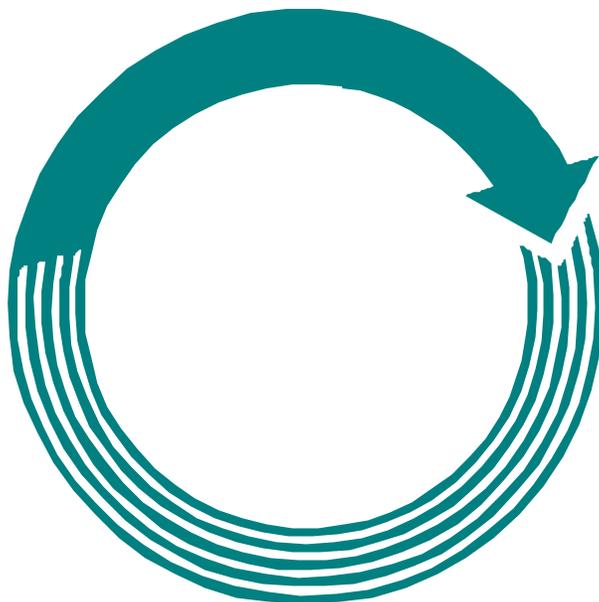# Ryan White Part A
Quality Management

AIDS Pharmaceutical Assistance (Local)

Service Delivery Model

Broward County/Fort Lauderdale Eligible Metropolitan Area (EMA)

Ryan White HIV/AIDS Program Part A
HIVPC Approved 3/23/2019
Last Reviewed 6/3/2021

AIDS Pharmaceutical Assistance (Local)

Broward County EMA Definition:
In Broward County, the AIDS Pharmaceutical Assistance (local) program (LPAP) is operated by the Ryan White HIV/AIDS Program (RWHAP) Part A as a supplemental means of providing medication assistance to clients when the AIDS Drug Assistance Program (ADAP) has a restricted formulary, waiting list, or restricted financial eligibility criteria.

AIDS Pharmaceutical Assistance (local) includes local pharmacy assistance programs implemented by Part A to provide HIV/AIDS medications to clients.

The LPAP program is not funded by the AIDS Drug Assistance Program (ADAP) earmark funding; does not take the place of the ADAP program; may not be used to make direct payments of cash/vouchers to a client; and shall not impose charges on clients with incomes below 400% of the Federal Poverty Level (FPL).

Health Resources Services Administration (HRSA) Definition[1]:
The service is defined as follows by the HIV/AIDS Bureau's Policy Clarification Notice (PCN) #16-02:

LPAP is a supplemental means of providing medication assistance for people living with HIV (PLWH) where there are various limits on the state ADAP; it is created and supported by the Ryan White HIV/AIDS Program recipient.

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[1] _Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds Policy Clarification Notice (PCN) #16-02_. Health Resources and Services Administration (HRSA)/ HIV/AIDS Bureau (HAB). [Online] October 22, 2018. https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf.

Service Description

The AIDS Pharmaceutical Assistance (local) program is critical to maintenance and management of HIV infection. The Broward HIV Health Services Planning Council approves the Ryan White Part A Formulary, which lists medications necessary for clients to successfully manage symptoms and illnesses associated with their HIV and comorbid conditions. The coordination of this service with other medical and support services can in many cases improve and maintain a client's quality of life over an extended period, which is consistent with the Public Health Services Guidelines and other treatment protocols.

The LPAP is designed to supply physician-ordered, FDA-approved pharmaceuticals based on the approved Ryan White Formulary Listing and include medical supplies and/or devices needed to administer drugs. Drugs and medical supplies shall be dispensed routinely as prescribed, or as a short-term supply to assist with an emergency need. Participating agencies are to dispense generic drugs rather than prescription brand name drugs if commercially available and consistent with the dispensing pharmacist's professional judgment and state and federal law. Non-clinical administrative services must be performed as necessary to manage and coordinate client care. These services shall include protocols, policy, and procedures for engaging clients who have not picked up their medication as prescribed.

PROTOCOL

The AIDS Pharmaceutical Assistance (local) Protocol identifies the specific ways to implement the program standards and processes inherent to this service category. The delivery of these services shall be conducted by trained culturally competent service providers. Providers are also expected to comply with applicable standards and guidelines that are relevant to individual service categories (i.e., Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents[2]).

Standards for pharmaceutical services for persons living with HIV/AIDS (PLWHA) are defined by the following sources:
1. The Florida Board of Pharmacy[3]
2. The American Pharmacists Association Policy Manual[4]

Eligibility Requirements for AIDS Pharmaceutical Assistance (local)
The targeted populations for these programs are persons diagnosed with HIV/AIDS who meet the Ryan White Part A medical and financial eligibility criteria of less than or equal to 400% of the federal poverty level to obtain medications. Pharmacist, or authorized designee, shall verify client's eligibility, which is established by reviewing the certification in the Provide Enterprise (PE) System. Pharmacist (or designee) shall perform an eligibility and financial assessment at each visit in addition to reviewing client's eligibility certification in the designated PE System. Pharmacist (or designee) will review client's eligibility for all funding streams and services for which client may qualify. The purpose of the assessment is to ensure that the client is provided with access to all eligible services and to verify that Ryan White is the payer of last resort.

<u>Intake</u>
The staff performing the intake shall explain the information below to the client and shall secure the client's initials, signature, and date as appropriate:
- Client Rights and Responsibilities
- Client Confidentiality
- Client Grievance Process

The provider shall have the Client Grievance Process posted in a visible location with copies of the client Grievance Report Form available upon request. Client Rights and Responsibilities shall also be displayed in a visible area.

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[2] https://aidsinfo.nih.gov/guidelines
[3] https://floridaspharmacy.gov/
[4] https://www.pharmacist.com/policy-manual

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Formulary

The Ryan White Drug Formulary is a working document for practitioners to reference, which lists the medications that are available for the treatment of Ryan White eligible patients. Tier I is a list of Ryan White Part A approved medications and Tier II is a list of the ADAP medications.[5]

Process for Additions of Medications to the Part A Formulary

The process for additions of medications to the Part A Formulary will be in accordance with the local pharmacy process.

Drug Utilization Review (DUR)

At a minimum, provider agencies are to ensure that an internal DUR process is in place that mirrors the following description: "Drug utilization review (DUR) is defined[6] as an authorized, structured, ongoing review of prescribing, dispensing and use of medication. It involves a comprehensive review of patients' prescription and medication data before, during and after dispensing to ensure appropriate medication decision-making and positive patient outcomes. As a quality assurance measure, DUR programs provide corrective action, prescriber feedback and further evaluations. DUR programs play a key role in helping managed health care systems understand, interpret, evaluate and improve the prescribing, administration and use of medications." DUR is classified in three categories: (1) Prospective - evaluation of a patient's drug therapy before medication is dispensed (2) Concurrent - ongoing monitoring of drug therapy during treatment and (3) Retrospective - review of drug therapy after the patient has received the medication.

Prospective Drug Use Review

Provider agencies must have at a minimum the following procedures in place:

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing to promote therapeutic appropriateness by identifying:

    (a) Over-utilization or under-utilization;

    (b) Therapeutic duplication;

    (c) Drug-disease contraindications;

    (d) Drug-drug interactions;

    (e) Incorrect drug dosage or duration of drug treatment;

    (f) Drug-allergy interactions;

    (g) Clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems, which shall, if necessary, include consultation with the prescriber.

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[5] http://www.brhpc.org/hivpc/resources-important-links/formulary-by-drug-classification/
[6] https://www.amcp.org/about/managed-care-pharmacy-101/concepts-managed-care-pharmacy/drug-utilization-review

Patient & Medication Adherence Counseling

Providers shall offer clients medication counseling. Consenting clients shall receive counseling to assist them with their needs. Providers shall document counseling and/or other assistance (Prescription Counseling Log).

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy, the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, or by toll-free telephonic communication and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

   (a) The name and description of the drug;
   (b) The dosage form, dose, route of administration, and duration of drug therapy;
   (c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);
   (d) Special directions and precautions for preparation, administration, and use by the patient;
   (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
   (f) Techniques for self-monitoring drug therapy;
   (g) Proper storage;
   (h) Prescription refill information;
   (i) Action to be taken in the event of a missed dose; and
   (j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

Office of Pharmacy Affairs (OPA) Report[7]

Ryan White AIDS Pharmaceutical Assistance funded Providers are required to enroll and report annually discounted drugs purchased through the HRSA's 340B Drug Pricing Program. Providers include Federally Qualified Health Centers, Ryan White HIV/AIDS Program recipients, and certain types of hospitals and specialized clinics. Providers must certify in writing with each monthly invoice that medications distributed through their Agreement were purchased and invoiced to Broward County at the Florida Medicaid rate, 340B Pricing (Public Health Service Pricing), or lower drug pricing. Providers are also required to complete an annual certification upon notification of the due date from OPA by Community Partnership Division (CPD). The agency on file will receive notification by the Recipient Office of the annual report due date to OPA.

Professional Requirements

The objectives for establishing standards of care for program staff is to ensure that clients have access to the highest quality of services through trained, experienced staff members. Staff hired by provider agencies will possess skills and the ability to interact with clients in a culturally and linguistically competent manner; convey necessary information to clients; manage detailed, time-sensitive, and confidential information; and complete documentation as required by their position.

The *Program Director* or designee will possess experience in HIV/AIDS issues and the delivery of pharmaceutical services.

The *Provider* has a current Florida pharmacy license. Dispensing pharmacists have a current Florida pharmacist's license.

Pharmacy technician, student pharmacist, or pharmacist intern is supervised by licensed pharmacist.

Florida Board of Pharmacy Continuing Education (CE) and Training Requirements

Provider agencies are required to complying to the following minimum requirements:

According to the Florida Administrative Code (FAC), 30 hours of approved CE within the 24-month period prior to the expiration date of the license. 64B16-26.103, F.A.C. Licenses expire September 30 every two years with a one-month temporary extension.

- 1-hour board-approved course on HIV/AIDS (first renewal ONLY). Sections 381.004 and 384.25, Florida Statutes (F.S.).
- 2-hour board-approved course that relates to prevention of medication errors, including a study of root-cause analysis, error reduction and prevention, and patient safety. 64B16-26.103 (1) (c), F.A.C.
- 2-hour board-approved course on the validation of prescriptions for controlled substances. 64B16-27.831, F.A.C.

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[7]

http://www.broward.org/HumanServices/CommunityPartnerships/Documents/ProviderHandbookFY19.GSRFP.final.10.29.18.pdf

- 10 live hours required. 64B16-26.103 (1) (m), F.A.C.
- All licensed pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances **during the biennium ending on September 30th.** A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period. 64B16-27.831, F.A.C.

For more information visit [The Florida Board of Pharmacy](https://floridaspharmacy.gov/)[8] or the [Florida Pharmacy Continuing Education](https://floridaspharmacy.gov/renewals/continuing-education-ce/)[9] websites.

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[8] https://floridaspharmacy.gov/
[9] https://floridaspharmacy.gov/renewals/continuing-education-ce/

OUTCOMES, OUTCOME INDICATORS, STRATEGIES, DATA SOURCES

Outcomes	Indicators	Strategies	Data Sources
1. Improve access to medication.	1.1. Attempts will be made to contact 95% of clients who do not pick up medications within 7 to 14 days of filling the prescription. (Clients can call in a prescription up to 7 days early. The maximum window between filling and picking up a medication will not exceed 14 days as each pharmacy will conduct a review of the Return to Stock list once a week).	1.1.1. Prescriptions are prepared and made available to clients 1.1.2. Document date and time prescription filled 1.1.3. Document contact with client 1.1.4. Offer client medication counseling	1.1.1.1. Tracking Log 1.1.1.2. Return to Stock Log
2. Clients provided an opportunity to improve medication adherence.	2.1. 95% of those clients who were not successfully contacted and/or did not pick up medications will be referred to appropriate provider (i.e., medical case management, Clinical pharmacist, prescribing physicians, Treatment Adherence) (Identifying clients who have difficulty with adherence and referring to appropriate provider for intervention with a goal of improving adherence).	2.1.1. Document the referral 2.1.2. Laboratory Results 2.1.3. Documentation showing medication adherence counseling was offered to client	2.1.1.1. Referral Log 2.1.1.2. Provide Enterprise

STANDARDS FOR SERVICE DELIVERY

Standard	Measure
1. Client receives drug utilization review (DUR) which includes an evaluation for and documentation of: side effect management, drug interactions, potential drug allergies, contraindications, adherence strategies, food interactions, medication safety, etc.	1.1 Pharmacist Signature on back of Prescription -OR- within the Electronic Records
2. 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.	2.1 Documentation of current licensure
3. Clients are offered counseling on medication adherence.	3.1 Provider shall maintain a Prescription Counseling Log
4. Every prescription includes proper indications and dosing instructions.	4.1 Each dispensed prescription has the proper labeling according to agency guidelines.
5. Patient receives education and counseling including a review of drug interactions specific to antiretroviral therapy and the HIV disease state.	5.1 Provider shall maintain an outline for reviewing drug interactions and HIV education.
6. Confidentiality statement signed and dated by pharmacy employees.	6.1 Signed and dated confidentiality statements of staff on file (HIPAA compliance)
7. Storage of Medications	7.1 Pharmacy shall maintain appropriate, locked storage of medications and supplies (including refrigeration) according to the State Board of Pharmacy regulations. 7.2 Documentation of policies.
8. Only authorized personnel may dispense/provide prescription medication.	8.1 Licensed pharmacists authorized by the applicable Florida State Board 8.2 Pharmacy to dispense medications. 8.3 Pharmacy technicians and other personnel authorized to dispense medications are under the supervision of a licensed pharmacist.

Resources

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