



Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary

AIDS Drug Assistance Program
Workgroup Meeting Minutes
October 17th, 2006

The meeting was called to order at 10:00 AM in Tampa, Florida. Present were: Linda Barnes, Susan Kramer, Joey Wynn, Jeff Beal, Michael Ruppal, Ken Barger, Jim Roth, Joe May, Paul Arons, Lorraine Wells, Stephanie Brown, Dena Hall, Allison Nist, Joseph Lennox-Smith, Don Kurtyka, Michael Ehren, Frank Didiano, Leslie Betts, Diana Travieso Palow and various interested parties.

Welcome/Introductions:

There were opening comments by Dr. Arons and then introductions were made around the room. Packet materials were reviewed and handed out by Dr. Arons. Workgroup minutes from the May 23, 2006 meeting were reviewed and approved.

Legislative Update:

Michael Ruppal of the AIDS Institute discussed legislative updates. The Ryan White HIV/AIDS Treatment Modernization Act was passed in the House on September 28th. Some felt that there was not adequate support for AIDS Drug Assistance Programs (ADAP) in legislation. The attempt to get changes passed in the Senate failed. Various problems that needed to be addressed include unrealistic funding levels and the increasing case load over the next five years. Without changes, the ADAP is looking at basically flat funding, with a small percentage increase that is not adequate to support the growing need. If the Senate approves the changes in the next session, then it would need to be approved by the House before going to the President for signing. If the bill is passed in its present form, there are negative implications for Florida as it relates to funding. Florida would lose about \$5.7 million for the first year under proposed funding methodology. Title I would possibly see what appears to be a small increase.

The Department has submitted legislative budget requests (LBRs) for the next Session. Mr. May stated an LBR for the AIDS Insurance Continuation Program has risen to the top of the planning process. A \$1.3 million figure is attached to LBR, but is still early in the planning process. A request for new ADAP funds is also in the works; approximately \$1.5 million was requested in additional ADAP funding at the state level. Linda Barnes discussed the continuation of Medicaid reform in Duval and Broward Counties. Contact Mike Ruppel for questions. (mruppel@theaidsinstitute.org)

Florida Patient Care Program Update:

Joe May, Program Administrator, discussed program updates, stating that ADAP county medication allocations are confirmed. Additional ADAP funds were provided from the legislature this year. An epidemiological component has been introduced into the allocation methodology, in addition to usage data. Furthermore, the number of living

HIV/AIDS cases was used. Some counties did get reductions in their allocations; however, every county received more than they used in the previous year for ADAP services. If there is an increase in demand, allocations can be adjusted to insure uniform access across the state. Mr. May also provided a Patient Care Eligibility rule update. The rule is nearly ready for promulgation. The Joint Administrative Procedures Committee, a state body that looks at technicalities of rules to make sure they are appropriate, had some concerns about the rule. These have been resolved, and the Department filed a second notice of technical changes in the Florida Administrative Weekly. We are looking at a possible late November implementation of the rule. There are plans to establish a schedule of three train-the-trainer sessions around the state to implement the rule. The rule will not change how the department conducts its business; it will merely streamline the process. If an Eligibility Determination is made, the financial/core component is valid for any program under the Patient Care umbrella. The rule will not affect everyone immediately, but as patients' eligibility needs to be re-determined, the new process will apply. Two eligibility components will change from the ADAP perspective. The asset limit will be changed to a standardized \$12,000 for all Patient Care programs, excluding a home and a car. This will be a reduction from the current \$25,000 cap the ADAP presently uses, but increases the asset limit for consortia, AICP, and HOPWA services. The financial eligibility will be capped at 300 percent of FPL for all programs governed by the rule. Patients over the caps will not be grandfathered into the program, but will be assessed on a case-by-case basis and gradually transitioned from the program. There will be detailed expectations of how the process will be handled so that patients can be assisted in locating other resources.

Since December 2005, 873 cases have been closed because of Medicare Part D benefits. The program has granted waiver for 151 clients who have standard Part D benefits as of October 9, 2006. Part D issues seem to have settled down for the moment. The ADAP Wrap Around Pilot Project (AWAPP) is up and running and the program is budgeted to serve up to 150 people next year. A question was raised about assisting patients in the ADAP and pay for therapy, rather than try to pay for benefits with limited AWAPP funds.

Concern was raised about the patients who will be losing dual eligible status in January 2007. The program is encouraging patients to apply for the low income subsidy (LIS) anyway. Ms. Barnes stated that Medicare and Medicaid dual eligibles are estimated at about 211,000 statewide. The majority are not HIV/AIDS patients, but the exact number is not available at this time. She noted that recipients who were automatically deemed eligible this year, will not be so next year. These persons will need to enroll for the LIS themselves. There will be a yearly enrollment process for the LIS. The LIS covers premiums and co-pays if the patient is 100% of the federal poverty level. The expectation is that patient's case managers would be assisting them with Part D/LIS enrollments.

Mr. May also indicated that ADAP now has an executed data sharing agreement with the Medicaid program to match with the ADAP database in an effort to eliminate duplicate files and correct inaccurate Social Security numbers. Ms. Wells indicated that this will help with quality assurance and unmet need estimation.

Lorraine Wells, ADAP director, provided a presentation on the direction of the ADAP. Prior to commencing, Ms. Wells asked each of the members to briefly describe something they would like to see changed, added, or removed from the ADAP. Responses included: quick program guide for patients, basic instructions only; program formulary to include drug treatment sections; reducing the frequency of lab reports for more stable patients; more anti-depressants on the formulary; something done about rural areas not being able to send in labs to ADAP; create mechanisms to inform external stakeholders of formulary updates (i.e. case management); more automated data collection and reduction of administrative burden; put ADAP formulary out on website. It was noted that the formulary is posted on the Department's website.

Ms. Wells stated, as she mentioned in the prior meeting, that she would assess the program and develop a plan. She noted that most of the assessment of the Program has been completed. She also has looked at what the stakeholders of the program needed. The mission of the program has been slightly modified as a result. ADAP is about disease management, adherence, clients, and holistic care. Ms. Wells also discussed the needed functions of the Program including quality assurance (QA), technical assistance (TA), and PDCA's (Plan, Do, Check, Act) in addition to quality improvement (QI). There also is a need to partner and create a relationship with county health departments to direct their efforts.

Major items to be addressed in the upcoming year involve six areas: improvement of overall services provided to ADAP clients, improvement of ADAP field processes, monitor and track appropriate use of drug allocation (linking drug cost to client usage), enhancement of utility for ADAP database, improvement of the enrollment of co-infected clients in hepatitis C program, review and monitor counties to enhance efficiency and effectiveness of program. Quarterly profile reports have been developed to provide snapshots of each county. Memoranda of Agreement will be used for shared understanding about the appropriate use of funds the program has provided to various counties. A new intranet site has been created to provide areas with quick access to program information. Asset and file attestation forms are a new requirement for corrective measures. Statewide quarterly conference calls are being conducted, and trainings are being held quarterly for new ADAP field staff. The ADAP Statewide Workshop Meeting will be held July 23-25, 2007 at the Rosen Center.

The ADAP Manual is currently undergoing revisions to address the programmatic portion of eligibility. The manual was sent to the workgroup for comments. The workgroup members were requested to return their comments by November 3, 2006. The program is trying to roll out the manual by 2007. Dr. Arons made it known that implementation of resistance testing will be required as apart of compliance with the Health and Human Services Guidelines. Persons initiating the antiretroviral (ARV) treatment for the first time who wish to enroll in the ADAP will be required to have resistance testing before ARV medications are provided. The program is working on the logistics of handling the testing component. There are some preliminary language issues regarding resistance testing in the medical eligibility portion of the manual. Regarding the hepatitis C statewide program, forms have been created and some items rewritten and the protocol is currently under review. ADAP is working to incorporate the Hepatitis C information in their application system. It was also noted that open enrollment for Medicare Part D begins November 15, 2006.

Central Pharmacy:

Dr. Arons, Bureau of HIV/AIDS Medical Director, provided the update on Central Pharmacy activities in the absence of Ms. Bennie Franks. Dr. Arons is retiring December 31, 2006. Jerry Hill resigned as Bureau Chief for the Central Pharmacy. Bennie Franks is managing the day-to-day operations of the Central Pharmacy. With regard to the drug pedigree plan, opponents were able to modify the process so that it ends at the wholesaler. Cardinal is the wholesaler for the Department.

Medicaid Update:

Linda Barnes of the Agency for Health Care Administration (AHCA) discussed Utilization Report. The numbers for the first quarter of 2006 did not appear to be correct, so they were recalculated. ARV therapy is estimated at about \$25 million per quarter. Medicaid has to pay back Part D a percentage of the total dollar amount for those patients who were dually eligible. This is known as the "clawback" requirement, and is roughly sixty to sixty-five percent of the cost. Medicaid reform is still going forward as pilot programs in Broward and Duval Counties. Counseling is set up to help patients choose plans that best suit their needs. Information is out on the website for viewing. Medicaid is still working to get a Prescribed Drug Services Handbook updated and published soon.

Medicaid is covering flu vaccines again this year for all recipients regardless of age except for those on Medicare. Enhanced benefits will go along with Medicaid reform. Patients can earn up to a certain amount of money in a special account for good behaviors, including timely refills, adherence, and disease management program participation.

Drug Update:

Dr. Arons discussed medication updates. Pregabalin and duloxetine have been under discussion as clinicians found it useful to treat HIV-associated neuropathy. After analyzing costs; duloxetine and pregabalin were twenty and sixteen times more expensive than generic gabapentin, which is currently on ADAP formulary. A motion was passed recommending that these two drugs be added to formulary and used for treating HIV neuropathy, with prior authorization based on the clinician certifying they previously tried gabapentin treatment.

Atripla was to be added after the last meeting if it was price neutral. Darunavir, after discussion was found to be in the middle of the range for protease inhibitors. Both drugs are now on formulary and in distribution.

Based on Health and Human Services revised treatment recommendations regarding hepatitis B medications, the ADAP has asked that patients not already on antiretroviral therapy present a hepatitis profile before initiating HAART treatment. Furthermore, providers will be asked to design regimens that cover both HIV and hepatitis B (e.g. tenofovir, emtricitabine, lamivudine) for HIV+ carriers of hepatitis B. Other medications specific to hepatitis B such as adefovir and entecavir will be available as backup for HIV patients who are also hepatitis B carriers if there is resistance, intolerance, or ineffectiveness related to the double-coverage drugs. With the

hepatitis C pilot program now statewide, hepatitis C medications will be published as part of the overall ADAP formulary, including a range of antidepressants for those patients on hepatitis C treatment only.

Dr Arons also reminded the group of the recent availability of deeply discounted generic medications through discounted retailers Wal-Mart, K-Mart and Target.

Next Proposed Scheduled Meeting:

There was discussion regarding the scheduling of next workgroup meeting. The first choice for the next meeting was June 19, 2007. If this date did not work for a majority of people June 12, 2007 was agreed upon as a replacement. Dr. Arons expressed his gratitude for everyone attending and adjourned the meeting.