INPUT
from the
HIV Medicine Access Workgroup

Provided to the LGBTQ Commission
as they prepare a Brief Report to the
Washington State Legislature
in accordance with
Budget Proviso via SB 5092 Sec 118.6.a

October 2021

I. Summary

The Washington State Legislature (Legislature) asked the LGBTQ Commission (Commission) to receive input from stakeholders on the following three topics related to access to HIV medications:

*I - **Access** to HIV antiretroviral drugs on the medicaid drug formulary, including short- and long-term fiscal implications of eliminating current prior authorization and fail-first requirements.*

*II - **Impact** of drug access on public health and the statewide goal of reducing HIV transmissions.*

*III - Maximizing pharmaceutical drug **rebates** for HIV antiretroviral drugs*

The Legislature further requested that the Commission, upon receiving this input, submit recommendations on the above three topics to the Legislature. The Commission chose to establish a Workgroup to assist with this task. In addition to the Workgroup, the Commission received additional input through two Public Town Hall Conversations.

A multitude of issues emerged during meetings of the Workgroup and in Town Hall meetings. The facilitation team, in consultation with the Executive Director and Program Manager of the LGBTQ Commission, has consolidated these into six key issues. The table below lists the issues and shows how each touches the three topics presented in the budget proviso from the Legislature that established the parameters for the LGBTQ Commission and the Workgroup. Section III goes into more detail about six key issues and offers options for addressing each.

Those who have been regular participants in Workgroup meetings generally concur with the characterization of the issues. The facilitation team knows that Workgroup members do not agree with the importance, necessity, or utility of pursuing each option. These options are given and described so the Executive Director of the LGBTQ Commission has a full array of ideas and strategies as they consider what to recommend to the Legislature.

The table below lists issues as the facilitation team understands them. Dots that are filled in (●) indicate the issue addresses fully the topic assigned by the Legislature. Dots that are open (○) indicate a relationship between this topic and the issue. No dot indicates no relationship.

Relationship of issues to topics from the Legislature:	Topic I. Access and Cost	Topic II. Impact on public health and statewide goals	Topic III: Rebates
Issue 1: Issue 1: The positive and negative consequences of shifting to an 'open access' system are disputed.	●	●	
Issue 2: Actual costs need to be comprehensively analyzed and understood.	●	○	●
Issue 3: The 'fail-first' system may create obstacles that have implications for both individual and public health.	●	●	
Issue 4: Lift the veil on drug pricing, drug costs and the role of rebates.	●	○	●
Issue 5: Pay attention to those who are left behind.	●	●	
Issue 6: The goals of the 2016 End AIDS 2020 Report have not been met.	●	●	

II. About this Input Report

Purpose; Direction from Washington State Legislature

The purpose of this Input Report is to meet the requirement of the Legislature for the Commission to collaborate with the "health care authority (HCA), department of health (DOH), advocates for people living with HIV in Washington, consumers, and medical professionals with expertise in serving the medicaid population living with HIV" to receive a broad array of perspectives, insights and ideas on the following three topics related to access to HIV medications:

*I - **Access** to HIV antiretroviral drugs on the medicaid drug formulary, including short- and long-term fiscal implications of eliminating current prior authorization and fail-first requirements.*

*II - **Impact** of drug access on public health and the statewide goal of reducing HIV transmissions.*

*III - Maximizing pharmaceutical drug **rebates** for HIV antiretroviral drugs*

Upon receiving this input, the Legislature further requested that the Commission submit recommendations to the Legislature on these three topics.

Authorship

This report was authored by the facilitation team with oversight from the Executive Director and Program Managers for the Commission. The report reflects what the facilitation team understood to be the depth and breadth of discussion in the four Workgroup meetings and two Town Hall Conversations.

Chronology

Workgroup meetings were held on August 23, September 13, October 4, and October 25. At each meeting information was presented; perspectives and opinions discussed. Town Hall Conversations were held on September 20 and October 12. A basic outline of this report was provided prior to the first meeting of the Workgroup, with content added after each subsequent meeting and Town Hall. The full budget proviso, meeting and town hall agendas, supporting materials, lists of participants and earlier versions of this report can be found at the [LGBTQ HIV Medication Access Workgroup website](https://lgbtq.wa.gov/advocacy/community-work/hiv-medication-access-workgroup) https://lgbtq.wa.gov/advocacy/community-work/hiv-medication-access-workgroup.

Representation

As noted above, the budget proviso from Legislature required the Commission to collaborate with the "health care authority (HCA), department of health (DOH), advocates for people living with HIV in Washington, consumers, and medical professionals with expertise in serving the medicaid population living with HIV".

The Commission chose to establish a Workgroup to assist with this task. The Commission sought and invited people in these broad stakeholder categories:

- LGBTQ Commission
- People Living with HIV/AIDs (PLWHA) Community
- HIV Service Organization(s)
- Pharmaceutical Companies or Representatives
- LGBTQ Medical Community; HIV/AIDS Doctors or Pharmacists
- Washington State Department of Health
- Peer Navigators
- Washington State Health Care Authority

The Commission chose not to limit access to Workgroup meetings or substantive discussions. As such, votes were not taken on potential recommendations, nor was consensus sought. Instead, the Workgroup was organized to be the conduit for a free flow of ideas, insights, and information.

Workgroup meetings were attended by a cadre of people with professions, vocations, products, services or practices or experiences relevant to questions surrounding HIV treatments. Attendance varied from meeting to meeting; not all participated in all meetings. All meetings were open to the public; anyone in attendance could participate in learning opportunities, discussion, small group work and commentary.

The facilitation team and the staff of the LGBTQ Commission feel it is important to note state that representation from persons living with HIV/AIDS did not participate as much as was hoped, especially those from underserved or marginalized communities. There was slightly better representation from these communities at the Town Hall Conversations. The facilitation team and the staff of the LGBTQ Commission were also informed it was difficult for some medical professionals to participate fully and consistently given schedules and the current demands of working in health.

In addition to the Workgroup and Town Hall Conversations, the Commission invited and received additional input conversations with individuals and groups outside the Workgroup meetings such as with the facilitators, advocates for people living with HIV in Washington, and HCA/DOH agency representatives, posted information on the Workgroup website, invitations for written commentary, and feedback forms.

III. Issues and Options

COMPETING FRAMES FOR PROBLEMS TO BE SOLVED

Reviewing the three topics listed in the Legislature's budget proviso, one could infer that the central issue was the structure of the Medicaid formulary (also known as the pre-authorization, or PA system) for anti-retroviral (ARV) drugs currently used by the HCA. Presentations, studies, and data analysis were offered at the first three meetings supporting, on the one hand, staying with a PA system and, on the other, moving to a system that would allow open access to ARV drugs.

Workgroup participants, however, advised that this may be a false dichotomy. Even so, we start with a description of how competing frames occurred:

First frame:

Those who make the case that the HCA should move to an open access system offer these perspectives:

- *The PA system is unduly burdensome to those with complex lives, for example those with other health and living challenges in addition to HIV. It is also burdensome to their caregivers.*
- *A fiscal analysis prepared by the HCA regarding the cost of moving to an open access system for HIV ARV drugs includes flawed assumptions.*
- *There is a fundamental equity problem with the PA system. People who access ARV medications through DOH programs or private insurers have access to whatever their providers think is best for them.*

A second frame:

The HCA counters that a PA system is justified for several reasons, including:

- *Clinical trials found and cited by the HCA indicate that the drugs on the PA list yield the same health benefits as those not on the list, and that compliance with drug regimens are the same.*
- *The HCA has a responsibility to keep costs in check, and the estimated costs of moving to an open access system are high. These costs were estimated using accepted and rigorous analyses. If an open access system is instituted with no additional funding, other health care benefits (e.g., dental benefits) could possibly be cut.*
- *Pharmaceutical companies are able to maintain and control drug pricing through confidential – and completely legal – contractual transactions defined at the Federal level. Pharmaceutical companies have influence over those making choices about which ARV drugs to prescribe.*

There are examples of programs outside the HCA where people with complex lives are allowed to pre-emptively qualify for drugs not on the PA list. Discussions within the Workgroup and input received at Town Hall meetings indicate that opting for the removal of the PA system is not a panacea for addressing the complex issues that create barriers to effective HIV treatment. However, removal of the PA system is seen by some as an important step toward viewing the rising rates of HIV infection through the lens of equity for all.

The remainder of this report describes the broad discussions held both at Workgroup meetings and Town Hall Conversations; discussions that go well beyond an "either-or" frame for making HIV medicines more accessible.

ISSUES AND OPTIONS VS. RECOMMENDATIONS

The Executive Director of the LGBTQ Commission and the facilitation team determined in late September they would not ask the Workgroup to vote on, or seek consensus on, recommendations. This decision was made because representation and participation on the Workgroup was incomplete, and a limited amount of time was available for the Workgroup to meet prior to the November 1 deadline. Instead, the Executive Director of the LGBTQ Commission and the facilitation team decided to use the rich discussions and information presented at Workgroup meetings and Town Halls to characterize issues and options as clearly as possible. This will allow the Commission to determine for themselves which options to recommend to the Legislature.

A multitude of issues emerged during meetings of the Workgroup and in Town Hall meetings. The facilitation team, in consultation with the Executive Director and Program Manager of the Commission, consolidated these into six key issues. The table below lists the issues and shows how each touches the three topics presented in the budget proviso from the Legislature, which established the parameters for the LGBTQ Commission and the Workgroup. Section III goes into more detail about each of the six key issues and offers options for addressing each.

The facilitation team understands that those who have been regular and consistent participants in Workgroup meetings generally concur with the characterization of the six key issues but do not agree with the importance, necessity, or utility of pursuing each option for addressing the issues.

The table below lists issues as the facilitation team understands them. Dots that are filled in (●) indicate the issue addresses fully the topic assigned by the Legislature. Dots that are open (○) indicate a relationship between this topic and the issue. No dot indicates no relationship.

Relationship of issues to topics from the Legislature:	Topic I. Access and Cost	Topic II. Impact on public health and statewide goals	Topic III: Rebates
Issue 1: The positive and negative consequences of shifting to an ‘open access’ system are disputed.	●	●	
Issue 2: Actual costs need to be comprehensively analyzed and understood.	●	○	●
Issue 3: The ‘fail-first’ system may create obstacles that have implications for both individual and public health.	●	●	
Issue 4: Lift the veil on drug pricing, drug costs and the role of rebates.	●	○	●
Issue 5: Pay attention to those who are left behind.	●	●	
Issue 6: The goals of the 2016 End AIDS 2020 Report have not been met.	●	●	

Issue 1: The positive and negative consequences of shifting to an ‘open access’ system are disputed.

An individual patient can receive different antiretroviral (ARV) drugs depending on whether the patient has private insurance, is on Medicaid, has drugs provided through a program funded by the Washington State Department of Health (DOH), or receives treatment via Medicaid the Washington State’s Apple Health program, administered by the Health Care Authority (HCA). The HCA has a set of ARV drugs available under a pre-authorization program (PA).

Patients or their health care providers must petition the HCA to receive different medications and/or demonstrate that the drug(s) available on the PA list have do not work for them (“fail-first”).

Many see this as fundamentally inequitable. They believe the HCA should move to an open access approach to address, at least partially, inequities in the system.

The HCA notes the ARV drugs available to patients through the PA program have been shown to be clinically effective. As such, the HCA believes there is no justification to move to an open access system. They further note moving to an open access system would increase costs to all Washington State taxpayers (see issue #2 on page 11). Some participants on the Workgroup believe a controlled clinical setting gives insight into limited aspects of overall efficacy.

Many on the Workgroup suggest there are other barriers to effective treatment that should be addressed (see issues #2 and #3 on page 11). Some believe that moving to a full open access system has been touted as a panacea, when a much larger set of concerns about treatment for HIV warrants attention.

<u>Options to address issue #1:</u>

1.1 Alter and amend the current PA and petition system from a 'one size fits all' approach to one that allows for customization based on needs and circumstances.

1.1.1 Accommodate immediate exceptions for patient and client groups who have chronically been underserved, and those who have other health conditions, or lead lives that prevent them from fitting into systems organized by and for the dominant culture.

1.1.2 Attend to the needs of who are unhoused or inadequately sheltered, non-English speakers, persons returning to society from incarceration, people ill with other conditions, those suffering from trauma, those living with mental health challenges and those who have been targeted by overt and systemic phobias, such as xenophobia, transphobia, homophobia perpetuated by the dominant culture.

1.2 Move to an open access system to make all ARV drugs available through the HCA

1.2.1 More fully examine additional barriers to effective HIV treatment, and how these could be instituted

1.2.2 Review and re-examine the assumptions in the fiscal analyses completed by the HCA regarding the costs of open access (see issue 2 on page 11).

1.3 Keep the current PA and petition system

1.3.1 Identify and use other mechanisms to address barriers for those for whom HIV treatment is challenging

1.4 Conduct additional studies to inform Option 1.1, 1.2 or 1.3 above

A frequent comment made during Workgroup meetings noted that it would be useful to conduct an independent qualitative study to examine how patients' health and ability to comply with a particular treatment program are affected by the constraints inherent in the prior-authorization system.

Equally strong was the sentiment that change cannot and should not wait for more studies and workgroups; there is sufficient information to make change.

Should the Commission choose to recommend additional studies, the following options suggest how these could be designed, conducted, and reviewed for applicability and scientific rigor:

1.4.1 Focus the study on the 'real-world' compliance with multi-pill regimens (as opposed to single-pill regimens) especially for at-risk populations; the effects of varying from the medications suggested by a health-care provider; and the effort required to prepare additional paperwork and justifications necessary to petition for an exception to the prior-authorization list.

1.4.2 If possible, in addition to looking at how individual patients are affected, the qualitative study should also examine the effect of these constraints on viral suppression and viral transmission. This would help establish whether these constraints create obstacles to the eleven goals set forth in the Washington State End AIDS 2020 report.

1.4.3 Qualitative data can be gleaned from any number of sources, while maintaining patient confidentiality:

  1.4.3.1 Interview and/or survey Title XIX care coordinators and health care providers on their experiences

  1.4.3.2 Review medical records with names redacted; progress notes, chart notes may be helpful. It is challenging, but not impossible, to do this within health confidentiality requirements.

1.4.4 Assure data is also collected on the social determinants of care and treatment that Workgroup members have identified impact the overall efficacy of treatment. For instance:

  1.4.4.1 Studying social determinants of health such as access to transportation; other diseases or conditions, effects of poverty, etc. could indicate that these aspects of treatment and compliance are as or more important to overall efficacy as the drug regimen itself.

  1.4.4.2 Workgroup members understand making correlations in a qualitative study is difficult and that showing causation is even more difficult. However, academic research techniques can be used in qualitative studies to allow sufficient rigor for policy making.

Issue 2: Actual costs need to be comprehensively analyzed and understood.

The HCA notes that the current system of using a PA list of clinically effective ARV drugs saves money for State taxpayers, thus making health care dollars go farther. Several Workgroup members believe the cost of drugs is but one aspect of overall cost. There is complex and competing information on the overall costs and savings associated with having a PA system. Several Workgroup members seek a comprehensive analysis of cost, with a closer look at assumptions in the analysis. While all Workgroup participants are appreciative of the efforts made thus far to catalog and analyze actual costs, several observe that an in-depth and comprehensive study is beyond the purview of busy health care professionals and administrators; they would have to fit this in as an ancillary task. In other words, funding should be made available to do this work.

During the legislative process, the HCA offered an analysis of the potential costs of moving to an open access system for ARV drugs. The analysis indicated that it could cost the State between $40 to $60 million per year to make the switch. Several Workgroup members question the assumptions in this analysis and would appreciate an analysis (a ‘deeper dive’) into the assumptions so they can be refined. Some Workgroup participants asserted that assumptions made based on the experiences and figures from other states are not applicable to Washington State.

There is competing information on how costs in other States are affected open access systems, prior-authorization programs, and other methods for making drugs available to patients served by medicaid funds.

Attempts to do an analysis of costs and results that compares Washington with other States, or uses the figures compiled by other States have been attempted and may be valuable, but many find these comparisons problematic. A cursory look at costs across states can yield an apples-to-oranges-to-watermelons comparison that useful only without additional in-depth analysis.

Workgroup members understand making correlations will be difficult; showing causation will be even more difficult.

<u>Options to address issue #2:</u>

2.1 Complete a study of short, mid- and long-term costs and life-cycle costs.

- **2.1.1** Explore the hypothesis that savings in ARV drug costs is a false economy if compliance is still a problem.
- **2.1.2** Consider having any comprehensive study be designed and reviewed by a panel of experts.

Issue 3: The ‘fail-first’ system may create obstacles that have implications for both individual and public health.

HCA has a program for patients and providers to petition to be able to use drugs not on the prior-authorization list, and/or to receive drugs without going through the ‘fail first’ system. HCA believes this covers the problem; others disagree. They offer information about the burden providers and patients must bear when preparing materials and justifications necessary to make the petition. The petition process is thought to interfere with the relationship between patient and health-care provider. Others believe the petition system is more likely to be needed by those who are already marginalized in the health care system.

As a part of the qualitative study described to address issue #2 above, more can be learned about how people – especially those with complex lives, navigate the ‘fail-first’ and petition systems. Ideas offered by the Workgroup include are listed as options below.

<u>Options to address issue #3:</u>

3.1 Use accepted qualitative and public health research techniques to understand if the 'fail-first' and petition processes are burdensome in ways that affect patient or public health.'

- **3.1.1** Ascertain if there are patients who have not received drugs, given up on treatment, or been otherwise adversely affected as a direct result of the 'fail-first' and petition programs.
- **3.1.2** Be systematic, thorough, and rigorous in identifying people with HIV who are adversely affected by a 'fail-first' system.
- **3.1.3** Ascertain if the 'fail-first' and petition systems compound other burdens to care for individuals.

Issue 4: Lift the veil on drug pricing, drug costs and the role of rebates.

It is profoundly disturbing to many in the Workgroup that drug prices are negotiated through confidential agreements between pharmaceutical companies, agencies, institutions, and insurers. And that, consequently, actual drug prices are unknown. The rebate system is similarly opaque, even though Federal and State guidelines for rebates are publicly available. It is unclear why some organizations and agencies accept rebates while others do not. For members of the general public, and even for the well-informed layperson, it is inscrutable why one patient with one form of insurance will receive drugs that qualify for a rebate while another patient with identical characteristics, but different insurance receives drugs that receive different rebates. Workgroup members understand the reality of opaque costs is unlikely to change anytime soon. But they ultimately hope for change in Federal and State policies to allow more transparency on drug pricing, drug costs and the role of rebates. Concerns were raised about the role of advertising in drug choice, and consequently drug costs.

Workgroup members do not see a readily available mechanism for affecting this issue, short of changing the way health care is priced and delivered in the United States.

<u>**Options to address issue #4:**</u>

4.1 Encourage Washington State elected officials and state agencies to advocate for an overhaul in how health care is provided and paid for.

Issue 5: Pay attention to those who are left behind.

By the numbers, Washington State is doing well in efforts to address HIV. Many Workgroup members indicate that while the numbers are hopeful, it is essential to look at who is not being served, who is not getting necessary treatment necessary. This is a fundamental equity issue that has implications for the overall health and well-being of all in Washington State.

Workgroup members believe that the qualitative study described in the options for issue #2 above can begin to get at this issue. Additional options are offered below.

<u>Options to address issue #5:</u>

5.1 Recognize, and secure through policy statements at the highest level, that the long history in this country of systemic racism, ableism, classism, homophobia, transphobia, and the inadequate provision of mental health care creates a group of people who are less likely to receive adequate care if they also live with HIV.

5.2 Recognize, and secure through policy statements at the highest level, that if any one person is receiving inadequate care for HIV, this is one person too many.

Issue 6: The goals of the 2016 End AIDS 2020 Report have not been met.

Topic II. from the budget proviso (“*Impact of drug access on public health and the statewide goal of reducing HIV transmissions.”)* suggests that the Workgroup could review how the goals of the 2016 Washington State report titled “End AIDS 2020” have – or have not – been met. Several Workgroup members offered opinions and insights about this. None believe the goals have been fully met, but the reasons why and what should be done about it were beyond the scope of the Workgroup.

<u>Options for addressing issue #6:</u>

6.1 Evaluate progress the State has made toward meeting the goals in the End AIDS 2020 report.

- **6.1.1** Include in the analysis which goals have and have not been met and why.
- **6.1.2** Update the End AIDS 2020 report with aggressive but attainable goals and strategies. Fund these.