Texas HIV Medication Advisory Committee Meeting Minutes

July 30, 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	No
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 1:32 pm and welcomed members, staff, presenters, and public in attendance.

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.

Agenda Item 3: Review and approval of the January 29, 2021, and April 30, 2021 meeting minutes

Ms. Allen advised members that the information provided in the January 29, 2021 minutes was reviewed against the archived recording and confirmed it to be correct as written. She requested a motion to approve the January 29, 2021, meeting minutes.

Motion:

Dr. Natalie Vanek motioned to approve the January 29, 2021 meeting minutes as written. Dr. Yolanda Rodriguez-Escobar seconded the motion. Ms. Allen conducted a roll call vote, and the motion passed.

Ms. Allen proceeded and requested a motion to approve the April 30, 2021 meeting minutes.

Motion:

Dr. Susanna Lazarte motioned to approve the April 30, 2021, meeting minutes. Dr. Natalie Vanek seconded the motion. Ms. Allen conducted a roll call vote, and the motion passed.

Agenda Item 4: Department of State Health Services Updates (DSHS) – Imelda Garcia, MPH, Associate Commissioner of Laboratory and Infectious Disease Services

Dr. Vanek introduced Ms. Imelda Garcia, MPH, Associate Commissioner of Laboratory and Infectious Disease Services, DSHS, and she provided the committee with an update on organizational changes and a legislative update.

Highlights and committee member discussion included:

a. Organizational changes

Ms. Imelda Garcia has resumed leadership of the TB/HIV/STD Section as of June 1st, 2021. Ms. Garcia shared that the DSHS Pharmacy Branch was moved from the TB/HIV/STD Section and is now reporting directly to the Division to better support the pharmacy's mission and vision. James Abshier, the Pharmacy Branch Manager retired at the end of July. The interim Pharmacy Branch Manager is Josh Hutchison.

Ms. Garcia reported that an internal audit was recently completed, and the report was released on June 10, 2021. The Department of State Health and Human Services is actively working to implement recommendations from the audit that include 73 recommendations, largely across budget processes and information technology. These recommendations are a top priority for the program, agency, and division.

The TB/HIV/STD Section currently has multiple vacancies including the HIV/STD Director. This position was posted, and the agency received over 170 applications. However, DSHS wanted to move forward with a restructure of the organization before selecting the new Director. Once the restructure is finalized DSHS will share with the MAC and all other stakeholders, as well as when the Director position will be reposted.

b. Introduction of Josh Hutchison, interim Pharmacy Branch Manager, DSHS Ms. Garcia briefly introduced the interim Pharmacy Manager, Mr. Josh Hutchison. Mr. Hutchison was formerly in the Immunizations Unit, where he was the vaccine data finance manager and worked with distribution of the vaccine.

c. Exceptional item update

Ms. Garcia shared that the Texas Legislature appropriated additional funding of over \$36 million dollars which equates to an estimated \$18.1 million dollars a year. Ten million dollars is dedicated to HIV contracts. This funding will allow the TB/HIV/STD Section to restore some contracts that were previously reduced. Additional general

revenue funds were received to support the Texas HIV Medication Program. While the agency did request more funding initially, the program received additional federal funds which led DSHS to reduce the initial funding request.

At this time, a wait list will not be implemented for THMP. DSHS assured the legislature that the HIV and Medication Program budgets would continue to be monitored and identify other cost containment measures. Key items that will determine the course of THMP are client growth and growth of program costs. DSHS continues to work with an actuary firm to help guide other cost containment measures that may need to occur along the way to support sustainable costs.

Other cost containment options such as elimination of the spenddown are still being considered. However, before the spenddown can be eliminated, changes to the Texas Administrative Code (TAC) must be formally amended. Additionally, the actuary firm will need to determine thresholds for a standard deduction that would replace the spenddown.

Changes to Rider 26 involving language added to the appropriations bill does not allow for THMP to purchase insurance. As a result, the program will continue to look at other cost containment measures within the next two years. Rider 26 also states that any changes to the TAC requires that DSHS notify its clients, partners, and stakeholders 60 days prior to making any program changes. To honor the spirit of Rider 26, DSHS is committed to notifying clients about any changes to eligibility, medications, and program rules 60 days in advance. The program will continue to monitor the budget and make changes as needed.

Discussion:

Dr. Vanek inquired about whether DSHS or DSHS Central Pharmacy staff would be reassigned soon given that COVID cases are increasing. Ms. Garcia shared that the DSHS is in a better place now than before vaccines were available. DSHS does not intend to reassign any TB/HIV/STD or pharmacy staff due to COVID.

Frank Rosas requested clarification regarding Texas Insurance Assistance Program (TIAP) enrollment as it pertains to Rider 26. Mr. Rosas inquired if TIAP would continue to be offered in the future. Ms. Garcia shared the TIAP program will not expand into insurance purchasing but will still continue to serve eligible persons with health insurance with insurance copayment and premium payment assistance. DSHS does not intend to expand insurance purchasing for uninsured THMP clients.

Dr. Susana Lazarte requested clarification on the status of the spenddown after August 31st. Ms. Garcia reported that the spenddown is still being applied. THMP will reassess options at the end of August. DSHS continues to work with an actuary firm to collect more data regarding what a proposed standard deduction would look like in lieu of the spenddown. The timing of this change is key because DSHS cannot make any program changes until the TAC has been amended and finalized. DSHS will post revisions to the TAC for final public comment before finalizing the new rules which are estimated to go into effect in April 2022. Additionally, DSHS needs to communicate with the Health Resource and Services Administration (HRSA) regarding program changes and timelines.

Mr. Rosas stated to the Committee that the TIAP issue is subject to discussion again in the Texas legislature in the next few years as the state is losing funds due to not expanding TIAP and not allowing insurance purchasing.

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Agenda Item 5: TB/HIV/STD 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 updates and referenced handouts, *Monthly THMP Budget Report and Moving Forward Together-Meeting Summary*.

Highlights and committee member discussion included:

a. THMP Budget report:

Mr. Rocha's report primarily focused on state budget year 2021 which runs from September 1st, 2020 to August 31st, 2021. Overall the 2021 budget year shows a combined total of approximately \$162.3 million dollars with expenditures totaling nearly \$110 million dollars with approximately \$51.3 million dollars obligated. DSHS does intend to move an estimated \$30 million dollars from HIV Care Formula Grants in budget year 2021 to the 2022 budget year bringing the 2022 budget year to approximately \$133.8 million dollars. Also noted was a one-time fund in the amount of \$4.8 million dollars from Maternal and Child Health Services Block Grant which has already been spent.

Mr. Rocha also reported that the program is anticipating donations from Ryan White Part A's in the future. Donations will be reflected in the budget presented at the next MAC meeting. Likewise, the transfer of HIV Care Formula Grant funds into budget year 2022 will also be reflected at the next MAC meeting.

Discussion:

Dr. Vanek inquired if the projections made by the actuary consider client growth and subsequent increasing medication costs. Mr. Rocha stated that the actuary firm is taking these things into account and is assured that the program has enough funding for budget year 2022. Additionally, DSHS will also continue to apply for supplemental funds as they become available.

Mr. Rosas shared that he appreciated the budget breakdown and transparency.

Dr. Vanek inquired about information pertaining to the pharmacy and shared that the MAC is interested in receiving additional details about the warehouse budget and operations. Mr. Rocha explained that the pharmacy is operating under a "just in time model" which operates by only purchasing medications to meet existing orders while maintaining minimal inventory in the warehouse. Typically, this looks like 1-3 weeks of medication on the warehouse shelves. Once DSHS observes more stability within the program the agency will reassess this model to determine if another model may be more beneficial.

Ms. Miertschin inquired about a decrease in new HIV diagnosis reported by the Center for Disease Control and Prevention (CDC) in 2020 specifically for Harris County, which accounts for many THMP clients. Ms. Miertschin wanted to know how this data could potentially impact projections for the program in the future. Mr. Rocha stated that DSHS data was slightly different. However, he stated that HIV testing and access to

medical treatment may have decreased in 2020 due to COVID. Dr. Vanek concurred with Mr. Rocha and shared that other health care visits like cancer screenings are also down.

b. Moving Forward Together – meeting summary
Mr. Rocha shared updates from the last Moving Forward Together Partnership
Meeting held June 30th. Nearly 300 people attended the virtual meeting. Updates on
the legislative exceptional item request shared at the meeting included: \$36.3 million
awarded from the 87th Texas Legislature; \$16.3 million is allocated for medications
and \$20 million for restoration of Ryan White, HIV Prevention, and Public Health
Follow-up contracts.

Mr. Rocha also reported that the legislature added Rider 26 to the exceptional item request that stipulates ADAP cannot be used for health insurance expansion. Additionally, Mr. Rocha reported that the Texas Insurance Assistance Program (TIAP) can continue and accept new clients who are eligible. Rider 26 language also mandates that any changes to the Texas Administrative Code (TAC) will require the community be notified 60-days in advance.

Mr. Rocha also noted that information about the eligibility spenddown and potential for a standard deduction were also discussed. Additionally, Mr. Rocha shared the announcement made during the partnership meeting about the pharmacy warehouse now reporting directly to the LIDS Division.

Other items discussed at the partnership meeting include: Take Charge Texas Portal is the new software application that is scheduled to be rolled out at the end of 2021; 17 medication formulary suspensions approved by the DSHS Commissioner; delay for the Cabenuva pilot; and the medication Daraprim that is back in stock.

Logistical program updates included: THMP staff are working overtime to address the application backlog; implementation of full THMP recertification process due to HRSA grant requirements following relaxed COVID eligibility; DSHS is not planning to implement a waitlist for the next biennium.

Mr. Rocha noted that the Moving Forward Together Draft Plan was posted on July 21, 2021, here: https://www.dshs.texas.gov/hivstd/meds/moving.shtm Comments and feedback will be accepted until September 1, 2021. The next partnership meeting is tentatively scheduled for Wednesday September 29, 2021.

Discussion:

Mr. Rosas inquired about the posting of the AIDS Director position and proposed timeline. Ms. Garcia shared that the program was estimating to have the position reposted in August and potentially have the position filled in September, depending on the applicant pool and availability.

Agenda Item 6: THMP Update - Rachel Sanor, THMP Manager

Dr. Vanek introduced Ms. Rachel Sanor, THMP Manager, and she provided the committee with an update and referenced PowerPoint handout, *THMP Update*.

Highlights and committee member discussion included:

a. Rules Change:

Ms. Sanor reported on the THMP rules change, which newly includes the Texas Insurance Assistance Program (TIAP); merges State Pharmacy Assistance Program (SPAP) and Texas HIV Medication Rules into one set of rules; removes a specific federal poverty level (FPL) from the rules, to be determined at the department level; removes the spend down and replaces it with a standard deduction; and updates language to reflect current structure of program. The informal comment period was extended from July 7th to July 16, 2021.

A second, formal comment period will be when they are posted on the Texas Register for 30 days.

b. Projections and demographic information:

Ms. Sanor shared that ADAP utilization for May indicated a slight decrease from previous month's utilization. Top 10 medication ordering had no significant changes since the last MAC meeting. The only notable change was that the percentage of clients using Biktarvy increased slightly.

Program demographics remain stable, as in previous quarters. The only notable change is the number of clients that are currently enrolled which is 18,608, down slightly from previous quarters. Breakdown of programs as of the April 1, 2021-June 30, 2021 quarter is as follows: ADAP 16,126; SPAP 2,018; and TIAP at 464.

ADAP projections from the actuary firm show program enrollment to increase in 2022 and 2023. SPAP projections show estimated cost increase but not client growth. TIAP projections indicate stable client growth with increase in program cost.

Discussion:

Ms. Nancy Miertschin inquired as to why the cost of medications increased but the number of prescriptions decreased. Ms. Sanor indicated that the cost of prescriptions increased due to THMP's COVID response which provided 60-day fills (a two-month supply of medication for each prescription).

Mr. Frank Rosas inquired about the backlog of applications waiting for processing by THMP. Ms. Sanor reported that the program is processing recertifications/self-attestations from the end of June and that new applications are further behind. Ms. Sanor shared that THMP has staff working overtime and is also hiring new contractor staff to address the application backlog.

Mr. Rosas expressed concern that clients are reaching out to him to share that they are applying to the ADAP program but due to the program backlog their applications are not being processed in time for them to receive their medications. Clients are not finding out until they go to the pharmacy to pick up their medications only to be told they are placed on hold. Ms. Sanor stated that THMP is aware of this serious issue and program staff are working to get caught up with processing. Agencies are encouraged to call THMP if they have a client that is running out of medications, and their application is pending, to troubleshoot this issue. Mr. Felipe Rocha echoed Rachel's concern to state that THMP is trying to resolve this issue as soon as possible.

c. Long-lasting injection medication update:

Mr. Rocha covered this in his update regarding the Moving Forward Together meetings.

Agenda Item 7: Procedure for Election of New Officers – Sallie Allen, Advisory Committee Coordination Office

Dr. Vanek introduced Ms. Sallie Allen and she provided the committee with an overview and referenced the handout, *Adoption of Procedure for Election of Officers and Officer Election Process.*

Highlights included:

Ms. Allen reviewed the election procedures with the members. She stated that in accordance with the Open Meetings Act election votes are conducted aloud and ballot votes are no longer used. This new process promotes transparency of the voting for members and the public. She also advised that the program staff solicit the members via email for nominations of the chair and/or vice chair positions. In turn, staff will contact the person and advise them of the nomination and confirm if they are willing to serve in that position. The day of the meeting the candidate names are announced, and members will cast their vote. The votes are tallied and the candidate with the most votes is announced to the committee. If the person elected is also nominated for the vice chair, their name is removed from that election.

Hopefully the new committee members will be onboard by the November meeting and the election of presiding officers will be conducted.

Agenda Item 8: Sub-Committee Reports

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

Formulary Sub-committee - Natalie Vanek, M.D.

- a. May 4th: The sub-committee discussed removing Amphotericin B from the THMP formulary since it has not been utilized in nearly a year. Also discussed the Cabenuva pilot project and suspending Top 10 Medications due to budget issues.
- b. June 1st: Members discussed updates on the Cabenuva pilot project. THMP reported that an action memo was submitted to the Division for approval. It is anticipated that the pilot program will be delayed due to logistical issues with implementation. Medications recommended for suspension from formulary were discussed as well as the discontinuation of 90-day supply of medications.
- c. July 6th: The sub-committee discussed the Cabenuva pilot project which is still on hold. Members discussed logistical issues with pilot at potential clinical sites and provided feedback to THMP.

Governance and Data subcommittee - Ms. Nancy Miertschin, Chair, provided the following update.

Governance and Data – Nancy Miertschin

a. May 28: Members discussed formulating a statement for sub-committee members who are non-MAC members to sign. THMP shared an update on the

- electronic MCF that can be submitted via DocuSign. THMP also provided an update on the last partnership meeting and the pending revision of THMP program rules. Sub-committee discussed budget format and preparation for new members.
- b. June 25: THMP provided an update on the last partnership meeting and the pending revision of THMP program rules. Sub-committee discussed budget format presentation and preparation for new members. Members also discussed the pharmacy warehouse budget. No updates on new members was available. Sub-committee discussed proposed THMP rules specific to the appeals process and those appeals may not be reviewed by an infectious disease physician.
- c. July 23: THMP provided update on June partnership meeting and indicated the Moving Together Plan has been posted on THMP website. Next partnership meeting is scheduled for September. Members discussed updates on the spenddown, and decisions on health insurance expansion. THMP informed members they are still working to identify the number of clients anticipated to be impacted by suspended medications. Members expressed concern with the lack of transparency around budget issues, medications being suspended as a result of budget issues and timeframe when medications will be restored to the formulary.

Discussion:

Dr. Susana Lazarte expressed her concern that more medications than were originally identified for suspension have been included on the list. The formulary sub-committee had identified 13 medications for suspension. It was later determined that the DSHS Commissioner added another four more to the list.

Dr. Vanek requested clarification on the appeals process pertaining to the revisions on the THMP rules. Members of the governance sub-committee were concerned with the possibility of not having an infectious disease physician as part of the appeals panel. Ms. Sanor confirmed THMP does have an appeals process for eligibility determination. The revisions to the THMP rules state that in the event of DSHS restructuring the program, the appeals panel will include the new, equivalent staff position created in that restructuring.

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

The sub-committee met in May and June. Members discussed eligibility issues with THMP.

Agenda Item 9: Public Comment

No oral or written comment was received for the meeting.

Agenda Item 10: Action Items and agenda topics for next scheduled meeting, November 5, 2021

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

Organization chart

- New MAC members and the officer election process
- Update on the THMP spenddown
- DSHS analysis on going back to 90-day medication supply
- THMP to report on application processing times
- Number of clients impacted by suspended medications
- Update on Cabenuva pilot

Agenda Item 11: Adjournment

Dr. Vanek, Chair, thanked the members and the public and advised next meeting is scheduled for November 5, 2021, and she adjourned the meeting at 3:39pm.

To view and listen to the archived video of the July 30, 2021, Texas HIV Medication Advisory Committee meeting in its' entirety, click on the link below.

https://texashhsc.swaqit.com/play/07302021-659