MINUTES

HIV/AIDS MEDICAL ADVISORY COMMITTEE

Meeting Held on OCTOBER 17th, 2007 via Teleconference. Called to Order at 12:02 PM.

MAC VOTNG MEMBERS	Regional Participation	Attended	Absent
PHYSICIANS - 5		**5**	**2**
1. Jerry Cade, MD	**South - UMC**	**YES**	
2. Brian Onbirbak, MD	South - UMC	**YES**	
3. Gary Schroeder, MD	South - UMC	**YES**	
4. Dino Gonzales, MD	South – UMC / Community		**X**
5. Steven Zell, MD	Northern NV	**YES**	
6. Trudy Larson, MD	Northern NV	**YES**	
7. Steven Parker, MD	Community		**X**
NURSES - 2		**2**	**0**
8. Leslie Kellum-O'Brien, RN	South - UMC	**YES**	
9. Karen Redding, RN	North - HOPES	**YES**	
PHARMACISTS - 2		**3**	**1**
10. Anthony Soto, RPh	South - UMC	**YES**	
11. Diana Bond, Director	South - UMC		**X**
12. Dennis Fuller, PharmD, Chairperson	South - UMC	**YES**	
13. Sue Trimmer, RPh	North - HOPES	**YES**	
CORRECTIONS DEPT - 1		**0**	**1**
Miguel Forero (for Dr. Bannister)	North - Corrections		
14. Robert Bannister, MD	North - Corrections		**X**
(8) Simple Majority for Quorum - MET	**Voting Members Present**	**10**	
(14) Voting Members from Categories	**Voting Members Absent**		**4**

Dr. Jerry Cade came into the meeting after roll call. These Minutes were amended to show his attendance as per discussion at the meeting held 02/28/2008.

NON-VOTING ATTENDANCE	Participation	Attended
Marti Fricano, ADAP Coordinator	Communicable Disease Program	**YES**
Steve Dion, RWCA & HIV-Prevention	Communicable Disease Program	**YES**
Rebecca Huddleston, Recording Secretary	Communicable Disease Program	**YES**
Catherine G. Sterk, PharmD	Roche Laboratories	**YES**
Sedrick Spencer, State Government Affairs	Roche Laboratories	**YES**
Ann Glasser, Regional Accounts Manager	Agouron Pharmaceuticals, Inc	**YES**
Dana Pierce-Hedge, Manager, National Accts	Gilead Sciences, Inc.	**YES**
Beverly Schaefgen, HIV/AIDS Coordinator	Division of Healthcare Financing and Policy - Medicaid	**YES**
	Total # Non-Voting Persons Present =	**8**

Nikki Isaacs, Ryan White CARE Act Program, Coordinator, State of Nevada, was scheduled to present on several topics listed on the Agenda; she was absent from this meeting.

Agenda Item #1: * Approval of Minutes for the May 15th, 2007 Meeting.

ACTION on Agenda Item #1:
Motion to accept Minutes for the May 15th, 2007 meeting as written and presented was made by Dr. Onbirbak and seconded by Dr. Schroeder.
Motion carried unanimously.

DISCUSSION:

- Correcting a clerical error, Larry Pinson's name is to be moved from the voting member roster and placed on the guest roster, as voting members are those in direct care of HIV patients.

Agenda Item #5: * Report on Committee By-Laws as approved 12-05-2005. Discussion and possible recommendation regarding current membership and co-chairperson.

ACTION on Item #5: **Motion was made by Dr. Larson and seconded by Karen Redding to appoint Sue Trimmer as Vice Chairperson for the Medical Advisory Committee.**
Motion carried unanimously.

DISCUSSION:

- This item taken out of order as listed on the Agenda.
- Per discussions at the time the By-Laws were being drafted and approved, voting members of the Committee shall be healthcare professionals currently involved in direct care of HIV/AIDS patients and clients.

Agenda Item #2: Report on current caseloads/number of clients enrolled in ADAP (AIDS Drugs Assistance Program) and Policies and Procedures for ADAP.

ACTION on Item #2: **None, report only. Not an action item.**

ADAP Caseload Data as of: August, 2007
Total number of clients enrolled in ADAP: 767 (North-HOPES-181 / South-UMC-586)
New number of clients enrolled in ADAP: 18 (North-HOPES-10 / South-UMC-8)
Number of clients receiving medications: 461 (North-HOPES-105 / South-UMC-356)
Number of prescriptions filled: 1,255 (North-HOPES-281 / South-UMC-974)

Policies and Procedures for ADAP:

- Updated ADAP Policies and Procedures are expected to be completed soon.
- New eligibility requirements are listed on the ADAP formulary.

Agenda Item #3: Report on Pharmacy Benefit Manager / Medicare Part D / SPAP (State Pharmacy Assistance Program).

ACTION on Item #3:	**None, report only. Not an action item.**

DISCUSSION:

Catalyst (Pharmacy Benefits Manager)

- Overall, the transition to Catalyst (Pharmacy Benefits Manager) has been relatively smooth. Some current clients are not yet in the system due to the approximately two-week lag time, where all input ceased during the transition to Catalyst from September 6th, 2007 to the go-live start date of October 1st, 2007. Clients will now be added as they come into the system.
- The renewal mechanism in place within the Catalyst Rx system allows a client a full thirty days buffer before a lapse in eligibility were to occur. For example, if the expiration of benefits date were September 25th, the system would allow to November 1st before a lapse in eligibility would occur.
- To help expedite the eligibility process, healthcare providers are urged to refer first-time patients to the respective regional eligibility processing office, AFAN in the southern region and ACCESS in the northern. Applications received and processed at these locations must then be submitted to the State Health Division along with the required supporting documentation for review before the final approval is granted.
- State Health Division requests 72-hours, from receipt of a completed application with all the required supporting documentation, to process and input into Catalyst the client's information. Once the information is entered and submitted to Catalyst, the pharmacies have immediate access to that record and can then dispense the prescribed medications.
- Clarification was made as to procedure for client qualification through AFAN:
  1. Applicants are not required to have a prescription in-hand to apply for and qualify for Ryan White or ADAP; and
  2. Any qualified HIV-positive patient is eligible to receive whichever medications from the ADAP formulary are prescribed by the attending physician, regardless if that patient is currently on an antiretroviral or not.

Medicare Part D – Drug Assistance Programs

- Medicare Part D 'enhanced' drug assistance programs are no longer available.
- Sierra Rx offers a rate of approximately $22 per month per client for the basic plan, a savings of over $60 per month per client over the previous 'enhanced' plans.
- Though not yet confirmed, clients, or their sponsoring agency, may be expected to pay any difference over the allotted rate for Sierra Rx, should they choose coverage with other plans, such as Humana, for example.

State Pharmacy Assistance Program (SPAP)

- Effective January 1st, 2008, the State Pharmacy Assistance Program (SPAP) covers co-pays, deductibles, and coverage gaps for Medicare Part D enrolled members.
- This program, designed to supplant the enhanced plans of the past by helping to cover the 'donut hole' expenses, will be administered through the Director's Office of Health and Human Services.

- Pharmacy personnel request notice of billing codes for secondary insurance premiums in advance of the January 1st, 2008 effective date.

Agenda Item #4: * Report on Statewide Quality Management Team – MAC Representation. Discussion and possible recommendations.

ACTION on Item #4:	**None. Item postponed.**

DISCUSSION:

- Postponed. Nikki Isaacs, posted presenter, was absent from this meeting.

Agenda Item #5: Agenda Item #5, taken out of order, follows Item #1 and precedes Item #2.

Agenda Item #6: * Report on drugs approved for addition to the ADAP formulary. Discussion and possible recommendation regarding interim care for EAP (Early Access Program) patients.

ACTION on Item #6:	**Motion was made by Dr. Cade and seconded by Dr. Onbirbak that once a drug from an early access program has FDA approval, it be immediately added to the formulary, using PHS pricing if necessary prior to the drug's approval by NASTAD.** **Motion carried unanimously.**

DISCUSSION:

- Regarding FDA approval of Raltregravir announced on Friday, October 13th, 2007:
  - Once FDA approval is announced, there is a 30-day window of continued coverage by the pharmaceutical company for EAP patients on the medication.
  - A mechanism needs to be in place to make certain there is no interruption in patient care for Early Access Participation (EAP) patients currently on this medication.
  - It was suggested that no new patients, that is, no patient not currently enrolled and taking the medication as part of the EAP, be prescribed Raltregravir until it can be added to the ADAP formulary.
- Current procedure for adding medications to the ADAP formulary requires:
  - recommendation from this Committee;
  - approval of the recommendation by Health Division Administration;
  - approval of the drug by FDA; and
  - approval of the drug and its pricing for inclusion on all ADAP formularies nationwide by NASTAD, per their written notice, once their pricing negotiations are complete with the respective pharmaceutical companies.
- Precedence is in place where drugs which had been approved by FDA were prescribed and dispensed using PHS pricing prior to NASTAD having announced its negotiated price. Pharmacies were able to bill the drug companies to recover costs where the PHS pricing was higher than that negotiated with them by NASTAD.

- One member noted that, prior to Fuzeon®, any drug recommended by the Committee which had been available to patients through the EAP, was immediately added to the formulary once FDA approval was announced.
- Etravirine and Maraviroc have not been added to Nevada's formulary as notification from NASTAD has not been received. It was noted that other states have added it to theirs. ADAP personnel will follow-up on this with NASTAD.
- One Committee member requested that it be clearly stated so they know who is responsible for disapproving any of the Committee's recommendations, not just referring to 'Health Administration' in general, but for the Committee to know a specific name of that person or persons.

Agenda Item #7: * Report from the ad-hoc subcommittee to examine and revamp the miscellaneous list on the formulary into a category of HIV-associated conditions requiring treatment and for medications to be removed, to include discussion and possible recommendations.

ACTION on Item #7:	**None. Item tabled for future consideration and recommendations.**

DISCUSSION:

- See the attached copy of the proposed 3-Tier System to organizing medications on the formulary: Tier 1 are HIV specific; Tier 2 as standard of care and for treating side effects to those in Tier 1; and Tier 3 for helping the patients in other areas.
- Benefits to this 3-Tier System include:
  - Organizing the format in a more user-friendly manner;
  - Identify the purpose and use for adding future medications;
  - Providing the structure for the possible need to trim certain medications from the formulary, starting from Tier 3, working up through the tiers.
- Committee members were asked to review the list, sending the Chairperson any changes or recommendations before the next meeting, asking that they note any corrections, additions, or a different view on the placement of a particular drug, etc., stating that he would forward the changes on this proposed tier system to the recording secretary, moving the proposal forward for consideration at the next meeting.

  (Note: While this item was not noted as missing from the proposed agenda for the February 2008 meeting, as forwarded for approval to the Chairperson and Vice-Chair, the recording secretary apologizes for not including this item on that proposed agenda.)

Agenda Item #8: * Discussion and possible recommendations regarding Fuzeon protocol for policy development.

ACTION on Item #8: **Motion was made by Dr. Onbirbak and seconded by Sue Trimmer to discontinue altogether the use of the Health Division Administration requirement to submit the forms "Nevada ADAP Fuzeon® (Enfuvirtide/T-20) Guidelines with its attached Patient Worksheet and Patient Approval Form" in order to prescribe Fuzeon® for HIV/AIDS patients.**

Motion carried unanimously.

Second ACTION on Item #8: **Motion was made by Dr. Onbirbak and seconded by Sue Trimmer that, in the event the motion to totally remove the additional protocol as noted above were not accepted, it be suspended until such time as the patient caseload exceeds ten (10).**

Motion carried unanimously.

DISCUSSION:

- The additional protocol which had been instituted by Health Division Administration prior to prescribing Fuzeon® for a patient requires submission of the three-page document: "Nevada ADAP Fuzeon® (Enfuvirtide/T-20) Guidelines with its attached Patient Worksheet and Patient Approval Form."
- While this policy or protocol was originally instituted by Health Division Administration to monitor the fiscal impact on ADAP resources for the use of Fuzeon®, only about four (4) patients statewide currently use Fuzeon®.
- ADAP personnel would notify the pharmacies and Committee members at the time the caseload were to exceed ten (10) patients statewide.

Agenda Item #9: * Scheduling of next meeting.

ACTION on Item #9: None.

DISCUSSION:

- No date was agreed upon, though either mid to late February was considered.
- Chairperson will send an email to all members and to the Recording Secretary proposing three choices for the next meeting date.

Agenda Item #10: Public comment (no action may be taken).

ACTION on Item #10: None, not an action item.

DISCUSSION:

- None. No members of the public were present or opted to make comment.

Agenda Item #11: * Adjournment.

ACTION on Item #11: Motion was made to adjourn the meeting by Dr. Larson and seconded by Karen Redding.

Motion carried unanimously.

DISCUSSION: None.

Meeting is adjourned at 1:06 P.M.

ADDENDUM 1 OF 1: Referencing *Agenda Item #6: * Report on drugs approved for addition to the ADAP formulary. Discussion and possible recommendation regarding interim care for EAP (Early Access Program) patients.*

"DISCUSSION:

- *Current procedure for adding medications to the ADAP formulary requires:*
  - *recommendation from this Committee;*
  - *approval of the recommendation by Health Division Administration;*
  - *approval of the drug by FDA; and*
  - *approval of the drug and its pricing for inclusion on all ADAP formularies nationwide by NASTAD, per their written notice, once their pricing negotiations are complete with the respective pharmaceutical companies."*