Comments on Local Pharmaceutical Assistance Program (LPAP)

Standards

#	Location	Comment	DSHS Response	Determination
1	Title - LPAP	What is the difference between this category and the Taxonomy category AIDS Pharmaceutical Assistance (local), or are they the same?	There are the same According to HRSA, the decision to fund a LPAP should be based on need within the State/ Territory, emerging community and/ or metropolitan area being served by the Part A or Part B grantee. The statement of need should clearly outline the limitations of the ADAP program. The statement of need is to be submitted in the yearly grant application.	
2	p. 1 Definition - "insufficient"	We currently use LPAP (APA) for providers to assist clients in getting HIV medication when they don't have another way to get it. Should we be using another service category for this?	This is what LPAP funds. Although the program must meet all of the other requirements establishing a LPAP.	
3	p. 1 Definition	Was a period proposed or is that duration determined by statute/regulation? What is the time frame, rest of the sentence?	According to HRSA, "As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time. " will add "of time" to the end of the sentence.	

4	p. 1 Definition	period of (this is not complete)	According to HRSA, "As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time. " will add "of time" to the end of the sentence.	
5	p. 1 Limitations LPAPs are not to take the place of the ADAP program	Can LPAP pay the dispensing fee for clients on ADAP?	According to HRSA, as part of a complete LPAP, some of the funds could be used to pay for distribution of medications and to provide adherence information. Depending on how the LPAP is structured and coordinated with the ADAP, it is possible that some of the LPAP funds can be used for distribution of ADAP medications. However, the LPAP must meet all of the requirements outlined in the National Monitoring Standards, including not duplicating or taking the place of the ADAP.	
6	p. 1 Limitations: LPAPs are not emergency financial assistance for medications	What service category should be used?	Emergency financial assistance service category: The provision of short-term payments to agencies or establishment of voucher programs to assist with emergency expenses related to essential utilities, food (including groceries, food vouchers, and food stamps), and medication when other resources are not available.	
7	p. 1 LPAPs should also not be used to supply medications during ADAP application	What service category should be used?	Will delete this limitation. DSHS is changing this restriction; the wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program.	
8	p. 1 Limitations	LPAPs should ~~also not~~ be used to supply medications during.... Contradicts definition above	Will delete this limitation. DSHS is changing this restriction; the	

			wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program.	
9	p. 1 Limitations: LPAPs should also not be used to supply medications during the initial ADAP application	This conflicts with what I've highlighted on page 2. (Individuals eligible for ADAP cannot receive Antiretroviral (ARV) medications under this program except during the ADAP application process not to exceed a period of one month (30 days). This states you cannot supply medications during ADAP application time period and the next page says you can use it for ARVs during application process.	Will delete this limitation. DSHS is changing this restriction; the wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program.	
10	p.2 Services Individuals eligible for ADAP cannot receive Antiretroviral (ARV) medications under this program except during the ADAP application process not to exceed a period of one month (30 days).	Above doesn't it say it can't be used during application period though?	DSHS is changing this restriction; the wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program.	
11	p. 1 Limitations: food pantry purchases	Don't understand why this is in the standard. ??	So that agencies do not purchase medications using food pantry (primarily over the counter medications)	

12	p. 1 Limitations Funds may not be used to make direct payments of cash to a client	Is this the same as "no cash payments can be made to service recipients" below?	Yes	
13	p. 1 Limitations Funds may not be used to make direct payments of cash to a client	Combine the following - one should be deleted. The service recipients are the clients. • Funds may not be used to make direct payments of cash to a client. • No cash payments can be made to service recipients	Agree. Will delete "no cash payments can be made to service recipients."	
14	p.2 Services Individuals eligible for ADAP cannot receive..... exceed a period of one month (30 days).	THMP may take longer than 30 days. Recommend extension to 60 days.	Agree, we are not going to set an exact date for payment for client using LPAP	
15	p. 2 Services "and/or have third party insurance but need assistance with co-payments for medications listed in Ryan White formulary"	Wouldn't these be paid for under CARE-HIPP?	Yes, when a client has either Medicaid/Medicare or another third party payor, then CARE-HIPP	
16	p. 2 Individuals eligible for ADAP cannot receive Antiretroviral (ARV) medications	Above doesn't it say it can't be used during application period though?	DSHS is changing this restriction; the wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program.	

			Does not dispense medication as the result of a primary care visit, in emergency situations or in the form of medication vouchers to clients on a single occurrence without arrangements for longer term access to medications	
17	p. 2 Individuals eligible for ADAP cannot receive Antiretroviral (ARV) medications	This contradicts the 4th point under Limitations above.	DSHS is changing this restriction; the wording will be changed to LPAPs can be used to provide medications during the ADAP application until 30 days after the client has been deemed enrolled in the program. Does not dispense medication as the result of a primary care visit, in emergency situations or in the form of medication vouchers to clients on a single occurrence without arrangements for longer term access to medications	
18	Funds may be used to promote enrollment in clinical trials as part of broader outreach activities or to support clinical costs of expanded access or compassionate use programs where efficacy data exist and where the FDA	(Can this be clearer and explain how this is different than what is described in page 1 – it seems to be contradictory?)	Will discuss during the conference call.	

	has authorized such expanded use.			
19		Clarification – It indicates that funds may not be used to support the costs of operating clinical trials,yet funds may be used to promote enrollment in clinical trials? • HIV service funds awarded through DSHS may not be used to support the costs of operating clinical trials of investigational agents or treatments (to include administrative management or medical monitoring of patients). • Funds may be used to promote enrollment in clinical trials as part of broader outreach activities or to support clinical costs of expanded access or compassionate use programs where efficacy data exist and where the FDA has authorized such expanded use.	Will discuss during the conference call.	
20	p. 2 Contracts must be set up with pharmacies to purchase medications for clients at 340B prices.	I am not sure this is possible in all of the rural areas.	HRSA states that the grantee is responsible for: "The RWHAP Part A or Part B role in coordinating 340B and LPAP: • Must certify to the HRSA Office of Pharmacy Affairs (OPA) that the sub-grantee is receiving funds to provide patient care as defined by OPA • Establish requirements for sub-grantees who are not currently participating in 340B to submit	

			application to OPA for 340B eligibility determination" Have sub-grantees set up contracts with pharmacies to purchase medications for clients at 340B prices	
21	p. 2 LPAP does not dispense medications as:	Although this comes directly from the Nat'l Monitoring Standards, it needs some interpretation. Should reference the use of EFA.	Training issue - will clarify during conference call	
22	Local AIDS Pharmacy Assistance Program (LPAP) does not dispense medications as: A result or component of a primary medical visit	(can we add – primary medical visit that is not related to HIV care)	According to HSRA LPAP presentation : Medications that <u>are dispensed</u> as part of a visit constitute emergency assistance, not an LPAP	
23	p. 2 Coordinated with the State's Part B ADAP	If the drug is not on state ADAP, how do you satisfy this?	According to HRSA, supplement to AIDS Drug Assistance Program (ADAP) when an ADAP has cost containments • Provide for HIV medications that are not included in the ADAP formulary	
24	p. 2 LPAP does not dispense medications as: A result or component of a primary medical visit	The physician who deems this medically necessary then cannot determine this during a primary medical visit?	According to HSRA LPAP presentation : Medications that <u>are dispensed</u> as part of a visit constitute emergency assistance, not an LPAP	

25	p. 2 LPAP does not dispense medications as: A result or component of a primary medical visit	I think this should be pay for and not dispense.	According to HSRA LPAP presentation : Medications that are dispensed as part of a visit constitute emergency assistance, not an LPAP.	
26	p. 2 A single occurrence of short duration (an emergency)	What category are these funds purchased under?	Emergency financial assistance service category: The provision of short-term payments to agencies or establishment of voucher programs to assist with emergency expenses related to essential utilities, food (including groceries, food vouchers, and food stamps), and medication when other resources are not available.	
27	p. 2 Facilities may provide Over-the-Counter (OTC) medication only	None of our agencies currently do this.	If your agency stocks over the counter medications, to include Vitamins, they should be following these guidelines. Will discuss further during conference call	
28	p. 2 Medications not included in the state/regional/local formulary cannot be purchased unless the provider can substantiate the importance of the pharmaceutical to promoting HIV treatment adherence or to	My understanding from HRSA webinar is that the provider would have to request the LPAP Advisory Board add a drug to the formulary. This bypasses that process.	Will discuss further during conference call	

	all the client time to consider the initiation of HIV treatment..			
29	p 2 Medications not included in the state/regional /local formulary cannot be purchased unless the provider can substantiate the importance of the pharmaceutical to promoting HIV treatment adherence or to all the client time to consider the initiation of HIV treatment.	Does this mean that only medications proven to improve adherence or has a cost/economic data supporting its use are allowable? If so, it certainly rules out everything in the above paragraph.	The LPAP board can add any medications they deem as needed through the local needs assessment; to include over the counter medications. "The purpose of an 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." The LPAP advisory board is tasked with developing a formulary that meets the needs of the jurisdiction. The LPAP board and grantee need to take into account other available resources, as well as the best use of funds, when developing and implementing an LPAP. HRSA/HAB does not provide a definitive list of medications that are to be included or excluded from a formulary, as each jurisdiction needs to determine what their clients' needs are. "	
30	p. 2 Staff qualifications Only licensed practitioners (i.e., pharmacists, physicians, nurses, dentists, and podiatrists) may dispense prescription	Does this mean that clinics just have medications on hand to give out to clients/patients? I thought only pharmacists could dispense medications.	You are correct. The wording will be changed to "administer."	

	medication			
31	p. 2 Facility Standards	Is this at the contracted pharmacy? Or is the intent that each of our providers also operate pharmacies?	Contracted pharmacies or in-house pharmacies	
32	p. 2 Facility standards 340B certification current and on file within Agency records	I am not sure this is possible for all of our rural areas.	HRSA states that the grantee is responsible for: The RWHAP Part A or Part B role in coordinating 340B and LPAP: • Must certify to the HRSA Office of Pharmacy Affairs (OPA) that the sub-grantee is receiving funds to provide patient care as defined by OPA • Establish requirements for sub-grantees who are not currently participating in 340B to submit application to OPA for 340B eligibility determination • Have sub-grantees set up contracts with pharmacies to purchase medications for clients at 340B prices	
33	p. 2 facility standards - confidentiality	Corporate or patient privacy related?	Patient privacy	
34	p. 3 Implement LPAP	The AA implements and the provider follows policies. Don't see the implementation being in a provider level standard.	HRSA has been silent regarding the level of implementation.	
35	p. 3 Implement A client enrollment and eligibility determination	Clients are already screened for third party payors. This shouldn't be any different.	It is not different.	

	process that includes screening for ADAP and LPAP eligibility with rescreening at minimum for every six months			
36	p. 3 Implement A LPAP advisory board	What is involved here?	According to HRSA, this is similar to the ADAP advisory board. The LPAP advisory board develops written policies and procedures that govern the purpose, structure, financing, eligibility criteria, formulary, quality-assurance and quality management of the program. LPAPs should be administered in a uniform and consistent manner across EMAs, TGAs.	
37	p. 3 Implement A LPAP advisory board	What are the requirements for the composition of such LPAP advisory board? Indicate the requirements of the composition and the frequency of the board to ensure it is active if it will be required as a element for this standard.	HRSA/ HAB does not specify the exact makeup of the LPAP advisory board, as grantees' needs vary. However, grantees are encouraged to include a combination of stakeholders including clients, prescribing providers, pharmacy professionals, ADAP representatives, as well as others who may be stakeholders in the community being served. The grantee needs to ensure that there is proper representation and that there is not conflict of interests of board members. A LPAP Board can be a sub-committee of a Planning Council; the ADAP Board can also be used as a LPAP Board as long as there is no conflict of interest.	

38	p. 3 drug distribution system	This is not addressed in the HIV treatment guidelines. The medications, yes. The system to distribute, no.	It is addressed in the National Monitoring Standards - the last bullet under implementation of the LPAP, page 7	
39	p. 3 drug distribution system	Is this intended to be very non-instructive?	Need clarification of the comment, please	
40	~~Providers wishing to prescribe~~ Dispensing other medications not on the formulary must obtain a waiver from the LPAP Advisory Board prior to doing so.	Providers must prescribe medication to address any medical conditions even if this program will not cover costs.)	Providers do prescribe medications; however, if the agency wishes to fund such medications through RW, they need to obtain a waiver from the LPAP Advisory Board	
41	p. 3 Implement LPAP	Recommend compliance with local enrollment and eligibility process	The LPAP program hopefully would follow local enrollment and eligibility process	
42	p. 3 A LPAP advisory board	Not a provider responsibility	HRSA has been silent regarding the level of implementation.	
43	p.3 Uniform benefits for all enrolled clients throughout the region	Should be compliance with uniform benefits.	This is the wording directly out of the National Monitoring Standards	
44	p. 3A system for drug therapy management	Where does this requirement come from? Not in NMS.	National Monitoring Standards, last bullet, page 7	
45	p. 3 all prescription medications	Vitamins and many OTC remedies are not considered medications	No, they are not. They are considered over the counter medications	

46	p. 4 LPAP programs must develop procedures for all feasible alternative revenues "explored"	Perhaps this should be “applied for” or “unable to provide assistance”? Explored doesn’t necessary require formal application and rejection and it seems the next paragraph is trying to communicate this.		
47	Payor of Last Resort	In order to be eligible for LPAP, patients must have successfully completed ADAP enrollment and requisite re-certifications. Eligibility for LPAP will be determined through the patient's medical provider, medical case manager or care coordinator. Documentation of eligibility will be kept on file in the primary client record system.	Correct	
48	Timeliness of Service	~~Provider will process prescription for approval within two (2) business days~~ (Medical provider does not approve prescriptions that are paid through LPAP. Medical case managers and supervisors determine eligibility.)	If the client is not being case managed, who determines?	
49	p. 5 Emergency purchase. Medications may be purchased for clients who are awaiting an eligibility decision. No more than a 30-day supply of medications can be purchased that are on the ADAP	This should probably clarify that ART cannot be purchased since there is no guaranteed funds to continue the therapy.	You are correct. According to HRSA	

	formulary for each client.			
50	p. 5 Emergency purchase. No more than a 30-day supply of medications can be purchased that are on the ADAP formulary for each client	Is this 30 days at a time, or 30 days, total?	LPAPs should not be used for emergency care -- will remove reference	
51	p. 5 No more than a 30-day supply of medications can be purchased that are on the ADAP formulary for each client	THMP may take longer than 30 days. Recommend extension to 60 days.	Even though it is averaging 8 weeks for completion of an ADAP application, wouldn't it still be prudent for a LPAP to pay for 30-days at a time pending enrollment in ADAP and not 60 day supply?	
52	p. 5 No more than a 30-day supply of medications can be purchased that are on the ADAP formulary for each client	Could the following two sentences be worded differently for clarity and /or combined both sentences. It might help if the word "pending" is changed to "until the application is complete and the client is eligible". 1. LPAPs should also not be used to supply medications during the time that the initial ADAP application is pending, as a client must have long term access to medications in place. 2. Individuals eligible for ADAP cannot receive Antiretroviral (ARV) medications under this program except during the ADAP application	Even though it is averaging 8 weeks for completion of an ADAP application, wouldn't it still be prudent for a LPAP to pay for 30-days at a time pending enrollment in ADAP and not 60 day supply?	

		process not to exceed a period of one month (30 days).		
53	p. 5 Emergency purchase. may include: manufacturers compassionate programs, religious groups, or other community resources.	These should have already been exhausted, right?	Correct	
54	p. 5 Emergency purchase manufacturers compassionate programs, religious groups, or other community resources.	If none of these are options for the client, can this category then cover the medications until the client is eligible for another payor?	The Emergency Financial Assistance service category should be used.	
55	p. 5 OTC - who are not licensed practitioners	Would actually recommend changing to "authorized". Physicians are allowed to designate authority to perform such actions as long as within state board guidelines. It would be better to perhaps say that if non-licensed individuals are involved in the physical handling of medications, clinics should have the appropriate standards in place that are within federal, state and professional guidelines (or something to that effect).	Agree	

56	Facilities may provide Over-the-Counter (OTC) medication only when the medication is approved by the Food and Drug Administration (FDA), sealed by the manufacturer, and not past the expiration date. Vitamins may be provided when they are sealed by the manufacturer. These items should be stored in a restricted, non-client flow area, which is locked when unattended. Vitamins containing iron must have a child-proof cap. No partially used or opened containers may be passed on to others.	Does this mean that the agency can purchase common vitamins with Pharmaceutical funds and keep them in-house to give to clients as needed?	If the LPAP Board agrees that these are on the formulary. The Board needs to deem that these drugs are important for the clients well-being - according to the LPAP definition of: "The purpose of an 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." The LPAP advisory board is tasked with developing a formulary that meets the needs of the jurisdiction. The LPAP board and grantee need to take into account other available resources, as well as the best use of funds, when developing and implementing an LPAP. HRSA/HAB does not provide a definitive list of medications that are to be included or excluded from a formulary, as each jurisdiction needs to determine what their clients' needs are. "	
57	p. 5 Cost efficient Prescriptions filled are the	Cost-efficient is beyond purchase price. If the intent is to ensure the charge for medications purchased are less than any	Agree - will reword to the receipt reflects charges according to 340B	

	most cost-efficient medications provided by pharmacy dispensing as evidenced by receipts	other purchaser or the same as the federal government (Medicare cost), then that should be simply stated.		
58	p. 5 Storage Pharmacy shall maintain appropriate, locked storage of medications and supplies when needed (including refrigeration	It would be better to replace the word "pharmacy" with "dispensary" or "medicine storage facility" as the term "pharmacy" could trigger State Board of Pharmacy oversight and applicable rules and regulations. This would be impossible for many to achieve.	Aren't most agency pharmacies a Class D pharmacy and as such must adhere to the State Board of Pharmacy oversight?	
59	p. 6 Medications may be purchased for clients who are awaiting an eligibility decision only if the client's physician determines that taking the medications is an emergency and if no more than a 30-day supply is purchased.	Limitations state that medications shouldn't be purchased during ADAP application period.	DSHS is revising the requirement.	
60	p.6 Agencies may charge up to	How is dispensing fee determined. Seems extremely low for a professional service.	One of the AAs have this amount specified in their policy. What do you think it should be?	

	$5.00 per prescription dispensing fee.			
61	p. 6 Agencies may charge up to $5.00 per prescription dispensing fee. However no charges can be imposed on clients with incomes below 100% of the Federal Poverty Level (FPL	Can this category pay the ADAP dispensing fee at pharmacies?	HRSA was silent on this and has not really considered. As such, this needs to be a state decision??	
62	p. 6 Documentation All prescriptions will be signed by a licensed physician before any pharmacy will fill them. A copy of the client's prescription from a medical provider is on file in the primary client record system.	This could be tricky to try to accurately reflect all that is entailed in this aspect of medication provision process. Perhaps simply alter to "Documentation consistent with federal, state and other applicable regulatory and oversight bodies must be adhered in all instances of LPAP medication provision." If you try to get too detailed, you could run into conflict with the state boards of pharmacy and medicine.	I think all we are asking for here is that a copy of the prescription, signed by a medical provider is on file in the clients record. And that the prescription is dated prior to filling.	

63	General	Concerning the tool. I think it needs to be clarified if this tool is to be used for in-house pharmacies, or if any pharmacy contracted with the agency needs to provide the information requested. For example, if we have client's go to Wal-Mart to fill their medications, do we need a copy of the Wal-Mart pharmacist's license, copies of any pharmaceutical asst. degrees, and have all their staff sign confidentiality forms? Since many large pharmacies have rotation of staff, this may be daunting.	The intent of the tool is to monitor the agency who is using LPAP funds to pay for medications. I understand your point that it would be difficult to obtain licenses from all pharmacies. What wording would be better?	