

**AIDS Drug Assistance Program  
Statewide Advisory Work Group  
Meeting Minutes  
June 19, 2007**

**In Attendance:** Jeffery Beal, Linda Barnes, Mike Wallace, Jerry Stambaugh, Ken Bargar, Joey Wynn, Joseph Lennox Smith, Butch Mckay, Don Kurtyca, Mike Ehren, Dan Wall, Evelyn Ullah, Bennie Franks

**Guests:**

Randy Russell, John McGurk, Nick Sullivan, Kathy Cavanaugh, Nicky \_\_\_\_\_, Frank Didiano, Daniel Basil, Randy Noles, Terry \_\_\_\_\_, Mark Barrett, Lisa Agate

**Bureau Staff:** Joe May, Patient Care Program Administrator, Tom Liberti, Bureau Chief, Gayle McLaughlin, Bureau Nurse Consultant, Stephanie Brown, ADAP Program Consultant.

The meeting convened on June 19, 2007 in Tampa, Florida. Joe May provided the opening remarks, and introductions were made. Minutes from the October 17, 2007 Workgroup meeting were approved, and a correction made to the spelling of Michael Ruppal.

An update regarding the reauthorization of the Ryan White CARE Act was presented by Tom Liberti. Extensive changes are in the process of being implemented. HRSA is working to send policy and interpretation of the changes made. Consequences of the reauthorization include elimination of some services previously provided by patient care. The reauthorization has been in effect since April 1. Under the funding structure the grant will be awarded in stages. Prior to the Ryan White Reauthorization there was an estimated \$206 million allocated to Florida in the Ryan White CARE Act. The funding will likely not reach that amount this year and the programs will not find out until the final allocation in September. Part A programs that were allocated \$70 million last year now have around \$64 million. Six million of this is tied into the Minority AIDS Initiative, funding which has not been announced. There was a total of \$4.4 million decrease in ADAP funds this year however, base monies for all Patient Care programs went up \$4.4 million. Information is still coming in for parts C, D, and F, because their grants are completed at separate times. For 2007, the legislature will provide an increase of \$1.3 million for AICP funds, and a funding of \$500,000 to jail programs. There is a coordinated effort in submitting a proposal to the Center for Disease Control for \$4-5 million in additional monies for HIV testing programs.

There was discussion on whether Florida saw an increase in the Puerto Rican population accessing the ADAP. The information is hard to obtain for various reasons, including the non-report of country of origin. A recommendation was

made to develop some forum to discuss the issue of AIDS in Puerto Rico and their migration to the US for services.

Joe May presented the new Patient Care Eligibility brochure application. The brochure and application are also available in Haitian-Creole, and Spanish. Other trainings will be scheduled to address program policy and coordination issues that have surfaced since the initial round of training. Additional policy resolutions as they relate to ADAP are forthcoming. The new ADAP manual, which will be released during the August statewide training, will answer many questions regarding programmatic policy.

HRSA's PowerPoint presentation which was reviewed gives states an idea of expectations for client level data. Accountability is a major component on the President's principles for the Reauthorization. There is a focus on quality, delivery, and standard of care for clients.

Daniel Wall presented on behalf of the Miami-Dade HIV/AIDS Partnership, Medical Care Subcommittee. His presentation discussed changes he and other members of the Medical Care Subcommittee would like to see regarding requirements for labs. Instead of having them required every 3 ½ months, make them mandatory only at enrollments, if at all. This would result in labs being required at most once every six months. Mr. Wall cited additional costs related to the 3 ½ monthly lab requirements as a reason to change this requirement. He added that he knew of only 4 other states, maybe eight, that required medical eligibility documentation at all.

Evelyn Ullah of the Miami-Dade County Health Department represented Lillian Rivera, Executive Administrator of Miami-Dade County Health Department; stating, Ms. Rivera will be the new Deputy Secretary for the Department of Health. Evelyn noted that the 3 ½ month requirement for labs is seen as an aid by providers to monitor drug interactions, drug efficacy, and adverse responses to treatment. She added frequent labs reduce the potential of missing early opportunities to make changes in clients' treatment that can cause serious health concerns if prolonged. Furthermore, she felt ADAP policy should be in alignment with Public Health Services recommendations and HRSA's guidelines of client level reporting and should not only be based on the provider point of view, but also the consumer perspective. Lastly, Evelyn believes there are adherence issues in the program that would not be solved by lab requirement changes. Javier Romero provided a briefing on the progress being made locally with reducing overdue labs and overdue re-enrollments.

Joey Wynn stated that lab data is not being transferred from medical providers to ADAP database, and the cost of human resources to do so would be great. Consequently, there is an inappropriate transfer of drug related costs being shifted from ADAP to local Title 1 systems, which is draining their money. He asked if there is currently a web-based system in progress that could address the

issues of how difficult it is to get lab data to headquarters. In his experience around the state, the majority of medical providers for Ryan White are health department clinics; he further noted that there should be a way for providers to enter labs into the database since it is an internal information system. He feels that this could reduce inaccurate and overdue lab data.

Frank Didiano from Hillsborough shared his experience on the lab issue and noted that he does not see a problem with getting labs. Frank discussed the "lab tracker" system they utilize and recommended the state do the same.

Daniel Wall requested clarity of the situation and asked the Advisory to consider lab requirements every six months instead of every 3 ½ months. The motion was made, seconded and approved with no disagreement. Effective date of new policy will be added in the revised manual that is due out in August. It was strongly expressed by Evelyn Ullah that the Miami-Dade County Health Department will continue to ask for labs every 3 1/2 months for the purpose of their clients, though not required.

Joe May discussed the Federal Poverty Level issue with core eligibility and that an amendment will be forthcoming. Joe May shared that when the rule was constructed, the bureau was not allowed to incorporate by reference the "current FPL" in the manual. Instead, an amendment must be made each year.

Gayle McLaughlin provided the drug update. She reiterated the purpose for the removal of Testim from the ADAP formulary and the discontinuation of Nandrolone. Gayle noted that there was limited to no impact in removing Testim from the formulary; citing that less than two dozen clients were on Testim, all of which have other testosterone medications that are good replacements. Less than ten clients were on Nandrolone when it was discontinued, and all are now using Oxandrin as a replacement.

#### Aptivus:

Gayle discussed Boehringer Ingelheim's concern about their product, Aptivus, potentially being disadvantaged due to ADAPs posing prior authorizations (PA). Boehringer Ingelheim would like any restrictions or prior authorizations placed by the states be removed. If this is not done, the rebate/discounts offered to ADAPs will be rescinded. Florida ADAP does not have prior authorization on Aptivus, but a checklist. ADAP Crisis Taskforce recommended that each ADAP make its own assessment regarding their responsibility for clinical management of Aptivus and the requirements of BI agreement to determine if it is appropriate for the state to sign the Aptivus agreement. Florida rejects the offer to modify its current policy regarding the checklist; and will not relinquish our responsibility to employ clinical quality management practices on selected drugs. Florida will not get the additional ADAP Crisis Task Force discount for Aptivus but will still receive PHS pricing. Under current utilization the net effect would be an increase of \$23,000 annually being spent on Aptivus. There was a motion to reject the

offer of Boehringer Ingelheim to modify the requirement of the checklist. The motion was seconded and passed with no disagreement.

Viramune:

Regarding Viramune there will be a ten percent increase in price on January 2008. We do not anticipate this being a large impact on the program. After this increase there is a price freeze until 2010.

Maraviroc:

ADAP is waiting on the approval of Maraviroc, a special entry inhibitor. The approval of the FDA is expected to occur tomorrow, June 20<sup>th</sup>. To date, there is no pricing information. Our potential clients for this drug are those that are currently using Aptivus and Fuzeon. There appear to be about 300-400 clients who would qualify to take this medication. It is the policy of the ADAP policy to add antiretrovirals to the formulary when they are approved by the FDA. A conference call will follow when Maraviroc is approved and pricing is made known. A question was raised whether the drug will require prior testing. The answer is yes. In order to receive Maraviroc a Tropism test must be taken. There is only one provider of the test and there is no set price as of this date. Tom Liberti stated that there has been money set aside to defray some of the costs associated with taking the Tropic test. Dr. Beal explained how the Tropism test works. Ms. Barnes added that Medicaid will cover Maraviroc and was not certain about Medicaid coverage of the Tropism test. She agreed to inquire.

A drug analysis was submitted by Dr. Thompson for formulary consideration. TriCor, an anti-hyperlipidemia drug was discussed as an option. The price of the medication is somewhere between the Crestor and Lipitor range. Adding this drug would expand treatment options for clients. A motion was raised to add TriCor to the formulary and then seconded.

Dr. Beal provided an abbreviated summary of Martin. Delany's presentation (*presented at the ADAP Technical Assistance Meeting, April 9, 2007 in Washington, DC*). A few new medications include an entry inhibitor (Maraviroc), an integrase inhibitor (Raltegravir), and a non-nucleoside reverse transcriptase inhibitor (Etravirine). Optimized background therapy was used to test Raltegravir. Joey mentioned that Maraviroc has been found useful in treating patients that are three class resistant, viremic, and who have had serious side effects using other medications. Furthermore, he has found that a lot of clinics and public health departments weren't using expanded access programs, due to lack of resources within the clinics to pursue these programs.

Stephanie Brown provided ADAP updates. She announced the Statewide Conference in Orlando, Florida, August 13-15, 2007. Preceding the ADAP training is a planned Patient Care Core Eligibility training as a refresher course. The ADAP manual is currently under revision and will be provided at the upcoming conference. There are various updates, to include: resistance testing

for clients who are yet to enroll in ADAP, and clarification for refills pertaining to migrant workers.

Michele Scavnicky provided a legislative update on behalf of Michael Ruppal. Joe May briefly commented on the ADAP supplemental grant application that is due to HRSA on July 20<sup>th</sup>. HRSA has targeted states to apply. Florida is not one of them and Joe didn't think Florida would be eligible based on HRSA's criteria. Updates will be coming when more is known. HRSA has standardized a minimum drug formulary for ADAP's, which includes at least one drug in each class of antiretroviral. Florida currently meets this requirement.

A question was raised regarding the reauthorization and portability actions during crisis times, for example a Hurricane Katrina situation. Joe responded by saying that the Secretary of HHS can suspend normal operations during crisis times. States can spend no more than 5% of award on crisis expenditures.

Bennie Franks provided an update on the Statewide Pharmacy Inventory Network project; it was not approved by the legislature. This project deals with a statewide inventory network for central pharmacy; all county health departments would be part of a centralized computer system. The Administration is currently discussing alternatives. Colonel J. Watkins will be joining the Bureau of Pharmaceutical Services in August as the bureau chief.

A Medicaid update was provided by Linda Barnes. Medicaid reform was not addressed during the last session; however, they are going ahead with reform in expansion counties such as Clay, Nassau, and Baker counties. She further stated that contracts are being signed by Health Maintenance Organizations. In September they will begin enrollments of beneficiaries. According to the current usage information, antiretroviral therapy is down from 40,000 per quarter. The total decrease equates to about a forty percent loss in clients and accounts for the 50% reduction in budget. Linda also reported that Jerry Wells is retiring.

Dan Wall requested that the bureau inform Part A programs about the upcoming ADAP conference in August and include a session for Part A. Mr. May responded that an e-mail was sent to all Part A representatives, but he would be glad to notice them again.

The next meeting date proposed was for Tuesday December 4, 2007. There is a scheduling conflict because of World AIDS Day and a Hepatitis meeting. The alternative date is December 11, 2007, with December 10, 2007 as a backup date.

The meeting adjourned at 2:00 p.m.