

July 1, 2021

Submitted via: CSBRFP8@dhcs.ca.gov

Director Will Lightbourne
Department of Health Care Services
Director's Office
P.O. Box 997413, MS 0000
Sacramento, California 95899-7413

Re: Request for Proposal (RFP #20-10029)

Dear Director Lightbourne;

ViiV Healthcare Company (ViiV), wishes to offer the following comments to the California Department of Health Care Services (DHCS) regarding the DHCS draft Request for Proposal (RFP #20-10029). ViiV previously submitted input to DHCS in 2020 for the RFI Medi-Cal for Managed Care Plan (MCP) Contracts, and we are very pleased that the state chose to prioritize LGBTQ health in the latest draft. ViiV also submitted comments to DHCS in 2021 about the CalAIM Section 1115 & 1915(b) Waiver, and again, we are pleased that this RFI makes mention of coordinating efforts with the Cal-AIM Initiative.

ViiV is the only independent, global specialist company devoted exclusively to delivering advancements in human immunodeficiency virus (HIV) treatment and prevention to support the needs of people with HIV. 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 and treatment.

As an exclusive manufacturer 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

¹ CA.gov, State of California Department of Health Care Services "Medicaid Section 1115 Demonstration Five-Year Renewal and Amendment Request: CalAIM Demonstration" DRAFT FOR PUBLIC COMMENT April 2021,

https://www.dhcs.ca.gov/provgovpart/Documents/CalAIM-1115-Waiver-Renewal-Application.pdf (Accessed April 26, 2021)

² Severe P, Juste MA, Ambroise 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. Available at

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=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. Available at

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=19339714.

⁴ 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 https://dx.doi.org/10.1016/S0140-6736(19)30418-0.

As requested by the DHCS, we have provided our feedback to the most recent RFP in the chart format suggested:

General (DRAFT RFP 20- 10029 RFP Main) Main) Met or exceed Minimum Performance Levels for quality, on the measures included in the Managed Care Accountability Set. Managed Care Accountability Set. Momet or exceed Minimum Performance Levels for quality, on the measures included in the Managed Care Accountability on the MCPs do as well to improve transparency and accountability on this effort. Considering the state has adopted the CMS Medicaid Adult Core Set, incentivizing viral load suppression rate among people with in California was 56 percent in 2018. (reference: Califor Continuum of HIV Care report, 2018 https://www.cdph.ca.gov/Programs/CID/DOA/CDPH% ument%20Library/2018 HIV CareContinuumFactShe Living ADA.pdf) The "HIV Viral Load Suppression & HIV Quality Reporting Viral Load Suppression & HIV Quality Reporting ViiV urges the state to prioritize addressing the challer low viral suppression rates over time. We ask that DHCS on Medi-Cal viral suppression rates quarterly, and requiral suppression rates and reporting in the accountability on this effort. Considering the state has adopted the CMS Medicaid Adult Core Set, incentivizing viral load suppression (VLS) rates and reporting is the appropriate step. The statewide viral suppression rate among people with in California was 56 percent in 2018. (reference: Califor Continuum of HIV Care report, 2018 https://www.cdph.ca.gov/Programs/CID/DOA/CDPH% ument%20Library/2018 HIV CareContinuumFactShe Living ADA.pdf) The "HIV Viral Load Suppression (VLS)" measure sign that a patient has reached viral suppression status.	RFP	Section and	Issue, Question	Remedy Sought
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RFP 20- 10029 RFP Main) Minimum Performance Levels for quality, on the measures included in the Managed Care Accountability Set. Minimum Performance Levels for quality, on the measures included in the Managed Care Accountability Set. Minimum Performance Levels for quality, on the measures included in the Managed Care Accountability Set. Minimum Performance Levels for quality, on HIV quality measures, and demonstrate improvement viral suppression rates over time. We ask that DHCS round accountability on this effort. Considering the state has adopted the CMS Medicaid Adult Core Set, incentivizing viral load suppression (VLS) rates and reporting is the appropriate step. The statewide viral suppression rate among people with in California was 56 percent in 2018. (reference: Califor Continuum of HIV Care report, 2018 https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%oument%20Library/2018 HIV CareContinuumFactSheLiving_ADA.pdf) The "HIV Viral Load Suppression (VLS)" measure sign that a patient has reached viral suppression status. (reference: HIV/AIDS Bureau Performance Measures,			1. Quality	Viral Load Suppression & HIV Quality Reporting
When a patient becomes virally suppressed, it means the virus has been reduced to an undetectable level in body with standard tests. (reference: National Institute Health (NIH) "Ten things to Know about HIV Suppressionhttps://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression) Achieving and maintaining a "durably undetectable" vir load not only preserves the health of PLWH, but also prevents sexual transmission of the virus to an HIV-ne partner. This builds a strong case for implementing a process and outcome HIV-focused, quality measures to encourage testing, linkage to care, and ongoing treatm so PLWH can achieve viral suppression and ultimately	(DRAFT RFP 20- 10029 RFP	for Medi-Cal managed care plans	Meet or exceed Minimum Performance Levels for quality, on the measures included in the Managed Care	ViiV urges the state to prioritize addressing the challenge of low viral suppression rates by requiring the MCPs to report on HIV quality measures, and demonstrate improvement in viral suppression rates over time. We ask that DHCS report on Medi-Cal viral suppression rates quarterly, and require the MCPs do as well to improve transparency and accountability on this effort. Considering the state has adopted the CMS Medicaid Adult Core Set, incentivizing viral load suppression (VLS) rates and reporting is the next appropriate step. The statewide viral suppression rate among people with HIV in California was 56 percent in 2018. (reference: California Continuum of HIV Care report, 2018 https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Doc ument%20Library/2018 HIV CareContinuumFactSheet All Living ADA.pdf) The "HIV Viral Load Suppression (VLS)" measure signifies that a patient has reached viral suppression status. (reference: HIV/AIDS Bureau Performance Measures, "HIV Viral Load Suppression," https://hab.hrsa.gov/sites/default/files/hab/About/clinical-quality-management/coremeasures.pdf) When a patient becomes virally suppressed, it means that the virus has been reduced to an undetectable level in the body with standard tests. (reference: National Institutes of Health (NIH) "Ten things to Know about HIV Suppressionhttps://www.niaid.nih.gov/diseases-conditions/10-things-know-about-hiv-suppression) Achieving and maintaining a "durably undetectable" viral load not only preserves the health of PLWH, but also prevents sexual transmission of the virus to an HIV-negative

Several state Medicaid programs have linked HIV quality measures to MCP performance, thus incentivizing achievement of viral suppression for their PLWH. For example, the New York State's Ending the Epidemic Plan recommends that HIV providers, facilities, and managed care plans report and monitor viral suppression rates and provide financial incentives for performance. Consequently, New York State's Department of Health requires MCPs to report HIV-specific measures, including the VLS outcome measure, and awards financial incentives based on performance on these HIV measures. New York MCP's efforts have significantly improved viral suppression rates among Medicaid beneficiaries by linking many PLWH to care. One year into the pilot, the state reported that more than 40 percent of those initially identified as not virally suppressed had been successfully engaged in care and had achieved viral suppression. (reference: NASHP. December 2017. Prioritizing Care: Partnering with Providers and Managed Care Organizations to Improve Health Outcomes of People Living with HIV. https://nashp.org/wpcontent/uploads/2017/09/HIV-Affinity-Provider-MCO-Engagement-Brief.pdf)

Louisiana's Medicaid managed care program, Bayou Health, has included the VLS outcome measure in its contracts with MCPs. To further drive improvement, MCPs have incorporated resources from the Louisiana Office of Public Health's (OPH) STD/HIV Program into disease management programs after the state added measures to their contracts. (reference: MCO RFP 2021 Documents | Department of Health | State of Louisiana:

https://ldh.la.gov/index.cfm/page/4199)

DHCS goals for Medi-Cal managed care plans (Page 11)

2. Access to care Ensure comprehensive networks that provide all members timely access to appropriate, culturally competent, and high-quality care, within time and distance standards.

HIV Care Providers

We encourage the state to require MCPs to contract with all essential care providers in the state, including federally qualified health centers, rural health centers, community health centers, Ryan White clinics, and local health departments. We also urge the state to require all MCPs to make current and updated provider directories available in standardized formats and multiple languages, so that beneficiaries and other stakeholders have access to comprehensive information on the providers available within a plan.

Access to HIV-specialized providers is vital for PLWH, as HIV patients see better outcomes when treated by an experienced HIV provider. Individuals with HIV whose care is managed by an experienced HIV medical provider are

more likely to be retained in care, virally suppressed, and to receive more cost-effective care. (reference: Kitahata MM, Koepsell TD, Deyo RA, Maxwell CL, Dodge WT, Wagner EH. Physicians' experience with the acquired immunodeficiency syndrome as a factor in patients' survival. New Engl J Med. 1996;334:701–7. [PubMed])

The importance of care continuity for medically underserved patients, particularly PLWH, 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.

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. CMS 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. Ryan White providers are designated as essential community providers (ECPs) by the federal government because of the role they play in caring for and treating medically underserved and low-income people with HIV/AIDS. (reference: Kaiser Family Foundation, "Contract Offering and Signing Standards for Essential Community Providers (ECPs) in Marketplaces," 2015

https://www.kff.org/other/state-indicator/contract-offeringand-signing-standards-for-essential-community-providersecps-in-

<u>marketplaces/?currentTimeframe=0&sortModel=%7B%22co</u> Ild%22:%22Location%22,%22sort%22:%22asc%22%7D)

ViiV requests that the state requires the MCPs to provide information about HIV education opportunities offered by the federal government to all physicians operating under the state Medicaid program as well as resources for consultation for inexperienced providers treating PLWH. Ongoing provider education with resources and information about HIV prevention and treatment, stigma and discrimination, populations disproportionately affected by HIV, and the role of pre-exposure prophylaxis (PrEP) in reducing HIV incidence among these at-risk populations is imperative.

The federal Health Resources and Services Administration (HRSA), which administers the Ryan White program, offers direct provider-to-provider consultation services through the National HIV/AIDS Clinician Consultation Center, including several consultation hotlines focused on HIV management post-exposure prophylaxis, perinatal HIV, and pre-exposure prophylaxis service. (reference: National Clinician Consultation Center: https://aidsetc.org/aetc-program/national-clinician-consulation-center)

Additionally, the Ryan White AIDS Education Training Centers (AETCs) are regional bodies which offer resources and programs for provider education on HIV. (reference: HRSA's AIDS Education and Training Center (AETC) Program: https://aidsetc.org/)

California has five AETC centers located across the state at: University of California, San Diego; University of California, San Francisco; University of California, Davis in Sacramento; University of California, Los Angeles David Geffen School of Medicine; University of California, Irvine. (reference: https://aidsetc.org/aetc-program/pacific-aetc)

DHCS goals for Medi-Cal managed care plans (Page 12) 7. Reducing health disparities Identify health disparities and inequities in access, utilization, and outcomes among racial, ethnic, language, and Lesbian, Gay, Bisexual, and Transgender and Questioning (LGBTQ) groups and have focused efforts to improve health outcomes within the groups and communities most impacted by health disparities and inequities.

HIV and Health Disparities

We applaud the state for including efforts around LGBTQ health in the RFI, as we recommended in our previous comments to the state.

ViiV requests that the state work to address health disparities in HIV, as evidenced by suboptimal rates of viral suppression among key populations. ViiV requests the state promote increased HIV education and awareness to MCPs and health care providers, which seeks to reduce stigma and discrimination against PLWH and populations at highrisk for HIV. Targeted outreach to minority populations, and providers that care for these populations, is imperative. This education could be done via the Medi-Cal Provider Bulletin, and other forms of communication such as educational webinars and engagement with HIV advocates.

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 race/ethnicity, gender, sexual orientation, or gender identity, drug use, or sex work. (reference: HIV.gov "Standing Up to Stigma" https://www.hiv.gov/hiv-basics/overview/making-a-difference/standing-up-to-stigma)

New diagnoses of HIV cases in the state decreased by 9.6 percent from 2014-2018. While there was a 20 percent reduction in new HIV diagnoses in white individuals, the state reports only a 3.9 percent reduction in Hispanic individuals, and a 2 percent increase among black individuals, confirming the disproportionate impact. (reference: 2018 California HIV Surveillance Report https://www.cdph.ca.gov/Programs/CID/DOA/CDPH
Document

Library/California_HIV_Surveillance_Report2018.pdf)

The inequity is also evident in viral load suppression rates of those living with HIV in California, with a statewide viral suppression rate of 56 percent. Latinxs and Native Hawaiian/Pacific Islanders were less likely to be virally suppressed (62 percent and 67 percent, respectively) compared to Whites, Asians, and multiracial persons (69 percent, 71 percent, and 72 percent, respectively). American Indian/Alaska Natives and Black/African Americans had lower viral suppression (58 percent and 57 percent, respectively) compared to all other groups. HIV also has a disproportionate impact in terms of gender, sexual orientation, and gender identity. Gender minorities face disparities in California. Cisgender men were more likely to be virally suppressed (65 percent) than cisgender women (62 percent), and transgender men were more likely to be virally suppressed (75 percent) than transgender women (60 percent). (reference: California Continuum of HIV Care report, 2018

https://www.cdph.ca.gov/Programs/CID/DOA/CDPH%20Doc ument%20Library/2018_HIV_CareContinuumFactSheet_All Living ADA.pdf)

We would like to further encourage the state to require that all providers in the state fulfill a minimum amount of continuing medical education (CME) training on HIV related topics. As an example, due to the high burden of HIV incidence, the District of Columbia requires licensed health professionals to complete at least ten percent of their continuing education in the public health priorities of the District, including HIV and LGBTQ cultural competency to help health care professionals to better understand the health challenges faced by these communities. (reference: District Of Columbia, DC.gov Board of Medicine, Continuing Education Requirements, https://dchealth.dc.gov/bomed)

ViiV suggests that the state issue a Medi-Cal Provider Bulletin to all providers in the state with resources and information about stigma, HIV, and the populations disproportionately affected by HIV including LGBTQ

for Medi-Cal managed care plans (Page 11)	presence and engagement Establish and expand a stable local presence and collaborate and engage with local community	ViiV would like to recommend the state establish a working group to bring the MCPs together with DHCS, the Office of AIDS and STD Branch to engage on topics related to HIV care and treatment, and to attempt to coordinate efforts to address HIV across these institutions. This not only works to align efforts, but also will impact issues related to social determinants of health with our most vulnerable populations.
DHCS goals	9. Local	populations, and the role PrEP can offer in reducing HIV incidence among these at-risk populations. Second, we suggest that the state require the MCPs to provide information about HIV education opportunities to all physicians operating under the Medi-Cal program as well as resources for consultation for inexperienced providers treating PLWH. Third, we would like to further encourage the state to require that all providers in the state fulfill a minimum amount of continuing medical education (CME) training on HIV related topics. Finally, we urge DHCS to partner with the local Departments of Health to provide information to the MCPs about U=U. In addition, providers should be made aware of the scientific breakthrough that HIV treatment also offers the benefit of prevention of HIV transmission. Multiple studies showed that PLWH on antiretroviral therapy (ART) who have undetectable HIV levels in their blood, have no risk of passing the virus on to their HIV-negative partners sexually. As a result, the CDC estimates viral suppression on effectiveness in preventing HIV transmission at 100 percent when HIV positive individuals maintain viral suppression on ART. (reference: CDC.gov "Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV" https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html/ This scientific revelation led to the development of a movement called "U=U" or "Undetectable = Untransmittable" which shares the message among PLWH that achieving viral suppression can help end the HIV epidemic. Several regional health departments in California have endorsed U=U. (reference: National Alliance of State and Territorial AIDS Directors (NASTAD), "UNDETECTABLE = UNTRANSMITTABLE: HEALTH DEPARTMENT ENGAGEMENT MAP" https://www.nastad.org/maps/undetectable-untransmittable-health-department-engagement-map)

partners and resources to ensure community needs are met.

We understand that a statewide advocacy coalition to End the HIV/HCV/STD Epidemics exists, but more could be done to pull this public health effort into DHCS and develop tangible goals for the MCPs. The state should make every effort to increase coordination between the plans and the other state agencies that serve PLWH, and the community in order to establish improvements in care and treatment. As background, in 2019, the federal DHHS announced a goal to end the HIV epidemic in the U.S. within 10 years and released the "Ending the HIV Epidemic: A Plan for America." This plan proposes to use scientific advances in antiretroviral therapy to treat PLWH and expand proven models of effective HIV care and prevention. The plan also focuses its efforts to stop the HIV epidemic across government agencies. The following counties in California have been targeted by the EHE initiative for high rates of new HIV infections: Alameda County, Los Angeles County, Orange County, Riverside County, Sacramento County San Bernardino County, San Diego County and San Francisco County. (reference: Ending the HIV Epidemic Counties and Territories, https://files.hiv.gov/s3fs-public/Ending-the-HIV-Epidemic-Counties-and-Territories.pdf)

ViiV asks that the state raise awareness of the federal "Ending the HIV Epidemic" initiative (EHE) especially in the 8 EHE-identified counties in California, and require the MCPs to engage with the jurisdictional plan leaders, and support EHE efforts in these jurisdictions as a goal in their contracts. As part of this request, we encourage the state to engage in contractual agreements that include HIV quality measures, such as VLS goals, and PrEP utilization.

In order to promote the goals of the EHE plan, it is imperative that state Medicaid programs, as the largest source of coverage for people with HIV, align with local and national efforts to end the HIV epidemic, and promote policies that contribute to HIV public health goals, such as preserving continuous access to comprehensive health care, including ART. Medicaid is the largest source of coverage for people living with HIV. (reference: Kaiser Family Foundation. Medicaid and HIV, http://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/)

Conclusion

Thank you for your consideration of our comments. We hope that California will continue to work towards the goal of ending the HIV epidemic. Please feel free to contact me at kristen.x.tjaden@viivhealthcare.com with any questions.

Sincerely,

Kristen Tjaden

Government Relations Director

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ViiV Healthcare