Texas HIV Medication Advisory Committee Meeting Minutes

April 14, 2023, 1:30 p.m.

Location: Microsoft Teams Virtual Hybrid Meeting Physical Location: Texas Health and Human Services Commission (HHSC), John H. Winters Building, Public Hearing Room 125, First Floor 701 West 51st Street, Austin, Texas 78751

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

Mr. Frank Rosas, Chair, called the meeting to order at 1:33 p.m. Mr. Rosas opened the meeting by introducing himself and turned the floor to Ms. Tessa Buck-Ragland, Advisory Committee Coordination Office (ACCO), HHSC. She proceeded with the logistical announcement, called roll, asked members to introduce themselves, and certified a quorum with a count of seven members at roll call. Member Dr. Ogechika Karl Alozie was present later at 2:00 p.m. to make eight members present for the meeting.

Member Name	Attended
Adjei, Margaret, M.D.	Yes
Alozie, Ogechika Karl, M.D.	Yes, joined at 2:00 P.M.
Heresi, Gloria, M.D.	Yes
Hillard, Lionel	Yes
Lazarte, Susana, M.D.	Yes
Rodriguez-Escobar, Yolanda, Ph.D.	No
Rosas, Frank (Chair)	Yes
Turner, Helen	Yes
Vargas, Steven	Yes
Vacant	
Vacant	

Table 1: The Texas HIV Medication Advisory Committee member attendance at the Friday, April 14, 2023, meeting.

"Yes" indicates attended meeting

"No" indicates did not attend meeting

Mr. Frank Rosas, Chair, acknowledged DSHS staff: Ms. Rachel Sanor, Director. Ms. Sanor introduced DSHS staff in attendance: Ms. Mary Richards, THMP Medication Supervisor; Ms. Hillary Alamene, Program Liaison, Program Specialist IV, from the Health Communication and Community Engagement Group; Ms. Imelda Garcia, Associate Commissioner for Laboratory and Infectious Disease Services; Mr. Josh Hutchison, HIV Section Director; Mr. Michael Roberts, Operations Director; Mr. Nathan Gauldin, Program Specialist; Mr. Samuel HebbeGoings, Director; Ms. Sabrina Stanley, Director; Mr. Gil Flores, Manager; and Ms. Terri Lemuel, THMP.

Agenda Item 2: Consideration of January 13, 2023, draft meeting minutes

Ms. Buck-Ragland requested a motion to approve the draft January 13, 2023, meeting minutes as presented.

MOTION

Mr. Lionel Hillard motioned to approve the January 13, 2023, draft minutes as presented. Mr. Steven Vargas seconded the motion. Ms. Buck-Ragland conducted a roll call vote, and the motion passed unanimously with seven approvals, no disapprovals, and no abstentions.

Agenda Item 3: Public Comment

The following individuals provided virtual oral public comment:

Andrew Edmondson, representing himself, addressed the following issues:

Mr. Edmondson spoke about the implementation of the standard deduction and its impact on the number of consumers dropped from the program. He also expressed concern about the unwinding of Medicaid due to President Biden's declaration to end the national emergency.

Two individuals provided written comments: Januari Fox, representing Prism Health North Texas - STI and HIV Medical Care (phntx.org), and Andrew Edmondson, representing himself. Program Staff shared the written comments with members electronically.

Agenda Item 4: Department of State Health Services Updates (DSHS)

Mr. Rosas introduced Ms. Imelda Garcia, Associate Commissioner of Laboratory and Infectious Disease Services, DSHS, and Mr. Josh Hutchison, Section Director, HIV/STD Section, to provide the following updates.

Highlights included:

- a. Agency Update
 - The legislative session is ongoing.
 - The agency had two exceptional item (EI) requests for additional funds for the Texas HIV Medications Program (THMP): \$7 million a year over the biennium to implement Cabenuva and the Health Resources and Services Administration's (HRSA) policy change to move to a yearly attestation and renewal (as opposed to every six months).
 - The House budget picked up the Cabenuva item and proposed to fund it for the two years; however, the House did not fund the HRSA policy change. They put it in Article 11 so if there are additional funds, they can fund it. If it is not included in Article 2, the Legislature cannot fund it.
 - The Senate budget did not fund either EI.
 - The House and Senate generate two different versions of the budget; the Senate will meet next week to discuss potential changes and adoptions.
 - Regarding the end of the public health emergency, the agency has been working with HHSC to identify and contact those who are no longer eligible for Medicaid but remain eligible for the AIDS Drug Assistance Program (ADAP). DSHS estimated that the number of people dropped from Medicaid and who DSHS would encourage to enroll in THMP would be about 1,800. DSHS updated this to show that less than 300 people would need to enroll in THMP. The program already accounted for these additions in the budget. Given where DSHS is financially, the agency is able to absorb the cost and include it in its projections.
- b. HIV organizational updates
 - The HRSA site visit in March resulted in four findings:
 - ADAP: Implement standard deduction.
 - Quality Management: Change reporting of performance measures from annually to quarterly.
 - Fiscal: Improve tracking among DSHS, administrative agencies, and provider agencies to improve fiscal oversight.
 - Appointment of new directors
 - Rachel Sanor, HIV Care and Medications Unit Director
 - Samuel HebbeGoings, HIV/STD Prevention Unit Director
 - Sabrina Stanley, Pharmacy Unit Director
 - The Manager V position is still vacant. This position will focus on Take Charge Texas (TCT) and the technical aspects of the care system. This position will also

oversee TCT's reporting capabilities.

- c. Budget report
 - DSHS spent the funds that were going to expire.
 - Aug 31 DSHS can roll over \$26 million in federal funds.
 - \$8 million in state general revenue (GR) will expire by August 31, 2023 (DSHS has plans to use these funds before the end of the fiscal year).

Discussion

The Committee discussed the state budget procedure and timeline and the HRSA recommendations.

- Ms. Helen Turner mentioned that improvement is needed in relation to communication and inquired about what systems exist to improve communication and foster trust among the public. She also requested more information about the Pharmacy portal.
- In response, Ms. Garcia shared that advocacy groups will help with communication in moving people into Ryan White programs. She acknowledged that sharing information about how to get people connected will be a big benefit to DSHS, as this is not a task that the agency can complete on its own.
- Regarding the pharmacy portal, Ms. Garcia shared that the plan is to include the portal in the enhancement project. The enhancements are underway. Ms. Garcia stated that the agency has heard concerns from individuals at the David Powell Health Center in Austin and other stakeholders across the state. Consequently, DSHS is spending \$6 million to expedite the implementation of these enhancements.
- Dr. Lazarte asked for clarification on the exceptional items after having been under the impression that these items would include the yearly recertification, the 90-day refill, Cabenuva, and Sunlenca. In response, Ms. Garcia shared that the cost of Sunlenca, as a new class of drug for the formulary, was unclear. The EI will only include Cabenuva because this is a cost that the agency can absorb. For similar reasons, the agency removed the 90-day refill from the EI.
- Steven Vargas thanked Ms. Garcia and her staff but expressed concern about the
 attestations or renewals, particularly for those on the program who are older and living
 with disabilities. He emphasized that these are two factors, in addition to the renewals,
 that complicate the process of ending the HIV epidemic. Complicating the process makes
 it easier for individuals to fall out of care. In turn, he asked Ms. Garcia to call on elected
 officials to reiterate the goal of ending the HIV epidemic. He emphasized that it is not only
 important to keep people on their medications but to also make it as simple as possible
 for individuals to remain on their medications.
- Mr. Rosas interjected to share that the budget is not finalized until early June, but he remains optimistic about advocates at the Capitol who are keeping stakeholders aware of the situation. He also reiterated that Sunlenca was not on the EI. Rather, there was verbiage that mentioned injectables to cover the broad spectrum of HIV medications.
- Dr. Lazarte congratulated Rachel for her promotion and welcomed the new directors as well. She also questioned why HRSA did not address the lack of adherence to yearly recertifications, and Mr. Hutchison shared that this was not a finding since it was merely a recommendation. Ms. Garcia interjected to inform members that the agency discussed this extensively with HRSA and that the agency could not implement such a notable change without additional funding. During their visit, they also discussed the limitations on insurance purchasing and why Texas has not expanded Medicaid.

- Ms. Garcia reiterated that since this was only a recommendation, HRSA would not categorize it as a finding. The only findings were those presented on the slide.
- HRSA was pleased to hear that THMP announced the implementation of the standard deduction, but they did document it as a finding because it was not yet implemented when they were on-site. When THMP provides a progress report, DSHS anticipates that HRSA will no longer categorize it as a finding.
- Frank Rosas followed up to remind consumers that they can promote change through HRSA's nationwide community stakeholder meeting. There was a virtual meeting at the beginning of the year where clients spoke about the two-year recertification, but they are also aware that Texas and many southern states are not Medicaid expansion states. He expressed ambivalence about the findings but reminded everyone that they should provide their input during these stakeholder meetings.
- When Mr. Hutchison presented the monthly THMP Financial Report, Mr. Vargas asked if there was any percentage of the federal funds that DSHS would lose if they were not spent. Mr. Hutchison replied that Ryan White funds not spent by March would remain on the table. We would do a carry-forward request to use those funds for the following year, but the agency would use this for any unexpired funds.
 - Mr. Rosas followed up to ask about what happens with unused funds from administrative agencies (AA). In the past, AA returned these funds to the state.
 Mr. Hutchison replied that expended contract funds carry over, but it is hard to spend every dollar. Our goal is to spend our portion of the funds, but through requests to HRSA, subrecipient funds from administrative agencies are typically used for medications.
 - Ms. Garcia clarified that Part A areas can donate funds to the state, typically at the end of the fiscal year, and then this gets included in the overall dollar amount. Since this comes at the end of the year, DSHS attempts to put this toward direct purchases.

Agenda Item 5: THMP Updates

Mr. Rosas turned the floor over to Ms. Rachel Sanor, Director, DSHS.

Highlights included:

- a. Standard Deduction Update
 - THMP will implement the standard deduction starting April 1, 2023. They will adjust this annually. THMP determines the amount by annualizing the cost of medications for clients in the program. Each year, the program informs the community of the new annual standard deduction amount by January 31. THMP will apply the standard deduction to new applicants and annual recertifications. It will take approximately a year for the program to apply this to everyone on THMP.
 - In the past, THMP used a drug cost sheet for everyone in TCT. THMP is currently working to ensure that the standard deduction amount appears in TCT so that the eligibility determination occurs automatically. Not only will this help standardize the process, but it will also encourage transparency.
- b. Take Charge Texas
 - Quarterly TCT Applications Submitted
 - Client portal
 - TCT received 734 applications from December 1, 2022, to February 28, 2023, which is a slight increase from the last quarter.
 - Of the 734 applications, 688 were for THMP. This mirrors what

THMP has seen in previous quarters.

- The total number of applications submitted for both THMP, and Care was 603.
- Agency portal
 - TCT received 13,896 applications from December 1, 2022, to February 28, 2023.
 - THMP received fewer applications through the agency portal, but the program expected this as community agency workers who are often engaged in care services manage the applications.
 - The total number of applications submitted for both THMP, and Care was 7,741.
 - The total number of pharmacy order batches was 1,135, which is an increase from the last quarter. During this time, THMP approved a total of 8,069 new clients.
- Quarterly TCT Support Issues
 - We have one new category: user agreements (there was a recertification, so their security trainings needed an update).
 - Annual TCT Applications Submitted
 - Client Portal
 - From March 21, 2022, to February 28, 2023, the total number of applications submitted through the client portal was 2,823. Of these applications, 95% were submitted for THMP only.
 - TCT received 2472 applications for care and THMP.
 - Agency Portal
 - TCT received almost 57,000 applications through the agency portal. Of these, 40,000 were for THMP, which is similar to the quarterly trend.
 - TCT received almost 29,000 applications for both Care and THMP.
 - The total number of pharmacy order batches was 4,115. Note that these batches can vary in size, from a few individual medications to over a hundred medications.
 - During this time, THMP approved a total of 19,075 new clients.
- Annual TCT Support Issue Types
 - Login issues were more prevalent in March.
 - Overall, problems decreased over time.
- For those interested in the enhancement project or who want to provide feedback on the enhancement project, they can email the Help Desk at <u>TCTHelpDesk@dshs.texas.gov</u> with 'TCT Feedback' in the subject line. Monthly sessions started in March, and they are ongoing. DSHS is putting together groups of TCT users who want to discuss their experience with the agency and the client portals. DSHS will also convene with participating pharmacies so pharmacies can get a sense of what the ordering system will look like. With feedback, DSHS can create systems that are user-friendly and efficient.
- The TCT Pharmacy Portal is in the enhancement phase, making communication and feedback more pertinent before rollout.
- c. Application Processing Update
 - THMP has stayed out of the backlog and is ahead of its proposed timeline.
 - THMP wants the window between receiving and processing applications to be quite narrow, and the TCT enhancements implemented thus far have made this possible.
- d. THMP Staff Updates, Projections, and Demographic Information
 - Staff Updates
 - THMP has filled all its permanent positions except the manager position that Rachel Sanor held. DSHS posted this position on April 13, 2023. DSHS encourages THMP-MAC members to share this information with their

networks.

- There are five vacancies among the temporary staff, but THMP still has the capacity for processing at this time. THMP is following up with clients who are not assigned to a particular agency, especially when there are incomplete applications.
 - For clients supported by a specific agency, THMP is also contacting ADAP liaisons to ensure clients are receiving their medication.
- As a part of the reorganization, THMP will add three TCT client support staff positions. The goal is to support clients and the pharmacy as DSHS begins the pharmacy portal enhancement project.
- Demographic Information
 - The medications used by ADAP clients in the last quarter have remained steady, with Biktarvy being the most frequently used medication.
 - Among the ADAP population, there are no significant changes from the last quarter.
 - Among the State Pharmacy Assistance Program (SPAP) population, the proportion of clients who identify as male is greater than that of the ADAP population. The majority of the population is White, and non-Hispanic or Latino.
 - The Texas Insurance Assistance Program (TIAP) is the smallest of the three. From December 2022 to February 2023, the program filled medications for 103 clients.
 - A majority of participants identify as White, non-Hispanic or Latino, and male, which is similar to ADAP clients. There are no significant changes to report at this time.
- Projections
 - ADAP estimates the cost for this year to be about \$92 million, with a gradual increase after 2023.
 - SPAP data indicates a lot of stability in these numbers, but utilization of this program tapers off throughout the year because participants are getting through the donut hole with reduced expenditures.
 - TIAP data indicates a lot of stability, but THMP is expecting a slight increase in the number of clients.
 - For 2023, THMP expects to have 143 clients. Compared to last year, this is a slight decrease.

Discussion

- Mr. Rosas asked about the functionality of the Help Desk line, given the technical issues that had taken place earlier that week. Ms. Sanor responded, stating that THMP has a 1-800 number that has been in service for many years. THMP had to get another phone system in place after an outage occurred. THMP now has a bridge system. The Help Desk is primarily receiving requests via email, but if individuals feel more comfortable calling by phone, THMP staff will share that information with the Help Desk. THMP is not seeing a decrease in our call volume, so Ms. Sanor remains confident that the calls are being managed and addressed.
- Mr. Vargas congratulated Ms. Sanor on her promotion but also questioned if THMP will have enough staffing to support those who fall off the Medicaid program, as well as how many people who once qualified for the program may become ineligible due to the implementation of the standard deduction. Ms. Sanor shared that THMP has sufficient staffing to support those who fall off Medicaid but join ADAP. In response to Steven's second question, Ms. Sanor stated that with the spend down, there were individuals on more expensive medications who would qualify for ADAP, while those on less expensive medications did not. Those with less expensive medications who did not qualify for the program will now be eligible with the standard deduction, whereas the converse is no longer true. With yearly recertifications, it is hard to predict who will fall into each

category; however, for those who are overscale, THMP provides information to the client or their agency (if they have one) about local resources.

• Dr. Heresi asked about new clients and those the program rejected. When she inquired about the reasons for their rejections, Ms. Sanor stated that THMP only denies about five to seven percent of applicants, primarily because of incomplete applications. In such situations, THMP provides information on next steps and alternative help for clients who no longer qualify.

Agenda Item 6: Sub-Committee Reports

a. Eligibility – Mr. Frank Rosas

• The Eligibility Subcommittee met on February 14, 2023, to discuss THMP updates and the TCT rollout. The ADAP liaisons, who represent El Paso, Dallas, Brazos Valley, San Antonio, and Houston, shared their updates as well.

b. Governance and Data – Mr. Steven Vargas

The Governance Subcommittee met on March 14, 2023. This was the first meeting that Mr. Vargas chaired. During this call, attendees discussed the attendance bylaws as well as data on age and gender identification. Mr. Vargas noted that there is standard reporting for HRSA and Ryan White, but THMP does not have data that acknowledges the ages at which people transition from one care system to another. He would like to see this distinction in THMP's data.

c. Formulary – Dr. Susanna Lazarte

- The Formulary Subcommittee met on January 31, 2023. During this call, they discussed TPOXX availability, although this is not a medication covered by THMP. They also discussed the reinstatement of ten non-HIV medications, along with the recommendation to add Sunlenca to the formulary.
 - Dr. Alozie was also asked to join the Formulary Subcommittee in lieu of Dr. Martinez.

Agenda Item 7: Presentation by Gilead related to Sunlenca and Formulary recommendation

Mr. Rosas introduced Ms. Porscha Showers, Principle Medical Scientist at Gilead to present details related to Sunlenca.

Highlights included:

- Sunlenca is a capsid inhibitor for use in combination with other antiretrovirals. The FDA approved it in December 2022.
- Ms. Showers presented on the Gilead medication trials, sample size, duration, and outcomes.
- One of the risk factors for this medication is pill burden.

Discussion

- Dr. Heresi expressed concerns due to Sunlenca's infancy on the market as well as the small sample size of Gilead's study.
- Mr. Hillard echoed similar sentiments but had confidence that Gilead would only provide a drug that was safe for the community.
- The normal lab regimen should be followed for resistance testing. The medication does not require refrigeration or mixing.
- Dr. Lazarte expressed concerns about the six-month recertification interfering with the dosing schedule if a client falls off of THMP. In return, Ms. Garcia stated that DSHS would be mindful of that concern.

Motion

Mr. Steven Vargas motioned to add Sunlenca to the THMP formulary as presented and seconded by Mr. Lionel Hillard. Ms. Buck-Ragland asked for further discussion by members on the motion; hearing none, Ms. Buck-Ragland conducted a roll call vote, and the motion passed with seven for, no against, and one abstention. Member Dr. Margaret Adjei was not present for the vote but later voiced her vote once she rejoined.

Agenda Item 8: Review of action items and agenda topics for next meeting

Mr. Rosas, Chair, asked Ms. Richards and Ms. Alamene to recap action items, then allowed members to provide additional topics or presentations to consider for the next meeting and stated the next meeting is scheduled for July 14, 2023.

Agenda items for the next Committee meeting included:

- Number of clients who will be dropped from Medicaid and added to ADAP
- Pitavastatin

Action items:

- Legislature final approvals decided upon at the Conference Committee meeting
- Update on the 90-day refills
- Changes to the 340B Will this impact the state budget?
- Insurance programs covering two medications? Impact on ADAP?
- Oral health care services and the 90-day rule

Agenda Item 9: Adjournment

Mr. Rosas, Chair, thanked the members and the public and adjourned the meeting at 4:37 p.m.

To view and listen to the archived video of the April 14, 2023, Texas HIV Medication Advisory Committee meeting in its entirety, click on the link below.

Texas HIV Medication Program Medication Advisory Committee