HHSC: THMP HIV Medication Advisory Committee
January 21, 2022

Texas DSHS HIV/STD Program - Texas HIV Medication Program - THMP Medication Advisory Committee. Texas began distributing HIV medications in late 1987 as temporary pilot program; the THMP was officially established in 1989 in Senate Bill 959. The statute that created the HIV Medication Advisory Committee is found in Texas Health & Safety Code, Chapter 85, Subchapter K, Sections 85.271 through 85.282. Rules related to this Committee may be found in Texas Administrative Code, Title 25, Part 1, Chapter 98, Subchapter C, Division 2, Rule 98.121. Committee members are appointed by the executive commissioner of the Texas Health and Human Services Commission.

Current THMP Medication Advisory Committee Members

Natalie Vanek - Committee Chair
Houston, Texas
Term expires 2020

Frank Rosas - Committee Vice-Chair
San Antonio, Texas
Term expires 2022

Margaret Adjei
San Antonio, Texas
Term expires 2022

Ogechika Karl Alozie
El Paso, Texas
Term expires 2022

Gloria Heresi
Houston, Texas
Term expires 2024

Lionel Hillard
Dallas, Texas
Term expires 2022

Susana Lazarte
Dallas, Texas
Term expires 2020

Nancy Miertschin
Houston, Texas
Term expires 2024

Ray Moore
Granbury, Texas
Term expires 2024

Yolanda Rodriguez-Escobar
San Antonio, Texas
Term expires 2024

Demetra Tennison
Austin, Texas
Term expires 2024

Texas DSHS HIV/STD Program - Texas HIV Medication Program

1. Call to order, welcome and opening remarks– The meeting was convened by Natalie Vanek, M.D., Committee Chair

2. Logistical announcement and roll call – Sallie Allen, Advisory Committee Coordination Office, HHSC made announcements concerning the meeting. A quorum was established.

3. Consideration of July 30, 2021 and November 5, 2021, draft meeting minutes

The minutes were approved with minor non-substantive edits.

4. Public Comment Written comments were received but not made available for this report.

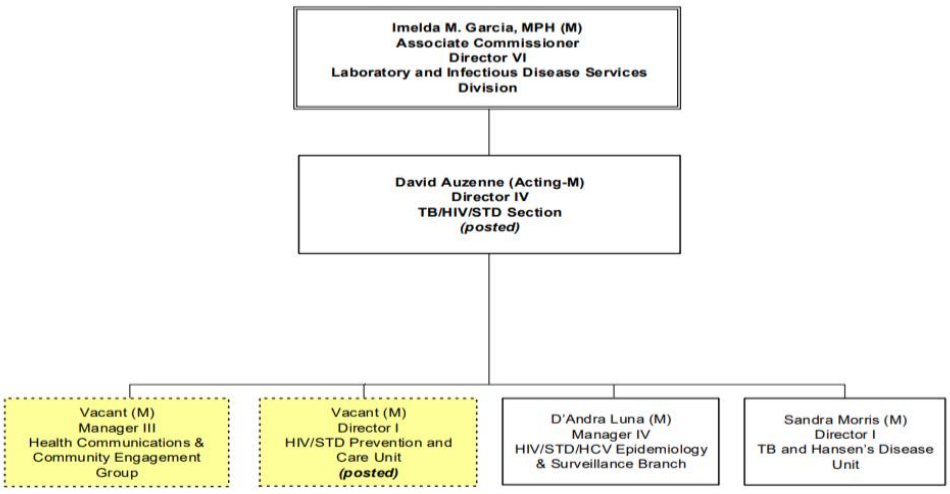
January Fox, Prism Health, North Texas commented on policy changes from HRSA form 2102. HRSA made the changes based on stakeholder feedback. DSHS has had a difficult time processing applications. Prism Health encourages DSHS to follow the changes from HRSA regarding 2102.

Masly Mohamadi, FQHC stated that there have been delays in approvals on the program and access to medication. Delays cannot be fixed overnight but they must be addressed. The pandemic has hit the HIV community very hard. She raised issues of access for people enrolled in the Cabenuva Pilot.

5. Department of State Health Services Updates – David Auzenne in lieu of Imelda Garcia, MPH, Associate Commissioner of Laboratory and Infectious Disease Services

a. Staffing update

LIDS/TB/HIV/STD Management Organization Chart,
description on next page
January 2022



Laboratory and Infectious Disease Services Imelda Garcia, MPH, Associate Commissioner Manages: David Auzenne (M), Acting TB/HIV/STD Section, Director IV (posted)

Manages:

- Vacant (M) Manager III, Health Communications & Community Engagement Group
- Vacant (M) Director I, HIV/STD Prevention and Care Unit (posted)
- D'Andra Luna (M), Manager IV HIV/STD/HCV Epidemiology & Surveillance Branch
- Sandra Morris (M), Director I TB and Hansen's Disease Unit

b. Cabenuva Pilot Once-a-Month HIV Treatment | CABENUVA (cabotegravir; rilpivirine). is a complete prescription regimen used to treat HIV-1 infection in adults as a replacement for their current HIV-1 treatment when their healthcare provider determines that they meet certain requirements.

6. TB/HIV/STD Section Updates – David Auzenne, MPH, Interim Director, DSHS TB/HIV/STD Section

c. Budget Report

Monthly THMP Financial Report

Budget Description	By 2021 Expanded	By 2022 Budgeted	By 2022 Obligated	By 2022 Expanded	By 2022 Remaining
General Revenue (GR)	$1,500,000	$5,693,151	$5,693,151	-	$5,693,151
GR Match/MOE	$566,661	$2,471,807	$2,471,807	-	$2,471,807
HIV Vendor Dug Rebates	$8,065,377	$15,552,875	$9,000,000	$6,000,000	$9,552,875
Coronavirus Relief Fund*	$34,400,000	$14,800,000	$14,800,000	$14,800,000	-
HIV Care Formula Grants	$69,670,440	$93,885,662	$82,179,592	$8,176,445	$85,709,217
Maternal & Child Health Services Block Grant (MCH)	$4,800,000	-	-	-	-
Appropriated Receipts – Misc. (Rx refunds; 3rd party)	$700,000	-	-	-	-
Total All Funds	**$119,702,477**	**$132,403,495**	**$114,144,550**	**$28,976,445**	**$103,427,050**

State Budget Year (BY) September 1 – August 31 annually. Obligated funding is on a PO for the current BY.
Due to rebate shortfall, BY2021 had one-time funding from other DSHS appropriations in addition to Coronavirus Relief Funds that are typically not available within this appropriation
Total EI for FY22 is $8,164,958
EI is represented in FY22 budget as GR for $5,693,151 and GR Match/MOE for $2,471,807
*Coronavirus Relief Funds received in BY21 for $34,400,000
Budgeted & Expended are HIV Medication activities

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Planning has begun for the next legislative session and an exceptional item will be requested related to the 6 month recertification (HRSA requirement). No changes to the program will occur until 2/28/22 but the program has a cushion. This includes: Cabenuva Pilot which is on hold, 90 day suspension, spend down standard deduction, HRSA policy change, formulary changes, Approval was received from HRSA for the spend down for the standard deduction. All these are being evaluated.

Questions/Answers/ Comments

No change to HRSA policy until after next legislative session. Other changes can occur though after February. DSHS answered in the affirmative.

The question of changes in the program should be addressed before the next meeting in April and timelines should be provided.

There are two HRSA issues and this is causing confusion. The two are:

- 6 month Recertification
- Spend down

We must have clarification on these issues that are under discussion by management looking at the financial issues.

The people dropped from the program under the 6 month attestation are being reviewed for the cost that would have been incurred.

If COVID goes away then there will be greater accessibility since the agents were working from home, limiting access during the pandemic. It is a hardship on communities extending this process. The pandemic has skewed all the data. It is difficult keeping people enrolled.

What is happening on approvals, re-approvals, and time for medication receipt? DSHS said the trend is going down but they do not have specifics.

Can associated documents be sent out a day ahead of time? DSHS stated they allow three days.

7. THMP Update - Rachel Sanor, THMP Manager THMP Update (texas.gov)

A. THMP - Projections and Demographic information

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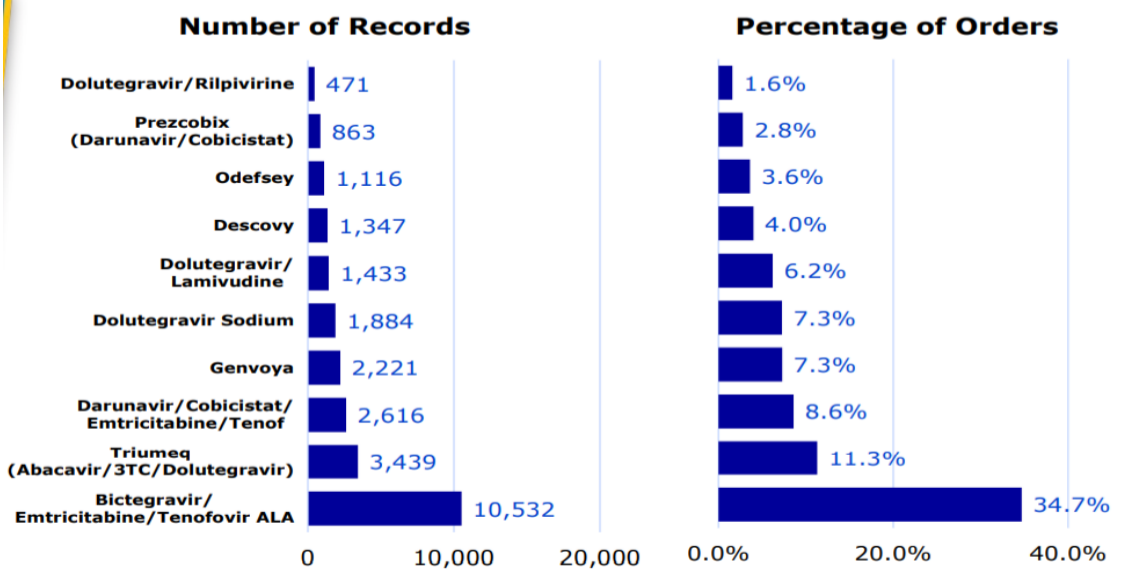
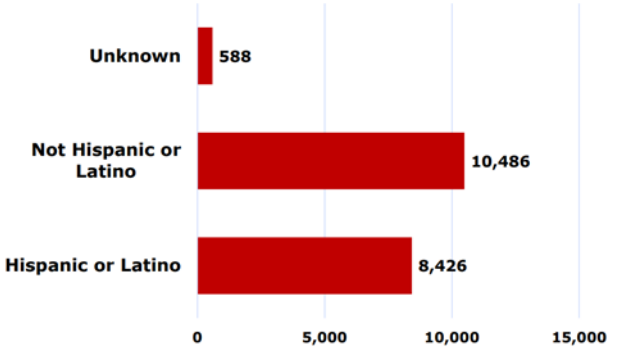
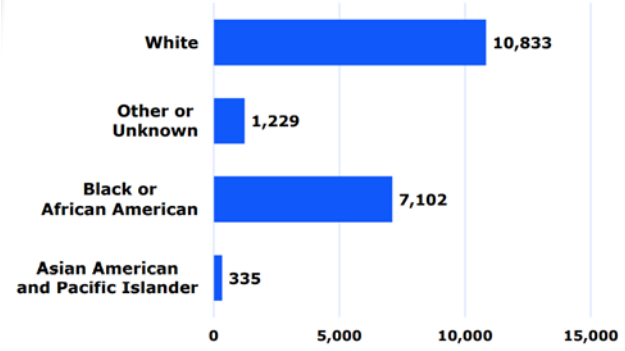
THMP Medications Ordered for Q4 2021
Total = 30,306
Top 10 Medications



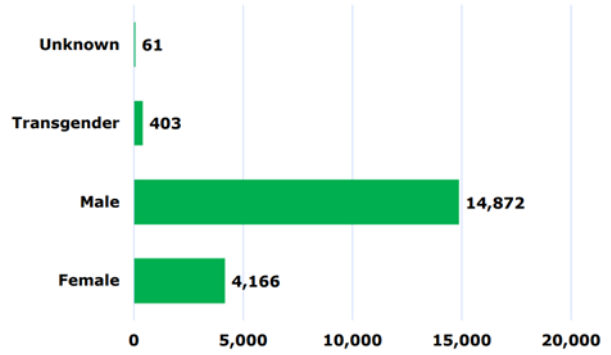
THMP Demographic Data Participants by Ethnicity



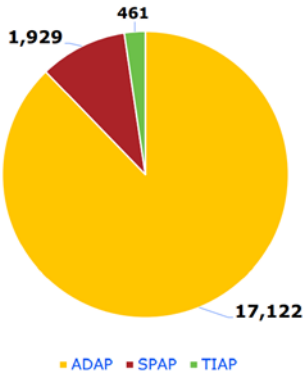
THMP Demographic Data Participants by Race



THMP Demographic Data Participants by Gender

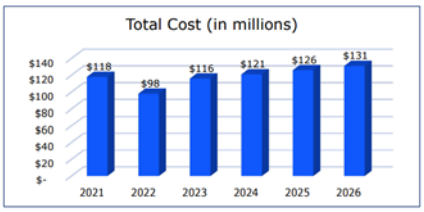


THMP Assistance by Category



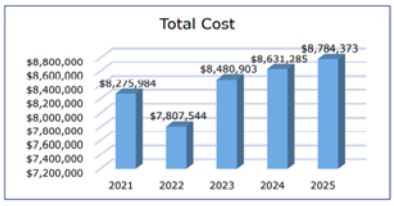
ADAP Projections

We anticipate growth within the ADAP program being driven by the number of clients, but we are seeing a visible dip currently in 2022.



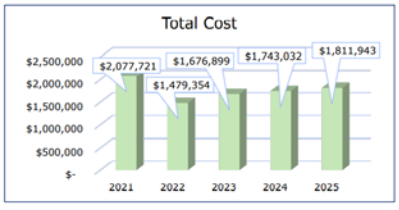
SPAP Projections

We anticipate the SPAP enrollment to remain stable but costs to increase.



TIAP Projections

We anticipate growth within the TIAP program being driven by the number of clients, but we are seeing a visible dip currently in 2022.



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B. 60-day and 90-day supply analysis

There is no inherent difference in the product cost of the prescription under the different scenarios (60 or 90 days) The cost comes from the excess cost (people dropping from the program before the prescription runs out. There can be more than 30 days of prescription when people are dropped. People are dropped because of failure to respond to an attestation. DSHS looked at the costs for the overfills.

- "Excess" costs occur when a participant who has filled a 60 or 90 day prescription drops from the program before the prescription runs out
- "Overfill" is when a participant has more than 30 days worth of drugs at the time they are dropped
- The most common reason for the drops is failure to respond to requests for self-attestation or recertification of eligibility

• Data on 90 day prescriptions was drawn from April 2019 through February 2021.

- We determined how many potential overfills occurred by counting the number of participants in this time period with at least one 90 prescription
- We separated out those who dropped out of the ADAP before a 90 day fill ran out
- We focused on those with more than 30 days left in the prescription (overfills)
- This got expressed as 30 day bottles
- We compiled the costs for the number of overfill bottles and divided by the number of participants with overfills to get a per participant overfill cost

Data on 60 day prescriptions was drawn from March 2020 to October 2020

- Same methodology was used for 90 day prescriptions to determine per participant overfill cost

While 60 day fills were more common, they were less likely to result in an overfill, less than 1% of participants with 60 day prescriptions had an overfill. To have an overfill of a 60-day fill, the participant would have to drop from the program in the first 30 days of the fills. Per participant overfill expenditure was about $866. Overfills of 90-day prescriptions were also rare with about 6% of the participants with 90-day fills having an overfill. For this group, per participant overfill expenditure was about $1211.

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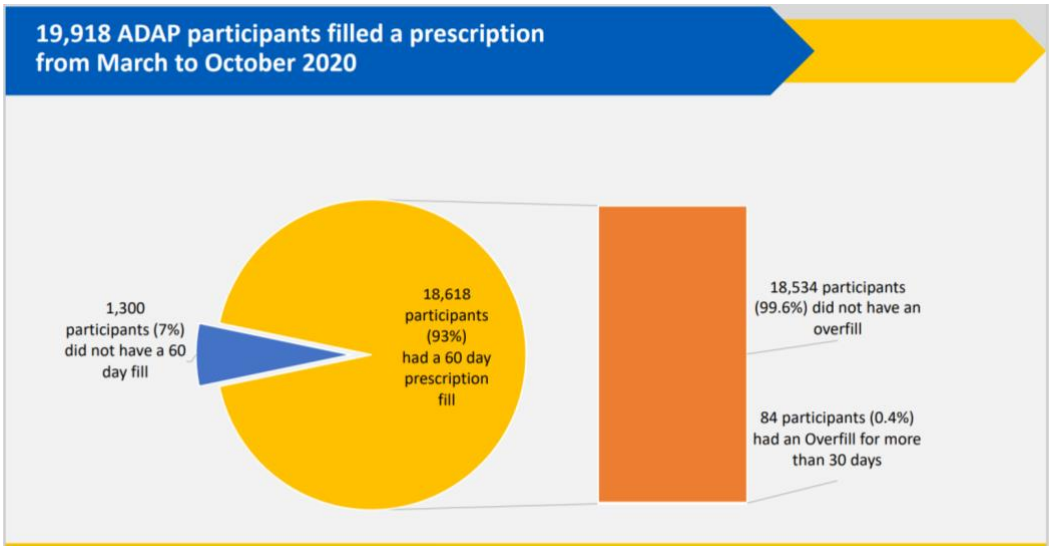
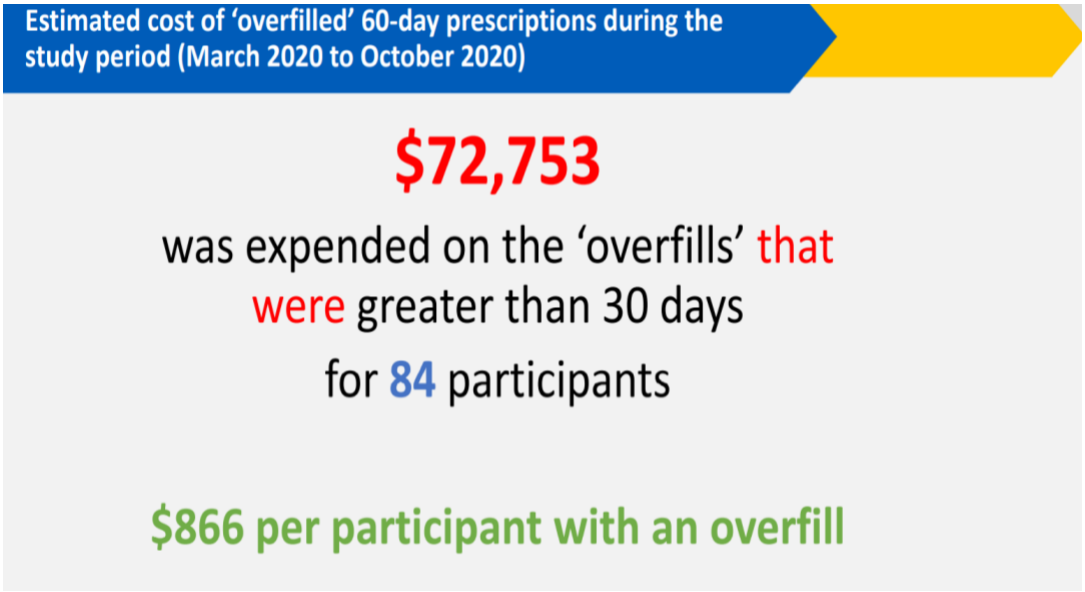


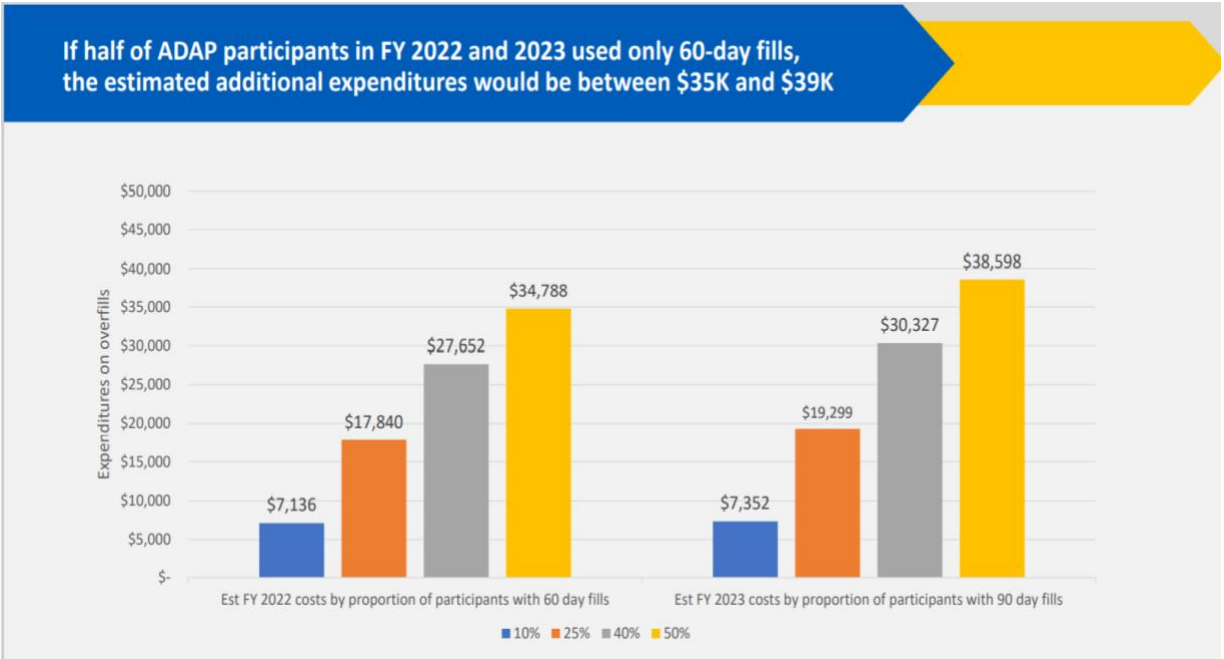
Less than one percent had an overfill.



DSHS examined how the volume of 60-day fills would impact expenditures if different proportions of projected ADAP participants in FY2022 and FY2023 used 60-day fills. During the study about 0.4% of those with a 60-day fill had an overfill of more than 30 days. This figure was then used to estimate the number of clients with an overfill and adjusted the per participant cost of the overfill to reflect predicted expenditure increases of 3% a year.

Example: projected participants and expenditures for FY 2022 (as of November projections)

Projected unique ADAP participants	19,521			
% of participants with 60-day fills	10%	25%	40%	50%
Projected participants with 60-day fills	1,952	4,880	7,808	9,761
Projected participants with overfills	8	20	31	39
Est overfill cost per client	$892			
Total overfill expenditures	$7,137	$17,842	$27,655	$34,792



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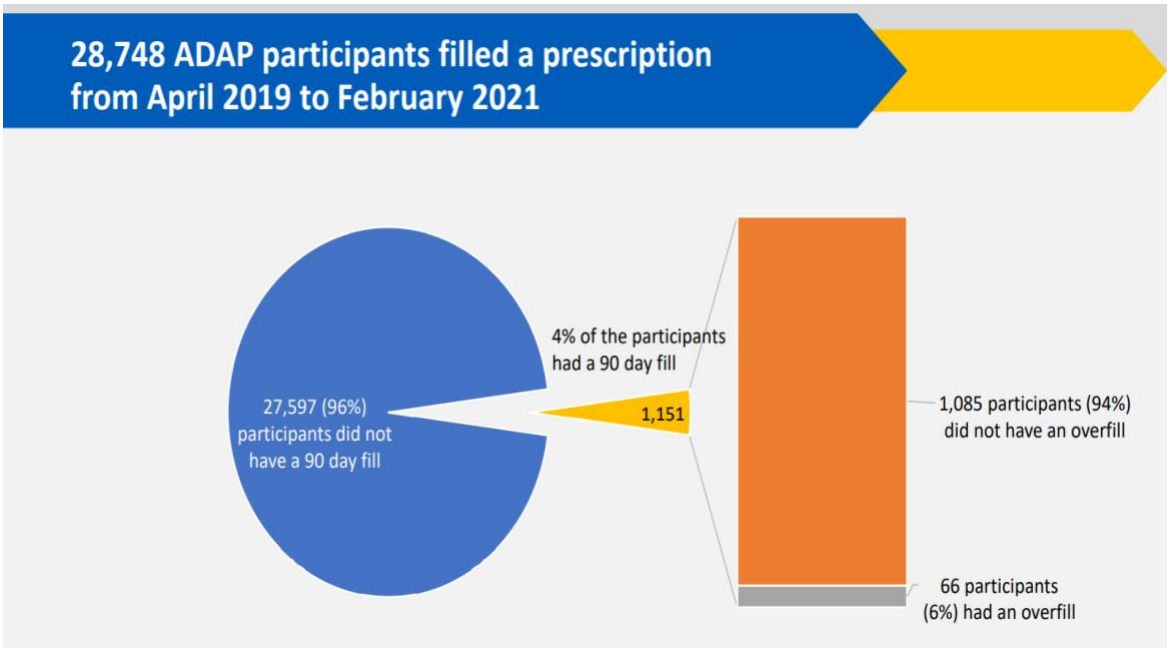
Examining 90 Day Fills

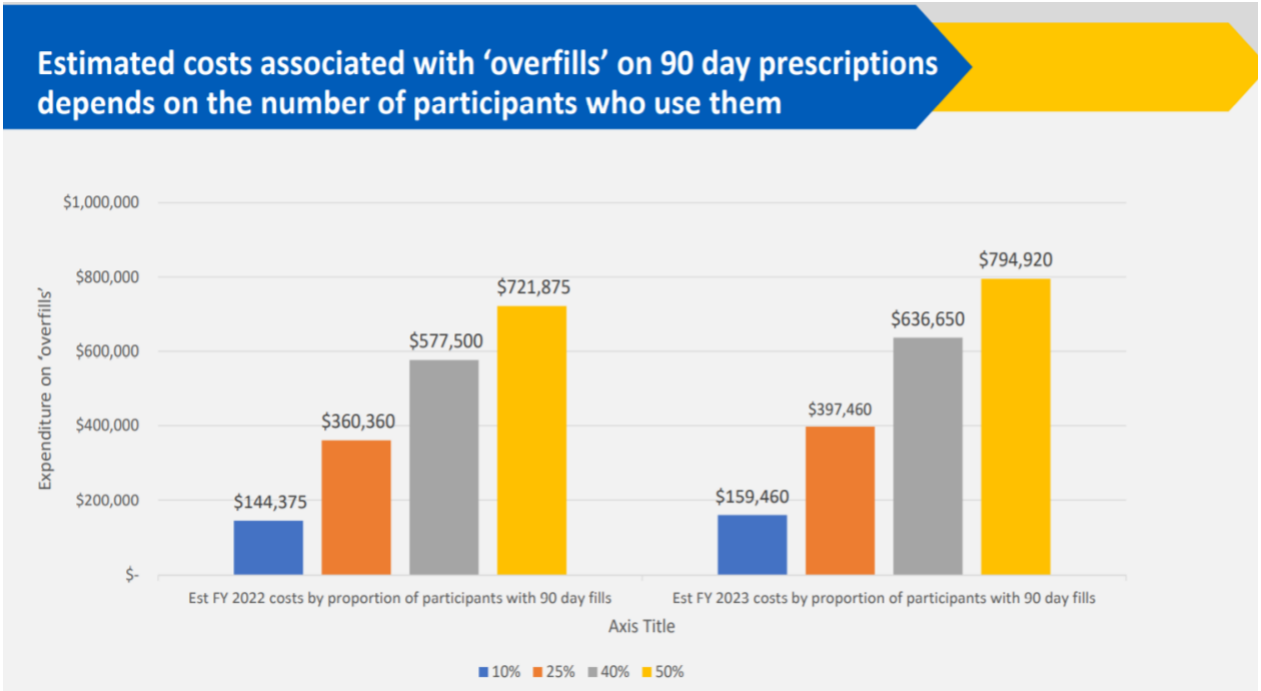


The percentage is higher for overfills for 90 day but the numbers are low.

DSHS estimated overfill costs if 10%, 25%, 40% and 50% of projected ADAP participants in FY 2022 and 2023 used 90 day fills. An overfill is when a participant with a 90 day fill is dropped from the program with more than 30 days of medication left on the prescription. During the study period about 6% of the participants who had a 90 day fills had an overfill, so they used that to estimate the number of clients with an overfill and adjusted the per participant cost of the overfill to reflect predicted expenditure increases of 3% a year.

Example: projected participants and expenditures for FY 2022 (as of November projections)

Projected unique ADAP participants	**19,521**			
% of participants with 90 day fills	10%	25%	40%	50%
Projected participants with 90 day fills	1,952	4,880	7,808	9,761
Projected participants with overfills	125	312	500	625
Est overfill cost per client	$1,155			
Total overfill expenditures	$ 144,375	$ 360,360	$ 577,500	$ 721,875



What is expected on overfills will be reflective of the number of people who use it and the recertification issues.

Questions/Answers/Comments

If there is an overfill, do we follow up if they are still taking the medication? DSHS stated that this could imply continuity of treatment. Until they re-enroll or move to another state.

Do we know why the people leave the program included in the analysis. DSHS stated About ¾ of people who were dropped are failure to re-certify or self-attestation. We are looking at doing a more thorough follow-up.

The question is are they completing taking the overfill that they had.

People often can't get into the system to do the recertification. We need data on the bugs in Take Charge Texas.

The program must live within a budget. If they go outside the budget, then the program could go away (be sunseted)

There seems to be an agreement that overfills continue viral suppression. A sixty day prescription helps in natural disasters. We should be looking at the 6 month re-attestation.

There was support expressed for a 60 or 90 day prescription. The benefit outweighs the cost. More than half people dropped for the program were eligible for the program.

C. Take Charge Texas Update

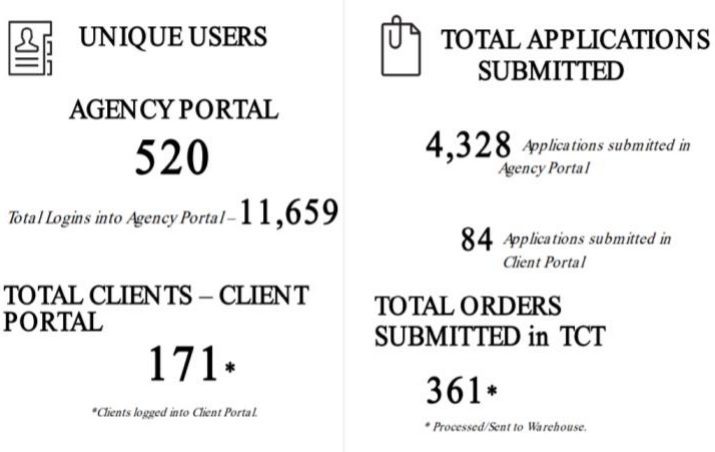
DSHS stated that they are aware there are bugs in the system, and they are working to address those, including those raised at this meeting.

TCT was launched on December 18, 2021

- Eligibility Determination
- Creating
- a Care Plan
- Medication Ordering o Interagency Referrals
- TCT enhanced version will be deployed on February 12, 2022
- Disease Management Report
- Client Eligibility Status Report
- Reminder Report for Clients

Training information

- 20 unique training modules developed and distributed to agency workers
- Client Portal training videos is in the process of being developed
- TCT user guide is in the process of being developed
- Help desk and support information
- For TCT technical assistance, please email the TCT Help Desk: at hiv.tcthelpdesk@dshs.texas.gov



Questions/Answers/Comments

Can we reach out to people who have used the portal to identify problems? DSHS answered in the affirmative.

There are five specific problems that people encounter when accessing the portal. The response time of the help desk is bad.

If people do have problems, does the help desk turn around quickly? DSHS stated they try to address the problems as quickly as possible.

Not all people have access to internet, computers or smart phones. Tech literacy is also a problem.

D. MAC appointment process: Members for 2022

Frank Rosas - Acting Chair
Nancy P. Miertschin, MPH
Margaret Adjei PharmD. RPh.
Dr. Ogechika Alozie
Dr. Gloria Heresi
Lionel Hillard
Dr. Susana Lazarte
Dr. Yolanda Rodriguez-Escobar
Helen Turner
Dora A. Martinez, MD, FAAFP, AAHIVS
Steven Vargas

8. Recommended changes for Bylaws Draft Texas HIV Medication Program Bylaws

The Committee was asked if they had any edits to the bylaws. New members asked for time to review them so they could be voted on at the next meeting. The by-law vote was tabled until the next meeting. A request was made to send out the document as a word document

MOTION: Table the bylaw vote until the next meeting prevailed.

9. Review and Adoption of the Procedure & Process for Election of Presiding Officers (The adopted process will be used at the next meeting to vote on officers). The HHSC standard advisory election process was presented.

MOTION: Accept the voting procedures and process prevailed.

10. Sub-Committee Reports

Governance/Data – Nancy Miertschin
No report

Eligibility – Frank Rosas
The committee met once and discussed the Take Charge Texas issues. The backlog was supposed to be caught up before the portal went live.

Formulary – Natalie Vanek, M.D. The committee met and they discussed the 60 and 90 day analysis. They went on to the suspended medication list and made recommendations which you will see below, Truvada generic was not available. They also discussed the utilization in the Cabenuva pilot and limited distribution of the product. They also discussed the suspended medications. There were ten medications recommended to keep and it is being brought to the full committee.

Consideration/recommendation of pediatric Biktarvy was discussed. The decision was made to bring this to the MAC for a vote. The subcommittee recommended it for the formulary. Vote today to follow.

11. MAC to recommend removal and re-activation of suspended medications

The recommendations under consideration are presented below. “Keep” means “Add back”

Enrollment -Suspended medications

Member recommendations are in red.

Number of Participants on Each Medication, Effective 6/30/2021

Name Brand (Generic)	Indications	Number of Participants
Egrifta (tesamorelin acetate P/F) Remove	HIV Side Effect	10
Mytesi (Crofelemer) Remove	HIV Side Effect	10
Amlodipine Keep	Hypertension	107
Atorvastatin Keep	Statin	200
Hydrochlorothiazide (HCTZ) Keep	Hypertension	101
Lisinopril Keep	Hypertension	156
Metformin HCL Keep	Diabetes	109
Metoprolol Tartrate Keep	Hypertension	23
Zypitamag (Pitavastatin) Keep on suspension (No action)	Statin	0
Amphotericin B - Remove	OI Injection	0
Roferon-A (interferon alpha) - Remove	OI Injection	0
Trazadone - Keep	Psychiatric	39
Duloxetine Keep	Psychiatric	12
Gabapentin Keep	Psychiatric	90
Sertraline Keep	Psychiatric	41
Baraclude Keep on suspension (no action)	Hepatitis B	9
Vemlidy (tenofovir alafenamide) Keep on suspension (no action)	Hepatitis B	9
Grand Total		916
Unduplicated		672

Number of Suspended Medications each Participant is Currently Prescribed, 6/30/2021

Number of Meds	Number Impacted
1	501
2	118
3	39
4	11
5	1
6	1
7	1
Grand Total	**672**

When medications are removed, a three month supply is sent to the recipient with a notice of the removal.

MOTION: remove 3 medications recommended for removal but keep Mytesi under the suspension category (no action) prevailed. (Egrifta, Amphotericin, Roferon were removed)

MOTION: Reactivate the ten medications designated above as keep prevailed

12. Consideration of pediatric Biktarvy. Resources are presented below. This action was recommended by the subcommittee.

BIKTARVY® | A One-Pill, Once-a-Day Treatment Option
BIKTARVY® | Official HCP Website from Gilead (biktarvyhcp.com)
Biktarvy Approval Expanded to Include Younger Children With HIV-1 - MPR (empr.com)

MOTION: Add pediatric Biktarvy to the formulary prevailed.

13. Consideration of extended fills. To keep the 60 and 90 day fills/refills.

MOTION: to keep extended fills prevailed.

14. Review and approval of 2022 MAC meeting dates

Traditionally meetings have been at the end of the month. Rooms have already been reserved for the following:

- 29th April
- 29th of July
- 28th of October

MOTION: to meet on the dates listed prevailed

15. Review of action items and agenda topics for next meeting

- Financial report sent three days in advance of the meeting
- Bylaws to be sent to members
- Election of new officers
- Update on timing of the medications from ship dates and new renewals and recertifications
- How things are going with the portal
- Update on the spenddown
- TAC revisions
- Update on Cabenuva

16. Adjourn. There being no further business, the meeting was adjourned.

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This summary contains supplemental information from third-party sources where that information provides clarity to the issues being discussed. Not every comment or statement from the speakers in these summaries is an exact transcription. For the purpose of brevity, their statements are often paraphrased. These documents should not be viewed as a word-for-word account of every meeting or hearing, but a summary. Every effort has been made to ensure the accuracy of these summaries. The information contained in this publication is the property of Texas Insight and is considered confidential and may contain proprietary information. It is meant solely for the intended recipient. Access to this published information by anyone else is unauthorized unless Texas Insight grants permission. If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted in reliance on this is prohibited. The views expressed in this publication are, unless otherwise stated, those of the author and not those of Texas Insight or its management.
