

VIRGINIA DEPARTMENT OF HEALTH ADAP ADVISORY COMMITTEE (AAC) MEETING – 5/24/2023

| NAME | ORGANIZATION | IN-PERSON | ZOOM | ABSENT |
|---|--|--------------------------|-------------------------------------|-------------------------------------|
| Kathleen A. McManus, MD, MSCR | UVA Health System, ID Fellow Program | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Robert Higginson, PA | VCU Medical Center Infectious Disease Clinic | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Daniel Nixon, DO, PhD | VCU HIV/AIDS Center | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Sarah West, MD | Infectious Disease Associates of Central Virginia | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Karen Council, OSS | Hampton Health Department | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Edward Oldfield, MD | Eastern Virginia Medical School | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Greg Townsend, MD | UVA, Div. of Infectious Diseases & Internal Health | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Linda Eastham, MSN, RN, FNP | UVA School of Nursing | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Rebecca Dillingham, MD, MPH | Center for Global Health at UVA | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| David Wheeler, MD | INOVA Juniper Program | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Doloresa (Dolly) Sikipa, (SA-KEEP-A), ACRN | Inova Juniper Program, Prince William Offices | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Juan Pierce | The Minority Health Consortium | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Mark Baker | Total Healthcare | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Michael Bane, PharmD | Pharmacist | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Stephanie Wheawill, PharmD | VDH/Division of Pharmacy Services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| <i>Laurie Forlano, DO, MPH</i> | <i>VDH/Office of Epidemiology</i> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> |
| Elaine G. Martin | VDH/Division of Disease Prevention | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Kimberly Scott | VDH/HIV Care Services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Kimberly Eley | VDH/HIV Care Services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Safere Diawara | VDH/HIV Care Services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Jasmine Ford | VDH/HIV Care Services | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| Jenny Calhoun, | VDH/Division of Disease Prevention | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Guest: Tinika McIntosh | VDH/HIV Care Services | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Guest: Lisa Jeanette Pettaway | VDH/Division of Pharmacy Services | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Guest: Diana Prat | VDH/Division of Disease Prevention | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| Guest: Dianna Williams | VDH/HIV Care Services | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

Meeting Start time: 3:38 pm

Discussion points

Membership of the Statement of Work for the Committee

- The members discussed the overall membership criteria with the following observations as important considerations or action steps:
 - Maintain a balance of new ideas and good institutional knowledge with new members and existing members.
 - Maintain diversity among the committee by role, discipline, agency affiliations, lived experience, and VDH health planning region. VDH staff will update the Committee chair about changes, region, and discipline/affiliations, etc. to assist with nominations for new membership.
 - Members will provide alternate contact information to assist the VDH staff in communications.
 - Request to VDH staff to send annual communications regarding member status and provide formal recognition (certificates) for their service and tenure. These communications will help members to identify where they are in their tenure and to help members make decisions about their membership.
 - Membership must agree that service is a time commitment they will honor for meeting participation.
 - Nominations for new members and departures of existing members need to allow for preparation smooth transitions, including service in leadership roles for the committee.
 - Current membership may change based on the proposed amendments to the scope of work.

Nomination for Chair:

- Amend to show that nominations can be from members in good standing and can be self-nominations. Good standing means regular attendance and having served on the committee for at least one year (or a minimum of two meetings).
- Make the Chair tenure three (3) years to be consistent with the rest of the terms to allow the time and opportunity for person to develop institutional knowledge.
- Add a provision for a “Chair Elect who can move into the position of chair when tenure is up, or current chair needs to step down. Formalize the mentorship of the Chair Elect to include shadowing the leadership to learn the processes, duties, and critical relationships to maintain or build.
- Chair elect should consider and plan for a time commitment beyond the actual committee meeting facilitation and attendance. There are at least 1-3 meetings spread out before the actual meeting to work with the VDH staff to generate the agenda, identify data needs for the meeting, and anticipate questions.
- Orientation by Dr. Forlano and VDH staff (including the RWHAP Program Investigator/Program Director).

- To honor composition of the diversity of the committee, the chair does not to be a clinician or physician. Any member in good standing is eligible to hold the post.

Decision-making and Authority

- Staff provided an overview of the process to make changes to the ADAP formulary including requirements by federal funder and other criteria such as clinical needs and funding sustainability. Committee did not recommend any changes.
- Request to VDH staff to send the meeting minutes out to the committee within 15 business days of the meeting, which are informational for the committee and do not require any formal adoption.

VDH staff will amend the scope document to reflect the Committee requests. The HCS Clinical Coordinator will send the revised scope back to the members, who will have an additional opportunity to make written comments by email to the HCS Clinical Coordinator, but there will not be another meeting convened to discuss the scope.

The committee chair adjourned the meeting at 4:36 p.m.

VIRGINIA MEDICATION ASSISTANCE PROGRAM ADVISORY COMMITTEE

PURPOSE AND OPERATING PROCEDURES

I. PURPOSE

The Virginia Governor's office receives federal funding from the Health Resources and Services Administration for Virginia's Ryan White HIV/AIDS Program, Part B (RWHAP B). This program includes the AIDS Drug Assistance Program (ADAP), known in the state as the Virginia Medication Assistance Program (VA MAP). The federal funder recommends the best practice of convening an ADAP Advisory Committee (the Committee) to provide guidance and recommendations on ADAP operations. The Committee's primary duties include:

- Advising the VDH VA MAP on formulary changes (the list of medications to treat HIV and other health conditions that affect the HIV clinical management and patient outcomes).
- Advising the VDH on clinical and educational issues as needed to facilitate timely patient access to HIV medications.

The Committee also provides feedback on policy, eligibility for services, and any changes that may affect clinical client services. The Committee meets at the request of the VDH, advising the Office of Epidemiology (OEpi) and the Division of Disease Prevention (DDP).

II. BACKGROUND

The Virginia Department of Health's (VDH) HIV Care Services Unit (HCS) administers the RWHAP B program. The HCS also complies with federal and relevant state legislation and regulations and administrative guidance from the federal funder. This compliance is documented through routine reporting, program audits, and sites visits by the federal funder that focus on compliance in all areas of operation.

The Virginia Medication Assistance Program (VA MAP) is part of the RWHAP B program, and it provides access to HIV medications to people with HIV who meet the program's eligibility requirements. Medication is provided through either direct provision to people who are uninsured or insurance-related services under the Affordable Care Act, Medicare Part D, or employer-based coverage. The legislation that authorizes the RWHAP funding has a payer of last resort requirement¹ for these funds, even after Medicaid.

The Committee was created in 1996 to advise the VDH on its HIV medication formulary.

¹ For ADAPs, this means that RWHAP resources can only be used to pay for allowable costs when there is no other public or private payer for services and that ADAPs must also make vigorous attempts to help people with HIV enroll in other programs that can provide access to medication and a continuum of care including Medicaid, Medicare, Patient Assistance Programs, and health insurance coverage. The exceptions to the payer of last resort requirement, for any allowable RWHAP service including medication access, is for people with HIV who are eligible to receive benefits through Veteran's Affairs or Indian Health Services.

III. MEETINGS

A. Frequency and Scheduling

The Committee meets at least twice each calendar year either in person or virtually. The VDH, in consultation with the Chair, may call additional meetings to address time-sensitive issues. The VDH will announce regular meetings of the Committee at least one month in advance, at a date and time that works for the calendars of the Chair and the membership majority. Generally, meetings will be scheduled for the spring and fall.

B. Agenda

The Chair and VA MAP staff develop the meeting agenda together. Requests for any HIV medication formulary changes must be submitted in writing to the HCS Clinical Coordinator and are reviewed by the VDH and the Chair prior to inclusion on the agenda. The request should state a reason for the change and include an indication for use in treating HIV. Prescribers' written requests for VA MAP formulary changes should be submitted at least 30 days in advance of the next meeting to give VDH staff time to prepare supporting materials. In the event of an emergent time-sensitive issue regarding this formulary, the VDH, in consultation with the Chair, may call a special meeting.

C. Decision Making and Final Authority

All medications, biologics, vaccines, other products, and devices needed for medication administration must have FDA-approval before addition to the ADAP formulary. The federal funder and the RWHAP legislation set other requirements for ADAP formularies, and these include

- consistency with the most recent HIV/AIDS Treatment guidelines published by the U.S. Department of Health and Human Services ([HIV/AIDS Treatment Guidelines| Clinicalinfo.HIV.gov](https://www.clinicalinfo.hiv.gov)),
- equitable and consistent access for all eligible enrolled people with HIV throughout the state, and
- inclusion of at least one drug from each class of antiretroviral medications.

VDH staff will consult with pharmacy staff regarding the medication cost, as well as the HIV services and data analysts as needed to examine utilization data of similar regimens being accessed and by medication access program type. VDH staff will also assess cost impact using both medication costs and estimated utilization. The Committee makes recommendations on policy or medication issues by consensus whenever possible; a vote occurs if consensus cannot be reached. Where feasible, voting on medication additions to the formulary should be considered after there is an established ADAP Crisis Task Force² negotiated price to support ADAP's fiscal sustainability. Motions are carried or defeated by a simple majority. Voting may be conducted at in-person or virtual meetings, by email or phone. Final decision-making authority rests with the VDH, guided by recommendations of the

² This task force, also known as the ACTF, negotiates reduced drug prices on behalf of ADAPs in all 50 states, the District of Columbia, and the U.S. Territories.

Committee. If there are complex issues related to logistics for access to approved medications or other program/operational issues, the VDH team must discuss and resolve these issues prior to formal updates of the formulary or notification to the public. VDH staff will include any formulary actions in the meeting notes and will also send an email to the members of the Committee to assure members are notified prior to any community or other stakeholder notifications.

D. Participation

Committee meetings are open to the public. The VDH posts a notice in the [Virginia Regulatory Town Hall](#) two weeks prior to the meeting. Visitors are allowed to listen and observe only, unless recognized and invited to participate by the Chair.

IV. MEMBERSHIP

A. Composition and Appointment

Committee Membership consists of HIV medical providers, pharmacists, people with HIV, local health department professionals, and other disciplines or stakeholders. Members represent Virginia's five health regions as well as Ryan White grantees funded through Parts A, B, C, D, and F. The Committee values diversity, equity, and inclusion to enhance its deliberations, recommendations, and advice to the VDH related to resource use, health systems strengthening, and health policy implications for equitable and rapid access to HIV medications for People with HIV in the Commonwealth.

The VDH appoints all new members to the Committee and those members serve at the discretion of OEpi leadership. Individuals interested in serving on the Committee may submit resumes with a brief statement of qualifications to the HCS Clinical Coordinator. Membership requests are reviewed and approved by the HCS Director, the Chair, the DDP Director, and OEpi leadership. VDH staff will maintain the roster with active members in good standing and notifications to the Committee; members will assist them by providing an alternate email or other contact information (e.g., phone number).

B. Terms

Members serve an initial three-year term and may choose to renew their membership for unlimited additional terms if they are in good standing and have met attendance requirements. Terms are not required to be consecutive. VDH staff will send annual emails to each Committee member to acknowledge the member's service and identify the time served to help members make decisions about their membership commitments including renewals. The emails may include a certificate from the VDH to acknowledge service in increments of years.

C. Chair and Chair-Elect Positions

The members in good standing elect the Chair by a majority vote for a three-year term. Candidates for the position must be in good-standing and served a minimum of one year (or at least two Committee meetings). Nominations may be from members in good standing or self-nominations.

Any member in good standing is eligible to run for the Chair position. Chairs may run for one consecutive term. If the Chair steps down prior to the end of the term the Chair-Elect will assume the role of Chair. If the Chair is temporarily unable to perform the duties of Chair but does not resign, the Chair-Elect will assume Chair duties for that period.

The members in good standing elect the Chair-Elect by a majority vote for the same term length as the Chair. The candidate(s) must be in good standing and nomination criteria are the same for the Chair. Since the Chair tenure may be for six years with consecutive terms, the members may elect a different candidate for Chair-Elect if the previously elected member is unable to serve for the consecutive term. The Chair will commit to mentoring the Chair-Elect for the role with individual meetings, meetings with the VDH staff, and other activities the Chair deems appropriate to help the Chair-Elect prepare for the time commitment and duties of the Chair position.

Elections occur at the fall meeting for terms beginning in the next calendar year.

D. Attendance

Members are expected to attend all meetings and should notify the HCS Clinical Coordinator if an absence is unavoidable. Regular meeting attendance is required since members vote on issues related to HIV services in Virginia and relevant information and expertise is available at meetings to inform decision-making.

E. Termination

Members who miss two consecutive meetings will be removed from the Committee and notified in writing by VDH. Members who choose to end their membership before the end of their term should notify the HCS Clinical Coordinator in writing. The Clinical Coordinator or Manager of the VA MAP will notify the Chair of any member resignations.

V. ROLES AND RESPONSIBILITIES

A. The Committee Members

- Advise the VDH on HIV medication formulary changes, and clinical and policy issues related to HIV treatment.
- Evaluate the impact of changes to statewide HIV services and medication access and use any findings to make recommendations.
- Review materials provided in advance of scheduled meetings.
- Request any additional information needed to make recommendations.
- Serve on ad-hoc committee assignments to review issues or information related to medication access, if applicable.

Clinician members may be contacted by VA RWHAP B staff for medical consultation concerning HIV treatment as it may affect timely access to HIV medications.

In public forums, only the Chair or their designee may speak for the Committee. If other members speak publicly and refer to their membership, they are expected to clarify that their views are personal and not necessarily those of the Committee. Members should take special care to ensure their statements and actions are not misrepresented as positions or actions of the Committee. Members should notify the Chair when any formal statements are made.

B. The Chair

- Serves as the liaison between VDH and the Committee.
- Acts as the primary spokesperson for the Committee in public meetings and settings.
- Develops meeting agendas in collaboration with the VDH.
- Facilitates meetings by setting time limits and priorities for discussions.
- Recognizes any visitors/guests wishing to speak on agenda items.
- Manages any conflict among the membership in consultation with VDH staff.
- Consults with the VDH about the removal of members who have not met attendance requirements.
- Determines ad hoc committee topics and assignments.

C. The VDH

- Coordinates all logistics for planning and conducting Committee meetings.
- Conducts recruitment activities to identify potential members to fill vacancies.
- Develops the meeting agenda in collaboration with the Chair and co-facilitates the meeting with the Chair as needed.
- Announces meeting times and locations to the public.
- Compiles any documents needed by the Committee to make informed decisions.
- Provides updates on medication use, costs, measures of HIV care, and any legislative, regulatory, or policy changes that affect operations of the ADAP.
- Sends documents to members at least one week in advance of any regularly scheduled meetings.
- Responds to Committee requests for information and provides a timeframe by which the information will be provided.
- Takes meeting minutes and submits them to the Committee for informational review within 15 days of each meeting. The Committee does not make formal motions for adoption of the minutes.
- Keeps minutes and other records needed to maintain an accurate history of the Committee and its recommendations.
- Provides an orientation session and primer for new Committee members.
- Records attendance and notifies the Chair about members who have exceeded allowed absences and prepares correspondence notifying individuals that their membership has been terminated.

