



# Local Pharmaceutical Assistance Program Statement of Need

Texas Department of State Health Services, HIV Care Services Group — [HIV/STD Program | Texas DSHS](#)

## Health Resources & Services Administration (HRSA)

### Guidance:

The Ryan White HIV/AIDS Program (RWHAP) Policy Clarification Notice 16-02 states that a Ryan White Part A or Part B recipient may use a Local Pharmaceutical Assistance Program (LPAP) to provide pharmaceutical services. Recipients must fund LPAPs using non-AIDS Drug Assistance Program (ADAP) funds and can operate an LPAP when an ADAP has a restricted formulary, waiting list, or restricted financial eligibility criteria.

RWHAP Parts A or B recipients using the LPAP to provide AIDS Pharmaceutical Assistance must establish the following:

- Uniform benefits for all enrolled clients throughout the service area
- A recordkeeping system for distributed medications
- An LPAP advisory board
- A drug formulary that is:
  - ▶ Approved by the local advisory committee or board, and
  - ▶ Consists of HIV-related medications not otherwise available to the clients due to the elements mentioned above
- A drug distribution system
- A client enrollment and eligibility determination process that includes screening for HRSA RWHAP ADAP and LPAP eligibility with rescreening at minimum of every six months
- Coordination with the state's HRSA RWHAP Part B ADAP

- ▶ A statement of need should specify restrictions of the state HRSA RWHAP ADAP and the need for the LPAP
- Implementation in accordance with requirements of the HRSA 340B Drug Pricing Program (including the Prime Vendor Program)

The Texas Department of State Health Services has determined that there is an ongoing need for LPAP services, and LPAP is an allowable core medical service under Ryan White Part B and State Services.

### **Statement of Need:**

The Texas ADAP (Texas HIV Medication Program or THMP) has a limited formulary and currently limits income eligibility to 200% of the Federal Poverty Level (FPL), with a standardized deduction to account for the cost of HIV medications. DSHS requires an LPAP to assist clients that have incomes above 200% of FPL, after a standardized deduction adjustment. Providers must first use Pharmaceutical Assistance Programs (PAPs) before using LPAP. However, these programs may not fully meet the needs of clients whose complete regimen of HIV-related medications are not affordable or available through PAPs. LPAP can assist clients requiring long-term HIV and HIV-related medications that cannot be obtained through the THMP or PAPs.

To ensure appropriate use of LPAP, the following criteria must be met:

- Eligible clients must access THMP before before using LPAP.
- LPAP may not duplicate services available through THMP.
- Agencies must assist clients needing long-term assistance with prescription medications with completing a THMP application and, when applicable, PAP applications.
- If the medication is not on the THMP formulary and is not available through other assistance programs, the agency may serve the client with LPAP funds if the medication is on the LPAP formulary.
- If short-term medication assistance is required and the client is eligible, the agency may meet this need with Emergency Financial Assistance (EFA) funds.
- Clients with insurance and other third-party payer sources are not eligible for LPAP assistance unless there is documentation on file that the medication is not covered by their prescription benefits.

LPAP shall, to the extent allocations permit, provide eligible clients with medications on the local area's LPAP formulary that a qualified medical provider has prescribed. Providers must prescribe medications consistent with the most current Health and Human Services [HIV/AIDS Treatment Guidelines](#).

Agencies must purchase LPAP medications at the lowest possible cost, such as 340B Program pricing. Clients must obtain their medications through a 340B covered entity or pharmacy or a comparable medication discount program. Agencies must set up contracts or memoranda of understanding (MOUs) to purchase medications at wholesale or another below-retail price.

All LPAP programs will use the statement of need and available standards of care to inform their services and will operate in accordance with legal and ethical standards. The importance of maintaining confidentiality is critical and all programs must comply with the Health Insurance Portability and Accountability Act (HIPAA) standards.

Programs may purchase prescribed over-the-counter (OTC) medications with LPAP funds if the medication is listed on the LPAP formulary and the provider has deemed that the medication is needed for the prevention and treatment of opportunistic infections or to prevent the serious deterioration of health. All OTC medications purchased with LPAP funds must be FDA-approved.

Medications not included in the LPAP formulary cannot be purchased. All prescription medications purchased with LPAP funds must be FDA-approved. The provider wishing to prescribe a medication that is not on the formulary shall make a request to the LPAP Board for approval to add the medication to the formulary. The agency may only purchase the medication after the LPAP Board has added it to the formulary.