

# Local Pharmaceutical Assistance Program (LPAP)

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# Background

- HAB LPAP *Letter of Clarification* (August 2013)
- HAB National Monitoring Standards
- HAB PCN 16-02: *Eligible Individuals & Allowable Uses of Funds*
- FY17 RWHAP Part A and Part B FOA guidance
- DSHS LPAP SOC
- April 2016 AA Survey

# HAB LPAP Letter (August 2013)

- Ryan White HIV/AIDS Part A and Part B Grantees should base the decision to fund a LP AP on demonstrated need within the state/ territory, emerging community and/or metropolitan service area. This statement of need should specify the restrictions of the state ADAP and be included in the annual application to HRSA/HAB.
- The LPAP needs to be coordinated with the state ADAP.
- The LPAP needs to be compliant with the Ryan White HIV/AIDS Program's requirement of payer of last resort.
- A client enrollment and eligibility process for the LPAP is required; this process should include screening for the LPAP, as well as ADAP eligibility, and other potential pharmacy program benefits, such as Medicaid, Medicare Part D, other public or private insurance, and local or state pharmacy assistance programs, and pharmaceutical company assistance programs. Client eligibility needs to be addressed in conformance with overall Ryan White HIV/AIDS Program requirements as cited in Policy Clarification Notice 13-02.
- The LPAP needs to have an advisory board that is responsible for developing written policies and procedures that will govern its purpose, structure, financing, eligibility criteria, formulary, quality-assurance, and quality management.
- The LPAP needs to be consistent with the most current HHS HIV/AIDS Treatment Guidelines
- The LPAP needs to be implemented in accordance with requirements of the 340B Drug Pricing Program, Prime Vendor Program and/or Alternative Methods Project in order to ensure "best price" to maximize resources.

# National Monitoring Standards

- Part A and B share identical standards in NMS
- NMS Part A Program Monitoring Standards
  - Core Medical Services/LPAP (pgs. 5-8)
- NMS Part B Program Monitoring Standards
  - Core Medical Services/LPAP (pgs. 6-9)

# HRSA/HAB PCN 16-02

- Local Pharmaceutical Assistance Program (LPAP) is operated by a RWHAP Part A or B recipient or subrecipient as a supplemental means of providing medication assistance when an ADAP has a restricted formulary, waiting list and/or restricted financial eligibility criteria.
- RWHAP Part A or B recipients using the LPAP service category 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 approved by the local advisory committee/board
  - A drug distribution system
  - A client enrollment and eligibility determination process that includes screening for ADAP and LPAP eligibility with rescreening at minimum of every six months
  - Coordination with the state's RWHAP Part B ADAP
  - A statement of need should specify restrictions of the state ADAP and the need for the LPAP
  - Implementation in accordance with requirements of the 340B Drug Pricing Program and the Prime Vendor Program

# HAB LPAP Requirements

## (from FY17 Parts A & B FOA Guidance)

Applicants must describe:

- a) The need for an LPAP in detail; include how the ADAP, other RWHAP funded service categories, and other resources (e.g., pharmaceutical assistance programs, patient assistance programs, local/state funded medication assistance programs) are failing to meet the jurisdiction's medication needs.
- b) The component of the medication need that the LPAP will fill.
- c) How the LPAP will be coordinated with the ADAP.
- d) The client enrollment and eligibility process including how payer of last resort is ensured.
- e) The existing LPAP advisory board composition; if this is a new service category, describe the process and timeframe for development of the LPAP advisory board.
- f) How the recipient ensures that the LPAP follows the most recent HHS HIV/AIDS Treatment Guidelines.
- g) The mechanism to ensure "best price" for medications, (e.g., 340B Drug Pricing Program and/or Prime Vendor Program).

# DSHS LPAP SOC

- Includes a Statement of Need to be used by all RW/B AAs; RW/A may also use
- LPAP is not funded with ADAP funding and is not to take the place of the ADAP
- LPAPs are not emergency financial assistance for medications.
- Clients cannot be enrolled in another medication assistance program for the same medication, excluding co-payment discounts.
- Funds may not be used to make direct payments of cash/vouchers to a client.
- No charges may be imposed on clients with incomes below 100% of the FPL.
- LPAPs do not dispense medications as:
  - A result or component of a primary medical visit
  - A single occurrence of short duration (an emergency)
  - Vouchers to clients on an emergency basis
- Emergency Financial Assistance (EFA) funds may be used in the above situations
- Medications not on the Formulary may not be purchased
- Allowance for Over-the-Counter meds if on the Formulary and prescribed by MD
- All medications must be FDA approved

# Survey of Part A and B AAs

## April 2016

- Surveyed all nine (9) RW/A & RW/B AAs
- 9 of 9 allocated funds to LPAP
- 3 of 9 had an approved Statement of Need
- 8 of 9 provided uniform LPAP benefits
- 6 of 9 had an LPAP Advisory Board in place
- 5 of 9 had an approved LPAP formulary
- 9 of 9 had a drug distribution system
- 9 of 9 had a record keeping system
- 9 of 9 required agencies funded for LPAP to be enrolled in the 340B/Prime Vendor program

# Managing Utilization and Expenditures

- Local areas may manage LPAP utilization and expenses through a combination of:
  - Allocations
  - Financial Eligibility
  - Caps on annual per client expenditures
  - Cost sharing for clients with incomes >100% of FPL
  - Benefits must be uniform for all clients in the area
- Clients with insurance are not eligible for LPAP
- Formulary restrictions are generally not an effective utilization or cost containment strategy

# LPAP SOC Elements

# Statement of Need

- RW/A and RW/B
  - The need for an LPAP in detail; include how the ADAP, other RWHAP funded service categories, and other resources (e.g., pharmaceutical assistance programs, patient assistance programs, local/state funded medication assistance programs) are failing to meet the jurisdiction's medication needs.
  - Both RW/A PCs & AAs and DSHS AAs may use the Statement of Need in the DSHS LPAP SOC (optional for RW/A Recipients, required for RW/B AAs)

# Coordination with ADAP

- A client enrollment and eligibility determination process for Ryan White/state (SS/SR) funding that includes screening/ applying for ADAP
- Additional LPAP eligibility (i.e. local financial eligibility criteria) if applicable

# Payer of Last Resort

- The AA must establish or adopt DSHS Policy of Last Resort for agencies in their region.
- RW/A must be compliant with the RWHAP requirement of Payer of Last Resort
- LPAP can fund prescribed medications deemed medically necessary by a provider for medication not on the TMHP formulary for TMHP enrolled patients. Patients denied TMHP can also access funding through LPAP if other payer sources has been exhausted
- Agencies providing EFA medications must develop policies and procedures to pursue all feasible alternative revenues systems (e.g., pharmaceutical company patient assistance programs) before requesting reimbursement through EFA.

# LPAP Advisory Board

- The AA shall establish a formal LPAP Advisory Board. At minimum, there must be an established advisory board in an HSDA where LPAP funding is allocated
  - There may not be more than one advisory board in a single HSDA to ensure uniform LPAP benefits within the HSDA.
  - A single advisory board may serve multiple HSDAs.
  - An advisory board may not be comprised solely of employees of the agency/agencies funded to provide LPAP services.

# Advisory Board Composition

- RWHAP and DSHS LPAP requirements are not prescriptive regarding composition of the LPAP Board
  - Local areas must determine what is the best configuration for their area and available resources
  - The AA shall support the advisory board to ensure actions taken by the board are documented and are in compliance with applicable standards of care and State and RWHAP requirements.
  - An AA, with a written agreement between the AA and the AA of another service area, may use an established LPAP advisory board in another HSDA or Part A jurisdiction to meet LPAP requirements (a sample letter of agreement may be found in Attachment 1 of the LPAP SOC)

# Advisory Board Responsibilities

- The LPAP must have an advisory board that is responsible for developing written policies and procedures that will govern its purpose, structure, financing, eligibility criteria, **formulary**, quality-assurance, and quality management.
- Eligibility is set by the AA and/or PC (RW/A)
- QM/QA functions are often set globally by the AA, and with PC input (RW/A).
- Financing is based on the approved allocation for LPAP in the respective service delivery area.

# LPAP Enrollment and Eligibility

- A client enrollment and eligibility process for the LPAP is required; this process should include screening for the LPAP, as well as ADAP eligibility, and other potential pharmacy program benefits, such as Medicaid, Medicare Part D, other public or private insurance, and local or state pharmacy assistance programs, and pharmaceutical company assistance programs. Client eligibility needs to be addressed in conformance with overall Ryan White HIV/AIDS Program requirements as cited in Policy Clarification Notice 13-02.
- RW/B and SS/SR funded LPAP services must conform to DSHS Policy 220.001 ([Eligibility to Receive HIV Services](#)).
- Local jurisdictions may implement additional financial eligibility criteria appropriate for their HSDA, EMA or TGA.

# LPAP Formulary

- The AA must maintain a published formulary listing the medications approved by the LPAP Advisory Board
- The formulary must at minimum meet the requirements listed in the Standards of Care.
- The formulary must be readily accessible to providers, clients and other stakeholders.
- There must be a formalized policy and procedure for medications to be added to, or removed from, the LPAP formulary by the advisory board.
- Over the Counter (OTC) medications are allowable if included in the formulary and prescribed by a provider

# Treatment Guidelines

- The LPAP must be consistent with the most current HHS HIV/AIDS Treatment Guidelines (<http://www.aidsinfo.nih.gov> ).

# LPAP Pricing

- The LPAP needs to be implemented in accordance with requirements of the 340B Drug Pricing Program, Prime Vendor Program and/or Alternative Methods Project in order to ensure "best price" to maximize resources. **(HAB)**
- It is preferable that LPAP medication be purchased at the lowest possible cost, such as 340B Program pricing. Where possible clients need to obtain their medications through a 340B covered entity or pharmacy that is under contract with the 340B Program. Another alternative for purchasing medication is to establish a cost reimbursement system with pharmacies licensed to distribute medications in Texas. Contracts/Memorandums of Understanding (MOU) must be set up to purchase medications at wholesale or another below retail price. **(DSHS)**

# Limitations

- Medications not on the approved LPAP formulary are not allowable
  - There must be an established process for adding medications to the LPAP formulary
  - EFA may be used to purchase medications not on the formulary so long as EFA standards are met
- No charges may be imposed on clients with incomes less than 100% of the Federal Poverty Level (FPL)
- Funds may not be used to make direct payments of cash or vouchers to a client
- Clients cannot be enrolled in another medication assistance program for the same medication, excluding co-payment discounts

# LPAP vs. EFA

- Only RWHAP Part A grant award funds or Part B Base award (*including State Services and State Rebate*) funds may be used to support an LPAP. ADAP funds may not be used for LPAP support. LPAP funds are not to be used for Emergency Financial Assistance. **Emergency Financial Assistance may assist with medications not covered by the LPAP. (PCN 16-02)**
- Emergency Financial Assistance provides limited one-time or short-term payments to assist the RWHAP client with an emergent need for paying for essential utilities, housing, food (including groceries, and food vouchers), transportation, and **medication. (PCN 16-02)**

# Recap

- If LPAP is funded, AAs must comply with HAB and DSHS LPAP requirements and standards
  - RW/A programs already must comply with HAB LPAP requirements and if RW/B, SS and/or SR funds are used for LPAP in the service area, the AA must ensure compliance with DSHS LPAP requirements as well
- DSHS will permit an AA to “pair” with another AA for an LPAP advisory board and formulary
  - A sample Letter of Agreement for sharing an LPAP advisory board and formulary included with SOC

# Questions/Discussion