Comments on Local Pharmaceutical Assistance Program (LPAP)

Standards

#	Location	Comment	DSHS Response	Determination
30	p. 2 Staff qualifications Only licensed practitioners (i.e., pharmacists, physicians, nurses, dentists, and podiatrists) may dispense prescription medication	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."	
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 process that includes screening for ADAP and LPAP eligibility with rescreening at minimum for every six months	Clients are already screened for third party payors. This shouldn't be any different.	It is not different.	
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 do 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.	If the client is not being case managed, who determines?	

		Medical case managers and supervisors determine eligibility.)		
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 formulary for each client.	This should probably clarify that ART cannot be purchased since there is no guaranteed funds to continue the therapy.	You are correct, unless the ART is also on the LPAP formulary.	
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 process not to exceed a period of one month (30 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?	
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	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.	

	resources.			
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	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	

	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.		their clients' needs are. "	
57	p. 5 Cost efficient Prescriptions filled are the most cost-efficient medications provided by pharmacy dispensing as evidenced by receipts	Cost-efficient is beyond purchase price. If the intent is to ensure the charge for medications purchased are less than any other purchaser or the same as the federal government (Medicare cost), then that should be simply stated.	Agree - will reword to the receipt reflects charges according to 340B	
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	Limitations state that medications shouldn't be purchased during ADAP application period.	DSHS is revising the requirement.	

	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.			
60	p.6 Agencies may charge up to $5.00 per prescription dispensing fee.	How is dispensing fee determined? Seems extremely low for a professional service.	One of the AAs has this amount specified in their policy. What do you think it should be?	
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	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	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.	

	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.	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.		
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 that 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?	