A MESSAGE TO THE WORKGROUP ON HOW TO VIEW AND READ THIS DOCUMENT:

The following pages describe what your facilitation team understands to be issues and options you have discussed, as a group, for addressing the three topics in the budget proviso. Yes, we are pushing you here. We'd like you to think hard about what is possible, and what is possible for you to say, unified, as the whole Workgroup. We will spend the next two Workgroup meetings talking about these issues and options and seeking as much agreement as possible. You will recall that this report will be advisory to the LGBTQ Commission. The Commission is charged with providing recommendations to the Legislature. If at all possible, the Commission would like their recommendations to be congruent with unified advice they receive from you, the Workgroup.

SETTING OUT ISSUES AND OPTIONS

The Washington State legislature asked the Workgroup to consult with the LGBTQ Commission on the following topics:

*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 Workgroup identified six issues associated with these three topics and discussed options for addressing each. [Workgroup members agree with the characterization of the issues (*Please note: agreement is what we will work toward in the wording. If it is not achievable,*

we'll change this wording so it indicates not all agreed with characterizations)]. However, not all Workgroup members agree with the importance, necessity, or utility of pursuing each option for addressing the issues.

Issue 1: The implications of shifting to an 'open access' system are not well understood. 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 DOH, or receives treatment via Medicaid the HCA ("Apple Health").

Many on the Workgroup believe this is fundamentally inequitable. Some within the Workgroup believe the HCA could move to an open access approach in order to address, at least partially, inequities in the system.

The HCA notes the ARV drugs readily available to patients through the prior-authorization program have been shown to be clinically effective. As such, the HCA believes there is no clinical reason to go to an open access system. Some participants on the Workgroup believe a controlled clinical setting only insight into one aspect of overall efficacy.

Given that the HCA finds no clinical difference between the efficacy drugs available through the HCA and those available through other programs, some on the Workgroup suggest there are other barriers that should be addressed. Some question whether an open access system needs to be a part of addressing the barriers.

Some members of the Workgroup note that new drugs can be added to the HCA prior-authorization list, and that individuals and their health care providers can petition the HCA to allow different drugs to be used if warranted for an individual patient.

> **Options to address issue #1:** Most on the Workgroup believe 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. The following options suggest how such a study can be designed, conducted, and reviewed for applicability and scientific rigor:

1.1 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.

1.2 If possible, in addition to looking at how individual patients are affected, the qualitative study should also estimate 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.

1.3 Workgroup members had several ideas for how to conduct a qualitative study that would yield robust results. Some noted that qualitative data can be gleaned from any number of sources, while maintaining patient confidentiality:

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

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

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

1.5 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 prior-authorization 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 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 have observed that an in-depth and comprehensive study is beyond the purview of busy health care professionals and administrators would have to fit this in as an ancillary task. In other words, there should be funding available to do this work.

Options to address issue #2: The following ideas were generated by the Workgroup for analyzing actual costs:

2.1 Complete a study of short, mid- and long-term costs and life-cycle costs. Explore the hypothesis that savings in ARV drug costs is a false economy if compliance is still a problem.

2.2 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 believe assumptions made based on the experiences and figures from other states are not applicable to Washington State.

2.3 As noted above, there is competing information on how costs in other States are affected by various programs for open access, prior-authorization programs, and other systems for making drugs available to patients served by medicaid funds. Some believe a cursory look at costs across states yields an apples-to-oranges-to-watermelons comparison that is not useful without more in-depth analysis.

2.4 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. Some Workgroup members believe this does not solve the problem; that it ignores or minimizes the burden providers and patients must bear when preparing materials and justifications necessary to make the petition. Others suggest the petition 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.

Options to address issue #3: As a part of qualitative study described above, more can be learned about how people – especially those with 'complicated and challenging lives' navigate the 'fail-first' and petition systems. Ideas offered by the Workgroup include:

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

3.2 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. Ascertain if the 'fail-first' and petition systems compound other burdens to care for individuals.

3.3 Be rigorous about identifying who these patients are demographically: Are these people who are always left behind due to systemic inequities in our health care system?

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 in 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 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. Some on the Workgroup are concerned about the role of advertising in drug choice, and consequently drug costs.

Options to address issue #4:

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.

4.1 Encourage Washington State elected officials 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 our 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.

Options to address issue #5:

Workgroup members believe that the qualitative study described above can begin to get at this issue. Additional options include:

5.1 Recognize, and secure through policy statements at the highest level, that systemic and historic racism, ableism, classism, homo-and-trans phobia, 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 Report titled End AIDS 2020 have not been met.

Topic II. from the budget provisio ("*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 during discussions. 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.

Options for addressing issue #6:

Workgroup members suggest an evaluation of the End AIDS 2020 report.

6.1 Conduct an evaluation of the goals of the End AIDS 2020 report, including which goals have and have not been met and why.

6.2 Update the End AIDS 2020 report with aggressive but attainable goals and strategies. Fund these.

The table below shows how each of the issues relates the topics in the budget provisio from the State legislature. Dots that are filled in (●) indicate the issue addressed this topic fully. Dots that are open (○) indicate there is 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 implications of shifting to an 'open access' system are not well understood.	●	●	
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 Report End AIDS 2020 have not been met.	●	●	

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.

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