

**AIDS Drug Assistance Program
Statewide Advisory Work Group
Meeting Minutes
May 23, 2006**

The meeting convened at 10 A.M. in Tampa, Florida. There were opening comments by Dr. Arons and introductions of the attendees. Present were: Paul Arons, Lorraine Wells, Jeffrey Beal, Michele Drengberg, Michael Ehren, Leslie Betts, Linda Barnes, Michael Thompson, Bennie Franks, Natalie Franklin, Jennett Baker, Joe May, Allison Nist, Judy Wray, Joey Wynn, Jesse Fry; Javier Romero, Diana Travieso-Palow, David Waldron, Mike Wallace, Dan Wall, and various interested parties including manufacturers representatives.

Dr. Arons reviewed packet materials. The minutes were approved with one correction. Dr. Arons introduced Lorraine Wells as the new state ADAP Manager. Workgroup member Mike Wallace was recognized for his receipt of the Red Ribbon Award. It was noted that this is the tenth anniversary year of the statewide workgroup.

Jesse Fry presented the state legislative update. The state general revenue budget for ADAP increased by \$1.5 million increasing the budget amount to \$10.5 million. The AIDS Insurance Continuation Program (AICP) received an increase of \$2 million in General Revenue funding. Other HIV/AIDS related bills died in committee. A bill permitting counties to implement mandatory testing of inmates in Florida's county and municipal jails did not pass. A bill regarding harm reduction programs including needle exchange also failed to pass. Mr. Fry also presented a federal legislative report. The President recommended an appropriations increase of \$70 million for 2007 to the Ryan White CARE Act. This has been divided into a \$30 million increase in the Title II base grants nationally; forty million in non-recurring funding was also allocated for AIDS Drug Assistance Programs, to be disbursed at the discretion of the Secretary of HHS. The funding is intended to eliminate waiting lists. The bill would require each state to have at least a standard minimum ADAP formulary. The bill also requires allocating 75% of federal funds for core medical services. The bill gives more metropolitan areas access to Title I funds by establishing "tiers" based on numbers of reported cases. The allocations are based on reported HIV-positive cases, not just AIDS cases.

There was discussion regarding the definition of core medical services. These include medical, dental, pharmaceutical, substance abuse and mental health counseling, home health, and durable medical equipment. Mr. Wynn has access to additional information, which he will forward to the AIDS Institute for e-mail distribution by the Bureau. There is some discussion about defining case management as either a medical or non-medical social service. It appears that transportation to rural areas and residential substance abuse counseling were omitted from the definition of core medical services. Two big issues with Title I approval and funding are census data and cumulative population of HIV/AIDS infected persons. The potential problem is that nationally, five current Title I areas will lose their status because of population or case information.

Mr. Fry added a point about ADAP TrOOP costs (true out of pocket) and Medicare Part D. ADAP funds currently cannot count toward true out-of-pocket costs for those who are Medicare Part D beneficiaries. There is a bill proposing a change in this prohibition to allow ADAP expenditures to count towards TrOOP.

Joe May stated the Title II funding level and funding received on April 1 was \$116 million. Title II program allocations were shifted, however. Since the base grant award was cut by \$1.2 million, consortia allocations were cut by five percent. Other funding was also shifted to absorb the remaining \$350 thousand loss. Federal ADAP funding increased by \$1.3 million to \$88 million. One emerging community grant has also been eliminated. This was in Volusia County (Daytona). Minority AIDS Initiative funding was cut \$18 thousand. Overall funding remained at the same levels as last year.

Mr. May provided an update on administrative rule of eligibility for patient care services. The Joint Administrative Procedures Committee (J.A.P.C.) has had technical concerns about one requirement and the rule is now in temporary suspension status. The Department sought legislative input to see if there could be a statutory fix to the J.A.P.C. concern, but the legislative session ended with no action on this issue. DOH attorneys feel comfortable that legal grounds for the rule are solid, and the plan is to publish a notice of change in the Florida Administrative Weekly stating that the approval process will be reactivated. The effective date should be within the next three months.

The most recent monthly report showed that the number of ADAP clients is now under 12,000 due to the larger counties continuing case load reviews of clients who are inactive, are overdue for re-enrollment, and/or are not picking up medication. These cases are being closed out of the system. Dade County has a large number of records under review, and we are expecting additional closures on an ongoing basis. Medication expenditures have not decreased, and the program continues to serve active clients.

ADAP continues to serve clients who are not enrolled in Medicare Part D. Previously, HRSA stated that everyone in ADAP with Medicare must be enrolled in a Medicare Part D plan. Now, HRSA has stated that it is permitting states to continue to assist Medicare and Medicare-eligible clients not enrolled in Part D. At present, this will have no impact on Florida. The number of Medicare Part D clients enrolled in ADAP is now 71. The AIDS Drug Assistance Program has closed over 200 clients to date due to adequate Medicare Part D coverage. There are still about 286 open clients who have Medicare benefits indicated. This number does include the 71 clients mentioned before. The program is still working with 200 clients in different counties to confirm their exact status. There are approximately 600 clients who may potentially have Medicare. The new pilot project, known as the ADAP Wrap Around Pilot Project (AWAPP) is to help a subset of Medicare Part D clients with their out-of-pocket expenses. Specifically it is aimed at those persons between 135 and 150 percent of the Federal Poverty Level who have no subsidy benefits. A contract is routing for final approval and execution. So far, it appears that this will affect about 20 clients, though up to 150 may be served through the contract. If the pilot project is successful, then additional funds may be allocated.

Florida has not been able to execute a workable data sharing agreement with the Center for Medicare and Medicaid Services (CMS). The purpose of the agreement was to get a direct comparison of ADAP patient database information with Medicare beneficiary data. Talks with Medicaid to do a similar exercise with the Medicaid database were also unsuccessful. There was a limited crosscheck more than 18 months ago; however, the Department needed a new data sharing agreement. This has not been executed pending resolution of questions in Medicaid's legal office.

The dialogue with Abbott to receive donated ritonavir at the DOH Central Pharmacy is ongoing. This is specifically for patients taking tipranavir who need a ritonavir booster with the drug. Abbott offered a year ago to provide free ritonavir to persons taking 400mg or more daily. The department has been discussing with Abbott the option of providing ritonavir directly to the DOH, which would then distribute the drug to the appropriate patients. This would eliminate the need for tipranavir patients to apply to the Patient Assistance Program (PAP) for ritonavir, which is the current requirement. There is a draft agreement to receive product with one issue remaining regarding documentation. Expectations are that the issues will be resolved in the next week or two.

As of this date, 119 patients have been prescribed generic zidovudine. Nine patients have discontinued the drug. The underlying causes are unknown. Dr. Arons referred to the previous meeting of the workgroup, where there were recommendations that the bureau not impose mandatory use of generic zidovudine. The bureau would then monitor usage to see if a pattern of any clinical complications appeared in those using the product. ADAP will attempt to identify the reason for discontinuations. The program will continue to monitor usage and give reports at future meetings. There was also discussion regarding a number of individuals who are taking tipranavir, which requires boosting with a 400mg per day dosage of ritonavir. The current usage is about 80 clients, consistent with FDA parameters for restricted usage in late stage disease with resistant HIV. About half of these patients are also using enfuvirtide, consistent with findings of maximum benefit when combined.

The hepatitis C pilot has been in place for two years. It was originally a one-year project, and the bureau agreed to extend it due to low demand and minimal fiscal impact. Eight pilot areas and ten slots were available to the counties. To date 58 persons have enrolled or been enrolled at some point. The total spent on pilot is a little under \$67 thousand. Utilization is still much less than anticipated. In addition to the pilot project that ADAP is sponsoring, there are also free slots Schering-Plough made available to ADAPs around the country. Schering provides hepatitis C treatment and ADAP has to provide the ancillary treatments needed by the client. To date there are seven persons in Florida participating in the Schering project from three counties: Pinellas, Bay, and Hendry.

Nationally there has been underutilization of the hepatitis C treatment resource. Schering at one time made available 1300-1500 slots nationwide and subsequently reduced them by a factor of ten. However, Schering has agreed to extend the availability of this resource. There is no set ending date. There was further discussion on how to approach the availability of hepatitis C treatment. Should it be available on a statewide basis or leave the pilot in place and allow anyone who wants to access it to the free slots available? There was discussion about the maximum amount of funding available for treatment. Mr. May stated that there were 100 slots and the program has never come close to using that. There were questions about the 58 non-duplicated people enrolled who used \$67 thousand in funds, and whether any tracking was done on those persons.

The ADAP imposed a number of conditions for use of hepatitis C treatments. It expected the national treatment guidelines to be followed, which include the availability of mental health assessment and counseling. Some intensive support services need to be available to treat a patient with a full course of medication that has significant toxicity and side effects. People have not been able to continue through entirely due to the side effects. Mr. May stated that he thought the number included people who were evaluated, but who did not necessarily start treatment. The patients may have opted out for any number of reasons. Dr. Nist felt that the project was not implemented because of a lack of nursing staff in Collier County. They are now in a position to bring on nursing staff in part to implement hepatitis C and B treatment more intensively for HIV patients. Providers should be able to organize a good program. Dr. Nist felt that there was adequate, expert support here in Florida. She proposed that the Hepatitis C Pilot Project be available statewide while retaining the limit of 100 people and monitoring expenditures. Providers would be expected to implement other treatments as outlined in national guidelines.

There was discussion regarding availability of sufficient staff statewide to monitor the program. Dr. Beal stated that from an AETC perspective, the reason the treatment hasn't been done in many cases was because the clinicians do not have the nursing support staff to be able to monitor the treatment on an ongoing basis. He stated that there may not be a tremendous increase in the number of people accessing the program until there was an assessment of a larger program problem; which is how to support a network of hepatitis C treatment centers in the state to treat the co-infected patients. A single LPN in a clinic cannot take care of all the patients receiving treatment and handle other job duties. He felt that someone needed to advocate for the state to look at this in a bigger perspective, such as regional centers of excellence that would not prohibit people from crossing county lines to access service.

Mr. May advocated to leave hepatitis C as a pilot project and increase access, with the understanding that the funding limitations could affect future availability. There was a suggestion that it would be helpful to track the variables of the enrollment and dis-enrollment of the people in the pilot project. It was agreed that this information could be gathered. The motion to continue the pilot project with access statewide, was passed by the workgroup.

Bennie Franks discussed the ongoing reorganization of statewide pharmacy services. During the last few months, the Bureau of Statewide Pharmacy Service has reorganized with a transfer of two sections to the Medical Quality Assurance section. These sections were responsible for regulation and permitting of drugs, devices, and cosmetics within the state of Florida. The Bureau of Statewide Pharmacy Services now reports to the office of Public Health Nursing. Charles McArthur is acting as the Chief for the Bureau of Statewide Pharmacy Services. Central Pharmacy continues to be responsible for providing the pharmaceutical tools to support our county health departments and their clients throughout the state of Florida. The statewide pharmacy inventory project is under review by Division of Information Technology staff (IT). The purpose of the common database is to ensure accountability for pharmaceuticals and allow pharmacies to have the pharmaceutical data ready and accessible for documenting inventory at all times throughout the state.

A question came up regarding bulk inventory during hurricane season. Dr. Arons stated that the program would follow the same procedures used in 2005. This involved allowing earlier pick-ups when forecasts indicate that storms are approaching specific areas. A memo was issued at the beginning of hurricane season last year, and can be updated and sent out again. There was discussion of a recently published book, "Dangerous Doses", concerning midlevel distributors acquiring drugs in Florida at low-level prices, then reselling them to wholesalers at below-market prices. It poses the whole question of whether there is a diversion of drugs in our system. Ms. Franks was asked if she had comments on any of the issues related to that or the safeguards that were being instituted. Ms. Franks replied that there was no evidence implicating Florida ADAP drugs in diversion, but additional safeguards are coming through a drug pedigree plan. Florida is the first state to take a stance in doing a drug pedigree, which would certify a chain of custody through all stages from manufacturer to front-line pharmacist. An amendment possibly weakening the pedigree system was added to a cancer drug donation bill at the end of this year's legislative session; the Governor's office had not yet decided whether to sign or veto it. Pharmacy is waiting for approval from the IT group, which takes a little bit of time. Ms. Franks also reported that the supply of the old formulation of Kaletra has been exhausted, and all new, non-refrigerated product was now on the shelves and in use.

Linda Barnes gave an update on Medicaid. Now that Medicare Part D is in place, it remains a challenge for those recipients who are both Medicare and Medicaid eligible (dual eligibles). With the implementation of Medicare Part D, it is estimated that between 350 thousand to 375 thousand dually enrolled recipients in the Florida Medicaid program became eligible for Medicare. During the transition period, it became a challenge for Medicaid to handle recipients who had "fallen through the cracks"; several hundred people either chose not to enroll or were not automatically enrolled during the implementation phase. CMS stepped up and gave states a waiver to cover those recipients in the program in the interim, and this program was initiated around the end of January 2006.

Medicaid allowed those recipients who fell through the cracks (dual enrolled) full coverage and continued this through March 8-9, 2006. Another challenge was trying to address the Medicare B issues that also came up with the implementation of Part D. This involves the drugs covered under Part B that Part D does not cover. Medicaid recipients who are dual and full Medicaid/Medicare still needed to find a way to cover the 20% co-insurance. Some programming had to be done, because the Medicare crossover claims system was not processing properly. There were some policy changes to address this, and hopefully by July 1, 2006, Medicaid will have its Medicare crossover system up and working properly. The pharmacists will submit the claim for Part B drugs directly to Medicare, and they will cross over as true claims from Medicare to Medicaid. This will result in only one transaction for the pharmacy.

For the last quarter of 2005, Medicaid had approximately 15,988 recipients. With the Medicare Part D implementation, it is down almost 50 percent. The second quarter of this year may look differently than the first quarter. Medicaid also lost a lawsuit over gabapentin. The agency decided to remove the prior authorization requirement for the brand name Neurontin and its generic, gabapentin. Brand name gabapentin is not on the preferred drug list (PDL). If a prescriber wants to use brand name gabapentin, he or she must fill out a miscellaneous form plus a multi-source brand form. The same criteria are likely to apply to duloxetine (Cymbalta®), approved as an antidepressant and for diabetic neuropathy, but not for HIV neuropathy for which clinicians have found it useful. There is no generic equivalent for Cymbalta® on the market. Generic gabapentin is available from Florida Medicaid without prior authorization, and is on the preferred drug list.

The Medicaid fiscal agent contract will not be implemented until March 2008. Medicaid is asking for a system that does not presently exist; involving web-based portals so that there is access for providers and recipients. Medicaid reforms are coming and contracts will be executed on July 1, 2006, with the first group of enrollees on September 1, 2006. Medicaid saved \$292 million of its pharmacy program budget last year with the cost effective PDL.

Dr. Thompson presented the pharmacy consultant report. The ADAP patient satisfaction survey report was distributed. Surveys were received through January 2006 and a few continued to come in up until last week. The analysis was given to ADAP in March of this year. It reflected a greater overall participation throughout the state, increasing from 500 to about 2000. Each county will have their own report sheet along with other data such as patient comments. There was a question regarding the ability to query responses by race and ethnicity. Because the survey is done anonymously, this information cannot be gathered at present. It was recommended that ADAP add a racial/ethnic background question on the survey. There was concern that non-patients helping to assist patients with the survey may skew findings based on responses of patient. Distribution of surveys differs in each county. Some set up suggestion or comment boxes, others distribute to patients directly with assistance if language barriers are present. Some results may have not been objective if assistance was provided from staff. *(Note: During the most recent survey period, AIDS Drug Assistance Program staff were told that they should not be assisting patients with the surveys)*

There was concern about getting an increase in response from the Spanish- and Creole-speaking populations (response rate was less than 15 percent of total surveys). It was suggested that the program make an effort to post survey data that is referenced to each work group member within the counties. There was a suggestion that the Bureau allow outside assistance, such as college interns in Public Health to help assist with filling out surveys and add a question on the survey that asks who is assisting with filling out surveys.

In reference to survey question number 6, it states 12.7 percent of respondents (from counties that do not have CHD pharmacies) wait five to seven days to get a prescription filled, and an additional 5.1 percent wait 7 days or more. In terms of adherence that's a big issue. Dr. Arons felt that could be corrected if ADAP could look at the particular county(ies) involved. Dr. Thompson will provide individual county survey summaries for such analysis. Another committee member also suggested that the program try to get away from using friends and family members of patients by going to telephone based translation services. This may help to alleviate some of the perceived bias.

Dr. Thompson discussed smaller county health departments (without pharmacies). He has provided the nurses and coordinators with education on how to search the internet for drug related problems. It was suggested that ADAP pool together the smaller counties such as Escambia, Santa Rosa, Okaloosa, in order to decrease travel and hold half-day training sessions on case conferencing. Dr. Arons stated that this should not be done if it decreases knowledge about smaller areas in terms of individual problems being assessed.

Formulary discussion was next on the agenda. There are several additions to the formulary. Two items for the workgroup's attention are excerpted from the May 2006 update of PHS treatment guidelines as an insert in the packet. Based on new recommendations, all patients should be tested for viral resistance before beginning treatment, and should be evaluated for chronic Hepatitis B, so that a regimen can be designed to cover that virus as well if indicated. HIV resistance testing is available from the state lab for ADAP patients. This testing is available for use prior to initiation of ARV therapy or a change in ARV therapy for patients (*but not to be used to establish eligibility for the program*). There are funds already in place to cover resistance testing.

For persons already on therapy, the recommendations are the same as in previous guidelines. Resistance testing is indicated when there is evidence of virologic breakthrough. Workgroup members were encouraged to notify Tallahassee of any cases of such resistance, and the AIDS Drug Assistance Program would address the need for a policy. It is not the intent of the program that everyone in ADAP automatically get a resistance test. The focus would be on patients that are initiating anti-retroviral therapy for the first time. Mr. May stated that when convening a statewide conference call, the program did put together checklists and tools to implement the policies in order to get that information across. Due to the minimal use of genotype testing, Mr. May felt the program could absorb the testing commitment with existing funding.

Dr. Nist discussed her concerns regarding the need for clients to be tested for hepatitis B and C, get treated, and stabilized before initiating antiretrovirals. The new DHHS guidelines discuss the need to treat HIV and hepatitis B (HBV). This is a standard of care for persons who have chronic hepatitis B, using tenofovir/emtricitabine, or equivalents such as the combination tenofovir and lamivudine, and other drugs as a treatment to prevent any type of resistant mutations in hepatitis B. Treating HBV without causing resistance in it and HIV is not simple. If the patient is not on antiretrovirals for HIV, the guidelines discuss either using pegylated Interferon- α or entecavir. These are very expensive but can be used for an ADAP patient who is not a candidate for ARV meds yet, but needs treatment for hepatitis B. Alternatively, if the patient, despite being on tenofovir/emtricitabine had a detectable or increasing hepatitis B viral load, entecavir could be added to the HIV regimen. If the program is going to add anything expensive like entecavir, this should be done in a tiered fashion. The protocol should make sure that the person had already been tried on tenofovir/emtricitabine. The AIDS Drug Assistance Program would also need to ensure that the clinician was experienced in treating both diseases. There was a recommendation that the AIDS Drug Assistance Program develop algorithms or checklists to illustrate pathways for treating hepatitis B and C and HIV simultaneously. One member felt that adefovir would have to be used with great care as it could create some cross-resistance to tenofovir. Another member stated that adefovir was still listed in the guidelines as an option and felt it should still be considered. Immunizations against Hepatitis A or B using ADAP program vaccines would also be part of the treatment plan, depending on results of initial hepatitis lab profiles.

There was further discussion about the potential numbers of patients and the costs of treatment. Dr. Arons pointed out that ADAP did not know what the budget was going to be like in the next cycle. Existing funding has already been committed for other uses. When something is a possible "budget buster" or the potential fiscal impact is unknown, then the best course of action is to require prior authorization. With hepatitis B and C, the protocol should inquire as to whether a patient has already had the option of treatment as part of their regimen. If current treatment is not working, then go to the other as a backup. It is expected that once any currently enrolled co-infected HBV patients are treated, the new enrollments every year are not going to produce substantial numbers of additional patients that need treatment. It won't be as much of a budget issue hopefully, as patients who are already taking the treatment don't necessarily have to continue on it, but there's no guarantee of that. It's possible that it could be financially feasible despite the high cost of the medications.

Dr. Arons felt that if ADAP looked at the data situation and front line providers, and tried to touch all of these other providers before putting hepatitis treatments in place, the local health department infrastructure could not take on the additional work burden. It would also be time consuming to talk with all those physicians, and that physician education would be a joint responsibility with AETC. Dr. Beal, who is the AETC Medical Director, agreed, and felt that since ADAP "asked a lot of questions when they enroll", the patients could also be asked if they are positive for hepatitis B or have been tested; if not, the patient needs to ask the doctor.

It was felt that unless a pre-condition of receiving the medication was that the patient have a hepatitis B test, it would be hard to get the information. There are already problems with getting the required CD4+ counts as it is. Dr. Beal stated that if the ADAP workers do not initially get them, they should go back to the doctors and get the information. In this way, it was not a question of withholding medication, it was a matter of empowering the patient to know his or her status.

Dr. Beal also felt that there would be an opportunity for somebody to make a call to the doctor. The issue was raised as to who that would be. It can't be the ADAP eligibility worker, who has other clients they're registering all day long; the pharmacists, who are filling scripts all day, so whose responsibility does it become? There is not sufficient infrastructure and the staffing capacity in the health departments to do that. In the larger areas, it becomes even more time consuming. Dr. Beal felt that an ADAP worker could have a prepared script written by ADAP that they can hand to the physician or they can send along with the patient's records asking whether they are hepatitis B infected. A question was raised as to whether the program should require that any patient enrolling in ADAP to start antiretroviral therapy have a hepatitis B screening. It was felt that all patients should be screened for hepatitis B.

There was discussion regarding the potential costs for the testing and timeframes for results, and putting the requirements for testing into the program manual. It was agreed that the workgroup would assist with evaluation and revision of the program medical criteria. A copy of the manual criteria will be provided to the workgroup members assisting with the revision. The completed manual will be circulated to the entire workgroup for comments at a later date.

Dr. Beal recommended adding requirements for documentation of hepatitis serology and viral loads. There was discussion about the potential costs of such requirements. Michele Drengberg discussed the difficulties of ADAP staff in getting lab results from some physicians, specifically non-health department physicians, as well as problems with patients following through with lab appointments for required testing. Dr. Arons suggested that perhaps such labs should be a precondition of enrollment for persons who needed treatment. There was further discussion about staffing limitations and workload issues in the health departments. There is not sufficient staff to track on all of the existing requirements, and the question was raised as to who was going to be able to handle all the additional lab results and other information needed. Dr. Beal stated that AIDS Drug Assistance Program workers should be trained like case managers. *Note: AIDS Drug Assistance Program staff all receive formal training in handling the program from Tallahassee.* Dr. Arons stated that front line staff are already under a huge amount of pressure, stress, and criticism to enforce the current standards and requirements.

There was additional discussion about adding the hepatitis treatments to the formulary, and what conditions should be placed on access to those medications. The recommendation was that the AIDS Drug Assistance Program could make available all of these medications to be used as a back up to the basic antiretroviral combination. This would include medications that would address a co-infected patient's status. The addition would be for the purpose of patients who are not ready for antiretroviral therapy or are not responding to optimum antiretroviral therapy.

It would also address hepatitis B, making clear to providers that this is not the first line of treatment, and enforce this standard. An ADAP staff conference call will be on the agenda coming up within the next 60 days. A recommended cap of no more than 100 persons was proposed. An interim assessment could be done at the next workgroup meeting to see if it is sufficient or needs to be revised.

Further discussion involved the generic version of Azithromycin. The generic has not yet been put on the shelf. The brand costs approximately three times as much as the generic. Recommendations were to add the generic Azithromycin. A question was raised regarding generic didanosine which is not currently on the formulary; it was previously determined that it did not offer a cost advantage. It will be reassessed for cost-effectiveness due to the request.

There are two new products awaiting approval by the FDA, possibly in June. One is a protease inhibitor currently called TMC114. The second is a joint effort between two drug companies to combine tenofovir/emtricitabine plus efavirenz in a single tablet for once daily dosing. We don't yet know the pricing of either product. One recommendation was not to pre-approve TMC-114 until the price is known, because there is such a wide range of protease inhibitor prices that the term "cost-neutral" is difficult to define. A conference call can be held when the drug is approved to discuss addition to the formulary. Another concern was the need to look at all variables in waiting for approval. The protease inhibitor, TMC114 needs to be boosted with ritonavir. Nelfinavir, which is the lowest cost protease inhibitor, doesn't need to be boosted. There was a recommendation to wait on this. The committee voted provisional approval to add the tenofovir/emtricitabine/efavirenz combination upon FDA approval if the cost is price-neutral or below the combined cost of the two products combined.

Dr. Nist addressed a proposal to add duloxetine (Cymbalta®). The indications are for diabetic neuropathy and major depressive disorder. A small number of her patients had responded well to the drug when used to treat HIV neuropathy. Pregabalin (Lyrica®), with a similar mechanism of action, was also considered as it is less expensive than duloxetine. There was some discussion about the costs of these drugs versus the cost of generic gabapentin, at least a four-fold difference. There was a request for additional information on duloxetine and pregabalin with estimated costs for the medication. Additionally, there was concern regarding the multiple uses of the drug and it was felt that there was not enough money to treat depressive disorders.

It will be realistic to talk about this at the next meeting. Dr. Beal stated that duloxetine is not available through patient assistance or the state because it is on the Medicaid formulary. It is available through Medicaid with prior authorization. For that reason the company will not give it through a PAP for Florida patients, Medicaid or non-Medicaid. A member suggested that it should be added with a prior medical review requirement through the medical consultant team. Until it was known what the utilization was, a cap could be imposed on the medication total annual usage. Then a decision could be made on whether it was financially feasible. There was a motion to defer recommendations until the next meeting and get some cost utilization data as duloxetine and/or pregabalin could be potential budget-busters. There was a request for information on an average course of treatment, and a suggestion to look at the patient assistance program issues in the interim.

There was a request that the State Lab again be queried about the possibility of adding PCR-RNA to the Branch-DNA viral load testing currently offered. This has been explored in the past and found to be logistically too challenging, but there are reports that some clinicians insist on PCR-RNA testing. Dr. Beal discussed what would happen if there is an interval between FDA approval of TMC-114 and appearance on the pharmacy shelves. It was explained that rather than continuation of their expanded access program, patients would be able to continue treatment via the company's patient assistance program. Dr. Beal also reported that a small workgroup from AETCs across the U.S. will try to address the conflict between restricted time slots to see patients in federally funded clinics vs. the extended time needed to deliver appropriate care to an HIV positive patient.

Dr. Arons stated that the program was working to consolidate the dispensing of ritonavir, available separately at no charge through the manufacturer's patient assistance program (PAP) when prescribed at 400 mg. per day or more, as when boosting tipranavir. Under an agreement between DOH and the manufacturer, ritonavir will be distributed along with other ADAP meds, and the Central Pharmacy supply will be replenished by the company. This will save patients from the additional burden of a separate PAP application, and potentially avoid suboptimal therapy if the drugs are not started together. An algorithm has been published based on national standards for how to use tipranavir, a very expensive protease inhibitor approved only for treatment of multi-drug resistant HIV, and information is being requested by Florida ADAP from providers to show that they are complying with that algorithm.

There was discussion regarding scheduling of the next workgroup meeting. Mr. May suggested that the group meet in October instead of November, as Dr. Arons may retire at some point in the near future. The dates of October 10th or 17th were agreed upon, and the program will give detailed notice prior to the meeting month. Dr. Arons thanked Tallahassee staff, committee members and guests, and adjourned the meeting at 3:00 p.m.