cabenuva to the formulary for ADAP.
- Response and written comment from the legislative body to not purchase health coverage using ADAP funds.

Agenda Item 9: Adjournment

Mr. Rosas, Chair, thanked the committee members and the members of the public for their attendance and adjourned the meeting at 5:21 p.m.

Below is the link to the archived video recording of the April 12, 2024, Texas HIV Medication Advisory Committee meeting. Individuals can view or listen to the meeting for approximately two years from the meeting date. DSHS posted the meeting in accordance with the HHSC records retention schedule.

Texas HIV Medication Advisory Committee - April 12, 2024