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From: Holly Kilness Packett <holly.k.packett@gsk.com>
Sent: Friday, June 3, 2022 1:57 PM
To: solicitation.questions
Cc: Cindy Snyder
Subject: Re: State of Florida Agency For Health Care Administration Request for Information Re-Procurement of the Statewide Medicaid Managed Care Program, May 6, 2022 [RFI-00909]
Attachments: ViiV Healthcare Comments to Florida - RFI - May 2022_Final.pdf

Dear Mr. Massa;

ViiV Healthcare Company (ViiV), wishes to offer the following comments to the State of Florida Agency for Health Care Administration (AHCA) "Request for Information (RFI) on Re-Procurement of the Statewide Medicaid Managed Care Program."

Best regards,

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June 3, 2022

Submitted via: solicitation.questions@ahca.myflorida.com

Cody Massa
Procurement Officer
Agency For Health Care Administration
State of Florida

Re: State of Florida Agency For Health Care Administration Request for Information Re-Procurement of the Statewide Medicaid Managed Care Program, May 6, 2022 [RFI-00909]

Dear Mr. Massa;

ViiV Healthcare Company (ViiV), wishes to offer the following comments to the State of Florida Agency for Health Care Administration (AHCA) *Request for Information (RFI) on Re-Procurement of the Statewide Medicaid Managed Care Program.*¹ We provide these comments without redaction so that they might be viewed and shared in full publicly.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention. From its inception in 2009, ViiV has had a singular focus to improve the health and quality of life of people affected by this disease and has worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV remains committed to developing meaningful treatment advances, improving access to its HIV medicines, and supporting the HIV community to facilitate enhanced care, treatment and prevention.

As a manufacturer exclusively of HIV medicines, ViiV is proud of the scientific advances in the treatment of this disease. These advances have transformed HIV from a terminal illness to a manageable chronic condition. Effective HIV treatment can help people with HIV to live longer, healthier lives, and has been shown to reduce HIV-related morbidity and mortality at all stages of HIV infection.^{2,3} Furthermore, effective HIV treatment can also prevent the transmission of the disease.⁴

In responding to the state's request for information (RFI) we hope to share some of the best practices, and innovations in health care and service delivery for people with HIV and people at risk of acquiring HIV within Florida's statewide Medicaid managed care system.

¹ State of Florida Agency for Health Care Administration. Request for Information Re-Procurement of the Statewide Medicaid Managed Care Program, May 6, 2022 [RFI-00909] <https://vendor.myfloridamarketplace.com/search/bids/detail/909>. Accessed May 18, 2022.

² Severe P, Juste MA, Ambrose A, et al. Early versus standard antiretroviral therapy for HIV-infected adults in Haiti. *N Engl J Med*. Jul 15 2010;363(3):257-265. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/20647201/>.

³ Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. Apr 30 2009;360(18):1815-1826. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/19339714/>.

⁴ Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *Lancet*. 2019 Jun 15;393(10189):2428-2438. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/31056293/>.

People with HIV in Medicaid Managed Care

Medicaid has played a critical role in HIV care since the epidemic began, and it is the largest source of coverage for people with HIV.⁵ In fact, more than 42 percent of people living with HIV (PLWH) who are engaged in medical care have incomes at or below the federal poverty level.⁶ Medicaid is an essential source of access to medical care and antiretroviral therapy (ART) drug coverage for people with HIV. This medical care and drug treatment not only preserves the health and wellness of people with HIV and improves health outcomes, but it also prevents new HIV transmissions. Despite groundbreaking treatments that have slowed the progression and burden of the disease, treatment of the disease is low – only half of people with HIV are retained in medical care, according to the Centers for Disease Control and Prevention (CDC).⁷

It is imperative that traditional Medicaid and Medicaid Managed Care Organizations (MMCOS) work to expand access to HIV prevention, and preserve continuous access to comprehensive high-quality health care, including antiretroviral therapy (ART) for people with HIV in order to improve health outcomes and reduce new transmissions. Florida is one of several states that prohibits restrictions on HIV antiretrovirals⁸ and is an example of a best practice for minimizing barriers to access for patients and providers. We encourage AHCA to continue to ensure that there are no barriers to access to ARVs in both traditional Medicaid and the MMCOS.

In 2019, the U.S. Department of Health and Human Services (DHHS) released the “Ending the HIV Epidemic: A Plan for America (EHE).”⁹ This plan proposes to use scientific advances in ART to treat people with HIV and expand proven models of effective HIV care and prevention. The plan also focuses its efforts to stop the HIV epidemic across government agencies. Florida’s Medicaid program has a significant role in achieving these goals. The state of Florida has seven counties targeted by the EHE initiative for high rates of new HIV infections (Broward, Duval, Hillsborough, Miami-Dade, Orange, Palm Beach, and Pinellas).¹⁰ According to the CDC, there were approximately 113,478 people living with HIV in Florida in 2019, and 4,378 new diagnoses that year.¹¹ Therefore, we urge AHCA, to consider how Florida Medicaid can align with the nation’s goals to end HIV in the U.S. as established by the EHE Initiative. If we are to end the HIV epidemic, it is imperative that state Medicaid programs align with local and national efforts to promote policies that contribute to HIV public health goals, such as preserving continuous access to comprehensive health care, including ART.

To that end, ViiV wishes to share the following information and best practice examples related to HIV care and prevention in the following areas identified by the state:

⁵ Kaiser Family Foundation. Medicaid and HIV. <http://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/>. Accessed May 24, 2022.

⁶ Centers for Disease Control and Prevention. Behavioral and Clinical Characteristics of Persons with Diagnosed HIV Infection—Medical Monitoring Project, United States, 2016 Cycle (June 2016–May 2017). HIV Surveillance Special Report 21. Revised edition. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published June 2019. Accessed May 31, 2022.

<https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-special-report-number-21.pdf>

⁷ Centers for Disease Control and Prevention (CDC). Understanding the HIV Care Continuum. July 2019. <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>. Accessed May 31, 2022.

⁸ The Florida Legislature. The 2021 Florida Statutes.

http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0409/Sections/0409.91195.html. Accessed May 31, 2022.

⁹ HIV.gov. Ending the HIV Epidemic. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>. Accessed May 31, 2022.

¹⁰ HIV.gov. Ending the HIV Epidemic – Priority Jurisdictions: Phase 1. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions>. Accessed May 31, 2022.

¹¹ AIDS Vu: Florida <https://aidsvu.org/local-data/united-states/south/florida/>. Accessed May 18, 2022.

Quality metrics and outcomes: Importance of HIV Viral Load Suppression measure reporting

ViiV applauds the Florida AHCA for building the data infrastructure to capture and report laboratory data on HIV viral suppression rates in both the HIV Special Needs Plan (SNP) and the managed care plan targets.^{12,13,14} We encourage the state to continue to require reporting of this data from all the MMCOs because HIV viral suppression is a critical component in ending the HIV Epidemic.

HIV quality measures are critical in elevating the care and treatment of people with HIV and for reducing the incidence of new HIV infections. The HIV Viral Load Suppression (HVL)¹⁵ [NQF #2082/ NQF#3210e](#)¹⁶ quality measure signifies that a patient has reached the current clinical goal of HIV treatment, to achieve viral suppression.^{17,18} In terms of best practices, many states use contracts between Medicaid agencies and MCOs to deliver health benefits and services to beneficiaries while reducing care costs and utilization.¹⁹ Several state Medicaid programs have linked HIV quality measures to MCO performance, incentivizing achievement of viral suppression for people with HIV within those programs.^{20,21,22,23}

The HVL measure has been included for many years in the Medicaid Adult Core Set and will also be included in the 2023 measure set. The Centers for Medicare and Medicaid Services (CMS) Medicaid Adult Core Set represents the health care quality measures that indicate the access to—and quality of—the health care adult Medicaid beneficiaries receive.²⁴

Unfortunately, the HVL quality measure is underutilized by states.²⁵ In an effort to address this, the Health Resources and Services Administration (HRSA), HIV/AIDS Bureau, initiated a four-year initiative that aims to increase state capacity to improve the collection and reporting of high-quality HIV viral suppression data as part of the annual state Medicaid Adult Core Set reporting. The National Alliance of State and Territorial AIDS Directors (NASTAD) will serve as the Systems Coordination Provider working to build the capacity of participating states to report viral suppression data to Medicaid and provide funds

¹² State of Florida Agency for Health Care Administration. Model Health Plan Contract 2018-23.

https://ahca.myflorida.com/Medicaid/statewide_mc/model_health_FY18-23.shtm. Accessed May 31, 2022.

¹³ State of Florida Agency for Health Care Administration. CY 2019 MMA Performance Measure Scores: HEDIS, Core Set, and Agency-defined measures.

https://ahca.myflorida.com/Medicaid/quality_mc/pdfs/CY_2019_MMA_Performance_Measure_Scores.pdf. Accessed May 31, 2022.

¹⁴ State of Florida Agency for Health Care Administration. Attachment II Exhibit II-A – Update: February 1, 2022 Managed Medical Assistance (MMA) Program. https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/Contracts/2022-02-01/Exhibit_II_A_MMA-2022-02-01.pdf. Accessed May 31, 2022.

¹⁵ Health Resources and Services Administration (HRSA). HIV/AIDS Bureau Performance Measures. January 2015.

<https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio>. Accessed May 25, 2022.

¹⁶ NQF. Measure Evaluation Criteria.

http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx. Accessed May 26, 2022.

¹⁷ Health Resources and Services Administration (HRSA). HIV/AIDS Bureau Performance Measures. January 2015.

<https://ryanwhite.hrsa.gov/grants/performance-measure-portfolio>. Accessed May 25, 2022.

¹⁸ National Institutes of Health (NIH). Ten things to Know about HIV Suppression. <https://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression>. Accessed May 25, 2022.

¹⁹ Medicaid.gov. Managed Care. <https://www.medicaid.gov/medicaid/managed-care/index.html>. Accessed on May 25, 2022.

²⁰ Dorr H, Sanborn L. Prioritizing care: Partnering with providers and managed care organizations to improve health outcomes of people living with HIV. National Academy for State Health Policy (NASHP). December 2017. <https://nashp.org/wp-content/uploads/2017/09/HIV-Affinity-Provider-MCO-Engagement-Brief.pdf>. Accessed May 25, 2022.

²¹ New York State Department of Health. 2015 Blueprint: End AIDS.

https://www.health.ny.gov/diseases/aids/ending_the_epidemic/docs/blueprint.pdf. Accessed May 25, 2022.

²² New York State Department of Health. Ending the Epidemic Progress Report. March 2018.

https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/Executive_Summary_2018_.pdf. Accessed May 25, 2022.

²³ Louisiana HIV Planning Group. Louisiana HIV/AIDS Strategy 2017-2021. August 2016. <https://www.louisianahealthhub.org/wp-content/uploads/2018/10/LouisianaHIV/AIDSStrategy.pdf>. Accessed May 25, 2022.

²⁴ Mathematica. Annual Review of the Medicaid and CHIP Child and Adult Core Sets of Quality Measures.

<https://www.mathematica.org/features/maccoresetreview>. Accessed January 28, 2022.

²⁵ Centers for Medicare & Medicare Services (CMS). Quality of Care for Adults in Medicaid: Findings from the 2020 Adult Core Set Chart Pack. January 2022. <https://www.medicaid.gov/medicaid/quality-of-care/downloads/performance-measurement/2021-adult-chart-pack.pdf>. Accessed May 31, 2022.

for state-specific infrastructure and capacity in the states of Alabama, Arizona, Colorado, District of Columbia, Iowa, Maryland, Michigan, Tennessee, Virginia, and Washington.^{26,27}

Additional states reporting the HVL measure will help to ensure their future inclusion on the CMS Medicaid Scorecard, which compares outcome measures that are reported by at least twenty-five states. Continued state reporting will also identify where there are gaps in care so that interventions can be developed to help HIV+ people in Medicaid achieve viral load suppression.

Plans addressing populations with specific health conditions or needs

We applaud the state of Florida for its HIV special needs plan (SNP).²⁸ It is very important that people with HIV have access to high quality care and treatment benefits. We encourage the state to retain an HIV SNP and to carry over some of requirements of the SNP into all Medicaid managed care contracts. Doing so would improve care for all HIV beneficiaries with HIV in all the contracts.

The following are some the provisions in the HIV SNP that we encourage be carried over into the contracts of all the managed care plans:

- **Medicaid Redetermination Assistance**

ViiV encourages AHCA to provide redetermination assistance for all people with HIV in all the MCOs, similar to the HIV SNP. Specifically, all people with HIV who are redetermined to be ineligible for Medicaid should be referred to the Florida Department of Health's HIV/AIDS Section because they may be eligible to receive services through the Ryan White HIV/AIDS Program.

- **Care Coordination/Case Management**

ViiV encourages AHCA to require all MMCOs to make care coordination/management services available to all people with HIV. When HIV infection is effectively managed to a state of viral suppression, it becomes, in effect, a chronic condition. Achieving this level of success in HIV care and treatment with a vulnerable population often requires addressing a combination of multiple health and social needs, such as housing, food, nutrition, and medical case management services, among others. The CDC's HIV treatment cascade highlights the fact that a significant portion of the HIV population is experiencing a poorly controlled chronic condition. Many PLWH also experience co-occurring conditions such as substance abuse and mental health disorders and increasing numbers of PLWH are joining the elderly population. These statistics further indicate that PLWH would benefit from increased care management. Additionally, health systems that have implemented care management services have been able to vastly improve clinical outcomes and quality while reducing overall health care costs.^{29,30}

²⁶ NASTAD, Project Fact Sheet, "Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set: Systems Coordination Provider (SCP), HRSA-21-083.

²⁷ HRSA.gov, U.S. Health Resources & Services Administration, "Building Capacity to Improve Collecting and Reporting Viral Suppression Data to the Medicaid Adult Core Set" <https://www.hrsa.gov/grants/find-funding/hrsa-21-083>. Accessed Jun 2, 2022.

²⁸ State of Florida Agency for Health Care Administration. Attachment II Exhibit II-C – Update: February 1, 2022 HIV/AIDS Specialty Plan. https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/Contracts/2022-02-01/Exhibit_II_C_HIV_AIDS_2022-02-01.pdf. Accessed June 1, 2022.

²⁹ Patient-Centered Primary Care Collaborative. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes Resource Guide 2nd Edition June 2012. <http://www.pccpc.org/sites/default/files/media/medmanagement.pdf>. Accessed June 1, 2022.

³⁰ Chen S, Hochman M. Care Integration Webinar #4: Integrating Pharmacy Care and Primary. Center for Care Innovations. <http://www.careinnovations.org/knowledge-center/care-integration-webinar-4-integrating-pharmacy-care-and-primary-care>. Accessed June 1, 2022.

- **Provider Education in HIV and Impacted Populations**

ViiV encourages AHCA to require MMCOs to provide information about HIV education opportunities, including information on stigma and HIV prevention, to all physicians operating under the state Medicaid program as well as resources for consultation for inexperienced providers treating people with HIV.

As mentioned above, seven counties in Florida are targeted by the federal EHE initiative for its high rates of new HIV infections.³¹ This indicates a need for increased attention and education on HIV prevention and treatment among providers in the state. Providers in the state should be made aware of the HIV education and consultation options offered by the federal government.

HRSA, which administers the Ryan White HIV/AIDS Program, offers direct provider-to-provider consultation services through the National HIV/AIDS Clinician Consultation Center, including several hotlines: the “HIV Management Service Warmline,” the Post-Exposure Prophylaxis Hotline (PEpline), Perinatal HIV Consultation and Referral Services (Perinatal HIV Hotline), the Pre-Exposure Prophylaxis Service (PrEpline), and the Clinical Substance Use Consultation (Substance Use Warmline).³²

Additionally, the Ryan White AIDS Education Training Centers (AETCs) are regional bodies that offer resources and programs for provider education on HIV.³³ MMCOs should advise network providers on the offerings of AETCs.

Stigma is a significant concern in addressing the HIV epidemic.^{34,35,36} HIV stigma - the negative attitudes or beliefs around HIV disease - can lead to discrimination and prejudice from others, and even by healthcare providers.³⁷ HIV stigma is often rooted in lack of information and awareness combined with outdated beliefs and scientific misconceptions about how HIV is transmitted and what it means to live with HIV today. According to the CDC, HIV stigma and discrimination can keep people from getting tested for HIV, learning their HIV status, accessing treatment, or staying in care. HIV stigma can also affect those at risk of HIV by discouraging them from seeking HIV prevention tools and testing.³⁸

HIV continues to have a disproportionate impact on certain populations, particularly racial and ethnic minorities and gay and bisexual men. Populations disproportionately affected by HIV are also often affected by stigma due to, among other things, their gender, sexual orientation, gender identity, race/ethnicity, drug use, or sex work.³⁹ Therefore, the CDC recommends that,

³¹ HIV.gov. Ending the HIV Epidemic – Priority Jurisdictions: Phase 1. <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/jurisdictions>. Accessed May 31, 2022.

³² Health Resources and Services Administration (HRSA). AIDS Education & Training Center Program. National Clinician Consultation Center. <https://aidsctc.org/aetc-program/national-clinician-consultation-center>. Accessed June 1, 2022.

³³ Health Resources and Services Administration (HRSA). AIDS Education and Training Center (AETC) Program. <https://aidsctc.org/>. Accessed June 1, 2022.

³⁴ Mahajan AP, Sayles JN, Patel VA, et al. Stigma in the HIV/AIDS epidemic: a review of the literature and recommendations for the way forward. AIDS. 2008 Aug; 22(Suppl 2): S67–S79. Accessible at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835402/>

³⁵ Centers for Disease Control and Prevention. Dealing with Stigma and Discrimination.

<https://www.cdc.gov/hiv/basics/livingwithhiv/stigma-discrimination.html>. Accessed June 1, 2022.

³⁶ HIV.gov. Standing Up to Stigma. <https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma>. Accessed June 1, 2022.

³⁷ Centers for Disease Control and Prevention (CDC). What is HIV stigma? <https://www.cdc.gov/hiv/basics/hiv-stigma/index.html>. Accessed June 1, 2022.

³⁸ Centers for Disease Control and Prevention (CDC). What is HIV stigma? <https://www.cdc.gov/hiv/basics/hiv-stigma/index.html>. Accessed June 1, 2022.

³⁹ HIV.gov. Standing Up to Stigma. <https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma>. Accessed June 1, 2022.

“The perspectives and needs of LGBT people should be routinely considered in public health efforts to improve the overall health of every person and eliminate health disparities.”⁴⁰

ViiV Healthcare supports appropriate education and awareness on HIV which seeks to reduce stigma and discrimination against people with HIV and populations at high risk for HIV. We suggest that the state issue a Medicaid Information Bulletin to all providers in the state with resources and information about stigma, HIV, and the populations disproportionately affected by HIV including LGBTQ populations, and also require the MMCOs to provide information to their networks on the same.

- **HIV Quality Metrics in addition to HVL**

In addition to requiring all MMCOs to continue to report HIV Viral Load Suppression (HVL), ViiV encourages AHCA to also promote reporting on additional HIV quality metrics that reflect optimal care for people with HIV.

Because long-term HIV care is strongly associated with viral suppression and optimal health outcomes for people with HIV, the state could consider measuring retention in care, which includes adherence and medical visits frequency quality measures. People with HIV who receive long-term clinical care are more likely to begin ART and achieve viral suppression, dramatically lowering the risk of transmitting HIV to others.^{41,42,43} Conversely, people with HIV who are diagnosed, but not retained in care are estimated to transmit the virus to an average of 5.3 people per 100-person years.⁴⁴

Another HIV measure, the Pharmacy Quality Alliance’s (PQA) *Antiretroviral Proportions of Days Covered* adherence measure (PDC-ARV),⁴⁵ could facilitate an improvement in adherence to HIV medications, which is especially important in HIV due to the impact to people with HIV on their quality of life and life expectancy, but also in terms of lowering HIV transmission risk to others.⁴⁶ Adding the PDC-ARV measure would not substantially increase burden to health plans, as many are already collecting and reporting this data to CMS.

Additionally, we encourage the inclusion of a HIV Screening measure as part of the state’s efforts to address opioid misuse. The HIV Screening measure would support preventive care and treatment while reducing transmissions of HIV. According to the CDC, substance use disorders are closely associated with HIV and other sexually transmitted diseases.⁴⁷ In people

⁴⁰ Centers for Disease Control and Prevention (CDC). Lesbian, Gay, Bisexual, and Transgender Health. <https://www.cdc.gov/lgbthealth/index.htm>. Accessed June 1, 2022.

⁴¹ Crawford TN. Poor retention in care one-year after viral suppression: a significant predictor of viral rebound. *AIDS Care*. 2014;26(11):1393-9. Accessible at: <https://www.ncbi.nlm.nih.gov/pubmed/24848440>.

⁴² Yehia BR, French B, Fleishman JA, et al. Retention in care is more strongly associated with viral suppression in HIV-infected patients with lower versus higher CD4 counts. *J Acquir Immune Defic Syndr*. 2014 Mar 1;65(3):333-9. Accessible at: <https://www.ncbi.nlm.nih.gov/pubmed/24129370>.

⁴³ Robertson M, Laraque F, Mavronicolas H, Braunstein S, Torian L. Linkage and retention in care and the time to HIV viral suppression and viral rebound – New York City. *AIDS Care*. 2015;27(2):260-7. Accessible at: <https://www.ncbi.nlm.nih.gov/pubmed/25244545>.

⁴⁴ Skarbinski J, Rosenberg E, Paz-Bailey G. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med*. 2015 Apr;175(4):588-96. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/25706928/>.

⁴⁵ Pharmacy Quality Alliance (PQA). Proportion of Days Covered: Antiretroviral Medications (PDC-ARV). <https://www.pqaalliance.org/measures-overview#pdc-arv>. Accessed June 1, 2022.

⁴⁶ HIVinfo.NIH.gov. HIV Treatment: The Basics. August 16, 2021. <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-treatment-basics>. Accessed June 1, 2022.

⁴⁷ Centers for Disease Control and Prevention (CDC). HIV and Substance Use. <https://www.cdc.gov/hiv/risk/substanceuse.html>. Accessed June 1, 2022.

with HIV, substance use can also lower adherence to treatment and worsen health outcomes.⁴⁸ Health officials in several states have reported increased HIV transmissions due to injection drug use currently driving the opioid epidemic.^{49,50} To address this increase, the US Preventive Services Taskforce (USPSTF) and the American Society of Addiction Medicine (ASAM) have both recommended frequent HIV screening for people who inject drugs, as well as screening for HIV while assessing and diagnosing opioid use disorders.^{51,52} The CDC recommends HIV screening as routine care for all adults and adolescents, but advocates for more frequent screening for people who inject drugs.⁵³

Optimal outcomes for people with HIV can only occur if systems are measured and are able to benchmark their performance against the current standard of care in the HIV care continuum. The use of HIV-related quality measures will promote standards of health care coverage that support adherence to current HIV clinical and federal guidelines.⁵⁴

Achieve cost savings throughout the Statewide Medicaid Managed Care Program

Cost savings can be achieved in the Statewide Medicaid Managed Care (SMMC) program through both effective HIV treatment for people with HIV, and also through preventing new HIV infections through both HIV prevention drugs and treatment as prevention.

- **Effective HIV Treatment**

We applaud the state of Florida for its statutory protection of access to antiretroviral treatments (ART) in Medicaid. Prescription drug treatment is essential to people with HIV, to effectively manage a deadly virus, to extend health and wellness, and to prevent transmission of HIV.

When a person with HIV receives and maintains effective HIV treatment and receives quality medical care, they can reach viral suppression. Viral suppression means that the virus has been reduced to an undetectable level in the body with standard tests.⁵⁵ Viral suppression results in reduced mortality and morbidity and leads to fewer costly medical interventions.⁵⁶ Viral suppression also helps to prevent new sexual transmissions of the virus. When successful treatment with an antiretroviral regimen results in virologic suppression, secondary HIV transmission to others through sex is effectively eliminated. In studies sponsored by the National Institutes of Health (NIH), investigators have shown that when treating the HIV-positive partner

⁴⁸ Centers for Disease Control and Prevention (CDC). HIV and Substance Use. <https://www.cdc.gov/hiv/risk/substanceuse.html>. Accessed June 1, 2022.

⁴⁹ Northern Kentucky Health Department. Health Officials See Increase in HIV Infection Among Individuals Who Inject Drugs. Press Release. January 9, 2018. <https://nkyhealth.org/2018/01/09/health-officials-see-increase-in-hiv-infection-among-individuals-who-inject-drugs/>. Accessed June 1, 2022.

⁵⁰ Massachusetts Department of Public Health, HIV Transmission through Injection Drug Use. November 27, 2017. <https://www.mass.gov/doc/clinical-advisory-hiv-transmission-through-injection-drug-use/download>. Accessed June 1, 2022.

⁵¹ American Society of Addiction Medicine (ASAM). The National Practice Guideline for the Treatment of Opioid Use Disorder. 2020 Focused Update. https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2. Accessed June 1, 2022.

⁵² US Preventive Services Task Force. Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. JAMA. 2019 Jun 18;321(23):2326-2336. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/31184701/>.

⁵³ Branson BM, Handsfield HH, Lampe MA, et al. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. MMWR. September 22, 2006;55(RR14):1-17. <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>. Accessed June 1, 2022.

⁵⁴ HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures. April 2015. http://paetc.org/wp-content/uploads/2015/04/Tools_for_Monitoring_Issue_Brief_update-April-2015.pdf. Accessed February 16, 2022.

⁵⁵ National Institutes of Health (NIH). Ten things to Know about HIV Suppression. <https://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression>. Accessed May 25, 2022.

⁵⁶ Stricker SM, Fox KA, Baggaley R, et al. Retention in care and adherence to ART are critical elements of HIV care interventions. AIDS Behav. 2014 Oct;18 Suppl 5:S465-7. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/24292251/>.

with ART, there were no linked infections observed when the HIV+ partner's HIV viral load was below the limit of detection.⁵⁷ The National Institute of Allergy and Infectious Diseases (NIAID) supported research that demonstrated when people with HIV achieve and maintain viral suppression, there is no risk scientifically of transmitting HIV to their HIV-negative sexual partner.⁵⁸ Multiple subsequent studies also showed that people with HIV on ART who had undetectable HIV levels in their blood, had essentially no risk of passing the virus on to their HIV-negative partners sexually.^{59, 60, 61} As a result, the CDC estimates viral suppression effectiveness in preventing HIV transmission through sex at 100 percent.⁶²

Reduced transmissions not only improve public health, but also save money. Preventing new transmissions offers a substantial fiscal benefit to the state. In studies sponsored by the NIH, investigators have shown that when treating the HIV-positive partner with antiretroviral therapy,⁶³ there were no linked infections observed when the infected partner's HIV viral load was below the limit of detection. It is estimated people with HIV who are not retained in medical care may transmit the virus to an average of 5.3 additional people per 100-person years.⁶⁴ A recent study of commercially insured PLWH compared to individuals without HIV found that mean all-cause costs were almost seven times higher in those with HIV, culminating in an average discounted incremental cost of \$850,557 in cumulative costs from ages 25-69.⁶⁵ Successful treatment with an antiretroviral regimen that results in virologic suppression virtually eliminates secondary HIV transmission through sex to others. As a result, it is possible to extrapolate that successful HIV treatment and medical care of each infected patient may save the system up to \$4.5 million by preventing further transmission to others. These savings can only occur if people with HIV have access to medical care, receive treatment, and remain adherent to their prescribed therapy.

ViiV encourages AHCA to work with the state to promote awareness of this separate but dual benefit of HIV "treatment as prevention" (TasP)⁶⁶ to all MMCOs, and provide education that the fact that achieving and maintaining viral suppression for people with HIV can also prevent new infections.

- **HIV pre-exposure prophylaxis (PrEP)**

Medicaid is also a significant provider of HIV prevention, specifically pre-exposure prophylaxis (PrEP).⁶⁷ We applaud AHCA for covering all the modalities of PrEP with minimal barriers. In fact,

⁵⁷ Rodger et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *The Lancet*. Published Online May 2, 2019 [http://dx.doi.org/10.1016/S0140-6736\(19\)30418-0](http://dx.doi.org/10.1016/S0140-6736(19)30418-0) .

⁵⁸ NIAID, <https://www.niaid.nih.gov/news-events/undetectable-equals-untransmittable>. Accessed August 1, 2018.

⁵⁹ Bavinton, et al. The Opposites Attract Study of viral load, HIV treatment and HIV transmission in serodiscordant homosexual male couples: design and methods. *BMC Public Health*. 2014; 14: 917. doi: [10.1186/1471-2458-14-917](https://doi.org/10.1186/1471-2458-14-917).

⁶⁰ Cohen, et al. Antiretroviral Therapy for the Prevention of HIV-1 Transmission. September 1, 2016. *N Engl J Med* 2016; 375:830-839. DOI: 10.1056/NEJMoa1600693.

⁶¹ "HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention" National Institute of Allergy and Infectious Diseases <https://www.niaid.nih.gov/diseases-conditions/treatment-prevention>.

⁶² Centers for Disease Control and Prevention (CDC) "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV" <https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> Accessed September 20, 2019.

⁶³ Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study. *Lancet*. 2019 Jun 15;393(10189):2428-2438. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/31056293/>.

⁶⁴ Skarbinski J, Rosenberg E, Paz-Bailey G, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. *JAMA Intern Med*. 2015 Apr;175(4):588-96. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/25706928/>.

⁶⁵ Cohen JP, Beaubrun A, Ding Y, et al. Estimation of the incremental cumulative cost of HIV compared with a non-HIV population. *Pharmacoecoon Open*. 2020 Dec;4(4):687-696. Accessible at: https://pubmed.ncbi.nlm.nih.gov/gsk_idm_oclc.org/32219732/.

⁶⁶ Collins F. For HIV, Treatment is Prevention. HIV.gov. <https://www.hiv.gov/blog/hiv-treatment-prevention>. Accessed May 2, 2022.

⁶⁷ Kaiser Family Foundation. Medicaid and HIV. <http://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/>. Accessed May 24, 2022.

ViiV highlights AHCA's PrEP coverage policies as a best practice. When taken properly, PrEP can reduce the risk of acquiring HIV from sex by 99 percent and reduces risk by 74 percent among those who inject drugs.⁶⁸ However, of the approximately 1.2 million people in the U.S. indicated for PrEP, only 18 percent are receiving it.⁶⁹ Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic. In Florida, the state's PrEP coverage ratio was only 17.9 percent in 2019 according to CDC.⁷⁰

Increase timely access to providers and services

We encourage AHCA to require that managed care plans contract with all available HIV providers in the state and to allow people with HIV to maintain access to their current HIV care management providers.

Access to qualified medical care providers is important for people with HIV in order to monitor disease progression and ensure viral suppression is maintained.^{71,72} Access to infectious disease specialists and HIV-specialized providers⁷³ is vital for PLWH, as better outcomes are achieved when treated by an experienced HIV provider.⁷⁴

Since the beginning of the HIV epidemic, providers from a variety of specialties (such as Infectious Disease Specialists and family medicine) and licensures (physician's assistants, nurses, nurse practitioners) have focused in HIV care and treatment and served this vulnerable population. The importance of continuity of care for medically underserved patients, particularly people living with HIV, is significant. Patients retained in active medical care often have long-standing, trusting relationships with their medical provider, which is a key piece of the successful management of HIV. Exclusion of these providers from coverage networks can lead to care interruptions and may cause beneficiaries to forgo care entirely, rather than visit an unfamiliar provider without experience caring for disadvantaged or complex care populations. Achieving control of the virus requires regular access to a medical provider. Gaps in HIV treatment of days to weeks can reverse viral suppression, increase risk of transmission to others, and lead to serious complications, including development of a virus that is drug resistant, and more difficult to treat.⁷⁵

⁶⁸ Centers for Disease Control and Prevention (CDC). HIV Risk and Prevention: Pre-Exposure Prophylaxis (PrEP). <https://www.cdc.gov/hiv/risk/prep/index.html>. Accessed April 5, 2022.

⁶⁹ U.S. Department of Health and Human Services. 2021. HIV National Strategic Plan for the United States: A Roadmap to End the Epidemic 2021–2025. Washington, DC. <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>. Accessed June 1, 2022.

⁷⁰ Centers for Disease Control and Prevention (CDC). Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021;26(No. 2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf>. Published May 2021. Accessed June 1, 2022.

⁷¹ Kitahata MM, Gange SJ, Abraham AG, et al. Effect of early versus deferred antiretroviral therapy for HIV on survival. *N Engl J Med*. Apr 30 2009;360(18):1815-1826. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/19339714/>.

⁷² Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV Care: a policy Paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. *Clin Infect Dis*. 2011 Dec;53(11):1043-50. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/22021928/>.

⁷³ HIV Medicine Association. Identifying Providers Qualified to Manage the Longitudinal Treatment of Patients with HIV Infection and Resources to Support Quality HIV Care Revised. March 2013. <https://www.hivma.org/globalassets/hivma/logos/revised-qualified-hiv-provider-policy-statement-approved-3-16-13-1.pdf>. Accessed June 1, 2022.

⁷⁴ Gallant JE, Adimora AA, Carmichael JK, et al. Essential components of effective HIV Care: a policy Paper of the HIV Medicine Association of the Infectious Diseases Society of America and the Ryan White Medical Providers Coalition. *Clin Infect Dis*. 2011 Dec;53(11):1043-50. Accessible at: <https://pubmed.ncbi.nlm.nih.gov/22021928/>.

⁷⁵ Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/guidelines-adult-adolescent-arv.pdf>. Accessed June 1, 2022.

We encourage AHCA to enforce requirements that the managed care plans contract with all essential care providers in the state, including federally qualified health centers, rural health centers, community health centers, clinics funded through the Ryan White HIV/AIDS Program, and local health departments.

Health care providers that serve a large proportion of low-income or medically underserved individuals are given a designation of “essential community providers” (ECP) under federal law. AHCA identifies Federally Qualified Health Centers (FQHCs) and FQHC “Look-Alike” clinics, Ryan White HIV/AIDS Program Providers, Indian Health Providers, and STD clinics as ECPs among others. Commercial plans in the state exchanges are required to have a sufficient number and geographic distribution of ECPs to ensure access to a broad range of such providers for low-income, medically underserved individuals.⁷⁶

We encourage AHCA to also require the managed care plans in the state to provide access to these same providers, as many of these entities serve people with HIV and at-risk populations. Including them in provider networks would further serve to ensure people with HIV can stay retained in care with their established provider.

Improve post-partum care

ViiV wishes to bring to the state’s attention the unique opportunity for the state to align with the goals of the nation’s public health effort to end the HIV epidemic, by advancing PrEP offered to women at risk for acquiring HIV as part of post-partum care.

Making PrEP available and accessible is an important step in reducing the number of new HIV diagnoses and ultimately ending the HIV epidemic. As stated previously, when taken properly, PrEP can reduce the risk of acquiring HIV, yet only 18 percent of the approximately, 1.2 million people indicated for PrEP in the U.S. are receiving it.^{77, 78} In Florida, the state’s PrEP coverage ratio was only 17.9 percent in 2019 according to CDC.⁷⁹

NIH in their clinical recommendations, “*Postpartum Follow-Up of Women*,” advises counseling around prevention of HIV transmission for partners with differing HIV status, including counseling on use of PrEP by the partner who does not have HIV.⁸⁰

For women at-risk for HIV, counseling, education, and utilization of PrEP is an important consideration. In 2012, PrEP was recommended by the CDC for individuals at high risk of HIV infection as part of a comprehensive HIV-prevention strategy.⁸¹ The American College of Obstetricians and Gynecologists (ACOG) recommends PrEP for individuals at risk of acquiring HIV infection and urges obstetrician–

⁷⁶ Kaiser Family Foundation. Contract Offering and Signing Standards for Essential Community Providers (ECPs) in Marketplaces. 2015. <https://www.kff.org/other/state-indicator/contract-offering-and-signing-standards-for-essential-community-providers-ecps-in-marketplaces/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>. Accessed July 30, 2020.

⁷⁷ Centers for Disease Control and Prevention (CDC). HIV Risk and Prevention: Pre-Exposure Prophylaxis (PrEP). <https://www.cdc.gov/hiv/risk/prep/index.html>. Accessed April 5, 2022.

⁷⁸ U.S. Department of Health and Human Services. 2021. HIV National Strategic Plan for the United States: A Roadmap to End the Epidemic 2021–2025. Washington, DC. <https://files.hiv.gov/s3fs-public/HIV-National-Strategic-Plan-2021-2025.pdf>. Accessed June 1, 2022.

⁷⁹ Centers for Disease Control and Prevention (CDC). Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. HIV Surveillance Supplemental Report 2021;26(No. 2). <https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-vol-26-no-2.pdf>. Published May 2021. Accessed June 1, 2022.

⁸⁰ Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Transmission in the United States. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Accessed June 1, 2022.

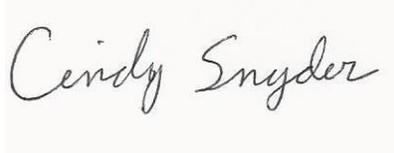
⁸¹ Centers for Disease Control and Prevention (CDC). CDC Fact Sheet. PrEP: A New Tool for HIV Prevention. https://img.thebody.com/cdc/2012/prep_factsheet.pdf. Accessed June 1, 2022.

gynecologists involved in the care of women to be aware of new developments in the medical science of PrEP.⁸² In addition, DHHS has said that PrEP may offer an effective option to protect mother and baby from getting HIV during pregnancy and while breastfeeding.⁸³

Conclusion

Thank you for your consideration of our comments. Please feel free to contact me at (919) 323-9084 or Cindy.C.Snyder@viivhealthcare.com with any questions.

Sincerely,

A handwritten signature in cursive script that reads "Cindy Snyder". The signature is written in black ink on a light-colored, slightly textured background.

Cindy Snyder
Community Government Relations Director
ViiV Healthcare

⁸² The American College of Obstetricians and Gynecologists. Preexposure Prophylaxis for the Prevention of Human Immunodeficiency Virus. Committee Opinion Number 595. May 2014. <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/05/preexposure-prophylaxis-for-the-prevention-of-human-immunodeficiency-virus>. Accessed June 1, 2022.

⁸³HIV.gov. Preventing Mother-to-Child Transmission of HIV. <https://www.hiv.gov/hiv-basics/hiv-prevention/reducing-mother-to-child-risk/preventing-mother-to-child-transmission-of-hiv>. Accessed June 1, 2022.