July 14, 2003

Janet D. Lawson, M.D., Acting Chief
Bureau of HIV and STD Prevention
Texas Department of Health
1100 West 49th Street
Austin, TX 78756-3199

Re: ***Proposed changes to Texas HIV Medication Program, 28 Tex. Reg. 4041-4045***

Dear Dr. Lawson:

Thank you for the opportunity to comment on the Department of Health's proposed amendments to 25 Texas Administrative Code Chapter 98. I submit these comments on behalf of Lambda Legal Defense and Education Fund and the people with HIV and AIDS we represent in our work in Texas. We commend the Department on its thoughtful attempts to amend the applicable rules without immediately implementing the extensive cuts that the Department contemplated earlier this year. Nonetheless, we have several concerns regarding the proposed rules which the Department is considering today. As detailed below, some of our concerns result from confusing language in the proposed rules that likely can be easily remedied. Other aspects of the rules present potential legal and constitutional violations that cannot be so readily fixed. Each of these comments is offered in the hope that the Department's Texas HIV Medication Program ("THMP") will continue to provide life-prolonging assistance to the thousands of people with HIV who currently rely on the program or will need it in the future.

1. Implementing cuts to the Texas HIV Medication Program will exacerbate a public health crisis and impose significant financial costs on the people of Texas.

The Department's apparent desire to contain costs by denying services to Texans with HIV is shortsighted and in fact will be quite costly. By definition, every individual currently eligible for THMP services lacks insurance coverage for

necessary life-saving medication. Changes to the HIV Medication Program that will result in current or future THMP clients losing the opportunity to obtain life-prolonging medication will have tragic effects. When granted access to adequate treatment, these individuals are more likely to live healthy lives, work to support their families, pay taxes and fully participate in society. Without the treatment that THMP affords, these individuals may face disabling or life-threatening illnesses, lose their ability to participate in activities of daily life, or be forced to turn to the state for costly emergency medical care and financial subsidies. Curtailing access to medication for uninsured and underinsured people with HIV will cause potentially irreparable harm to the health of those individuals, harm to their families, and great cost to the state as a whole.

These dangers are even more glaring in light of expected increasing numbers of people who will be tested for HIV in the coming months. In the past year, the federal government's Centers for Disease Control and Prevention has increasingly emphasized the importance of HIV testing for all individuals.[1] With the introduction and FDA approval of a new "rapid" HIV test, growing numbers of people likely will learn in the next years that they are infected with HIV. Unfortunately, studies have indicated that a disproportionate percentage of people who are now testing positive for HIV are low-income or uninsured. In other words, as more people discover that they are HIV-positive, a greater portion of the HIV-infected population in Texas will need the services that THMP was created to provide. Additionally, because many people at risk for HIV learn their HIV status only after they experience symptoms of the disease, many of these newly tested individuals will immediately need medication which they will not be able to access without THMP services. Denying necessary services to those individuals will exacerbate a public health crisis and lead to increased costs for the state.

Moreover, as a matter of fiscal responsibility, scaling down the HIV Medication Program would be penny wise but pound foolish. Recent research presented at the International AIDS Conference in Barcelona demonstrates that treating people with HIV and AIDS before they become ill reduces the long-term costs of care. The average cost of caring for a person with early HIV disease is approximately $14,000 a year. If the state fails to treat that person until he or she

---

[1] See "Advancing HIV Prevention: New Strategies for a Changing Epidemic – United States, 2003," United States Department of Health and Human Services Morbidity and Mortality Weekly Report (MMWR) Volume 52, No. 15, April 18, 2003.

becomes disabled, the cost of treatment more than doubles to approximately $34,000 per year. The "cost-containment measures" and changes in financial eligibility that the Department suggests today will predictably result in drastic costs to the people of Texas tomorrow, when low-income citizens of the state begin to check into public hospitals for emergency or long-term care. We understand that THMP is not an inexpensive program, and that the medications that are used to treat HIV remain costly. Placing the burden of those costs on individuals who cannot afford them, however, is not the answer to the program's fiscal challenges. In the long run, that course will cost the state and the taxpayers even more, and may cost thousands of individuals their livelihoods or their lives.

2. The Department has a legal and ethical obligation to ensure that THMP clients are not terminated from the program as a result of changes to the eligibility criteria.

The most troubling aspect of the Department's proposed rules is that the rules appear to require THMP to terminate certain individuals who currently participate in the program. For the reasons described below, the termination of current THMP clients, even under the banner of "cost-containment measures," is neither morally nor legally acceptable and will have undeniably detrimental effects on public health. Therefore, the Department should amend the proposed rules to ensure that no active THMP clients will be terminated from the program.

a. The Department's proposed rules indicate that current clients may be terminated from the program as a result of the rule changes.

Although the Department's proposed rules do not explicitly state that individuals actively enrolled in the program may be terminated for cost-saving purposes, two separate provisions in the rules indicate as much. First, section 98.109(a)(3) of the proposed rules establishes an immediate change in THMP's financial eligibility criteria. Like the current rules establishing financial eligibility, proposed section 98.109 permits individuals to participate in the program if their "annual gross income" does not exceed 200% of the federal poverty level. However, unlike the current rules, proposed section 98.109 does not permit individuals to deduct the cost of their prescribed medications before calculating their "annual gross income." There are undoubtedly many low-income working people currently participating in THMP whose gross incomes exceed 200% of the poverty level, but who became eligible under the current rules because they were permitted to deduct the high cost of their medications. These individuals will become ineligible

for THMP services if the Department adopts its proposed rules, as proposed section 98.117(1) states that THMP services "*will be* . . . terminated if. . . the annual gross income does not meet the criteria set in § 98.109. . . ." (emphasis added) The Department's proposal would result in the harsh consequence of immediately terminating treatment for current THMP clients whose actual incomes are over 200% of the poverty level but who qualified for services under current section 98.107.

Second, the Department's proposed "cost-containment measures" in section 98.115(c)(1) similarly appear to threaten the termination of individuals actively enrolled in the program. Specifically, the proposed "cost-containment" provisions authorize the Department to implement five separate cost-saving measures, in a particular order, if budgetary constraints require. The second and third "cost-containment measures" (ceasing enrollment of new clients in eligible metropolitan areas, and ceasing enrollment of all new clients, respectively), while ill-advised, will not result in the termination of active THMP clients. In contrast, the first, fourth and fifth measures (restricted medical eligibility criteria, sliding fee scale, and restricted financial eligibility criteria, respectively) are not limited to "new clients." We fear that these provisions, particularly the first and fifth "cost-containment measures," which alter the medical criteria and the financial criteria for program eligibility, will result in the termination of a large number of active THMP clients.

b. By terminating current clients from THMP, the Department will leave those individuals in a worse position for having participated in the program.

Both the financial eligibility changes that the Department proposes to implement immediately and the possible additional eligibility changes that the Department proposes to adopt in the case of anticipated financial shortfalls in the future will cause drastic harm to THMP clients. Restricting the eligibility criteria for THMP will have three predictable results for low-income people with HIV/AIDS in Texas: they will get sicker, they will be forced to spend what little savings they may have to pay for basic health care needs, and many of them will die. As these events unfold, people with HIV will be forced to drop out of the workforce and seek costly emergency medical services, harming the state as a whole. The Department can mitigate these tragic outcomes by ensuring that THMP's eligibility criteria are maintained at current levels, at least for individuals who are already receiving THMP services.

What makes this situation uniquely disturbing is that many of those who are currently benefitting from THMP services and who would be effectively terminated by the proposed rule changes have likely developed a reliance on the medications that the program has made available to them. Many people living with HIV rely on highly active anti-retroviral therapy, or HAART, which typically consists of a combination of anti-retroviral medications that retard the progression of the disease. It is often difficult to find a regimen of medications that benefits a particular individual without causing overwhelming side effects, and, when a person with HIV finds such a combination and begins to take it regularly, he or she generally should not stop taking the medication unless a medical provider advises him or her to do so. If an individual starts a medication regimen and then stops against medical advice, even temporarily, the virus may mutate and develop resistance to the otherwise effective treatment. For that reason, medical providers typically consider an individual's ability to adhere consistently to the requirements of a medication regimen before prescribing a particular course of treatment. If a doctor knows that a person with HIV likely will be unable consistently to take prescribed medications–because of a lack of stable housing, for example, or, as in this instance, because the program that pays for medications may arbitrarily terminate his or her eligibility–then the doctor may advise the individual not to start a course of anti-retroviral therapy. Here, medical providers who decided to suggest certain medications to then-eligible clients could not have foreseen that the Department would take the drastic step of terminating those clients' eligibility for the program and medications. As a result, people terminated from the HIV Medication Program will not only suffer the adverse health effects that come with losing their medical treatment, but they also may be unable to return to their medications because of drug resistance if or when they regain insurance or are readmitted to the program. By changing THMP's eligibility criteria, the Department may exacerbate the public health threat of drug-resistant HIV.

c. The Department's proposed termination of current clients from THMP violates two distinct legal principles.

By placing current program clients in such a terrible position, the Department's proposed rules violate two established legal principles and may invite legal challenge from those who will be harmed by the cuts. First, the U.S. Constitution promises that the state will not put its own citizens in physical danger or exacerbate their risk of harm. When the state acts with deliberate indifference that creates or increases danger to an individual, the state violates the right to due

process that is guaranteed under the Fourteenth Amendment.[2] When it created the HIV Medication Program, the State of Texas took responsibility for providing a certain level of care to thousands of people with HIV and AIDS. If the state turns its back on those individuals now, it will be doing more than simply retreating from its promise. Because THMP clients may develop resistance to otherwise effective medications if they are terminated from the program, the Department's proposed rules will affirmatively harm the health of those individuals. Aware of the medical consequences of its proposed actions, the Department cannot willfully place THMP clients in a position that the Department knows to be harmful. The Constitution does not permit the state to act in such a dangerous and indifferent manner.

Second, equitable estoppel, a legal principle adopted by Texas courts, obligates the Department to continue providing services to current THMP clients. Under the estoppel doctrine, when the state makes a promise to a person and induces reliance on the promise, the state is obligated to carry out its promise so that the individual is not put in a worse position. When it invited the people of Texas to participate in the HIV Medication Program, the state made an implicit representation that the state would endeavor to help them, not to hurt them. If the Department adopts its proposed rules and terminates the eligibility of current THMP clients, many individuals will be unable to continue taking their medications and may develop resistance to those medications. As a result, they will be in a worse position because they relied on the state's representations in joining the program and seeking its life-prolonging medication. The law does not allow the state to treat its citizens in such a harmful manner.

The Department should explicitly state in sections 98.115 and 98.117 that changes in eligibility criteria will not apply to any clients who are receiving THMP services at the time that the changes go into effect. In other words, if the Department adopts the financial and medical eligibility changes suggested in proposed sections 98.109(a)(3) and 98.115(c)(1), it should simultaneously institute "grandfather" provisions to ensure that no THMP client–current or future–loses eligibility because of changed eligibility standards after he or she has begun receiving THMP services.

---

[2] See generally DeShaney v. Winnebago Cty. Dept. of Social Services, 489 U.S. 189, 109 S.Ct. 998, 103 L.Ed.2d 249 (1989).

3. The Department must ensure that individuals who reside in Title I eligible metropolitan areas are treated the same as individuals who reside elsewhere in the state.

In addition to the serious concerns discussed above regarding the Department's proposed "cost-containment measures," we must stress our particular concerns regarding section 98.115(c)(1)(B) of the proposed rules. Section 98.115(c)(1)(B) proposes that, as a second-level cost-containment measure, the Department will "[c]ease enrollment of new clients who reside in an eligible metropolitan area." In other words, if an uninsured or underinsured person with HIV lives in a Title I eligible metropolitan area ("EMA") such as Austin, Dallas, Houston, Fort Worth or San Antonio, he or she will be denied services by THMP. If the same individual lives outside of an EMA, he or she will be eligible for services. This provision violates U.S. Department of Health and Human Services' policy, the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution, and simple reason.

Most importantly, the proposal contravenes the written policy of the Division of Service Systems of the Health Resources and Services Administration's HIV/AIDS Bureau. Specifically, DSS Program Policy Guidance Number 5, titled "AIDS Drug Assistance Program: Eligibility and Formulary Parity and Uses of Funds," states:

> Eligibility criteria for enrollment of persons living with HIV disease in a CARE Act-funded State AIDS Drug Assistance Program (ADAP), and treatments available on the approved ADAP formulary to enrolled individuals, must be equally and consistently applied across the state.

This guidance from the agency that administers Titles I and II of the Ryan White CARE Act clearly mandates that ADAP programs such as THMP must not treat applicants or participants in a disparate manner on the basis of their place of residence. Rather, the program must be administered "equally and consistently" everywhere in the state. The Department's proposed section 98.115(c)(1)(B) violates that proscription, and, for that reason, it must be withdrawn.

Not only does the Department's proposed rule violate federal guidance, but it also suggests a system of geographic discrimination that is fundamentally unfair and irrational. Regardless of an individual applicant's residential area, he or she must be uninsured or have inadequate health insurance to be eligible for THMP services. Because THMP is a payor of last resort, the Department need not engage

in speculation that people with HIV who reside in EMA's may be more capable of accessing medication and health services without aid from the program. If an individual otherwise qualifies for THMP services, he or she clearly needs those services, wherever that individual may reside. The state may not deny equal provision of services to individuals based on an arbitrary factor of residence that bears no relationship to need.[3] Accordingly, the Department should not adopt section 98.115(c)(1)(B).

4. The Department should clarify the meaning of the term "medical eligibility criteria" and explain when the criteria may be waived.

We are also concerned that the Department's proposed rules do not adequately define the discretionary authority of the Chief of the Bureau of HIV and STD Prevention to make exceptions to the program's "medical eligibility criteria" on behalf of individual clients. As described below, the rules appear to indicate that the Chief can exercise power to waive the medical criteria only if cost-containment measures have not been implemented. Because this limitation on the Chief's discretionary authority is arbitrary and unreasonable, we suggest that the Department clarify that the Chief has broader power to waive medical eligibility criteria in any case.

In section 98.107, captioned "Medical Eligibility Criteria," the proposed rules explain that an individual "is medically eligible to participate in the program" if the person establishes that he or she (1) is HIV-positive, and (2) is under the care of a licensed physician. Section 98.107(b) goes on to grant to the Chief of the Bureau of HIV and STD Prevention the discretionary power to waive the "Medical Eligibility Criteria," although the rules do not indicate when that discretion might be exercised. However, section 98.115(c)(1)(A), which appears to impose additional medical criteria if the Department decides to implement "cost-containment measures," contains no waiver provision. This section states that, as an initial cost-containment measure, "[m]edical criteria must meet the most recent Federal Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-infected adults and adolescents." The proposed rule goes on to explain that "[p]resent medical criteria is a CD4+ T-cell count at or below 350 cells per cubic millimeter and/or an HIV viral load greater than" 30,000 or 55,000 copies per milliliter, depending on the test administered. But, unlike section 98.107, section

---

[3] See City of Cleburne v. Cleburne Living Center, 473 U.S. 432, 105 S.Ct. 3249, 87 L.Ed.2d 313 (1985).

98.115(c)(1)(A) contains no provision allowing the Chief to waive medical eligibility criteria in any individual case.

For the reasons discussed in sections 1 and 2, above, we strongly urge the Department to avoid restricting the eligibility criteria in any way, even as a cost-containment measure. If the Department does adopt the cost-containment measures detailed in section 98.115, however, then we suggest that the rules must clarify that the Chief of the Bureau of HIV and STD Prevention may waive the "medical eligibility criteria" described in section 98.115 as well as those criteria described in section 98.107. Indeed, it is difficult to imagine a situation in which the Chief would want or need to waive the requirements of section 98.107 that an applicant be HIV-positive and under the care of a prescribing physician, while one can certainly foresee circumstances in which the Chief might determine that the more restrictive health-based criteria listed in section 98.115(c)(1)(A) should be waived to allow access for an applicant with a slightly elevated T-cell count and a low viral load. To the extent that the Department maintains these criteria in its final rule, we urge the Department to clarify that the Chief of the Bureau of HIV and STD Prevention retains discretion to waive the medical eligibility criteria for every client, regardless of the implementation of cost-containment measures.

5. The Department should ensure that no clients are terminated because they have participated in a "structured treatment interruption" or "drug holiday" pursuant to the advice of a medical provider.

In section 98.117(a)(2)(C), the Department proposes to permit THMP to terminate an individual from the program if the individual "has not requested or used services during any period of three consecutive months." At first glance, this proposal might appear to be a reasonable method of ensuring that the program serves only the neediest individuals. However, the proposed rule ignores the fact that people with HIV may legitimately withdraw from medications for extended periods of time in the course of doctor-recommended treatment. Medical providers may suggest such "structured treatment interruptions" ("STI's") or "drug holidays" in an attempt to alleviate side effects of anti-retroviral medication regimens or to assess the effectiveness of certain medications or the strength of the body's immune system.[4] Because of the complicated risks and uncertainties involved, not all medical

[4] See Mitsuyasu, "Immune Reconstitution With Antiretrovirals, Immunotherapy, and After Structured Treatment Interruption," 7th Conference on Retroviruses and Opportunistic Infections, January 31, 2000, at 3 ("This approach

providers rely on STI's as a treatment tool, so not every person with HIV will be able to take advantage of an STI or "drug holiday." However, those who do should not be punished merely for following medical advice. The Department's proposal may put at least some THMP clients in the untenable position of choosing between following their doctors' advice and maintaining their eligibility for THMP. To avoid forcing this unacceptable dilemma upon THMP clients, the Department should amend section 98.117(a)(2)(C) to permit consideration of whether an individual has temporarily declined access to THMP benefits pursuant to the advice of a medical provider. Accordingly, the section should state:

> (C) the client has not requested or used services during any period of three consecutive months, and the program has established that the client's failure to access services during that period was not the result of reliance on the advice or suggestion of a medical provider.

6. The Department should ensure that individuals whose current insurance provides less than full prescription coverage may be financially eligible for THMP regardless of the type of insurance they currently receive.

Section 98.109 describes the Department's proposed criteria for financial eligibility for THMP. In subsection (a)(2), the Department indicates that an individual will be eligible for services if he or she "does not qualify for assistance under any State compensation program, [or] under an insurance policy unless the insurance company provides less than full coverage for prescription medication, or under any other state or federal health benefits program." For reasons that remain unclear, the proposed rule treats those who are insured by an insurance company differently from those who are insured through a federal or state benefits program. If an individual with private insurance receives less than full coverage for prescription medication from his or her health plan, he or she may be eligible for

---

may be useful in acute primary HIV infection after HAART therapy, where the patient may already have the immune capability to respond to exogenous antigens, and in the chronic HIV setting after some degree of immune reconstitution with HAART. STI may also be useful in patients with multidrug-resistant HIV, where stopping therapy may allow emergence of wild-type virus and permit use of recycled antiretroviral drugs to suppress virus replication.") See also Hirschel, B., "Strategic Treatment Interruptions: Where Are We?," 9th Conference on Retroviruses and Opportunistic Infections, Session 21, February 26, 2002.

THMP services. If, on the other hand, the individual participates in a state or federal benefits program that provides less than full prescription medication coverage, then he or she is not eligible for THMP services. This disparity lacks a reasonable basis and should therefore be eliminated. The Department's rules should treat all underinsured individuals in the same manner, regardless of whether their health care is provided in part by the government or by a private insurer. For that reason, section 98.109(a)(2) should state that an individual may be eligible if he or she:

> (2) does not qualify for assistance under any State compensation program, or under an insurance policy, or under any other state or federal health benefits program, unless the program or insurance company provides less than full coverage for prescription medication.

For these reasons, on behalf of Lambda Legal and the people with HIV and AIDS whom we represent, I urge the Board to reaffirm this state's commitment to the health of its most vulnerable citizens and to adopt the amendments suggested in this letter. Thank you again for considering these comments.

Sincerely,

Jonathan Givner
Staff Attorney