

**HIV/AIDS MEDICAL ADVISORY COMMITTEE (MAC) MEETING
MINUTES
JULY 29, 2013
12:00 PM**

Nevada Division of Public and Behavioral Health
4150 Technology Way, Room #153
Carson City, NV 89706

University Medical Center of Southern Nevada (UMC) -
Wellness Center
Nevada AIDS Research and Education Society (NARES)
701 Shadow Lane, Suite 200
Las Vegas, NV 89106

COMMITTEE MEMBERS PRESENT:

Dennis K. Fuller, Committee Chairperson, PharmD, University Medical Center of Southern Nevada (UMC) Wellness Center
Alireza Farabi, MD, UMC Wellness Center
Anthony Soto, BPharm, UMC Pharmacy Services
Charles Krasner, MD, Northern Nevada HIV Outpatient Program, Education and Services (HOPES)
Jerry L. Cade, MD, UMC Wellness Center and Southwest Medical Associates, Inc. (SMA)
Mary Staples, PharmD, Assistant Director, UMC Pharmacy Services
Paul McHugh, MD, UMC Wellness Center
Steven Zell, MD, University of Nevada – Reno (UNR)
Trudy A. Larson, MD, University of Nevada School of Medicine (UNSONM) and HOPES
Vicki A. Koceja, RN-BC, OCN, MBA, FAAMA, PhD, Outpatient/Ambulatory Clinical Manager, UMC Medical Center Ambulatory Division
Gail Thompson, RN – HOPES – Proxy for Ivy Spadone, HOPES

COMMITTEE MEMBERS ABSENT:

Sue Trimmer, RPh, Committee Vice-Chairperson, Chief Pharmacist, HOPES
Dino Gonzales, MD, Community Physician – Southern Region
Ivy Spadone, PA-C, HOPES
Kevin Prince, MD, UMC Wellness Center
Meddie Nazifir, PharmD, MBA, Director, UMC Pharmacy Services
Steven Parker, MD, Sierra Infectious Disease Specialists, Community Physician – Northern & Rural Region

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH STAFF PRESENT:

Dan Olsen, MPH, HIV/AIDS Section Manager, Ryan White HIV/AIDS Part B Program (RWPB), Bureau of Child, Family and Community Wellness (BCFCW)
Lyell Collins, MBA, PhD-C, Nevada HIV Prevention Program Manager, BCFCW
Barbara Weisenthal, Fiscal and Grant Management, RWPB, BCFCW
Steve Dion, Research, Development, and Data Coordinator, RWPB, BCFCW
Martha Fricano, RWPB Eligibility Coordinator, RWPB, BCFCW
Tami Smith, Office Manager, BCFCW
April Romo, Administrative Assistant, HIV/AIDS Section, BCFCW
Rebecca Huddleston, Administrative Assistant, RWPB, BCFCW

OTHERS PRESENT:

Antioco Carrillo, Executive Director, Aid to AIDS of Nevada (AFAN)
Charlie Collins, Manager, National Accounts, Gilead Sciences
Debbie Criswell, Merck & Co., Inc.
Debbie Malenke, Merck & Co., Inc.
Frances Ashley, HIV/AIDS Program, Carson City Health and Human Services (CCHHS)
Renee' Tanner, Catamaran Rx
Scott Burns, Pharmaceutical Representative, Merck & Co., Inc.

Wayne Young, Rebuilding All Goals Efficiently, Inc. (RAGE)
Virginia Johnson, Community Counseling Center of Southern Nevada (CCC)
Yvonne Curtis, Governmental Grants Specialist, Access to Healthcare Network, Inc. (AHN)

Dr. Dennis Fuller called the meeting to order at **12:08 pm**. This meeting was properly posted in accordance with the Nevada Open Meeting Law (NOML).

1. ROLL CALL AND INTRODUCTIONS

Introductions were made and a quorum was established.

2. VOTE ON MINUTES FROM THE JANUARY 12, 2012 HIV/AIDS MEDICAL ADVISORY COMMITTEE (MAC) MEETING

Dr. Fuller called for any discussion or comments regarding the minutes from January 12, 2012.

MOTION: Dr. Trudy Larson moved to accept the minutes as presented

SECOND: Dr. Charles Krasner

PASSED: UNANIMOUSLY

3. UPDATES AND REQUESTS FROM PREVIOUS MAC MEETINGS

There were none

4. STAFF REPORTS

A. Ryan White HIV/AIDS Part B (RWPB) program and the AIDS Drug Assistance Program (ADAP)
Steve Dion reported the drug costs over the past year were \$8,700,000 for the ADAP; \$500,000 for the Continuation of Benefits (COB) program; and \$590,000 for the State Pharmacy Assistance Program (SPAP). He noted the use of Stribild had influenced the increase in ADAP costs. Spending in COB increased due to adding former Ryan White HIV/AIDS Part A (RWPA) program clients. The increase in client caseloads for SPAP is good news as it lowers the costs to ADAP. There were 1,260 unduplicated clients getting drugs, an increase over the last quarter. It is expected things will change January 1, 2014 when the Affordable Care Act (ACA) goes into effect.

Mr. Dion reported the use of generic drugs, which saves only 10-15% at the time it is dispensed greatly impacts the potential rebates available for the RWPB program. The pharmaceutical companies may lower or drop partial pay rebates, which traditionally give the program the greatest yield. A rebate-rich example: Efavirenz (Sustiva™) DuPont (ARV - NNRTI); even though the generic Efavirenz is available at a reduced price, using the brand name Sustiva had a much greater return to ADAP in terms of the rebates received from Bristol Myers Squibb. Dr. Fuller noted the bottom line is ADAP money goes farther if the doctors prescribe and use brand name drugs instead of generics. Anthony Soto commented buyers and prescribers can use either brand names or generics. Writing prescriptions for name brands when generics are available may be a problem with COB and SPAP as the RWPB ADAP is not the first payor. As a cautionary note, Dr. Larson stated required use of generics by some insurance providers may cause problems for clients and impact adherence.

Most pharmaceutical companies have their own respective Patient Assistance Program (PAP), though there is a universal form available on the HIV/AIDS webpage under the Division site. Prior authorization is currently a non-issue as there is no alternative to Stribild. Mary Staples requested a list of which drugs offered the most rebate potential; Mr. Dion will send a list to her and to the ADAP pharmacists.

B. Impact on ADAP

Dan Olsen stated Mr. Dion had covered the benefits to ADAP/RWPB regarding the use of branded medication versus its generic counterpart in terms of the rebate potential.

The transition of the RWPB clients is a concern for staff with up to half of the client base moving to Medicaid and 15-16% going to the marketplace. As ADAP transitions to the marketplace, Mr. Olsen expects to see a shift from

the current focus on ADAP medications to health insurance monitoring. RWPB/ADAP remains the payor of last resort. Mr. Olsen still has to meet with Medicaid to bridge the RWPB clients into the program; addressing such questions as co-pays. He expects direction from the Health Resources and Services Administration (HRSA) on this transition period and how the funding will change as a result of the transition.

A media surge of insurance companies advertising for their market share could cause confusion for RWPB clients. To assist with this, plans include town hall meetings and coordinating efforts with other bureaus for resources. Nevada's Silver State Health Insurance Exchange (SSHIX) funded non-profit agencies to serve as navigators, enrollment assisters, and certified application counselors statewide. The program plans a combined effort in using these providers and subgrantees as resource portals, tapping into existing networks, for transitioning RWPB clients into the marketplace. There is a great need to educate the clients, insuring each one has the best possible options for their circumstances. There is a challenge in preparing our clients for October 1, 2013 as the insurance plans are not complete causing some struggle in implementing the transition. Mr. Olsen reminded the Committee not all RWPB services are covered in the ACA plans; we still need to budget accordingly to help keep services in place.

C. Resource allocation and budget projection

Barbara Weisenthal explained the ADAP earmark amount is set by HRSA which includes the 2.5% sequestration reduction applied to all portions of the grant award. Funding is down over the past two years and the costs of medications fluctuate. Rebates are not paid up front; they are billed quarterly, and paid at the back end after medication charges have been paid to Catamaran Rx. The program must budget according to the expected expenditures for the medications regardless of the possible rebates. HRSA has allowed flexibility in the use of rebate funds and suggested enhancing existing services. The program is currently working these funds into a spend plan for support services not yet offered. The cost of medications must first have funding from the grant award regardless of any expected rebate. Over the last three months ADAP costs alone have averaged \$825,211; an increase of \$191,000/month over the previous average of \$633,922.08/month. If the current trend continues, the program will just break even by March 31, 2014 even with rebates.

Regarding additions to the ADAP formulary, it was noted with the new drugs and a priority to have no waiting list, a plan needs to be in place to reduce costs. The recent increase in the use of Stribild had caused increases in the budget. Dr. Krasner offered his opinion regarding spending more for a medication to be taken once a day rather than one taken twice a day for the sake of convenience may need to have pre-authorization. Dr. Larson shared previous use of pre-authorization with fuzeon kept costs down. Ms. Weisenthal stated pre-authorization could be a budget issue and should be addressed before approval.

D. AB251 - Public contact information for committees & boards

Mr. Olsen stated the program is required to address Assembly Bill 251 (AB251), which requires disclosure of full work-related contact information for all members of Nevada committees and boards. The information currently on the website is generic. Dr. Larson thought this applied to providing information only upon request. Mr. Olsen will follow-up on this clarification. Until clarified, Rebecca Huddleston will email current contact information on record to MAC members. Members are asked to verify the information, making changes as needed.

5. DISCUSSION AND POSSIBLE RECOMMENDATIONS TO ADD THE FOLLOWING MEDICATIONS TO THE ADAP FORMULARY; AND UPDATE PROTOCOLS AND ADD DISCLAIMERS

Mr. Olsen stated the program is in process of updating protocols covered in the policies and procedures section of the bylaws. He suggested a disclaimer to be added to the ADAP formulary: use of a generic drug is always an alternative to the branded counterpart giving physicians & practitioners the option to use generics as they become available; keeping in mind the possible impact on ADAP regarding rebate funds.

Dr. Larson had submitted the required requests for addition/deletion to the ADAP formulary forms. Dr. Larson reported it is the general recommendation for all HIV positive persons to have the Hepatitis vaccines, as needed. Lyell Collins mentioned Southern Nevada Health District (SNHD) gets free vaccines from the state immunization

program. HIV positive patients can go there for free vaccines. Dr. Larson noted Washoe County had some monies set aside specifically for these vaccines. She stated it becomes a medical adherence issue if the clients cannot get the vaccines at the time of their scheduled clinic visits. The question was raised as to how the clinics in southern Nevada are currently paying for vaccines. The clinics pay for the vaccines from revenues with pricing through 340B Outpatient or Wholesaler Average Cost (WAC) accounts; they do get some vaccines from the State Immunization Program.

Martha Fricano reminded the Committee ADAP is payor of last resort and all medications, including vaccines, must be prescribed and run through the Catamaran Rx system as with all drugs on the ADAP formulary. If there are free vaccines available those would have to be used first. Ms. Staples noted it would be incumbent upon the nurses to evaluate the patient needs and to verify the pay source at the time of administering the vaccines.

Discussion followed regarding meeting to work out a process for dispensing and administering the vaccines in all regions of the state, including the documentation that funding is used only for RWPB eligible clients. The Committee was reminded any subcommittee must also observe the OML in planning, posting, and carrying out that meeting.

MOTION: Anthony Soto moved to accept the five hepatitis vaccines listed below as part of the ADAP formulary; working out the details on dispensing and identifying RWPB eligibility for clients receiving these at a later date

- Monovalent Hepatitis A Vaccine [HAVRIX (GlaxoSmithKline (GSK))]
- Monovalent Hepatitis A Vaccine [VAQTA (Merck)]
- Monovalent Hepatitis B Vaccine [ENGERIX-B (GSK)]
- Monovalent Hepatitis B Vaccine [RECOMBIVAX-HB (Merck)]
- Bivalent (Combination) Hepatitis A and Hepatitis B Vaccine (TWINRIX (GSK))

SECOND: Dr. Larson

PASSED: UNANIMOUSLY

In discussion regarding Fulyzaq (crofelemer), Dr. Fuller noted no prescriptions had been written for this so far; it may have been the best drug for these symptoms years ago. Dr. Fuller noted the price at \$300/60 count bottle may not be the most economical use of funds since there are other medications already available for these symptoms.

MOTION: Dr. Larson moved not to accept Fulyzaq for addition to the ADAP formulary at this time

SECOND: Dr. Steven Zell

PASSED: UNANIMOUSLY

In discussion regarding the two new antiretroviral (ARV) medications, S/GSK1349572 (dolutegravir, DTG) (ARV) and Tri-572 with HIV RNA, DTG combination dosage, Dr. Fuller noted clinical trials for S/GSK1349572 (dolutegravir, DTG) (ARV) had been very effective and it is due to receive the Federal Drug Administration's (FDA) approval in August 2013. This drug requires no booster like other combination therapies; it is a second generation combination which is better and stronger. There is no published pricing information for either drug yet, but it is expected the Tri-572 with HIV RNA, DTG combination dosage, due out in February 2014, will be cost neutral in that its' use will replace other drugs currently on the formulary.

MOTION: Dr. Larson moved to accept both S/GSK1349572 (dolutegravir, DTG) (ARV) and Tri-572 with HIV RNA, DTG combination dosage for addition to the ADAP formulary

SECOND: Dr. Jerry Cade

PASSED: UNANIMOUSLY

6. DISCUSSION AND POSSIBLE RECOMMENDATIONS TO REVISE THE CURRENT MAC BYLAWS TO REFLECT AND INCLUDE UPDATES AND PROCEDURAL CHANGES

Mr. Olsen noted the majority of the changes are findings from HRSA specific to MAC; to include possible changes and/or amendments to the MAC bylaws regarding [a] adding a policies and procedures section; and [b] to amend the membership section.

Dr. Fuller asked if there are members of the community available to fill the new category for one nurse or physician's assistant in both the south and the north. He will pursue candidates for these and other open positions. Dr. Larson noted it appears HRSA is looking to have more of a community presence on the Committee.

MOTION: Dr. Larson moved to accept the amended bylaws as presented

SECOND: Dr. Paul McHugh

PASSED: UNANIMOUSLY

7. DISCUSSION AND POSSIBLE RECOMMENDATIONS TO APPROVE NEW MEMBERS TO MAC

Dr. Fuller opened the floor for discussion, requesting any other nominations. Total membership is twelve counting the representation per category; a simple majority is seven.

A. A minimum of one (1) to the position vacated in the physicians' category at UMC Wellness Center
Nominees are Dr. Alireza Farabi, Dr. Kevin Prince, and Dr. Paul McHugh

MOTION: Dr. Cade moved to accept Dr. Farabi

SECOND: Dr. Larson

PASSED: UNANIMOUSLY

B. A minimum of one (1) as community physician from the southern communities
Nominees are Dr. Dino Gonzalez and Dr. Rubin Saavedra

MOTION: Dr. Larson moved to accept Dr. Gonzalez

SECOND: Dr. Cade

PASSED: UNANIMOUSLY

C. A minimum of one (1) to the position vacated in the nurse or physician's assistant category at UMC Wellness Center. Nominee is Dr. Vicki Koceja

MOTION: Dr. Cade moved to accept Dr. Koceja

SECOND: Dr. Larson

PASSED: UNANIMOUSLY

8. DISCUSSION AND POSSIBLE RECOMMENDATIONS IN RESPONSE TO THE HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA) MAC FINDINGS FROM THE RWPB COMPREHENSIVE SITE VISIT OF MARCH 12-14, 2013

Mr. Olsen read through each section, allowing for discussion or comment.

- A. Process for formulary recommendations
- B. Formulary plan for adding non-antiretroviral medications
- C. Bylaws – membership term limits
- D. Bylaws – member recruitment and selection
- E. Formulary medication review process established as part of BCFCW policies and procedures
- F. Suggest adding two consumer members, one from south and one from north

Items A – E were covered with the newly approved bylaws. It was agreed adding non-ARV medications for mental health to the ADAP formulary requires further research regarding which drugs would be appropriate, the

costs and how to control them. If added to the membership, the proposed community members would be counted in the quorum of the Committee.

MOTION: Dr. Larson moved to table adding mental health drugs to the ADAP formulary and Item F regarding adding consumers to the membership for consideration as action items at the next MAC meeting

SECOND: Dr. Farabi

PASSED: UNANIMOUSLY

9. DISCUSS AND RECOMMEND NEXT MEETING DATE(S) AND AGENDA ITEMS

Dr. Fuller suggested October for the next meeting. He will send a list of possible dates to Ms. Huddleston.

Mr. Olsen stated he would like to see the Committee meet at least twice a year, especially with all the changes in play to make certain the program had the Committee's input.

Agenda items for consideration at the next regular meeting include the following:

- Addition of psychotropic medications to the ADAP formulary per HRSA's recommendation
- Possible addition of consumers to the MAC membership
- RE AB251: Verification of disclosure of full work-related contact information for all MAC members
- Possible candidates for the community nurses or physician's assistants category of MAC's membership
- HEP vaccines - details on dispensing and identifying RWPB eligibility for clients receiving these
- Corrections/updates to the formulary
- Discuss possible classification of non-ARV medications on the formulary
- Possible deletion of medications from the formulary

10. PUBLIC COMMENT

No public comment

11. ADJOURNMENT

The meeting was adjourned at **1:39 pm**