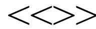
HOUSTON AREA HIV SERVICES RYAN WHITE PLANNING COUNCIL



STEERING COMMITTEE

AGENDA

12 noon, Thursday, March 4, 2021

Join Zoom Meeting by clicking onto:
https://us02web.zoom.us/j/85782189192?pwd=YmtrcktWcHY5SlV2RE50ZzYraEErQT09
Meeting ID: 857 8218 9192
Passcode: 885832
Or, dial in by calling 346 248-7799

I. Call to Order — Allen Murray, Chair, RW Planning Council
   A. Welcoming Remarks
   B. Moment of Reflection
   C. Select the Committee Co-Chair who will be voting today
   D. Adoption of the Agenda
   E. Adoption of the Minutes

II. Public Comment and Announcements
(NOTE: If you wish to speak during the Public Comment portion of the meeting, please sign up on the clipboard at the front of the room. No one is required to give his or her name or HIV status. All meetings are audio taped by the Office of Support for use in creating the meeting minutes. The audiotape and the minutes are public record. If you state your name or HIV status it will be on public record. If you would like your health status known, but do not wish to state your name, you can simply say: "I am a person living with HIV", before stating your opinion. If you represent an organization, please state that you are representing an agency and give the name of the organization. If you work for an organization, but are representing yourself, please state that you are attending as an individual and not as an agency representative. Individuals can also submit written comments to a member of the staff who would be happy to read the comments on behalf of the individual at this point in the meeting. All information from the public must be provided in this portion of the meeting.)

III. Reports from Committees
   A. Comprehensive HIV Planning Committee — Daphne L. Jones and Rodney Mills, Co-Chairs

   Item: Committee Orientation
   Recommended Action: FYI: The Committee dedicated the first portion of their February meeting to general orientation, which included a review of the purpose of the committee and the definition of conflict of interest, the requirements of the Open Meetings Act, Petty Cash restrictions, work products, meeting dates and more.

   Item: Comprehensive Planning
   Recommended Action: FYI: Although the 2017-2021 Comprehensive Prevention and Care Plans will expire at the end of the year, the instructions for the next Comprehensive Plan have not yet been released. See the attached letter from HRSA dated June 17, 2020.

Item: Joint Trainings with CPG
Recommended Action: FYI: Although the instructions described above have not been released, the Committee feels that it would be helpful to start gathering information for the next comprehensive plan and the FY22 How To Best Meet the Need process by co-hosting joint trainings with members of the Community Planning Group (CPG) and the Planning Council. Trainings will be organized around the four pillars of the Ending the HIV Epidemic initiative and will 1.) review services that address each pillar, 2.) review data available about the services, 3.) ask a panel of front line workers if there are gaps in services, if the services can be improved and if the services interface effectively. Soon, detailed information about the trainings will be announced. All are welcome and encouraged to attend the trainings.

Item: 2021 Joint Epidemiological Profile
Recommended Action: FYI: The 2021 supplement to the current Joint Epidemiological Profile will be developed in the second half of 2021 when updated data will hopefully be available.

Item: Committee Vice Chair
Recommended Action: FYI: Steven Vargas was elected as the vice chair for the 2021 Comprehensive HIV Planning Committee.

B. Affected Community Committee — Rosalind Belcher and Tony Crawford, Co-Chairs
No meeting due to inclement weather

C. Quality Improvement Committee — Kevin Aloysius and Steven Vargas, Co-Chairs
No meeting due to inclement weather

D. Operations Committee — Ronnie Galley and Veronica Ardoin, Co-Chairs
No meeting due to inclement weather

E. Priority and Allocations Committee — Peta-gay Ledbetter and Bobby Cruz, Co-Chairs
Item: Committee Orientation
Recommended Action: FYI: The Committee also dedicated the first portion of their February meeting to general orientation.

Item: Training: Preparing for Changes in 2021
Recommended Action: FYI: Charles Henley, a consultant for the DSHS* HIV/STD Branch Care Services Group, shared the attached Information with the Committee, which will help them make informed recommendations to the Council in response to changes currently taking place with statewide, Part B funded services, such as ADAP.

Item: 2021 Policy for Addressing Unobligated and Carryover Funds
Recommended Action: **Motion:** Approve the attached FY 2021 Policy for Addressing Unobligated and Carryover Funds.

V.	Report from the Office of Support	Tori Williams, Director
VI.	Report from Ryan White Grant Administration	Carin Martin, Manager
VII.	Report from The Resource Group	Sha’Terra Johnson, Health Planner
IX.	Announcements	
X.	Adjournment	

HOUSTON AREA HIV SERVICES RYAN WHITE PLANNING COUNCIL

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STEERING COMMITTEE

MINUTES

12 noon, Thursday, February 4, 2021
Meeting Location: Zoom teleconference

MEMBERS PRESENT	MEMBERS ABSENT	OTHERS PRESENT
Allen Murray, Chair		*Ryan White Grant Administration*
Denis Kelly, Vice Chair		Carin Martin
Crystal Starr, Secretary		
Tony Crawford		*The Resource Group*
Rosalind Belcher		Sha'Terra Johnson
Daphne L. Jones		
Rodney Mills		*Office of Support*
Veronica Ardoin		Tori Williams
Ronnie Galley		Ricardo Mora
Bobby Cruz		Diane Beck
Peta-gay Ledbetter		
Kevin Aloysius		
Steven Vargas		

Call to Order: Allen Murray, Chair, called the meeting to order at 12:04 p.m.

During the opening remarks, Murray welcomed the new members of the Leadership Team. He then called for a Moment of Reflection.

Murray invited committee co-chairs to select the co-chair who would be voting on behalf of their committee. Those selected to represent their committee at today's meeting are: Crawford for Affected Community, Mills for Comprehensive HIV Planning, Ardoin for Operations, Ledbetter for Priority and Allocations and Vargas for Quality Improvement.

Adoption of the Agenda: ***Motion #1:*** *it was moved and seconded (Starr, Galley) to adopt the agenda.* **Motion carried.**

Approval of the Minutes: ***Motion #2:*** *it was moved and seconded (Starr, Kelly) to approve the December 3, 2020 minutes.* **Motion carried.** Abstentions: Aloysius, Crawford, Ledbetter.

Public Comment and Announcements: None.

Reports from Committees
Comprehensive HIV Planning Committee: No report.

Affected Community Committee: No report.

Quality Improvement Committee: No report.

Priority and Allocations Committee: No report.

Operations Committee: Ronnie Galley, Co-Chair, reported on the following:
2021 Mentor/Mentee Luncheon: Galley said that he was unable to attend the January 14, 2021 luncheon but heard that it went well.

2021 Council Orientation: Galley said that the 2021 Orientation was well attended and included great speakers.

2021 Council Activities: Williams pointed out the memorandum regarding Petty Cash procedures, Open Meetings Act Training and the 2021 Timeline of Critical Activities. They will also be reviewed at the first meeting of each committee. She said that the HRSA site visit will be April 6-9, 2021. Members of the Steering Committee should budget time to meet with the HRSA visitors before the Council meeting on April 8, 2021.

Report from Office of Support: Tori Williams, Director, summarized the attached report.

Report from Ryan White Grant Administration: Carin Martin, Manager, summarized the attached report. Kelly asked if transportation could be provided to get a COVID test and vaccine. Martin said yes that is covered by Medical Transportation.

Report from The Resource Group: Sha'Terra Johnson, Health Planner, submitted the attached report.

Texas AIDS Drug Assistance Program Updates: Martin said that clients who do not qualify for ADAP can use Emergency Financial Assistance (EFA) at Ryan White funded clinics and should get therefore get their medication with no delays. If they need assistance for longer then they should eligible for the Local Pharmacy Assistance Program (LPAP). This would not apply to those who get their prescriptions at Kroger or other pharmacies that are not a Ryan White funded provider. Clients will need to have their eligibility up to date in the CPCDMS in order to access EFA and LPAP so they will need to go through eligibility first if they are not up to date. She added that the clients can contact the complaint line if they need help. There are also pharmaceutical company patient assistance programs available. Johnson pointed out that the ADAP eligibility workers in the clinics should help clients navigate the different services to get their medication.

Announcements: Murray, Belcher, Mills, and Vargas each expressed thanks to Aloysius for contacting the Office of Support to offer the COVID vaccine to Planning Council members.

Adjournment: The meeting adjourned at 1:42 p.m.

Submitted by:		Approved by:	
Tori Williams, Director	Date	Committee Chair	Date

2021 Steering Committee Voting Record for Meeting Date 02/04/21

C = Chaired the meeting, JA = Just arrived, LM = Left the meeting,
VP = Participated via telephone, nv = Non-voting member

Aff-Affected Community Committee, Comp-Comprehensive HIV Planning Committee, Op-Operations Committee, PA-Priority and Allocations Committee, QI-Quality Improvement Committee

	Motion #1 Agenda **Carried**				**Motion #2** Minutes **Carried**			
MEMBERS	**Absent**	**Yes**	**No**	**Abstain**	**Absent**	**Yes**	**No**	**Abstain**
Allen Murray, Chair				**C**				**C**
Denis Kelly, Vice Chair		**X**				**X**		
Crystal Starr, Secretary		**X**				**X**		
Tony Crawford, Aff		**X**						**X**
Rodney Mills, Comp		**X**				**X**		
Veronica Ardoin, Op		**X**				**X**		
Peta-gay Ledbetter, PA		**X**						**X**
Steven Vargas, QI		**X**				**X**		
Non-voting members at the meeting:								
Rosalind Belcher, Aff ja 12:58 pm								
Daphne L. Jones, Comp ja 12:35 pm								
Ronnie Galley, Op								
Bobby Cruz, PA ja 12:14 pm								
Kevin Aloysius, QI								

Comprehensive HIV Planning Committee Report

DEPARTMENT OF HEALTH & HUMAN SERVICES

June 17, 2020

Dear Ryan White HIV/AIDS Program and Centers for Disease Control and Prevention HIV Prevention Colleagues:

The Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB) and the Centers for Disease Control and Prevention (CDC), Division of HIV/AIDS Prevention (DHAP) issued guidance for the Integrated HIV Prevention and Care Plan, including the Statewide. Coordinated Statement of Need (SCSN), a legislative requirement for Ryan White HIV/AIDS Program (RWHAP) Part A and B Grantees in June 2015 This guidance established that health departments and planning groups funded by DHAP and HAB develop an Integrated HIV Prevention and Care Plan. The guidance format allowed jurisdictions to submit one Integrated HIV Prevention and Care Plan, including the Statewide Coordinated Statement of Need (SCSN), to CDC and HRSA by September 30, 2016, covering calendar years 2017 – 2021. Submission of the Integrated HIV Prevention and Care Plan not only meets the legislative and programmatic requirements of CDC and HRSA, but also serves as a jurisdictional HIV/AIDS Strategy or roadmap.

HAB and DHAP had anticipated issuing the updated Integrated HIV Prevention and Care Plan guidance this summer for the calendar years 2022 – 2027 submission; however, due to the unprecedented COVID-19 pandemic, HAB and DHAP have determined that we will postpone the issuance of the guidance. We appreciate the work that you all are doing to support people with HIV and people at risk for HIV through your programs during this public health emergency. We believe that postponing the guidance provides you with an opportunity to stay focused on the work at hand and to consider how HIV prevention and care planning may need to evolve going forward.

We will notify HAB and DHAP grant recipients of the updated timeline for the guidance and the submission later this year. In the meantime, our joint expectation is that RWHAP Part A and B recipients and DHAP funded state and local health departments continue to utilize the existing Integrated HIV Prevention and Care plans as their jurisdictional HIV/AIDS Strategy or roadmap.

HRSA and CDC know that many RWHAP and HIV prevention programs at the local and state levels have integrated planning activities; such activities encompass joint comprehensive needs assessment, information and data sharing, cross representation on prevention and care planning bodies, coordinated/combined projects, combined meetings, and fully merged planning bodies. Overall, we continue to encourage planning groups to streamline their approaches to HIV planning even as those approaches evolve in the context of a public health pandemic.

We also acknowledge that many of you have developed your Ending the HIV Epidemic Plans that were required as part of the Ending the HIV Epidemic initiative funding from CDC and may be in the process of further refining those plans now. We encourage you to incorporate your community engagement for the EHE plans and your integrated planning activities to the extent that is helpful. The Integrated HIV Prevention and Care Plan is the umbrella plan for all of your

Priority and Allocations Committee Report

Responding to the impact of potential THMP Changes

Changes & Solutions

Charles Henley, LCSW

The Challenge – ADAP Clients

- THMP statement issued 2/23/21: ***"We are delaying the elimination of the spend down for the AIDS Drug Assistance Program (ADAP) through at least June 30, 2021. THMP will review any denials based on income from December 1, 2020 forward."***
- Previously, DSHS had stated the spend down had ended in December 2020, and current participants with an income greater than 200% of FPL began rolling off the ADAP beginning in December 2020
- Until at least June 30th if a **prior applicant** qualifies for the program after applying the spend down, THMP will send an approval letter. The applicant will be **reinstated** into the program.
- For **new** applications, uninsured clients with an income greater than 200% of FPL but who qualify after applying the spend down will remain eligible

Solutions for uninsured clients not eligible due to income (e.g. > THMP's FPL Limit)

- Transition to Local Pharmacy Assistance Program (LPAP)
  - LPAP standards mandate use of Pharmaceutical Assistance Program (PAP) prior to LPAP dollars being expended
  - The Houston LPAP formulary mirrors the ADAP formulary plus **additional drugs**, ensuring equitable access to meds and ensures continuity of care
- Transition to Health Insurance Assistance (HIA)
  - HIA may be less expensive over time than PAP + LPAP
    - RW/A **may rely on** DSHS policies 260.002 (HIA) and 270.001, cost calculation for Covered Clinical Services (CCS), to make their determination of medications vs. insurance
    - RW/B funds **must adhere to** DSHS policies 260.002 & 270.001
    - Treatment cost for HCV when needed may factor into decision
    - QHP-equal "off-market" plans are available for ACA-ineligible clients

Houston EMA/HSDA Criteria (FY-21)

- Local Pharmacy Assistance Program (LPAP)
  - HIV medications: income ≤ 400% of FPL
  - May include an *estimated* **373** ADAP clients formerly served by THMP*
  - Non-HIV medications: income ≤ 500% of FPL (this includes HCV treatment meds)
  - LPAP Formulary **Statement of Need** (Houston RW/A and DSHS) requires the use of Pharmaceutical Assistance Programs (PAP) prior to using local funds
- Health Insurance Assistance (HIA)
  - Income ≤ 400% of FPL
  - May include an *estimated* **159** SPAP and **37** TIAP clients formerly served by THMP*
  - RWPC-approved cost containment measures in place if funds are limited (Premium payments have priority followed in descending order by):
    - HIV med co-pays/deductibles
    - non-HIV med co-pays/deductibles
    - doctor visit co-pays/deductibles
    - Medicare Part D premiums

**numbers may change due to THMP's decision to delay implementation through at least June 30, 2021*

Houston EMA/HSDA LPAP Criteria (FY-21)

- HIV medications: income ≤ 400% of FPL
- Non-HIV medications: income ≤ 500% of FPL
  - HCV treatment meds fall under this category
  - Enrollment in the THMP's HCV Pilot has ended
- Originally included an *estimated* **373** clients served by ADAP*
- Both local LPAP Statements of Need imply/require the use of Pharmaceutical Assistance Programs (PAP) **prior to** using local funds
  - ✓Your Part A LPAP Formulary Statement of Need reads *"...maximizes utilization of other 3rd party payers, such as **pharmaceutical assistance programs**..."*
  - ✓The DSHS LPAP SOC Statement of Need reads *"...LPAP is further needed to assist clients requiring long-term HIV and HIV-related medications that cannot be obtained through the TX ADAP program or **PAPs**."*

**numbers may change due to THMP's decision to delay implementation through at least June 30th, 2021*

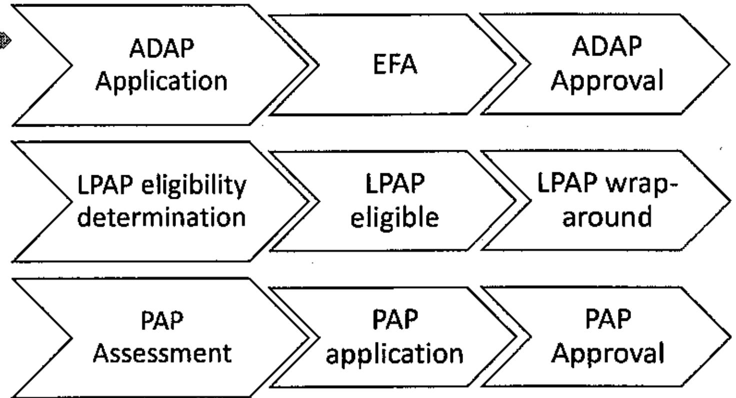
SCENARIOS

Client Navigation Options - LPAP

Medications/LPAP

Uninsured Client with income ≤ THMP FPL Limit

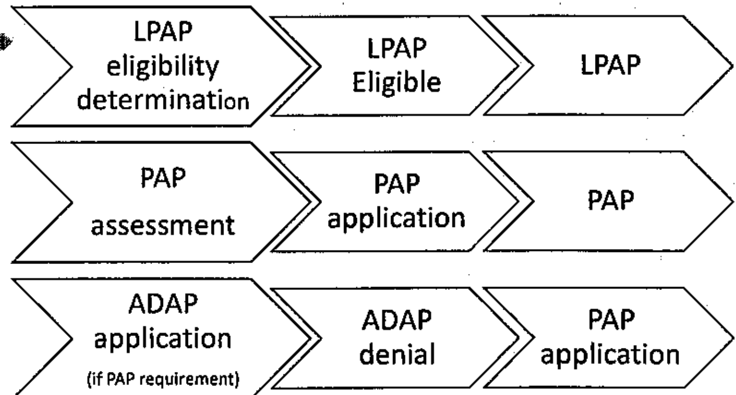
- Submit application to THMP
  - EFA should be used for ADAP drugs while THMP application is pending
  - Eligibility screening for LPAP
  - If eligible for LPAP, that may be used for drugs not on the ADAP formulary
  - Must utilize PAPs whenever available for drugs not on the ADAP formulary
  - **Spend down remains in place through at least June 30, 2021**



Medications/LPAP

Uninsured Client with income > THMP FPL Limit

- Perform local eligibility for LPAP
  - If LPAP eligible use LPAP for drugs on the LPAP formulary
  - Must utilize PAP when available for drugs on the LPAP formulary
  - LPAP formulary mirrors the ADAP formulary plus other drugs
  - Clients forced off ADAP will have denial/termination letter, hence no need to use EFA funds for drugs



The Challenge – SPAP/TIAP Clients

- Spend down for SPAP & TIAP will end beginning **May 1st****
- This change, once finalized, may continue for the foreseeable future
- Aging of the HIV population may lead to more clients needing SPAP
- Clients who have unstable employment related to the economic impact of the coronavirus may lose or already have lost employer-based insurance coverage but may still earn enough income to be ineligible for TIAP assistance

***As of 2/24/21 THMP has **not** altered this date*

Solutions for insured clients not eligible due to an income > 200% of FPL

- Current SPAP/TIAP participants who become ineligible because of income limits should transition to local HIA support
- **New** Medicare or employer-insured clients formerly eligible for SPAP or TIAP will become eligible for Houston EMA/HSDA HIA
- Revisit financial eligibility for HIA in anticipation of discontinuation of the spend down – what will be the impact on HIA resources
  - local eligibility may have taken into account that clients with incomes >200% of FPL were often eligible for THMP SPAP/TIAP assistance via the spend down

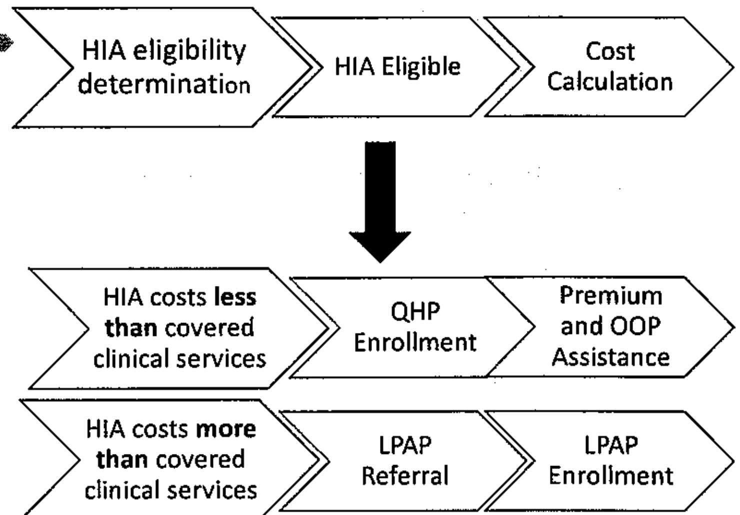
Scenarios - HIA

Client Navigation Option - HIA

Health Insurance Assistance

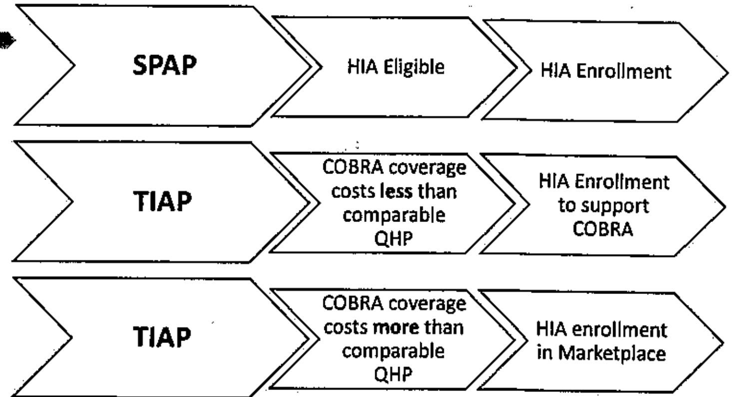
Uninsured Client with income > THMP FPL Limit

- Screen for HIA cost effectiveness per DSHS Policy 270.001 or rely on local Part A calculations as applicable
  - The 2020 average ADAP cost for the Houston HSDA was **$5,443** per client
  - 2020 avg. total CCS cost was **$7,714** per client
- Is the cost of HIA less than the cost of covered clinical services <u>including</u> HIV-related medications
  - Factor in the cost of premium **and** out-of-pocket expenses (OOP)
    - Premiums
    - Co-payments
    - Co-insurance
    - Deductible



SPAP/TIAP

Medicare or Employer-insured with income > THMP FPL Limit



- Perform screening for HIA eligibility
- If Medicare, HIA can cover premiums and OOP expenses
- If employer-based or COBRA, HIA can cover premiums and OOP expenses
- Respect client choice

ADAP to LPAP or HIA comparison

LPAP		HIA	
Pros	Cons	Pros	Cons
Straightforward transition (client continues with medication assistance)	PAP applications and renewals require staff resources (MCM, AEW)	Provides coverage for non-HIV-related medical needs and inpatient care	**Preferred** provider out of network and/or **preferred** medications not covered
Little or no OOP costs (sliding scale charges may apply due to income)	Unpredictable costs (PAPs are dependent on drug maker rules/policies)	Client has choice of care provider and pharmacy	Unfamiliarity with health insurance use and/or privacy concerns
Use of PAPs reduces costs to the LPAP category	Influx of ≈373 clients may strain available resources	Predictable costs premium cost + max OOP	COBRA costs can be high compared to ACA-plans
		Potential 340B revenue	Local HIA provider may be a *new* agency for client

Thank you!

Responding to the impact of potential THMP Changes

charleshenley9@gmail.com

DRAFT

2021 Policy for Addressing Unobligated and Carryover Funds

(Priority and Allocations Committee approved 02-25-21)

Background
The Ryan White Planning Council must address two different types of money: Unobligated and Carryover.

Unobligated funds are funds allocated by the Council but, for a variety of reasons, are not put into contracts. Or, the funds are put into a contract but the money is not spent. For example, the Council allocates $700,000 for a particular service category. Three agencies bid for a total of $400,000. The remaining $300,000 becomes unobligated. Or, an agency is awarded a contract for a certain amount of money. Halfway through the grant year, the building where the agency is housed must undergo extensive remodeling prohibiting the agency from providing services for several months. As the agency is unable to deliver services for a portion of the year, it is unable to fully expend all of the funds in the contract. Therefore, these unspent funds become unobligated. The Council is informed of unobligated funds via Procurement Reports provided to the Quality Improvement (QI) and Priority and Allocations (P&A) Committees by the respective Administrative Agencies (AA), HCPHS/ Ryan White Grant Administration and The Resource Group.

Carryover funds are the RW Part A Formula and MAI funds that were unspent in the previous year. Annually, in October, the Part A Administrative Agency will provide the Committee with the estimated total allowable Part A and MAI carryover funds that could be carried over under the Unobligated Balances (UOB) provisions of the Ryan White Treatment Extension Act. The Committee will allocate the estimated amount of possible unspent prior year Part A and MAI funds so the Part A AA can submit a carryover waiver request to HRSA in December.

The Texas Department of State Health Services (DSHS) does not allow carryover requests for unspent Ryan White Part B and State Services funds.

It is also important to understand the following applicable rules when discussing funds:

1.) The Administrative Agencies are allowed to move up to 10% of unobligated funds from one service category to another. The 10% rule applies to the amount being moved from one category and the amount being moved into the other category. For example, 10% of an $800,000 service category is $80,000. If a $500,000 category needs the money, the Administrative Agent is only allowed to move 10%, or $50,000 into the receiving category, leaving $30,000 unobligated.

2.) Due to procurement rules, it is difficult to RFP funds after the mid-point of any given fiscal year.

In the final quarter of the applicable grant year, after implementing the Council-approved October reallocation of unspent funds and utilizing the existing 10% reallocation rule to the extent feasible, the AA may reallocate any remaining unspent funds as necessary to ensure the Houston EMA/HSDA has less than 5% unspent Formula funds and no unspent Supplemental funds. The AA for Part B and *State Services* funding may do the same to ensure no funds are returned to the Texas Department of State Health Services (TDSHS). The applicable AA must inform the Council of these shifts no later than the next scheduled Ryan White Planning Council Steering Committee meeting.

DRAFT

Recommendations for Addressing Unobligated and Carryover Funds:

1.) Requests from Currently Funded Agencies Requesting an Increase in Funds in Service Categories where The Agency Currently Has a Contract: These requests come at designated times during the year.

A.) In response, the AA will provide funded agencies a standard form to document the request (see attached). The AA will state the amount currently allocated to the service category, state the amount being requested, and state if there are eligible entities in the service category. This form is known as a *Request for Service Category Increase*. The AA will also provide a Summary Sheet listing all requests that are eligible for an increase (e.g. agency is in good standing).

The AA must submit this information to the Office of Support in an appropriate time for document distribution for the April, July and October P&A Committee meetings. The form must be submitted for all requests regardless of the completeness of the request. The AA for Part B and State Services Funding will do the same, but the calendar for the Part B AA to submit the Requests for Service Category Increases to the Office of Support is based upon the current Letter of Agreement. The P&A Committee has the authority to recommend increasing the service category funding allocation, or not. If not, the request "dies" in committee.

2.) Requests for Proposed Ideas: These requests can come from any individual or agency at any time of the year. Usually, they are also addressed using unobligated funds. The individual or agency submits the idea and supporting documentation to the Office of Support. The Office of Support will submit the form(s) as an agenda item at the next QI Committee meeting for informational purposes only, the Office of Support will inform the Committee of the number of incomplete or late requests submitted and the service categories referenced in these requests. The Office of Support will also notify the person submitting the Proposed Idea form of the date and time of the first committee meeting where the request will be reviewed. All committees will follow the RWPC bylaws, policies, and procedures in responding to an "emergency" request.

Response to Requests: Although requests will be accepted at any time of the year, the Priority and Allocations Committee will Review requests at least three times a year (in April, July, and October). The AA will notify all Part A or B agencies when the P&A Committee is preparing to allocate funds.

3.) Committee Process: The Committee will prioritize recommended requests so that the AA can distribute funds according to this prioritized list up until May 31, August 31 and the end of the grant year. After these dates, all requests (recommended or not) become null and void and must be resubmitted to the AA or the Office of Support to be considered in the next funding cycle.

After reviewing requests and studying new trends and needs the committee will review the allocations for the next fiscal year and, after filling identified gaps in the current year, and if appropriate and possible, attempt to make any increase in funding less dramatic by using an incremental allocation in the current fiscal year.

4.) Projected Unspent Formula Funds: Annually in October, the Committee will allocate the projected, current year, unspent, Formula funds so that the Administrative Agent for Part A can report this to HRSA in December.

COVID-19 Vaccines and People with HIV

Frequently Asked Questions

Version: 1/26/21

The HIV Medicine Association and the Infectious Diseases Society of America developed this document to respond to questions from HIV clinicians, and as a resource for HIV clinicians to respond to patient questions regarding COVID-19 vaccines. Unless otherwise noted, the information provided is based on the IDSA COVID-19 Real-Time Learning Network's Vaccine Information and FAQs and the following Centers for Disease Control and Prevention (CDC) resources: Facts About COVID-19 Vaccines, Frequently Asked Questions About COVID-19 Vaccination, COVID-19 ACIP Vaccine Recommendations, and Vaccine Considerations for People with Underlying Medical Conditions. Please email us if you or your patients have a question that is not covered.

Thank you to Natasha Chida, MD, MSPH, Medical Editor of IDSA's COVID-19 Real-Time Learning Network and an Assistant Professor of Medicine at the Johns Hopkins University School of Medicine for her assistance in developing and reviewing this resource.

SAFETY
PRIORITY GROUPS
SIDE EFFECTS
HIV MEDICATIONS
COVID-19 VACCINES & HIV RISK
VACCINE ACCESS & ADMINISTRATION
HIV VACCINE
PREGNANCY & BREASTFEEDING
DNA
STEM CELLS
IMMUNITY OR LEVEL OF PROTECTION
HIV CLINICIAN QUESTIONS

SAFETY

ARE THE COVID-19 VACCINES SAFE FOR PEOPLE WITH HIV?

- Safety data specific to people with HIV are not yet available but based on how the vaccines work, we do not anticipate safety concerns unique to people with HIV. Because people with HIV may be at increased risk for severe illness due to COVID-19, the CDC guidance advises that people with HIV may receive the vaccine as long as they do not have other conditions that would exclude them, such as a known allergic reaction to the COVID-19 vaccine or its components. The vaccines authorized for use in the United States (the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine) do not contain infectious virus.
- It is possible that the level of protection from the vaccines may not be as strong for people with HIV who are immunocompromised although it is also possible that the level of protection will be the same in people with HIV as people without HIV. Everyone who receives a COVID-19 vaccine, including people with HIV, should continue to wear face coverings, stay 6 feet apart from others,

avoid crowds and regularly wash their hands to protect themselves and others until more is known.

- People with stable HIV have been included in the COVID-19 vaccine clinical trials so information specific to people with HIV should become available in the future.

PRIORITY GROUPS

WHEN WILL PEOPLE WITH HIV BE ABLE TO GET VACCINATED? WILL I BE PRIORITIZED HIGHER BECAUSE I HAVE HIV?

- Due to limited vaccine supplies, the CDC has made recommendations for the groups that should receive vaccines first. Initially, health care workers and individuals in long-term care facilities were prioritized. Now in many states persons who are 65 years and older and other essential workers are eligible to receive the vaccine, but there are still not enough vaccines to meet demand in most areas. **People with HIV who fall into a group that is prioritized (e.g., a health care worker or 65 or older) should be eligible to receive the vaccine.**
- The guidance about groups that are prioritized for vaccination will continue to change based on vaccine availability. Check with your local or state health department for the latest information specific to your community. Information on your state plan is available online.
- While people with HIV may be at higher risk for serious illness due to COVID-19, the data available so far do not indicate that their risk is as high as those with other underlying conditions, such as heart disease, diabetes and obesity, and people with HIV have not been specifically named as a priority group. People with HIV may also have these higher-risk conditions, however, that make severe COVID-19 more likely.

SIDE EFFECTS

WILL I HAVE MORE SIDE EFFECTS BECAUSE I HAVE HIV?

- The effects of the vaccine on people with HIV are still being studied, so we do not yet know if it will affect people with HIV differently. Side effects common among study participants included pain and swelling at the injection site, fatigue and headache. A smaller number reported having a fever. These side effects did not last longer than a few days at most. Rare, serious allergic reactions have occurred and are being monitored by the CDC. The CDC also recommends that everyone who receives a COVID-19 vaccine is monitored onsite for at least 15 minutes, and for at least 30 minutes if they have had a reaction to a vaccine or an injectable therapy.

WHAT IS THE FREQUENCY OF BELL'S PALSY?

- Bell's palsy is one of the conditions that is monitored in all vaccine trials. While there were cases of Bell's palsy in clinical trials for both approved vaccines, it is not clear that they were caused by the vaccine, and the number of people who got Bell's palsy in the studies was the same as the number who get Bell's palsy annually in the general population.
- There have been four reported cases of Bell's palsy for the Moderna's COVID-19 vaccine among more than 30,000 clinical trial participants. Three of the participants who got Bell's palsy received the vaccine instead of a placebo.
- Similarly, Pfizer-BioNTech's trial had four reported cases of Bell's palsy out of some 43,000 participants. All four Bell's palsy cases in Pfizer-BioNTech's trial got the vaccine and not the placebo. There is ongoing monitoring for Bell's palsy as more people receive the vaccines.

SHOULD I WAIT FOR ANOTHER COVID-19 VACCINE SINCE I HAVE HIV? HAVE ANY OF THE OTHER VACCINES BEEN FOUND TO BE SAFER OR MORE EFFECTIVE FOR PEOPLE WITH HIV?

- Currently the only vaccines available in the U.S. are the Pfizer-BioNTech and Moderna COVID-19 vaccines. Based on the current data available, these vaccines have strong safety and effectiveness data for the general population. We do not yet know what the safety and efficacy data will look like for the other vaccine candidates.
- Data specific to people with HIV is not yet available, but both of the vaccine trials included people with HIV so additional data should become available in the future.

WHAT ARE THE LONG-TERM SIDE EFFECTS OR COMPLICATIONS OF GETTING THE VACCINE?

- Currently no data suggest that the vaccines cause long-term side effects. Data will continue to be collected and monitored for signs of long-term side effects or complications.

SHOULD I TAKE THE VACCINE IF I ALREADY HAD COVID-19? IF SO, WHAT ARE THE SIDE EFFECTS? HOW LONG SHOULD I WAIT BETWEEN MY COVID-19 ILLNESS AND THE VACCINE?

- Because people's immune responses to having COVID-19 can vary (some people may develop a weak immune response, others a stronger one), and because we don't know how long people maintain an immune response after getting COVID-19, the CDC currently recommends offering the vaccine to individuals who have already had COVID-19. For individuals who are still experiencing symptoms of COVID-19, vaccination should be delayed until they have recovered and can be delayed for up to 90 days after illness. Data will be collected on people who have had COVID-19 receiving vaccinations so we will learn more.

DOES THE VACCINE CAUSE "LONG-COVID" SYNDROME?

- None of the vaccines available contain the virus that causes COVID-19. They cannot make you sick from COVID-19 nor can they cause "long-COVID."

WHY DO SOME PEOPLE DEVELOP COVID-19 AFTER BEING VACCINATED?

- According to the CDC, it takes a few weeks for the body to develop enough immunity to protect you from the virus, so you could still get sick from COVID-19 while your body is in the process of developing immunity. For this reason, and because we do not know if the vaccine prevents infection even if it prevents getting sick with COVID-19, it is important to continue to wear a mask, stay at least 6 feet from others, avoid large crowds or gatherings and regularly wash your hands.

WHAT DO I DO IF I HAD BAD REACTIONS TO OTHER VACCINES? WHAT IF I HAD GUILLAIN-BARRE SYNDROME FROM SHINGRIX (OR ANY OTHER VACCINE)? CAN I TAKE THE COVID-19 VACCINE SAFELY?

- It is important to let your health care provider know if you have had a bad reaction to other vaccines, but there have been no cases of Guillain-Barre syndrome reported in people receiving the mRNA COVID-19 vaccines to date. Based on the data currently available, you may receive an mRNA COVID-19 vaccine safely. Even if you have had a bad reaction to another vaccine, if that vaccine doesn't have any of the same ingredients that are in the COVID-19 vaccines, you should not have the same reaction.

HIV MEDICATIONS

I'VE HEARD MY HIV MEDICINES PROTECT ME FROM GETTING COVID-19 SO DO I EVEN NEED THE VACCINE?

- There is **no evidence** that HIV medications can prevent or treat COVID-19. Some HIV medications, such as a combination of tenofovir/emtricitabine, are currently being studied to see if they can treat COVID-19 but the results of these studies are pending. Studies on lopinavir/ritonavir, a protease inhibitor combination, have not found it to be effective. Read more in the CDC's What to Know About HIV and COVID-19.
- Because there is no evidence that HIV medications can treat or prevent COVID-19, guidelines recommend against changing your HIV treatment regimen to prevent or treat COVID-19. More information on HIV treatment recommendations and COVID-19 is available in the HHS Interim Guidance on COVID-19 and Persons with HIV.

WILL THE VACCINE BE CONTRAINDICATED BY MY HIV MEDICATIONS? SHOULD I STOP TAKING THEM WHILE I AM GETTING THE VACCINE DOSES?

- The two authorized vaccines have no interactions with HIV medications. It is not recommended that people with HIV stop their HIV medicines when they receive a COVID-19 vaccine. Stopping your HIV medications could put you at greater risk for HIV-related illnesses and at greater risk for serious infection due to COVID-19.

WILL THE VACCINE BE EFFECTIVE OR RECOMMENDED IF I HAVE CD4 < 200 / A LOW IMMUNE SYSTEM?

- The CDC advises that people who are immunocompromised, including people with HIV, receive the vaccine because of their potential increased risk for serious illness due to COVID-19. The safety and effectiveness in immunocompromised populations is not yet known, however, particularly whether the protection from COVID-19 will be as strong as it is for the general population.

COVID-19 VACCINES & HIV RISK

DOES THE COVID-19 VACCINE INCREASE THE RISK OF CONTRACTING HIV?

- There is no reason to think COVID-19 vaccines will increase a person's risk of acquiring HIV, nor are there any data to suggest that this is the case. These concerns have been raised because a certain type, an adenovirus vector, of vaccine being studied to prevent HIV about a decade ago may have increased risk for HIV infection, but that vaccine was constructed differently and was not related to the structure of the COVID-19 vaccines authorized in the U.S.

VACCINE ACCESS & ADMINISTRATION

CAN I CHOOSE WHICH COVID-19 VACCINE I GET?

- The supply of vaccines is very limited. When it is your turn to receive a vaccine, you will most likely not have an option to choose which vaccine you will receive. Based on the clinical trial data, both the Moderna and Pfizer-BioNTech vaccines have high levels of safety and efficacy and there is no information available to indicate at this time that one is better for people with HIV.

CAN I GET VACCINATED AT MY HIV CLINIC?

- Vaccines are being provided in a variety of settings and while some HIV clinics may be providing vaccines, many may not yet have access to the COVID-19 vaccines. Check with your state or local health department or your HIV provider to see who is eligible to receive a vaccine in your state, how to sign up and where vaccines are being provided

WILL I HAVE TO PAY WHEN I GET VACCINATED? IS IT COVERED BY MY INSURANCE OR THE RYAN WHITE PROGRAM?

- The federal government is covering the cost of the vaccines for everyone. There may be a fee for administering the vaccine, but that fee should be charged to your health insurance provider, including Medicaid or Medicare. If you are uninsured, your provider should bill the Provider Relief Fund that is administered by HRSA, or your Ryan White Program may be covering it.

IS IT NECESSARY TO GET THE SECOND DOSE OF THE MODERNA OR PFIZER-BIONTECH VACCINES? WHAT IF I MOVE AFTER I GOT THE FIRST DOSE – HOW DO I GET THE SECOND?

- Receiving two doses of the vaccine is important to achieve the highest level of protection based on the clinical trials data that we have now. Not only do people have a lower response after one dose compared to two, but we also don't know how long immunity lasts after a single dose of the vaccine lasts. Let your vaccine provider know if you are unable to come back to the same location for your second dose so they can help you make arrangements to ensure you receive your second dose on time.

CAN I GET ONE DOSE OF ONE VACCINE AND THE SECOND DOSE OF THE OTHER VACCINE?

- The second dose of your vaccine should be the same as the first one. Mixing the two vaccines has not been studied and may not provide the same level of protection.

HIV VACCINE

A COVID-19 VACCINE WAS DEVELOPED IN LESS THAN A YEAR AND WE STILL DON'T HAVE AN HIV VACCINE AFTER 40 YEARS – WHY CAN'T THEY DEVELOP AN HIV VACCINE AS QUICKLY? WHEN IS AN HIV VACCINE GOING TO BE APPROVED?

- The virus that causes COVID-19 and the HIV virus are very different. The body rids itself of the virus that causes COVID-19 within weeks, while the HIV virus stays in the body and is not removed or eradicated. This difference, and many others, makes it much more complicated to create an HIV vaccine.
- Work on developing an HIV vaccine continues and some of the early work in developing an HIV vaccine contributed to the creation and the success of the COVID-19 vaccines. We also have learned a lot from the development of the COVID-19 vaccines that should contribute to the future development of other effective vaccines, including for HIV.

PREGNANCY & BREASTFEEDING

CAN I TAKE THE VACCINE IF I AM PREGNANT? BREASTFEEDING?

- Individuals who are pregnant or breastfeeding may choose to be vaccinated, according to the CDC. While there are limited data about the safety of COVID-19 vaccines in these situations, experts believe the authorized mRNA-based vaccines are unlikely to pose a risk for women who are pregnant or to the breastfeeding infant. The American College of Obstetricians and Gynecologists recommends that COVID-19 vaccines not be withheld from pregnant individuals

who meet criteria for vaccination based on ACIP-recommended priority groups. Of note, pregnancy has been associated with an increased risk of having severe COVID-19.

CAN THE MRNA VACCINES CAUSE INFERTILITY?

- There is no evidence to suggest that the COVID-19 vaccines cause infertility. This idea has arisen because some people online falsely stated that COVID-19 proteins and the proteins in the human placenta are similar, and so if the vaccine makes people immune to COVID-19 it can also make the body attack the placenta. This is not true. Coronavirus proteins and placental proteins are very different, so there is no reason to think the vaccines will affect the placenta. In addition, theoretical damage to a placenta and infertility are different; if a woman has a placenta she is pregnant. If the placenta is damaged, she could lose her pregnancy, or her fetus could be affected. Infertility is the inability to get pregnant. **There is no evidence that either placental damage or infertility arise from vaccination with an mRNA COVID-19 vaccine**.

DNA

CAN THE MRNA VACCINES ALTER MY DNA BECAUSE IT IS AN MRNA VACCINE?

- The mRNA delivered by the mRNA-based COVID-19 vaccines do not enter the cell nucleus where DNA is located, so it cannot alter your DNA.

STEM CELLS

WERE FETAL STEM CELLS USED TO MAKE THE COVID-19 VACCINES?

- No. Neither of the COVID-19 vaccines authorized for use in the U.S. were developed using fetal stem cells.

IMMUNITY OR LEVEL OF PROTECTION

HOW LONG WILL THE IMMUNITY LAST AFTER THE VACCINE?

- The length of time the vaccine will prevent you from getting sick from COVID-19 is still being studied. Because the virus is so widespread in the U.S., even short-term immunity or protection from the virus can help to prevent you from getting sick due to COVID-19 and help slow the spread of the virus.

CAN I GET INFECTED WITH COVID-19 AFTER THE VACCINE, HAVE NO SYMPTOMS, AND THEN SPREAD THE VIRUS TO OTHERS EVEN IF I AM NOT SICK?

- The two vaccines currently authorized were studied to see if they prevented people from getting sick due to COVID-19. The study did not indicate whether the vaccines prevented infection. Until more is known about whether the vaccines prevent infection itself, everyone, even those who are vaccinated, should continue to wear masks, keep a safe distance from others, avoid crowds and regularly wash hands.

DOES THE VACCINE PREVENT ILLNESS?

- The trials for the vaccines available in the U.S. found that the mRNA-based vaccines were highly effective at preventing illness due to COVID-19. The trials did not look at whether the vaccines prevented asymptomatic infection (that is getting the virus without getting sick). Data collection continues as the vaccines roll out and learning if the vaccines also prevent infection will be important. In the meantime, all of us should continue to wear masks, stay 6 feet apart, avoid large gatherings or crowds and regularly wash our hands to protect others.

HOW SOON AFTER I GET VACCINATED WILL I BE PROTECTED FROM BECOMING ILL FROM COVID?

- According to the CDC, it typically takes a few weeks after vaccination for the body to develop enough immunity for protection. For the mRNA-based vaccines, they are most effective a few weeks after both doses have been received.

HIV CLINICIAN QUESTIONS

ARE THERE ANY PLANS TO DO PHASE 4 STUDIES IN IMMUNOCOMPROMISED HOSTS? PEOPLE WITH TRANSPLANTS, PEOPLE CHRONICALLY IMMUNOSUPPRESSED FOR AUTOIMMUNE DISORDERS? PEOPLE WITH HIV?

- The FDA emergency use authorization (EUA) recommends that immunocompromised individuals and other subpopulations with specific comorbidities be studied in post-authorization observational studies. People with stable HIV were included in both the Pfizer-BioNTech and Moderna trials, although their numbers were low.

IN PATIENTS WITH HIV, ARE THERE ANY RECOMMENDATIONS FOR GETTING THE VACCINE IN PATIENTS BASED ON CD4 COUNT AND VIRAL SUPPRESSION?

- The CDC currently states that individuals who are immunocompromised, including people with HIV, may receive the mRNA-based vaccines if there are no contraindications, such as known allergic reaction to an ingredient in the vaccine. The recommendation is for all people with HIV and is not based on CD4 count or viral suppression. Given that the mRNA vaccines do not contain SARS-CoV-2 (live or attenuated), there is no reason to believe the vaccine will be less safe in persons with low CD4 counts. People with HIV should be counseled that we do not yet know if their level of protection from the virus will be as strong as for those who do not have HIV, or for those with lower CD4 counts or measurable viral loads. Everyone, including people with HIV, should continue to wear face coverings, stay 6 feet apart from others, avoid crowds and regularly wash their hands to protect themselves and others until more is known

IF THE PFIZER OR MODERNA MRNA IS INTRODUCED INTO A CELL IN WHICH HIV-1 IS REPLICATING, WILL ANY PORTION OF THE VACCINE MRNA BE REVERSE TRANSCRIBED INTO DNA?

- HIV-1 replication occurs in the cell nucleus; the mRNA delivered by the mRNA COVID-19 vaccines does not enter the nucleus. Rather, it stays in the cytoplasm to be translated. Therefore, the mRNA cannot be transcribed into DNA.