

Ryan White Part A Quality Management

Local AIDS Pharmaceutical Assistance
(LPAP)
Service Delivery Model

Palm Beach County

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Palm Beach Care Council
LPAP Committee
Quality Management Committee

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Local AIDS Pharmaceutical Assistance (LPAP) Service Delivery Model

Statement of Intent

The purpose of a Local Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals including measures for prevention and treatment of opportunistic infections. Each LPAP is to establish a LPAP Board that will develop a formulary that meets the needs of the jurisdiction and each LPAP Board must have a process in place to add or delete medications in a timely manner as the need changes.

Local AIDS Pharmaceutical Programs provide:

- HIV medications that are not included in the ADAP formulary
- Medications when the ADAP financial eligibility is restrictive
- Medications if there is a protracted State ADAP eligibility process and/or other means of accessing medications are not available (i.e., pharmaceutical company assistance programs)

Purchase of pharmaceuticals must be:

- Consistent with the most current HIV/AIDS Treatment Guidelines
- Coordinated with the State's Part B AIDS Drug Assistance Program (ADAP)
- Implemented in accordance with requirements of the 340B Drug Pricing, Prime Vendor Program, and/or Alternative Methods Project

LPAP can be used to fund dispensing fees associated with ADAP/LPAP medications. It is required that LPAP medication be purchased at the lowest possible cost, preferably 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.

All LPAP programs will use 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 for information disclosure. The provider wishing to prescribe a medication not on the formulary shall make a request to the Grantee approved LPAP Clinical Review Committee. Approval or denial will be granted within 3 working days.

Service Definition

The purpose of a Local AIDS Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for prevention and treatment of opportunistic infections. An LPAP is a program to ensure that clients receive medications when other means to procure medications are unavailable or insufficient. As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time.

Limitations

Local pharmacy assistance programs are not funded with AIDS Drug Assistance Program (ADAP) earmark funding.

LPAPs are not to take the place of the ADAP program.

LPAPs are not emergency financial assistance for medications; please refer to Emergency Financial Assistance- HIV Medications/Prior Authorization Standards of Care.

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 Federal Poverty Level (FPL).

Standards of Care

Facility Standards	Indicator	Data Source
1. Agencies dispensing medications shall adhere to all local, state and federal regulations and maintain current facility licenses required to operate as a pharmacy in the State of Florida.	1.1 Active pharmacy license is on site.	1.1 Documentation of licensure
2. Program must have a Florida licensed pharmacist designated as pharmacist in charge.	2.1 Documentation of Florida licensed pharmacist on file.	2.1 Documentation of licensure
3. Confidentiality statement signed by pharmacy employees.	3.1 Signed confidentiality statements of staff on file (HIPAA compliance).	3.1 Documentation of confidentiality statement
4. Storage of Medications	4.1 Pharmacy shall maintain appropriate, locked storage of medications and supplies (including refrigeration) according to the State Board of Pharmacy regulations.	4.1 Documentation of compliance by Pharmacy Supervisor
5. Client Grievance Policy	5.1 Pharmacy or medication or site providing medications will have a policy and procedure in place for clients to voice complaints or grievances with services.	5.1 Documentation of policies

Staff Standards	Indicator	Data Source
6. Only authorized personnel may dispense/provide prescription medication.	6.1 Licensed pharmacists authorized by Florida State Board of Pharmacy to dispense medications. 6.2 Pharmacy technicians and other personnel authorized to dispense medications are under the supervision of a licensed pharmacist.	6.1 Documentation of licensure 6.2 Documentation of licensure

Program Standards	Indicator	Data Source
7. LPAP is payer of last resort	<p>7.1 Documentation that client is eligible for Ryan White Part A LPAP services (NOE) and that medications are not covered by any insurance client is covered by.</p> <p>7.2 Written program procedure outlining steps to assure all feasible alternative revenue systems (pharmaceutical company patient assistance programs, PANF, and other funding) are pursued before requesting reimbursement through LPAP.</p> <p>7.3 Documentation of attempts to access medications through other sources maintained in client file.</p>	<p>7.1 Documentation of eligibility in Grantee database</p> <p>7.2 Documentation of written procedures</p> <p>7.3 Documentation in Grantee database</p>
8 Provider works to establish relationships with other health professionals and drug companies to ensure best services are given to the participant.	8.1 Provider offers refill history directly to client's health providers whenever possible or requested, in compliance with HIPAA regulations.	8.1 Documentation of history

Patient Standards	Indicator	Data Source
9 Every prescription is filled correctly.	9.1 Provider maintains quality assurance logs showing any irregularities, complaints regarding errors, etc.	9.1 Documentation of logs
10 Every prescription includes proper indications and dosing instructions.	10.1 Packaging instructions available for review by monitors upon request.	10.1 Documentation of instructions
11 Patient receives education and counseling including a review of drug interactions specific to antiretroviral therapy and the HIV disease state.	11.1 Provider procedures provide an outline for reviewing drug interactions and HIV education.	11.1 Documentation of patient education on medications

<p>12 Patient receives counseling on how his/her medication should be taken and any possible side effects. At least 5 minute initial consultation when dispensing to a patient that is new to antiretroviral therapy.</p>	<p>12.1 Provider procedures describe guidelines for counseling participants on medications and possible side effects. Providers can demonstrate how counseling is given.</p>	<p>12.1 Documentation of policies</p>
<p>13 New prescriptions and refills are available to participants in a reasonable amount of time.</p>	<p>13.1 Client files document causes of any delays in the availability of medications and steps taken to reduce delays.</p>	<p>13.1 Documentation in client file</p>
<p>14 Prescription label directions in Spanish, whenever appropriate.</p>	<p>14.1 Provider demonstrates labeling in Spanish as requested.</p>	<p>14.1 Documentation of Spanish language instructions</p>

*Standards of Care are guidelines or flexible directions to be used in the treatment of HIV/AIDS. Departures from these standards may arise due to a client's unique situation and/or based on an experienced professional's judgment.