INPUT from the HIV Medication Access Workgroup

Provided to the LGBTQ Commission as they prepare a Brief Report to the Washington State Legislature in accordance with Budget Proviso SB 5092 Sec.18.6.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. 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 the 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 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: Access to HIV treatment is an equity issue; pay attention to those who are left behind. Significant barriers to effective HIV treatment remain regardless of whether a prior-authorization system is in place.	●	●	
Issue 2: The positive and negative consequences of shifting to 'open access' system vs the current prior-authorization system are disputed.	●	●	
Issue 3: Actual costs need to be comprehensively analyzed and understood.	●	○	●
Issue 4: The prior-authorization system[1] creates obstacles that have implications for both individual and public health.	●	●	
Issue 5: Lift the veil on drug pricing, drug costs and the role of rebates.	●	○	●
Issue 6: The goals of the 2016 End AIDS 2020 Report have not been met.	●	●	

[1] Budget proviso SB 5092 Sec 118.6.a mistakenly refers to the HCA pa process as a 'fail-first' system. This nomenclature and resulting misunderstandings are discussed in Sections II and III of this Input Report.

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 in a budget proviso delivered in the late spring of 2021 via SB 5092 Sec 118.6.a. The proviso called 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.

Glossary

The following words are defined here for the purpose of this Input Report only. The facilitation team observed that during Workgroup meetings, words were often misapprehended, or used interchangeably when they were not synonymous. Consistency and clarity with health care nomenclature is notoriously difficult, but we attempt it here. Again, emphasizing that this glossary is for the purposes of this report alone.

- **Access:** The ability to have, obtain or retrieve something. In this report, issues related to people being able to access Antiretroviral drugs (ARV), basic services and needs (transportation, food, shelter, income) that might in turn impact access to ARVs, access to ARVs not on the Preferred Drug List (PDL) and barriers to access are all discussed. Equal access for all groups is seen as a goal.

- **Equity:** The Task Force that helped establish the new Office of Equity in Washington State asserts this vision equity in our state: "Everyone in

Washington has full access to the opportunities, power and resources they need to flourish and achieve their full potential." This is also the definition of equity used for this report.

- **Equity "lens":** To examine a policy, program, or practice by methodically and thoroughly identifying who is being left out, why, and how this can be remedied.
- **'Fail-first', 'Fail-twice', 'Step-wise Therapy':** Programs that ask health care providers to have HIV patients try drugs on the PDL prior to being eligible to ask to be reimbursed for drugs that are not on the PDL.
- **Health care organizations and agencies of service to those with HIV/AIDS:**
    - **Apple Health:** The Medicaid program administered by the Washington State Health Care Authority (HCA)
    - **Medicaid:** Federally funded health care in Washington State, administered by the Washington State Health Care Authority (HCA)
    - **Medicare:** Federally funded health care for people over 65 and some disabled persons.
    - **Private medical insurance:** Usually financed by an employer and/or individual, private medical insurance is the most common way Washington State residents pay for their medical care (estimated to be over 70% in 2017, inclusive of programs for government employees and retirees).
    - **Washington State Health Care Authority (HCA):** The agency that administers the Apple Health (Medicaid) program in our state.
    - **Washington State Department of Health (DOH)**: Administers programs such as Early Intervention Program (EIP) and Medical Case Management Program and Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)
- **Lists of preferred or pre-approved drugs:**
    - The term "formulary" is used by many health care organizations and insurers to mean the list of drugs that are automatically covered.
    - The "Preferred Drug List" (PDL) includes HIV drugs that can be prescribed, and will be reimbursed by the HCA, without prior-authorization.
- **HIV Medical Case Management:** HIV Medical Case Management is the provision of a range of client-centered activities focused on improving health outcomes in support of the HIV care continuum. HIV Medical Case Managers connect people living with HIV with health services and resources necessary to gain and maintain access to antiretroviral medications, maintain adherence to treatment and medications, receive benefit counseling and enrollment support to get and maintain coverage, and live as independently as possible. HIV Medical Case Management is funded by HRSA, paid for by DOH and HCA, and administered by DOH's Office of Infectious Disease. The HIV Case Management

workforce is managed by the Office of Infectious Disease following statewide standards. The Office of Infectious Disease's HIV Community Services program ensures access to case management, outreach services, substance use outpatient treatment services, mental health services, medical transportation, food bank or home-delivered meals, psychosocial support, linguistic services, housing, and emergency financial assistance. More information about HIV Medical Case Management can be found on DOH's website at HIV/AIDS Care - Case Management: Washington State.

- **Prior-authorization (PA):** The process used to ask for permission to prescribe, and be reimbursed for, a drug not on the PDL. Words used in association with prior-authorization include, "petition", "apply" and "demonstrate need" and "opt-out procedures".
- **Treatment:** Drug regimens and other practices and systems use to manage HIV/AIDS, or to provide pre-exposure prophylaxis (PrEP) for HIV/AIDS.

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 and relevant content in four Workgroup meetings, two Town Hall Conversations, numerous conversations (via email, online meetings and phone calls) with Commission staff from mid-July through October. Documentation of each of these interactions is available at the Workgroup website https://lgbtq.wa.gov/advocacy/community-work/hiv-medication-access-workgroup.

Chronology

2018: The HCA implements a prior-authorization system for access to HIV drugs on a Preferred Drug List (PDL). Aspects of this new program are understood to be a 'fail-first'.

August 2020: The HCA establishes a prior-authorization system that does not require a patient to 'fail-first' in their use of a drug on the PDL to potentially qualify to use drugs not on the PDL.

May 2021: The Washington State legislature passes the budget (SB 5092) which includes the proviso in Sec 118.6.a for the LGBTQ Commission to take on the task of looking a 'fail-first', prior-authorization, access to HIV drugs, and rebates.

June 2021: Staff to the LGBTQ Commission initiates a process to meet the requirements of the budget proviso. Staff consults with others about the process.

August 2021: A Workgroup is established to provide input to the LGBTQ Commission.

August 2021 through October 2021: 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. Also during this time, the staff to the Commission held numerous conversations and meetings were held via phone and online with interested parties and stakeholders. Agendas, supporting materials, lists of participants and earlier versions of this report and records of conversations can be found at the LGBTQ HIV Medication Access Workgroup website https://lgbtq.wa.gov/advocacy/community-work/hiv-medication-access-workgroup.

October 2021: On October 29, this Input Report was submitted to the Commission.

November 2021: The Commission will submit recommendations to the Legislature. The Legislature will decide if they wish to act on any of the recommendations. If so, a public process will ensue.

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 listed below. The Commission understands that each of these groups has a responsibility and/or a desire to be of service to those living with HIV/AIDS, or at risk of being infected.

- LGBTQ Commission
- People Living with HIV/AIDD (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, 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 Commission feel it is important to note 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 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; AGREEMENT ON BARRIERS

It is a fact that there is a Medicaid Preferred Drug List (PDL)[2] in Washington State and that patients and their providers must go through a prior-authorization process should they want to access anti-retroviral (ARV) drugs not on the PDL. Reviewing the three topics listed in the Legislature's budget proviso, one could infer that the primary issue is whether Washington State should *move away* from a prior-authorization system *toward* an open access system.

Through the course of the four Workgroup meetings, participants began to deftly articulate that this is a false dichotomy. The facilitation team understands that all discussants believe there are significant barriers to effective HIV prevention and treatment for people who quality for HCA/Medicaid. Barriers that extend well beyond those posed by the current prior-authorization system. In response to this recognition of significant barriers, representatives of Washington State agencies re-iterated their commitment to coordinated care for Medicaid patients.

Even with these revelations, we believe it is useful to describe how the frame of "prior-authorization vs open access" was posed early on:

Advocates for open access:

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 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 prior-authorization system. People who access ARV medications through several DOH program, some private insurers and some government insurers have access to whatever their providers think is best for them.*

Advocates for keeping a prior-authorization system:

The HCA counters that a prior-authorization system is justified and responsible for several reasons, including:

- *Clinical trials found and cited by the HCA indicate that the drugs on the PDL yield the same health benefits as those not on the list, and that compliance with drug regimens both on and off the PDL are the same. The majority of*

[2] The budget proviso refers to the PDL as a "formulary". This is technically not correct, even though in common parlance the PDL and formulary are often used interchangeably.

available ARVs are on the PDL.

- *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 maintain and manage drug pricing through confidential – and completely legal – contractual transactions defined at the Federal level. Moving to an open access system will remove HCA's leverage with pharmaceutical companies and eliminate incentives for manufacturers to make medications affordable. Pharmaceutical companies influence choices by providers 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 PDL without petitions, and without justification from health care providers. Discussions within the Workgroup and input received at Town Hall meetings indicate that opting for the removal of the prior-authorization system is not a panacea for addressing the complex issues that create barriers to effective HIV treatment. However, removal of the 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 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 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: Access to HIV treatment is an equity issue; pay attention to those who are left behind. Significant barriers to effective HIV treatment remain regardless of whether a prior-authorization system is in place.	●	●	
Issue 2: The positive and negative consequences of shifting to 'open access' system vs the current prior-authorization system are disputed.	●	●	
Issue 3: Actual costs need to be comprehensively analyzed and understood.	●	○	●
Issue 4: The prior-authorization system[3] creates obstacles that have implications for both individual and public health.	●	●	
Issue 5: Lift the veil on drug pricing, drug costs and the role of rebates.	●	○	●
Issue 6: The goals of the 2016 End AIDS 2020 Report have not been met.	●	●	

Issue 1: Access to HIV treatment is an equity issue; pay attention to those who are left behind. Significant barriers to effective HIV treatment remain regardless of whether a prior-authorization system is in place.

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, and the barriers that will be in place regardless of whether a prior-authorization system is in place.

[3] Budget proviso SB 5092 Sec 118.6.a mistakenly refers to the HCA pa process as a 'fail-first' system. This nomenclature and resulting misunderstandings are discussed in Sections II and III of this Input Report.

This is a fundamental equity issue that has implications for the overall health and well-being of all those who live in Washington State.

Options to address issue #1:

1.1 Recognize that if any one person is receiving inadequate care for HIV, this is one person too many. Recognize 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.

1.2 Act now to remove barriers.

1.2.1 Enhancing a peer navigator and case manager programs for HCA patients is one example that could be readily instituted.

1.2.2 Removing other barriers may require policy changes or alterations to standard practices. These need to be identified, solutions offered and implemented as soon as possible. An example of such a barrier is the fact that un-housed people often cannot maintain safe storage of a month's worth of their ARV medicines. Systems that would allow weekly prescriptions or dispensing of medicines at an easy-to-access location would increase the efficacy of treatment for some in the unhoused population.

1.3 Have the HCA apply an 'equity lens' to policies, practices and rulemaking.

1.3.1 The new Washington State Office of Equity will soon be able to work with state agencies such as the HCA to provide an equity analysis and recommend changes.

1.3.2 Similarly, a Public Health Report can be requested that can review the impact of a policy, program, or practice on public health.

1.4 Conduct additional studies to identify the root causes of barriers, including those inherent in a prior-authorization system.

A frequent comment made during Workgroup meetings was 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 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 some changes now.

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. 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.

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 PDL.

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.

Issue 2: The positive and negative consequences of an 'open access' system vs the current prior-authorization system are disputed.

As noted above, health care providers must petition the HCA on behalf of patients should they wish to prescribe medications that are not on the PDL. The petition must describe why the drug(s) on the PDL are not suited for the patient and/or demonstrate that the drug(s) on the PDL will not work for them. The HCA authorizes payment for HIV medications that are not on the PDL when they are medically necessary and when equally effective, less costly alternatives are not available. HCA can also determine whether or not a given medication is medically appropriate for the patient. In several circles, this has been known as a 'fail-first' system. Technically this is not a 'fail first' system, in that a provider can pro-actively petition for a medication for their patient.

Some perceive that the petition requirement is fundamentally inequitable. They point out that many patients[4] who are not on Medicaid are able to access whichever drugs their healthcare provider deems necessary without regard to a PDL. Others believe this is system interferes with the patient/provider relationship, making

[4] HCA points out theirs is not the only managed care program that has a prior-authorization requirement for ARVs.

the HCA the arbiter of which drugs are most appropriate for any given patient. The HCA counters that advertising may unduly influence drug preferences and is another reason for a PDL and a prior-authorization program.

The HCA notes the ARV drugs that are not on the PDL are not more effective in clinical trials than those on the PDL. 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 issues 3 and 5 for more discussion). Some participants on the Workgroup believe a controlled clinical setting gives insight into some, but not all, aspects of the overall efficacy and costs of a drug regime.

Many on the Workgroup suggest there are other barriers to effective treatment that should be addressed (see issue 1 above for more discussion). 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.

Options to address issue #2:

2.1 Alter and amend the current prior-authorization system from a 'one size fits all' approach to one that allows for immediate and/or expedited customization based on needs and circumstances.

2.1.1 Create a program that allows immediate exceptions, only post-facto authorization under specific circumstances. Those circumstances should include patients and client groups who have chronically been underserved, and those who have other health conditions that confound or compound HIV treatment. It should also include people whose lives prevent them from fitting into systems organized by and for the dominant culture. This may include those 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.

2.2 Move to[5] an open access system to make all ARV drugs available through the HCA without the need for prior-authorization.

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

2.2.2 Review and re-examine the assumptions in the fiscal analyses completed by the HCA regarding the costs of open access.

2.3 Keep the current prior-authorization system

2.3.1 Identify and use other mechanisms to address barriers for those for whom HIV treatment is challenging (see issue 1 for more discussion).

[5] Workgroup members have noted that an open access system was in place in prior years; a prior-authorization system is a newer development.

Issue 3: Actual costs need to be comprehensively analyzed and understood.

The HCA notes that the current system of using a PDL 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 PDL and a prior-authorization 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[6]. 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 by 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.

Options to address issue #3:

3.1 Complete a study of short, mid- and long- term costs using a holistic and inclusive approach to actual costs.

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

[6] DOH is currently conducting an analysis of when providers choose to switch drugs for clients; this study may address some of the questions listed here.

Issue 4: The prior-authorization system creates obstacles that have implications for both individual and public health.

Some providers and people living with HIV offered information about the burdens encountered when preparing materials and justifications necessary to justify a prior-authorization. They believe the process interferes 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. It is important to note some providers do not perceive the prior-authorization system as burdensome.

As a part of the qualitative study described to address issue #1 above, more can be learned about how people – especially those with complex lives, navigate the prior-authorization system even with the assistance of their health care provider. Ideas offered by the Workgroup are listed as options below.

Options to address issue #4:

4.1 Use accepted qualitative and public health research techniques to understand if the process to obtain a prior-authorization is indeed burdensome in ways that affect patient or public health.

- 4.1.1 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 prior-authorization system.
- 4.1.2 Be systematic, thorough, and rigorous in identifying people and including people with HIV who are adversely affected by the prior-authorization system.
- 4.1.3 Ascertain if the prior-authorization system compounds other burdens to care for individuals.
- 4.1.4 Evaluate the prior-authorization and where it works well and easily for some health care providers (and their patients) and not for others.

Issue 5: 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 set 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 public, and even for the well-informed layperson and professional, 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.

Options to address issue #5:

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

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.

The Department of Health is creating an End AIDS Washington report to summarize the achievements and areas of continued focused in this effort. It is expected to be completed by the end of the 2021. Many of the populations disproportionately impacted by HIV also experience high rates of other sexually transmitted infections (STIs), viral hepatitis, and overdose. This overlap demonstrates the need to address these epidemics with more coordinated strategies. Therefore, the next steps towards ending the HIV epidemic is planning and implementing strategies that focus on "Ending the Epidemics" (EtE). DOH has contracted with a consulting firm to support OID's efforts to build a strong integrated and equity-focused approach to "End the Epidemics" (EtE). Consultant driven activities are currently underway.

Options for addressing issue #6:

6.1 Continue the efforts currently underway to 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** Review the options listed under Issue 1 regarding equity. Take these into account when evaluating progress on the goals in the End AIDS Washington report.

Additional Considerations

Two developments have implications for the issues examined in this Input Report and were brought up in both Workgroup meetings and in Town Halls meetings. They are:

- A new set of drug classes may be on the market soon. Specifically, a new generation of single-tablet regimens have been discussed at length, yet little data exists to demonstrate potential impacts to health outcomes or costs. Washington State DOH assessment staff conducted an analysis outlining the uptake and efficacy of Biktarvy and Gilead's [7] other medications (e.g., Tenofovir

[7] Pharmaceutical companies

Alafenamide) in Washington state AIDS Drug Assistance Program (ADAP). This information could be used to inform decision-makers about ADAPs experience as an example of what may occur if Gilead's new generation of therapies are approved for Medicaid. Changes made to HCA systems – be they eliminating or changing the prior-authorization system – should actively seek to accommodate these new drug classes.

- The Washington State Board of Health is finalizing rules for passed Engrossed Substitute House Bill (ESHB) 1551, which modernizes the control of certain communicable diseases (Chapter 76, Laws of 2020). This bill ends statutory HIV/AIDS exceptionalism, reduces HIV-related stigma, defelonizes HIV exposure, and removes barriers to HIV testing. The new law took effect June 11, 2020. Changes made to HCA systems – be they eliminating or changing the prior-authorization system – should be attentive to the requirements and rules associated with this law.