



April 27, 2018

Submitted via email to: [publicinput@dhcs.ca.gov](mailto:publicinput@dhcs.ca.gov)

Director Jennifer Kent  
Department of Health Care Services  
P.O. Box 997413  
MS 0000  
Sacramento, CA 95899-7413

**Re: MEDI-CAL Managed Care Quality Strategy Report**

Dear Director Kent,

ViiV Healthcare appreciates this opportunity to comment on the California Department of Health Care Services' (DHCS or Department) Medicaid Quality Strategy. ViiV Healthcare is the only pharmaceutical manufacturer devoted exclusively to supporting the needs of people living with or affected by human immunodeficiency virus (HIV). From ViiV Healthcare's inception in 2009, we have had a singular focus to improve the health and quality of life of people affected by this disease, and have worked to address significant gaps and unmet needs in HIV care. In collaboration with the HIV community, ViiV Healthcare remains committed to developing meaningful treatment advances, and supporting the HIV community to facilitate enhanced care and treatment.

ViiV Healthcare supports the Department's commitment to improving the quality and delivery of care in the California Medicaid program, Medi-Cal. We believe it is critically important to ensure that policies in this program advance what is of value to the patient, particularly for people living with HIV (PLWH). In alignment with the DHCS' vision to provide continuous quality improvement in population health and health care across all departmental programs, we provide comments in the following areas:

- Expand existing (measured) focus areas to prioritize HIV quality measures and their association to chronic diseases, i.e. diabetes
- Expand (non-measured) focus area of reducing opioid misuse and overuse to include reducing new cases of HIV through Performance Improvement Activities (PIA)
- Adopt Pharmacy Quality Alliance (PQA) and Health Resources and Services Administration (HRSA)-Owned, HIV Core Measures, specifically viral load suppression outcome measure

**I. Expand existing (measured) focus areas to include HIV quality measures and their association to chronic diseases, i.e. diabetes**

ViiV Healthcare supports DHCS's continual updates to and consideration of new measures that can enhance quality, patient-centric care and encourages the Department to consider the adoption of quality measures that improve patient outcomes for their given health condition. The Medicaid Managed Care and Children's Health Insurance Program (CHIP) Managed Care Final Rule (Final Rule), at 42 Code of Federal Regulations (CFR) 438.340, requires each state Medicaid agency to implement a quality strategy to assess and improve the quality of health care and services furnished by all Medicaid managed care entities in that state. Additionally, the Final Rule requires the Medicaid quality strategy to include the State's goals and objectives for continuous quality improvement, which must be measurable and take into consideration the health status of *all* populations in the State. To that end, we respectfully request the inclusion of quality measures to address the population health of people living with HIV (PLWH) into the

Medi-Cal quality reporting program. Doing so will address an important gap in care and prioritizes a population that is managing multiple co-morbidities now that PLWH are living longer.

HIV co-morbidity with non-communicable diseases such as diabetes, cardiovascular disease, and mental, neurological and substance use disorders has become more prevalent in recent years.<sup>1</sup> As antiretroviral therapy (ART) is now recommended for all patients regardless of CD4 T lymphocyte (CD4) cell count, and because therapy should be continued indefinitely, the focus of patient management has evolved from identifying and managing early ART treatment to also addressing these and other co-morbidities.<sup>2</sup> Currently, Medi-Cal uses solely Healthcare Effectiveness Data and Information Set (HEDIS) quality measures to report performance data for its diabetic population. The deficiency of HEDIS is that it does not include HIV measures in the specifications, thus limiting California's ability to address this disease.

ViiV Healthcare encourages DHCS to expand its measure-focus on chronic diseases to include HIV with the assistance of the Health Services Advisory Group (HSAG). They can provide technical assistance to support measurable improvement in the quality of service delivery and health outcomes for both HIV and comorbid chronic conditions. An example can be seen in Florida, who uses a suite of measures pulled from various sources such as HEDIS, the Children's Health Insurance Program Reauthorization Act (CHIPRA) Child Core Set measures, and State-defined measures, (e.g. as the percentage of enrollees with HIV/AIDS that were seen by a doctor outside of the hospital). Florida also requires health plans to report on the Health Resources and Services Administration (HRSA)-owned measure, HIV: Viral Load Suppression Measure.<sup>3</sup> Utilizing quality measures from varied sources will ensure that DHCS will address and quantify the quality of care delivered to all of its Medicaid constituents without neglecting any vulnerable populations.

## **II. Expand (non-measured) focus area of reducing opioid misuse and overuse to include reducing new cases of HIV through Performance Improvement Activities (PIA)**

ViiV Healthcare applauds DHCS for addressing the misuse and overuse of opioids. We encourage the Department to consider the explicit linkage between the rise in new diagnoses of HIV and the opioid epidemic. The CDC has published data on 220 U.S. counties with the highest rates of opioid addiction<sup>4</sup>, and has identified 32 states and 7 counties experiencing or at-risk of an HIV outbreak due to injection drug use.<sup>5</sup> According to the CDC, substance use disorders are closely associated with HIV and other sexually transmitted diseases. Injection drug use (IDU) can be a direct cause of HIV transmission if people share needles, syringes, or other injection materials. However, drinking alcohol and ingesting, smoking, or inhaling drugs are also associated with increased risk for HIV, as substance use can alter judgment and lead to high-risk behaviors for HIV transmission. Health officials in several states and regions have reported increased HIV transmissions due to the opioid epidemic.<sup>6,7</sup> In PLWH, substance use can also hasten disease progression, affect adherence to antiretroviral therapy (HIV medicine), and worsen the overall consequences of HIV.<sup>8</sup>

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<sup>1</sup> Narayan KM, Miotti PG, Anand NP et al. HIV and noncommunicable disease comorbidities in the era of antiretroviral therapy: a vital agenda for research in low- and middle-income country settings. *J Acquir Immune Defic Syndr* 2014;67(Suppl 1): S2–7.

<sup>2</sup> Panel on Antiretroviral Guidelines for Adults and Adolescents. [Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV](#). Department of Health and Human Services.

<sup>3</sup> [http://www.fdhc.state.fl.us/medicaid/Policy\\_and\\_Quality/Quality/docs/CQS\\_Final\\_Draft\\_2017\\_03-02-2017.pdf](http://www.fdhc.state.fl.us/medicaid/Policy_and_Quality/Quality/docs/CQS_Final_Draft_2017_03-02-2017.pdf). Accessed April 23, 2018.

<sup>4</sup> *J Acquir Immune Defic Syndr*. 2016 Nov 1 "County-Level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infections Among Persons Who Inject Drugs, United States." <https://www.ncbi.nlm.nih.gov/pubmed/27763996>

<sup>5</sup> CDC. Drug Use and HIV. CDC Consultations on Determination of Need Requests: <https://www.cdc.gov/hiv/risk/ssps-jurisdictions.html>

<sup>6</sup> Northern Kentucky Health Department. Press Release: "Health Officials See Increase in HIV Infection Among Individuals Who Inject Drugs." January 9, 2018. <https://nkyhealth.org/2018/01/09/health-officials-see-increase-in-hiv-infection-among-individuals-who-inject-drugs/>

<sup>7</sup> Massachusetts, Department of Public Health, MDPH Clinical Advisory, HIV Transmission through Injection Drug Use, November 27, 2017 [https://hmcrcg3.org/wp-content/uploads/sites/90/2017/12/112707ClinicalAdvisory\\_HIV.pdf](https://hmcrcg3.org/wp-content/uploads/sites/90/2017/12/112707ClinicalAdvisory_HIV.pdf)

<sup>8</sup> CDC data: <https://www.cdc.gov/hiv/risk/substanceuse.html>. Accessed April 23, 2018.

In February 2018, the National Committee for Quality Assurance (NCQA) published for public comment new measures to assess risk of chronic opioid use.<sup>9</sup> We encourage DHCS to support the development of PIA to address HIV testing for all patients with opioid use disorder. This research can underpin the development of future performance measures that link opioid patients to those patients identified with HIV infection, to facilitate improved HIV treatment and care.

### **III. Adopt Pharmacy Quality Alliance (PQA) and Health Resources and Services Administration (HRSA)-Owned, HIV Core Measures, specifically viral load suppression outcome measure**

Innovative advances in the treatment and prevention of the HIV virus have played a significant role in transforming HIV from what was once considered to be a terminal illness to, in many cases, a manageable, chronic disease. As the size of U.S. HIV positive population has grown over time, so too have the number of people with HIV 65 years of age and older. The number of Medicare beneficiaries with HIV have tripled since the 1990s, rising from 42,520 in 1997 to 120,000 in 2014.<sup>10,11</sup> Many Medicare beneficiaries with HIV are dually-eligible for Medicare and Medicaid, and receive low-income subsidies under Medicare Part D, thus increasing the federal spending for PLWH.<sup>12</sup>

Evidence-based quality measures assessing HIV care exist, are endorsed by the National Quality Forum (NQF), and used in federal programs, such as the Merit-based Incentive Payment System (MIPS) and the Ryan White HIV/AIDS Program.<sup>13,14</sup> HIV quality measures are critical to elevating the importance of the care and treatment of patients living with HIV and for reducing the incidence of new HIV infections. The HIV care continuum and measurement framework of diagnosis, treatment, and viral load suppression leading to prevention is aligned with the Institute for Healthcare Improvement's Triple Aim of improving patient experience, reducing cost and improving population health.<sup>15</sup>

A 2011 interim analysis of the National Institutes of Health (NIH) HIV Prevention Trials Network study HPTN 052 found that treating HIV-1-infected patients with antiretroviral therapy (ART) reduced the risk of transmitting the virus to HIV-negative sexual partners by 96%.<sup>16</sup> The final analysis involved over five years of follow up in the full set of HIV-1-infected partners, and found a 93% reduction in transmission

ViiV Healthcare highly recommends the adoption of PQA and HRSA HIV/AIDS Bureau-owned, HIV quality measures for Medi-Cal quality reporting for specialty plans, i.e. AIDS Healthcare Foundation.<sup>17</sup> Currently, this specialty health plan is required to report on two HEDIS measures, not related to the HIV population for whom they provide care. Optimal outcomes for PLWH can only occur, if providers and plans are measured along 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 guidelines and federal guidelines.<sup>18</sup>

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<sup>9</sup> <http://blog.ncqa.org/hedis-public-comment-2/>

<sup>10</sup> Kaiser Family Foundation. [Medicare and HIV](#). October 2016.

<sup>11</sup> The 1997 estimate is from Gilden DE, Kubisiak JM, Gilden DM. Managing Medicare's HIV Caseload in the Era of Suppressive Therapy. *AJPH*. Vol. 97, No. 6; June 2007. The 2014 estimate is based on Kaiser Family Foundation's analysis. Kaiser Family Foundation analysis of the 5% sample (see endnote 2) and CDC. (2014) [Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV](#) — United States, 2011. *MMWR*. 63(47):1113-1117.

<sup>12</sup> <https://www.kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hiv-aids-trends-over-time/#footnote-242359-3>

<sup>13</sup> See: [Quality Measures](#), Quality Payment Program.

<sup>14</sup> [Performance Measure Portfolio](#). HRSA. Accessed April 16, 2018.

<sup>15</sup> The IHI Triple Aim. IHI. <http://www.ihio.org/Engage/Innovates/TripleAim/Pages/default.aspx>.

<sup>16</sup> Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *N Engl J Med* 2011; 365:493-505. See also <http://www.cdc.gov/hiv/prevention/research/art/>;

<sup>17</sup> Cohen MS, Chen YQ, McCauley M, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. *N Engl J Med* 2016; 375:830-839. Available at: <http://www.nejm.org/doi/full/10.1056/NEJMoa1600693>

<sup>18</sup> HIV Medicine Association. Tools for Monitoring HIV Care: HIV Clinical Quality Measures (Updated) February 2015. Available at: [http://www.hivma.org/uploadedFiles/HIVMA/Policy\\_and\\_Advocacy/Policy\\_Priorities/Increased\\_Federal\\_Funding/Comments/Tools\\_for\\_Monitoring\\_Issue\\_Brief\\_update%20Jan%202015.pdf](http://www.hivma.org/uploadedFiles/HIVMA/Policy_and_Advocacy/Policy_Priorities/Increased_Federal_Funding/Comments/Tools_for_Monitoring_Issue_Brief_update%20Jan%202015.pdf). Accessed: March 20, 2018.

ViiV Healthcare highly recommends the inclusion of the following PQA and HRSA HIV/AIDS Bureau-owned, HIV quality measures:

- Prescription of HIV Antiretroviral Therapy
- HIV Medical Visit Frequency
- HIV Viral Suppression
- Adherence to Antiretroviral Medications – Proportions of Days Covered (PDC) measure

Adoption of these measures into the Medi-Cal quality reporting program presents an opportunity for the expanded use of HIV quality measures across public quality programs and to promote evidence-based care for aging HIV patients.

We appreciate the state's consideration of these comments and applaud the state for its commitment to improving health outcomes for our most vulnerable patients. ViiV Healthcare looks forward to working with the DHCS and other stakeholders to ensure California's Medicaid quality reporting program supports PLWH have access to quality care and to improve health outcomes.

Sincerely,

**Original Signed by**

Kristen Tjaden  
Community Government Relations Director  
ViiV Healthcare