

Texas HIV Medication Advisory Committee Meeting Minutes

November 5, 2021, 1:30 p.m.

Location: Microsoft Teams. Virtual Hybrid Meeting

John H. Winters Building

Public Hearing Room 125, First Floor

701 West 51st Street

Austin, Texas 78751

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.	No
Rodriguez-Escobar, Yolanda, Ph.D.	Yes
Rosas, Frank (Vice-Chair)	Yes
Vanek, Natalie, M.D. (Chair)	Yes
VACANT	
VACANT	

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

Dr. Natalie Vanek, Chair, called the meeting to order at 1:42 p.m. and welcomed members, staff, presenters, and public in attendance.

Agenda Item 2: Logistical Announcement and Roll Call

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

Agenda Item 3: Consideration of the July 30, 2021, draft meeting minutes

Ms. Allen requested a motion to approve the July 30, 2021, meeting minutes.

Members raised concerns about information related to agenda item #8, Formulary Subcommittee comments, and requested that the minutes for that meeting be reviewed. Ms. Mary Richards will review those subcommittee minutes and provide clarification. Based on the discussion, Dr. Vanek advised that the July 30, 2021 meeting minutes would be tabled until the next meeting.

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

Ms. Imelda Garcia, MPH, Associate Commissioner of Laboratory and Infectious Disease Services, DSHS, provided an update on DSHS and referenced the handouts entitled LIDS/TB/HIV/STD Organizational Chart and the Monthly THMP Financial Report.

Highlights included:

- a. Staffing Updates
 - Felipe Rocha, TB/HIV/STD director, is retiring in January. The interim TB/HIV/STD section director will be announced on November 8th; Mr. Rocha's position will be posted in the coming weeks.
 - Sheena Pryce-Fegumps is a new manager with the HIV/STD Prevention and Care Branch.
 - Michael Lozano also joined the HIV/STD section as a financial analyst.
 - The agency will continue to keep partners and community members informed with announcements related to the onboarding of new personnel, including the organizational restructure as it evolves.
 - The initial selection criteria for the Director, HIV STD Prevention position, (formerly held by Shelley Lucas) has been refined, which caused a delay in hiring and ultimately required it to be reposted.
 - The agency has hired a recruitment company to conduct a national search for the director positions and help solicit strong candidates for consideration.
 - All the positions are on the DSHS website, (<https://www.dshs.state.tx.us/Search-Jobs.aspx>) and applications can be accessed through the HR portal where they can be downloaded. We encourage the members to share the information with others that have an interest.

- b. HIV Budget Report
 - Expended dollars for last fiscal year, ending 8/31/2021, was approximately \$132 million within the HIV medication program alone.
 - Received an increase in the General Revenue match as a result of exceptional items, and we also received an increase in HIV Drug Rebates.
 - Coronavirus Relief Funds for FY22 are still pending approval.
 - The agency has applied for the usual additional ADAP supplemental funds and will also be applying for the emergency relief dollars.
 - On October 19, 2021, HRSA released new policy changes in line with Ending the Epidemic that will affect program expenditures without changing eligibility guidelines. One of the significant policy changes is that the six-month self-attestation requirement is specifically removed. A second recommendation is regarding rapid eligibility determination, and a third is regarding best practices regarding gathering electronic data.

- The Program will need to examine financial long-term effects of the HRSA policy changes.
 - Imelda Garcia requested that team works with the actuarial firm to go through and model the results of each change, prioritizing the effects on clients, budget, and options. The potential changes being modeled include the new HRSA policies regarding discontinuing the six-month recertification, 60- and 90-day fills of medication, the shift from the spend-down to a standard deduction, and resuming suspended medications.
 - Take Charge Texas initial client portal will go live on December 20, 2021, with a second stage in February 2022.
 - New HRSA guidelines may affect built-in TCT workflows—will hold user documents and only submit client applications once complete, which would help streamline the process for clients.
 - Ryan White year starts on April 1 through March 31— the current assumption is that Texas receives similar funding as last year but with rising costs of Ending the Epidemic it will be difficult to maintain the diagnosis component of the program.
- c. September 29, 2021 Partnership meeting summary update
- Key message from the meeting, we want to transition out of the agency hosting the meeting and attendees being boxed into a government-style meeting.
 - Requested the partners in the field host local meetings with their stakeholders and invite DSHS staff to participate and hear directly from everyone across the state.
 - Allow the communities to drive the conversation more, focusing on the topics, needs and challenges that are within their areas.
 - Consistent feedback from stakeholders expressed concern about public comments being held at the end of the committee meeting.
 - After discussion with the legal team, the only topics that can be discussed in these proposed meetings will be those on an agenda posted to the public, though the committee chair can bring them up in any order at their discretion.
 - Public comment would have to be specific to that meeting’s agenda.
 - Dr. Vanek acknowledged there was much to consider and will take the concerns into consideration when discussing the proposed meeting style in the Governance and Data subcommittee meeting.
 - Recommendations from the Governance and Data subcommittee meeting will be brought to the next THMP-MAC meeting.

Agenda Item 5: THMP Update

Ms. Rachel Sanor, THMP Manager, DSHS, provided an update on THMP and referenced the handout entitled Nov. 2021 MAC Meeting THMP Presentation.

Highlights included:

- a. MAC Process
 - Still waiting on the final approval from the Executive Commissioner for the member appointments.
- b. TMHP-Projections and Demographic Information
 - ADAP utilization over the last six-month comparison of clients served and

- prescription filled reflects a slight decrease.
 - Top THMP Medications ordered for Q3-2021 totaled 28,608, with Biktarvy at number one, and Triumeq at second.
 - Demographics remain unchanged from last quarter. The majority of clients served in the program are male and of white or non-Hispanic origin.
 - Projected ADAP data shows the 60-day refill influx from March-September 2020
- c. THMP Backlog
- Department obtained approval to hire six contract workers to assist with backlog. Currently, four are trained and processing applications.
 - Staff completed the self-attestations process before the October deadline.
 - All pending and backlog applications must be completed before the Take Charge Texas (TCT) portal can go live.
- d. Spend down suspension
- All applications using the spend down criteria will be processed through February 28, 2022.
 - On schedule to present the rules change to the HHSC Executive Council in February; will communicate any changes between now and the end of February to the committee.
- e. 90-day supply analysis
- Rationale is to:
 - Prevent a waiting list
 - Prevent shortages; and
 - Ensure payer of last resort/reduce wasted medications.
 - Return of the 90-day supply would not be decided before the end of February.

Agenda Item 6: Pharmacy Annual Inventory Update and Report

Mr. Josh Hutchinson, Pharmacy Director, DSHS, provided an update on the pharmacy's annual inventory and referenced the handout entitled Pharmacy Annual Inventory and Report.

Highlights included:

- Actual inventory numbers on August 31st resulted in \$14 million, of which \$12.6 million represented HIV medication.
- Based on the fiscal year purchases minus the year-end balance, the pharmacy distributed \$114 million worth of inventory, of which \$110 million represented HIV.
- A full inventory is conducted annually, with a monthly reconciliation of the larger box products.
- A pharmacy inventory management system is being developed and is intended to be deployed at the end of the state fiscal year 2022.
- Going forward a pharmacy staff member will provide updates as needed to the committee.

Agenda Item 7: Election of New Officers

Dr. Vanek advised that due to the pending THMP-MAC member appointments, this agenda item would be tabled and proceeded to agenda item 8.

Agenda Item 8: Sub-Committee Reports

a. Governance and Data subcommittee –Ms. Nancy Miertschin, Committee Chair was not in attendance at the meeting, so Dr. Vanek provided the following update.

- The Subcommittee reviewed the MAC bylaws, their legal authority, review schedule, member terms, responsibilities, and expectations.
- Updates on the THMP rules process, and in February they will be presented to the HHSC Executive Council and open for public comment, slated for March-April 2022.
- Frequency of subcommittee meetings. The Program is suggesting moving the subcommittee meetings to quarterly, and the subcommittees will discuss needs.
- The Public Comment period was discussed by the subcommittee, who also wanted clarification on when the public agenda is to be posted; Sallie Allen stated the agenda needs to be posted in the Texas Register 9 days before the meeting.
- Frank Rosas mentioned the Texas Open Meetings Act states that agendas have to be posted 72 hours prior to the start of the meeting, which conflicts with the 9-day notice previously mentioned.
- Mr. Rosas further stated that 72 hours is not early enough notice for consumers to participate in meetings.
- Sallie Allen clarified that the 72-hour policy was regarding the time frame in which consumers register to post public comments in response to a posted public agenda.
- Imelda Garcia suggested having written documentation sent to MAC meetings that clearly outline relevant statutes and procedural rules, and how internal policies require HHSC to comply with said policies in order to avoid confusion.

b. Eligibility subcommittee – Mr. Frank Rosas, Chair, provided the following update.

The sub-committee discussed issues related to:

- Eligibility, the rollout of the new portal, and the impact of the waitlist.
- Mr. Rosas states he did not download all three-month subcommittee reports but mentions that most of the focus points were brought up by Rachel Sanor in the THMP update.
- Mr. Rosas had previously recommended inviting four regional ADAP liaisons recently hired by Ryan White planning councils, which greatly helped the subcommittee receive feedback and updates from rural areas.

c. Formulary subcommittee - Dr. Vanek, Chair, provided the following update.

- The Formulary subcommittee met on September 7, 2021, to discuss:
 - the approval of Raltegravir 25mg and Tivicay PD 5mg for pediatric patients;
 - the suspension of 17 medications and the impact on 672 unduplicated clients;
 - status of 90-day supplies; and
 - status on the Cabenuva project, and that there are no updates.
- During the October 12, 2021 meeting, the subcommittee discussed medications previously mentioned for pediatric use.
- Confusion regarding suspended medications was addressed regarding if they were to be suspended or taken off the formulary; the MAC did not vote to have the medications removed.
- The Subcommittee feels that suspended meds should be brought back as soon as

fiscally possible.

- Dr. Lazarte clarified the medications were suspended due to finances and brought up the top 10 non-HIV medications of most concerns to consumers, especially those for mental health and Hepatitis B.
- Rachel Sanor stated that 12 of the 17 suspended medications were recommended by the MAC, and 4 mental health medications (Sertraline, Gabapentin, Duloxetine, and Trazodone) and Baraclude were included with the suspension motion.
- Dr. Lazarte proposed a discussion to return the 4 mental health medications to the formulary, and Dr. Vanek agreed they would do so at the next subcommittee meeting.

Agenda Item 9: Committee to vote on addition of Raltegravir 25mg and Tivicay PD to THMP formulary

Dr. Vanek presented the Formulary Subcommittee recommendation to the members and requested the addition of two pediatric medications, Raltegravir 25mg, and Tivicay PD, be added to the THMP formulary and she called for a motion.

MOTION:

Mr. Frank Rosas motioned to approve the recommendation to add the medications, Raltegravir 25mg and Tivicay PD to the THMP formulary. Dr. Susana Lazarte seconded the motion. Ms. Allen conducted a roll call vote, and the motion carried with no objections or abstentions.

Agenda Item 10: Public Comment

The following individuals provided public comment:

- Josh Mica
- Andrew Edmonson
- Tana Pradia
- Helen E Turner
- Ruston Taylor
- Crystal Townsend

Agenda Item 11: Action Items and agenda topics for next scheduled meeting, January 28, 2022

Dr. Vanek, Chair, asked Mary Richards and Liza Hinojosa for action items, and agenda topics for the next meeting.

Items to consider:

- Move public comment up in the meeting agenda
- Visit and discuss suspended medications
- Provide a cost analysis for the 90-day medication supply
- Discuss addition of Cabenuva to formulary
- Officer elections at next meeting
- Clarify information pertaining to Formulary subcommittee minutes

Agenda Item 12: Adjournment

Dr. Vanek, Chair, adjourned the meeting at 4:36 p.m.

To view and listen to the archived video of the November 5, 2021, Texas HIV Medication Advisory Committee meeting in its' entirety, click on the link below.

<https://texashhsc.new.swagit.com/videos/151560>