

**HIV/AIDS MEDICAL ADVISORY COMMITTEE MEETING
MINUTES
September 22, 2011
12:00 PM**

MEETING LOCATIONS

Nevada State Health Division

4150 Technology Way
Conference Room #301
Carson City, NV 89706
775-684-4285

Northern Nevada HOPES

467 Ralston Street
Conference Room
Reno, NV 89503
775-348-2893

University Medical Center of Southern Nevada (UMC) - Wellness Center

Offices of Nevada AIDS Research and Education Society (NARES)
701 Shadow Lane, Suite 200
Las Vegas, NV 89106
702-383-2691 or 702-384-9101

CALL IN NUMBER: Toll Free: 1-888-363-4735 Conference Code: 6540475

NOTE: SOME COMMITTEE MEMBERS MAY ATTEND FROM ANY OF THE THREE LOCATIONS OR
FROM OTHER SITES VIA TELECONFERENCE

AGENDA ITEMS MAY BE TAKEN OUT OF ORDER, COMBINED FOR CONSIDERATION, AND/OR
REMOVED FROM THE AGENDA AT THE CHAIRPERSON'S DISCRETION

COMMITTEE MEMBERS PRESENT:

Dennis Fuller, PharmD, Committee Chair, HIV/AIDS Clinical Pharmacy Specialist, University Medical Center of Southern Nevada (UMC) Wellness Center and Nevada AIDS Research and Education Society (NARES)
Sue Trimmer, RPh, Committee Vice-Chair, Chief Pharmacist, Northern Nevada HIV Outpatient Program, Education and Services (HOPES)
Diana Bond, RPh, Director, UMC
Dino Gonzales, MD, UMC Wellness Center
Leslie Kellum O'Brien, RN, Ambulatory Care Manager, UMC
Anthony Soto, BPharm, Ambulatory Pharmacy Services Supervisor, UMC
Steven Zell, MD, HOPES
Jerry Cade, MD, UMC and Southwest Medical Associates, Inc (SMA)

COMMITTEE MEMBERS NOT PRESENT:

Steven Parker, MD, Sierra Infectious Disease Specialists
Trudy Larson, MD, University of Nevada-Reno (UNR), School of Medicine and HOPES

HEALTH DIVISION STAFF PRESENT:

Marti Fricano, AIDS Drug Assistance Program (ADAP) Coordinator, Ryan White CARE Act Part B Program (RWPB), Bureau of Child, Family and Community Wellness (BCFCW)
Steve Dion, Data Management Coordinator, RWPB, BCFCW
Rob Langguth, Management Analyst, Quality Management Coordinator, RWPB, BCFCW

Rebecca Huddleston, Administrative Assistant, RWPB, BCFCW

OTHERS PRESENT:

Jason Smith, Therapeutics Specialist, Gilead Sciences

Stuart Pappas, Rebates Member Manager, Janssen/Tibotec

Michelle Cho, Science and Research Liaison, Janssen/Tibotec

Sarita Bewan, Access to Healthcare Network (AHN)

Dr. Charles Krasner, Northern Nevada HOPES

Miguel Forero, Disease Control Specialist, Nevada Department of Corrections (DOC), Proxy for R.B.

Bannister, DO, Medical Director

1. Welcome and Introductions

Dr. Dennis Fuller called to order the HIV/AIDS Medical Advisory Committee (MAC) meeting at **12:10 PM**, held via teleconference from Nevada State Health Division (NSHD) in Carson City, University Medical Center of Southern Nevada (UMC) Wellness Center, Nevada AIDS Research and Education Society (NARES) Office in Las Vegas, and at Northern Nevada HIV Outpatient Program, Education and Services (HOPES) in Reno. This was a public meeting where the public was invited to make comments. In accordance with the Nevada Open Meeting Law (OML), this meeting's agenda was posted at the following locations: NSHD, Elko County Library, Northern Nevada HOPES, UMC Wellness Center, Nevada State Library and Archives, and on the NSHD website at <http://health.nv.gov>.

Rebecca Huddleston called roll and stated a quorum had been met.

2. Approval of October 13, 2010 Minutes

Dr. Fuller asked for any discussion on the minutes for approval from the previous meeting held on October 13, 2010. Rebecca Huddleston noted one change to be made in the heading. No public comment.

MOTION: Sue Trimmer moved to accept the minutes as presented with the one correction.

SECOND: Leslie Kellum O'Brien

PASSED: Unanimously

3. Reports (Informational)

Updates on Ryan White Part B Program and the AIDS Drug Assistance Program (ADAP).

Ryan White Part B (RWPB) Program Manager; Martha Fricano, RWPB Eligibility and ADAP Coordinator; and Steve Dion, RWPB Research, Development, and Data Coordinator

Rob Langguth reported the AIDS Education and Training Center (AETC) staff at University of Nevada-Reno (UNR), under the direction of Dr. Patty Charles, is updating the Statewide Coordinated Statement of Need (SCSN) and Comprehensive Care Plan (CCP) for Nevada. Both reports are due to the Health Resources and Services Administration (HRSA) by mid June, 2012. AETC staff may be contacting members of this Committee for their input and expertise. These documents should be useful to all clinics, programs and agencies as they strive to identify performance standards, seek funding, and provide rationale for new programs and projects. Ms. Kellum O'Brien asked to be contacted; UMC Wellness Center gets Part C funding. Meetings will be held in Carson City and Reno, then in Las Vegas.

Steve Dion referenced the summaries included in the meeting packet, noting a little over \$7,000,000 expended to date for AIDS Drug Assistance Program (ADAP), about \$433,000 for Continuation of Benefits Program (COB), and \$527,000 for State Pharmacy Assistance Program (SPAP). Dr. Fuller asked if there are any concerns about funding at this time or anticipated. Mr. Dion stated there are none; the rebates coming in have helped tremendously. There is no anticipated wait list required for the next two years, barring any drastic changes. RWPB staff is currently working to identify options for any surplus rebate monies across fiscal years.

Program	Enrolled	Active	Utilization	Est. \$ to Date
ADAP- AIDS Drug Assistance Program	791	597	75.6%	\$7,087,685
COB – Continuation of Benefits	164	111	67.7%	\$432,604
SPAP- State Pharmacy Assistance Program	298	124	52.7%	\$527,003

Ms. Huddleston reported that Beth Handler, former RWPB Program Manager, has taken another position within the Health Division. Ms. Handler is available to the Program as Acting Program Manager until the position is filled.

There was no public comment.

Items #6 and #5 were taken out of order.

6. Discussion and possible recommendations regarding revising the Committee By-Laws for Committee membership.

Sue Trimmer, RPh, Co-Chair, Chief Pharmacist, Northern Nevada HIV Outpatient Program Education Services (HOPES)

At the time of the previous MAC meeting, the Request for Proposal (RFP) process for the ADAP pharmacy providers was in effect with the State. Depending on which pharmacies won the contracts, the membership on this Committee could be affected. With this in mind, the suggested revisions have been made to make the wording more encompassing and generic, using 'designated ADAP pharmacies'. Also related to changes related to the RFP process, HOPES is no longer under contract to fill gate meds for Nevada Department of Corrections (NDOC); inmates are now released with a 2-week supply of HIV medications, then ADAP kicks in. Since that relationship is severed with NDOC, she suggested moving NDOC from a voting member position to that of ex-officio standing along with Ryan White Program and Health Division staff; Miguel Forero agreed. Dr. Fuller conveyed his concern about taking a vote regarding the ADAP formulary that might affect them without some representation from NDOC, requesting they be kept in the loop for information purposes. Committee members will continue to be selected by the respective agency as listed in the By-Laws. Another proposed change with respect to the duties of the Chairperson or Acting-Chairperson where no vote would be cast by that position unless and only in the event of a tie vote. Dr. Fuller stated this has been his own practice and would have no problem with making it official. Ms. Trimmer noted other spelling, grammatical, and formatting corrections had been made to this draft without changing the content or intent.

No public comment.

MOTION: Ms. Trimmer moved the By-Laws be accepted as presented with the noted changes (reference Section IV – Members and Section VI – Officers.)

SECOND: Diana Bond

PASSED: Unanimously

5. Discussion and possible recommendations to appoint one (1) new Committee member to the position vacated by Dr. Gary Schroeder, one of two (2) voting members in the physicians from UMC Medical Center/Wellness Center category.

Dr. Fuller, Chairperson

Dr. Fuller stated that given the outcome of Item #6 above, this agenda item is moot.

No public comment.

4. Discussion and possible recommendations to add the following medications to the ADAP formulary: [A] Alinia (nitazoxanide); [B] Gilead's "QUAD" [elvitegravir, GS9350 (cobicistat), and Truvada® (emtricitabine and tenofovir disoproxil fumarate); [C] Complera (emtricitabine, rilpivirine, and tenofovir disoproxil fumarate); and [D] Endurant (rilpivirine), given the standing requirements that each is FDA approved and NASTAD has negotiated and published approved ADAP pricing prior to being added to the ADAP formulary.

Dr. Fuller, Chairperson

Dr. Fuller noted the three drugs already approved by the Federal Drug Administration (FDA) and pricing negotiated by the National Alliance of State and Territorial AIDS Directors (NASTAD) be considered separately from the QUAD from Gilead. Nitazoxanide (Alinia) is used for patients having trouble with is also used to treat diarrhea caused by the protozoa *Cryptosporidium parvum*; several patients have needed it this year. Concern was expressed about not getting the drugs on the ADAP formulary more quickly, that waiting on the Committee to meet before these HIV medications can be added jeopardizes the treatment outcome for ADAP patients. Dr. Jerry Cade believes they all want the drugs on the formulary immediately once approved; being anxious about how patient treatment is affected. Complera, for instance, is safe for use in pregnancy. Medical science pushes harder now for starting hard therapy sooner. Ms. Trimmer noted the delay also affects the co-pays for COB and SPAP patients; the delay also causes extra work for the ADAP pharmacies. Martha Fricano noted other aspects of the NASTAD drug pricing negotiation process. The process went smoothly for Endurant. With no cost breaks offered by Gilead Sciences, Inc for Complera, NASTAD did accept the cost-neutral pricing offered for ADAP formularies, with reservations to re-negotiate the pricing structure. It is their concern this situation could set precedence for other pharmaceutical companies in negotiating ADAP pricing, adversely affecting all ADAPs.

No public comment.

MOTION: Dr. Cade moved to add the three medications already approved and having NASTAD pricing to the ADAP formulary: Alinia (Nitazoxanide); Complera (emtricitabine, rilpivirine, and tenofovir disoproxil fumarate); and Endurant (rilpivirine).

SECOND: Dr. Dino Gonzalez

PASSED: Unanimously

MOTION: Dr. Cade moved to add Gilead's "QUAD" [elvitegravir, GS9350 (cobicistat), and Truvada® (emtricitabine and tenofovir disoproxil fumarate)] to the ADAP formulary upon FDA approval and NASTAD pricing is negotiated.

SECOND: Ms. Bond

PASSED: Unanimously

7. Schedule next meeting and recommendations for agenda items.

Dr. Fuller, Chairperson

Given the question regarding adding HIV medications to the ADAP formulary immediately once approved by FDA and NASTAD has come up again, Dr. Fuller stated this issue needs to be addressed and decided once and for all, as soon as possible; mid-January was cited as the next best opportunity to meet. The recording secretary will email possible dates out to the Committee. Discussion included adding other medications, listed below, to the formulary for treatment of opportunistic infections and related conditions in ADAP patients. Dr. Fuller will forward the forms for the listed medications.

Proposed Agenda Item #1: HIV Drugs on the ADAP Formulary

The procedure regarding HIV-specific medications to be re-instated by Health Division's Administration for HIV-specific medications to be added to the ADAP formulary where the drug is a combination drug therapy and is expected to be cost neutral; the drug is a replacement/alternative of an existing drug on the formulary; or the new HIV-specific drug does not combine or replace existing drugs and is not more than maybe +10% above the cost of our most expensive drugs on the formulary. The MAC would still meet to consider and recommend drugs that are not HIV-specific, such as those for opportunistic infections; to consider and recommend removal of drugs from the formulary; or to consider and recommend HIV drugs that are expected to have greater than an estimated +10% cost impact to ADAP.

Proposed Agenda Item #2: Additions of medications to the ADAP Formulary

The following medications are to be considered and recommended for addition to the ADAP formulary: Cobicistat; Scopalamine patch; Moxifloxacin; and Posaconazole.

No public comment.

8. Public Comment

Dr. Charles Krasner stated he would like to be considered for membership on this Committee. Ms Trimmer noted this would be discussed at HOPES.

9. Adjournment at 12:52 PM

Dr. Fuller, Chairperson