



July 1, 2022

Xavier Becerra
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Recommendations for Future Guidance to State Medicaid Programs on HIV Prevention, Care, and Treatment Services

Dear Secretary Becerra:

The HIV Health Care Access Working Group (HHCAWG) is a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV-related health care and support services. The Biden Administration has made ending the HIV epidemic a priority, as part of its overall effort to address racial and ethnic health disparities and increase access to health care for vulnerable Americans. As a concrete step toward that goal, **we urge you to update the 2016 HHS bulletin** entitled *Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries* (“HIV Bulletin”), which encouraged state Medicaid programs to adopt policies to increase access to appropriate HIV prevention, care and treatment services.¹

Since 2016, there have been significant developments in HIV testing, biomedical prevention, and treatment. On December 1, 2021, the White House Office of National AIDS Policy released the 2022-2025 National HIV/AIDS Strategy,² designed to closely align with its ambitious initiative to End the HIV Epidemic.³ These initiatives further align with community-led demands that call for action to address the epidemic.⁴ Because Medicaid plays such an outsize role providing

¹ Joint HHS, CMCS, HRSA, and CDC Informational Bulletin, Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries, December 1, 2016, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf>.

² White House Office of National AIDS Policy, National HIV/AIDS Strategy for the United States 2022-2025, available at <https://hivgov-prod-v3.s3.amazonaws.com/s3fs-public/NHAS-2022-2025.pdf>.

³ HHS, Ending the HIV Epidemic Initiative, available at <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

⁴ AIDS United and Act Now: End AIDS, Ending the HIV epidemic in the United States: A roadmap for Federal action, available at <https://aidsunited.org/ending-the-hiv-epidemic-in-the-us/>.

access to HIV prevention and treatment, achieving the goal of ending the epidemic cannot be accomplished without the full participation of state Medicaid programs.

Overview of Recommendations

The chart below provides a summary of the topics that HHS should include in an updated HIV Bulletin as guidance for states, by category. Compare with a similar chart in the 2016 HIV Bulletin.⁵ (Bolded content represents new recommendations included in this letter, which are not included in the 2016 HIV Bulletin.)

HIV Prevention/Care Service	Opportunities for Medicaid Program
Health Equity and Addressing Disparities	<ul style="list-style-type: none"> • Ensure that HIV treatment and prevention efforts are executed in a way that considers and responds to health disparities in transmission and access to treatment
HIV Testing and Diagnosis	<ul style="list-style-type: none"> • Cover USPSTF recommended HIV screening without cost sharing for all Medicaid and CHIP beneficiaries • Cover HIV screening services when provided by unlicensed providers that meet qualifications established by the state • Cover HIV self-testing and point-of-care testing for HIV and other STIs
Pre-Exposure Prophylaxis (PrEP)	<ul style="list-style-type: none"> • Cover PrEP and associated ancillary services without cost sharing, in line with the USPSTF Grade A Rating • Ensure that utilization management techniques are not designed or implemented in ways that limit access to PrEP among persons for whom it is indicated, including all sexually active adults and adolescents • Cover PrEP services, including FDA-approved covered drugs approved for PrEP, including Descovy and Apretude with lead-in oral regimen • Cover PrEP when administered as a “2-1-1” or “event-based” prescription • Cover all medically necessary ancillary services, including RNA testing every three months • Cover access to clean needles and syringes for people who inject drugs and drug treatment services (where legal) • Cover PrEP in limited-benefit Medicaid programs, including family planning Medicaid programs
Linkage and Retention in Care for People Living with HIV (PLWH)	<ul style="list-style-type: none"> • Include HIV-infection among the eligibility criteria for state Medicaid Health Home models

⁵ *Supra* note 1, at 18.

	<ul style="list-style-type: none"> • Leverage Targeted Case Management service options and waiver authorities to develop unique programs to coordinate and improve access to medical, behavioral, and social services for PLWH • Coordinate benefits with other programs that support access to HIV prevention, care and support services (e.g., Ryan White HIV/AIDS Program service providers, Medicare)
Effective Treatment for PLWH	<ul style="list-style-type: none"> • Cover all regimens described for potential use (including those labeled as “Recommended,” “Alternative,” and “Other”) in DHHS Guidelines for providing antiretroviral therapy (ART) to PLWH • Cover Cabenuva, including lead-in oral regimen • Design and implement utilization management techniques that promote adherence (e.g., include single table regimens on preferred drug lists) • Promote “rapid ART”
Quality Improvement and Monitoring Activities	<ul style="list-style-type: none"> • Collect and report to CMS results for the HIV Viral Load Suppression measure, or proxy measures based on claims data • Collect and report to CMS results for PrEP uptake and persistence • Implement the VLS and other HIV prevention and care-related quality measures as part of targeted quality improvement activities
Addressing Syndemics and Other Health Needs	<ul style="list-style-type: none"> • Cover USPSTF recommended screening for viral hepatitis • Remove any barriers to hepatitis C treatment access, including restrictions based on fibrosis score, sobriety, and prescriber type • Cover substance use disorder treatment • Cover all medically necessary gender affirming care for adults and adolescents, including surgery, hormone therapy, electrolysis, mental health services, and necessary ancillary services • Take advantage of waiver flexibilities to provide housing supports

Additionally, the chart below provides a summary of the activities that HHS should undertake to promote access to HIV treatment and prevention, by category.

HIV Prevention/Care Service	Opportunities for HHS
HIV Testing and Diagnosis	<ul style="list-style-type: none"> • Work with the FDA to ensure testing sites, manufacturers, and consumers are aware of any limitations on self-testing products

Pre-Exposure Prophylaxis (PrEP)	<ul style="list-style-type: none"> Clarify that the USPSTF Grade A Rating of PrEP requires coverage of ancillary services without cost sharing for members of the Medicaid expansion population and conduct a nationwide audit to ensure the requirement is implemented without inappropriate barriers. Work with states to encourage them to cover preventive services, including PrEP, for all Medicaid enrollees, inclusive of all necessary ancillary services.
Effective Treatment for PLWH	<ul style="list-style-type: none"> Release guidance required by the SUPPORT Act, to allow states the opportunity to provide Medicaid coverage to incarcerated individuals up to 30 days pre-release
Quality Improvement and Monitoring Activities	<ul style="list-style-type: none"> Add to the Adult Core Data Set an alternative measure for viral load suppression that allows states to use claims data to track rates of adherence
Addressing Syndemics and Other Health Needs	<ul style="list-style-type: none"> Explicitly prohibit categorical exclusions to gender affirming care, such as those for minors

Health Equity and Addressing Disparities

Fully addressing the HIV epidemic requires addressing disparities in transmission and treatment access. We ask HHS to require state Medicaid programs to consider how to address disparities when implementing HIV treatment and prevention policy.

Although significant improvements in HIV treatment and prevention have been made over the last several decades, the epidemic continues to persist in large part because of unequal access to treatment and prevention services and structural factors that disproportionately impact certain populations. The result is pronounced disparities in infections and health outcomes across groups.⁶ Federal and state strategies to end the HIV epidemic must focus on increasing access to HIV treatment and prevention to the communities at greatest risk and impact, including Black and Latinx communities, transgender and cisgender women, people who use drugs, men who have sex with men, and people with experience in the criminal justice system, among others, are at higher risk of acquiring HIV.⁷ Many of these same people also have diminished access to treatment and prevention services and are more likely to be subject to discrimination, including in health care settings. We urge HHS to recommend that states actively consider and address the needs of these communities, including by addressing structural factors that limit access to prevention, testing, and treatment. An updated HIV Bulletin should apply a health equity lens to all of its recommendations and propose health equity as a guiding principle for ongoing and future state efforts to address the HIV epidemic.⁸

⁶ NIH, To end the HIV epidemic, we must address health disparities, February 19, 2021, available at <https://www.nih.gov/news-events/news-releases/end-hiv-epidemic-we-must-address-health-disparities>.

⁷ *Supra* note 5, at 7.

⁸ See, e.g., The Department of Housing and Urban Development released recommendations about how to improve access to housing, centered on the principle of health equity. HUD, Equity Action Plan, available at <https://www.hud.gov/sites/dfiles/PA/documents/HUDEquity508compliant.pdf>.

HIV Testing and Diagnosis

New guidance must include updated information about HIV testing technology and testing algorithms.

Updated CDC Guidelines on Testing Algorithms

Since publication of the 2016 HIV Bulletin, testing sites are incorporating different combinations of point-of-care and lab-based tests into their testing protocols. The CDC has subsequently updated its guidelines to provide more information to testing partners on appropriate uses and any limitations associated with each test. HHS should incorporate and reference the updated testing guidelines issued by the Centers for Disease Control and Prevention (CDC) since the original publication of the HIV Bulletin.⁹ Further, HHS should reemphasize long-standing CDC recommendations that promote widespread access to testing, including recommendations for opt-out HIV testing in hospital emergency departments and other health care settings, in order to increase uptake of testing and to reduce stigma. An updated HIV Bulletin should also promote awareness among relevant parties of opportunities for point-of-care testing for other sexually transmitted infections (STIs).

New Guidance on Self-Testing

Self-testing technology for HIV has increased rapidly, particularly over the past two years as testing programs adapted to COVID precautions. In response to this uptick in self-testing demand, CDC has issued new guidance on self-testing products and best practices for self-testing programs.¹⁰ We urge HHS to work with the Food and Drug Administration (FDA) to ensure testing sites, manufacturers, and consumers are aware of any limitations on self-testing products pending FDA approval and to facilitate full approval of self-tests and supplies. Additionally, we recommend that HHS promote awareness and opportunities for at-home specimen collections for other STIs.

Pre-exposure Prophylaxis (PrEP)

The inclusion of detailed information about PrEP and best practices for Medicaid coverage and delivery in the 2016 HIV Bulletin has provided a critical education resource for Medicaid programs. Since the publication of the 2016 HIV Bulletin, the PrEP space has continued to evolve rapidly. We recommend that HHS issue new guidance reflecting the advent of new PrEP antiretroviral products and updated CDC guidelines, including new recommendations with regard to who is indicated for PrEP, the requisite lab testing, and considerations for different PrEP formulations.

New CDC Guidelines

In 2021, CDC released an updated version of the PrEP Clinical Practice Guidelines.¹¹ These new guidelines include several important updates that should be incorporated into an updated HIV Bulletin, including the following changes of particular relevance to Medicaid:

⁹ CDC, HIV Testing Guidelines, available at <https://www.cdc.gov/hiv/guidelines/testing.html>.

¹⁰ CDC, HIV Self-Testing Guidance, available at <https://www.cdc.gov/hiv/testing/self-testing.html>.

¹¹ CDC, Preexposure Prophylaxis for The Prevention Of HIV Infection In The United States – 2021 Update, available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

- The guidelines include new information on two additional products for PrEP, including product-specific prescriber guidance. The first is emtricitabine/tenofovir alafenamide, sold under the brand-name Descovy.¹² This product was approved in 2019 for a PrEP indication for sexually active men and transgender women (it was not approved for cisgender women). The second product is a long-acting cabotegravir, sold under the brand-name Apretude.¹³ When the CDC guidelines were published, the FDA had not yet approved Apretude, but it was subsequently approved in December 2021.¹⁴
- The guidelines also update the indications for PrEP, including a broad recommendation that all sexually active adults and adolescents are informed about PrEP,¹⁵ and simplified assessment of PrEP appropriateness if given for all sexually active individuals and individuals who inject drugs.¹⁶
- The guidelines include new information on novel and innovative delivery mechanisms for PrEP, including best practices for “same-day” access to PrEP as well as telehealth models.¹⁷ In addition, the guidelines include a recommendation for “2-1-1” or “event-based” PrEP prescribing for tenofovir/emtricitabine (TDF/FTC), a practice that is better able to meet consumer needs when 30-day prescriptions may not be warranted. The CDC acknowledges that this practice constitutes an off-label use of TDF/FTC.¹⁸
- The guidelines update the HIV testing algorithm in keeping with new testing technologies. The guidelines now recommend an HIV RNA test at every three-month interval and update the interval for regular creatine testing, recommending eCrCl every 12 months for persons <50 years of age or with eCrCL \geq 90 ml/min at PrEP initiation and every 6 months for all other people.¹⁹ This is a particularly important lab test, in addition to regular HIV and STD testing, because of the potential impact PrEP medications may have on renal functioning for some people.
- The guidelines include an explicit recommendation to provide people who inject drugs access to clean needles/syringes (where legal) and drug treatment services every three months.²⁰

USPSTF Grade A for PrEP: Coverage and Cost-Sharing Requirements

In June 2019, The U.S. Preventive Services Task Force (USPSTF) issued a Grade A for PrEP,²¹ recognizing the overwhelming efficacy and safety of the intervention. The ACA requires most private health insurance plans and Medicaid expansion programs to cover all USPSTF Grade A and B recommended services without cost sharing. For traditional Medicaid, if states opt to

¹² *Id.* at 15.

¹³ *Id.* at 16.

¹⁴ FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention, December 20, 2021, available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-injectable-treatment-hiv-pre-exposure-prevention>.

¹⁵ *Supra* note 11, at 22.

¹⁶ *Id.* at 27.

¹⁷ *Id.* at 35.

¹⁸ *Id.* at 55.

¹⁹ *Id.* at 15.

²⁰ *Id.* at 15.

²¹ USPSTF, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis, June 11, 2019, available at <https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

provide USPSTF Grade A and B recommended services as well as Advisory Committee on Immunization Practices (ACIP) recommended services, they will get a one percent increase in their Federal Medical Assistance Percentage (FMAP). Any updated HIV Bulletin should include reference to the USPSTF recommendation for PrEP, including the coverage and cost-sharing requirements. HHS should conduct a nationwide audit to ensure the requirement is implemented without inappropriate barriers for Medicaid expansion populations. HHS should further work with states that do not accept the enhanced FMAP, by providing resources on the health equity and financial benefits of this opportunity, to ensure that there is equal access to preventive medication. HHS should also consider and address the likelihood of additional USPSTF recommendations related to Apretude.

We commend the Departments of Health and Human Services, Labor, and Treasury for publishing a set of “Frequently Asked Questions” for insurance plans on how to implement the coverage and cost-sharing requirements associated with the USPSTF Grade A for PrEP.²² We urge HHS to explicitly adopt these recommendations for Medicaid programs. The guidance includes clarification that the PrEP intervention is more than just the antiretroviral (ARV) therapy and includes a suite of services that are both clinically recommended and integral to safe and effective use of ARVs for PrEP. This includes the requisite lab tests at initiation of PrEP and at specified intervals while someone is taking PrEP (HIV testing, hepatitis B and C testing, STI testing, pregnancy testing, and creatine level testing) as well as medical visits and adherence counseling. We urge HHS to also include additional ancillary services referenced in the 2021 update to the CDC PrEP Guidelines, including access to clean needles/syringes (where legal) and drug treatment services for people who inject drugs.

The tri-agency guidance referenced above also includes important protections to ensure access to the PrEP formulation appropriate for each individual. There are now several PrEP formulations approved by FDA and more in the approval pipeline. We urge HHS to adopt guidance for Medicaid programs that requires coverage, without cost sharing, of the PrEP formulation that is necessary for the individual based on clinical guidelines. For instance, while TDF/FTC is an appropriate first-line choice for most individuals indicated for PrEP, there are some individuals with bone and kidney functioning markers for whom a TAF-based regimen may be clinically appropriate. In this example, Medicaid programs and plans should have clear and easy-to-navigate processes to ensure access to a TAF-based regimen in these cases, with no cost sharing. We also urge HHS to include guidance with regard to inappropriate uses of prior authorization for PrEP. For instance, prior authorization should never be used to identify if someone is at high risk for HIV. CDC guidelines make it clear that the screening for HIV risk should be broad and flexible. To ensure that prior authorization requirements do not inadvertently create stigmatizing and potentially discriminatory barriers to PrEP, Medicaid programs should leave identification of HIV risk to the provider.

²² Tri-agencies, FAQs about Affordable Care Act Implementation Part 47, July 19, 2021, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf>.

Long-Acting Injectable Formulation for PrEP

New modalities of PrEP – including long-acting injectable formulations – have the potential to increase access to PrEP, particularly for individuals for whom adherence to a daily oral pill regimen is difficult.

In December 2021, the FDA approved long-acting cabotegravir for the prevention of HIV, sold under the brand Apretude and manufactured by ViiV Healthcare. The approval of long-acting cabotegravir provides more options for individuals and has the potential to increase overall PrEP uptake in the U.S. The FDA label indicates Apretude for individuals who have tested negative for HIV. These individuals are administered an oral lead-in dosing to assess their tolerability to Apretude.²³ However, the novel administration route may pose challenges for both consumers and providers, and we urge HHS to issue guidance on best practices for coverage, including:

- Directing Medicaid programs and plans to the FDA label for information on appropriate indications;
- Ensuring coverage of ancillary services associated with Apretude without cost sharing, including administration costs, in addition to the suite of services described above and referenced in the updated CDC guidelines for PrEP;
- Ensuring access to individuals indicated for Apretude and that any utilization management is based on clinical guidelines;
- Ensuring that information regarding coverage for long-acting injectables is easily accessible via state Medicaid websites and Medicaid managed care materials, including when it is included on a separate medical benefit formulary; and
- Ensuring appropriate coverage of the lead-in oral regimen and the monthly injectable, without separate prior authorization processes for each.

Coverage of PrEP in Limited-Benefit Programs

Access to PrEP as a key preventive health tool should be a covered benefit across Medicaid programs, including limited-benefit Medicaid programs (e.g., family planning Medicaid programs). Currently, not all family planning Medicaid programs cover PrEP, and some impose utilization management controls in the administration of PrEP.²⁴ We encourage HHS to provide guidance to states to include PrEP in their definition of family planning services, and to ensure that this medication is not made inaccessible through over-use of utilization management. In particular, expanding coverage of PrEP across limited-benefit Medicaid programs is an important way to help increase access to PrEP in non-expansion states.

Effective Treatment with Antiretroviral Therapy (ART) for People Living with HIV

Since the initial publication of the HIV Bulletin in 2016, there has been rapid development in the HIV ARV space for treatment. We urge HHS to update their recommendations in line with the latest science to ensure access to novel and innovative products. In addition, we ask HHS to communicate to states the importance of treatment as prevention and that helping people achieve viral suppression can prevent new infections.

²³ FDA, Highlights of Prescribing Information (Apretude), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215499s0001bl.pdf

²⁴ Usha Ranji et al., Medicaid Coverage of Family Planning Benefits: Findings from a 2021 State Survey, February 17, 2022, available at <https://www.kff.org/womens-health-policy/report/medicaid-coverage-of-family-planning-benefits-findings-from-a-2021-state-survey/>.

Access to ART

State Medicaid programs continue to vary in their prescription drug formulary design, leading to unequal access to necessary care in states that impose undue barriers through utilization management. However, momentum is growing, as more states adopt the guidance put out in the 2016 HIV Bulletin by ensuring appropriate access to ARVs and removing unnecessary barriers.²⁵ We encourage HHS to reemphasize the importance of aligning Medicaid policy with HHS HIV treatment guidelines and minimizing unnecessary utilization management techniques.

Long-Acting Injectable Treatment

The first long-acting injectable product for the treatment of HIV was approved by the FDA in January 2021.²⁶ The FDA approved Cabenuva, a product manufactured by ViiV and consisting of cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension co-packaged for intramuscular use. It is approved for once monthly injections for individuals with HIV. The FDA also approved Vocabria (cabotegravir) 30 mg tablets, which should be taken in combination with oral rilpivirine (Edurant) for one month prior to starting treatment with Cabenuva. Uptake of this novel product has been slow, in part because of complexity in coverage, financing, and delivery. We urge HHS to include guidance to state Medicaid programs to:

- Ensure appropriate use of prior authorization. The FDA label indicates Cabenuva for individuals who are already virally suppressed. Yet some Medicaid programs are requiring demonstration of adherence problems with daily oral regimens as a requirement for Cabenuva. Medicaid programs and plans should be directed to federal HIV treatment guidelines²⁷ and the FDA label for information on appropriate indications; and
- Ensure appropriate coverage of the lead-in oral regimen and the monthly injectable, without separate prior authorization processes for each.

Rapid ART Programs

To meet the goals of the federal Ending the HIV Epidemic initiative, jurisdictions are accelerating efforts to quickly diagnose new HIV infections and link individuals to care and treatment, ideally on the same day. This also has important quality and cost implications for Medicaid, with studies finding that people with delayed antiretroviral therapy initiation accumulated more total health care costs in the 36-month period after HIV diagnosis than those initiated within 14 days.²⁸

²⁵ For example, in 2019 Texas passed legislation making clear that Medicaid plans may not require clinical, nonpreferred, or other authorization for any ARV, or a step therapy or other protocol, that could restrict or delay the dispensing of the drug except to minimize fraud, waste, or abuse. Tex. Gov. Code. § 531.073.

²⁶ FDA Approves Cabenuva and Vocabria for the Treatment of HIV-1 Infection, January 27, 2021, available at <https://www.fda.gov/drugs/human-immunodeficiency-virus-hiv/fda-approves-cabenuva-and-vocabria-treatment-hiv-1-infection>.

²⁷ HHS, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>,

²⁸ Carmela Benson, MS, MSHP, et al., Long-Term Benefits of Rapid Antiretroviral Therapy Initiation in Reducing Medical and Overall Health Care Costs Among Medicaid-Covered Patients with Human Immunodeficiency Virus, *J Manag Care Spec Pharm.* 2020;26(2):117-28.

Care Coordination and Transitions of Care

People living with HIV often rely on a large and complex network of health care coverage and services. Many receive their care across a number of programs, including Medicaid, Medicare, and the Ryan White HIV/AIDS Program (RWHAP). However, to the extent that these programs are administered in siloes, there may be missed opportunities to improve care coordination and service delivery, identify individuals that are eligible for other services, and streamline billing systems. We applaud HHS' inclusion of CMCS and HRSA's guidance on coordinating Medicaid and RWHAP in the 2016 HIV Bulletin.²⁹ We encourage CMS to reemphasize this guidance in an updated HIV Bulletin, and also to include guidance urging states to streamline care coordination for people living with HIV who are dually-eligible for Medicaid and Medicare.

Similarly, we urge HHS to urge states to streamline transitions between Medicaid and other coverage, including but not limited to: Marketplace plans, carceral settings, Medicare, and inpatient and institutional settings. Without appropriate support, these transitions are opportunities for care networks to break down and for people living with HIV to lose access to key services. Dedicated transition coordination services and seamless data exchange are two important ways that state Medicaid programs can help avoid care disruption. With regard to transitions for people leaving prison or jail and enrolling in Medicaid, we further encourage CMS to issue the guidance required by the SUPPORT (Substance Use Disorder Prevention that Promotes Opioid Treatment for Patients and Communities) Act, to allow states the opportunity to provide Medicaid coverage to incarcerated individuals up to 30 days pre-release.³⁰ Such policies will facilitate smooth transitions of care for people living with or at risk for HIV, who are reentering the community.

Quality Improvement and Monitoring Activities

We urge HHS to include specific recommendations for how HIV public health programs can work with their Medicaid counterparts to improve quality measure reporting in Medicaid for key HIV indicators, particularly those that align with the metrics included in the Ending the HIV Epidemic Initiative.

HIV Viral Load Suppression

We appreciate the 2016 HIV Bulletin's extensive discussion of the benefits of adopting the HIV viral load suppression quality measure, a measure already included in the Medicaid Adult Core Set. However, state Medicaid adoption of this measure is still relatively low. In FY 2018, only six states (Delaware, Louisiana, Nevada, New York, Rhode Island, and Texas) reported data for the HIV viral load suppression measure.³¹ The HRSA HIV/AIDS Bureau has recently funded an ambitious project to increase capacity of Medicaid programs to collect and report on this measure through a Special Project of National Significance (SPNS) award, which will support

²⁹ Joint CMCS and HRSA Informational Bulletin, Coordination between Medicaid and Ryan White HIV/AIDS Programs, May 1, 2013, available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CIB-05-01-2013_64.pdf.

³⁰ MaryBeth Musumeci & Jennifer Tolbert, Federal Legislation to Address the Opioid Crisis: Medicaid Provisions in the SUPPORT Act, at 2, available at <https://files.kff.org/attachment/Issue-Brief-Federal-Legislation-to-Address-the-Opioid-Crisis-Medicaid-Provisions-in-the-SUPPORT-Act>.

³¹ CMS, Quality of Care for Adults in Medicaid: Findings from the 2019 Adult Core Set, October 2020, available at <https://www.medicare.gov/medicaid/quality-of-care/downloads/performance-measurement/2020-adult-chart-pack.pdf>.

implementation of the viral suppression measure for Medicaid programs in up to ten states.³² We urge CMS to work with HRSA/HAB to identify replicable best practices to increase adoption of the measure and to note this SPNS initiative in an updated HIV Bulletin. We also encourage HHS to provide grant opportunities or other financial support to states to coordinate between Medicaid programs and health departments, both to facilitate data sharing in order to respond to this data measure, as well as to improve general program coordination and develop strong working relationships.

However, we recognize that this kind of coordinated data sharing can be difficult to implement. In states where sharing of viral load suppression data is logistically impractical, states should be encouraged to pursue alternative monitoring methods using claims data (e.g., tracking prescription of ARVs, gaps in HIV-related medical visits, etc.). We recommend that CMS consider adding at least one other HIV quality measure to the Adult Core Set to give states an alternative to the viral suppression measure.

PrEP

Because increased access to PrEP is a key pillar in the federal Ending the HIV Epidemic initiative, it is imperative that Medicaid programs and plans collect information about PrEP uptake and persistence and work collaboratively with governmental public health programs to increase the number of Medicaid beneficiaries using PrEP, particularly in communities of color. We urge HHS to include guidance for state Medicaid programs to:

- Regularly monitor PrEP uptake among Medicaid beneficiaries using the CDC and public health program developed algorithm to identify this group.³³ HHS should encourage states to collect this data alongside sexual orientation and gender identity (SOGI) data and other demographic data to help identify health disparities.
- Using the algorithm identified above and applying it longitudinally, explore opportunities to measure PrEP persistence among Medicaid beneficiaries. This is particularly important given research suggesting that PrEP persistence is lower among Medicaid beneficiaries than other groups.³⁴

The revised HIV Bulletin should explicitly reference CDC PrEP Guidelines and any recommended practice quality measures included, such as those outlined on page 42 of the 2021 PrEP Guidelines Clinical Providers' Supplement.³⁵

³² HRSA, NOFO 21-083, available at https://targethiv.org/sites/default/files/media/documents/2020-12/HRSA-21-083_final.pdf.

³³ Laufer et al., Vital Signs: Increased Medicaid Prescriptions for Preexposure Prophylaxis Against HIV infection — New York, 2012–2015, MMWR November 27, 2015. 64(46):1296-1301.

³⁴ Ya-Lin A Huang, Guoyu Tao, Dawn K Smith & Karen W Hoover, Persistence with Human Immunodeficiency Virus Pre-exposure Prophylaxis in the United States, 2012–2017 Clinical Infectious Diseases. 2021;72(3):379–385.

³⁵ CDC, Preexposure Prophylaxis for The Prevention Of HIV Infection In The United States – 2021 Update, Clinical Providers' Supplement, available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf>.

Section 11 Potential Practice Quality Measures^{37,38}

Primary (Outcome) Measures

Quality Indicator	Eligible Population	Numerator	Denominator
HIV testing, baseline	All persons prescribed PrEP medication	Number of patients with negative HIV test result documented within 1 week prior to initial prescription of PrEP medication	Number of persons prescribed PrEP
HIV testing, interval	All persons prescribed PrEP medications	Number of PrEP patients with an HIV test result documented at least every 3 months (F/TDF or F/TAF) or every 4 months (CAB) while PrEP medication prescribed	Number of persons prescribed PrEP for >3 months continuously
PrEP medication adherence	All persons prescribed PrEP medications	Number of PrEP patients with adherence assessment noted in the medical record for any visits when prescribed PrEP medication	Number of persons prescribed PrEP medication
Seroconversion	All persons prescribed PrEP medications	Number of patients with a confirmed HIV positive test result while PrEP medications prescribed	Number of persons prescribed PrEP medication for >1 month
Seroconversion, resistant virus	All persons prescribed PrEP medication who received a genotypic resistance test within 4 weeks after an HIV positive test result	Number of persons seroconverting while taking PrEP who have resistant virus detected by genotypic test	Number of persons prescribed PrEP medication who received a genotypic resistance test within 4 weeks after a confirmed HIV positive test result

Addressing Syndemics and Other Health Needs

We encourage HHS to support states in responding to the HIV epidemic by addressing other important health issues that disproportionately impact people living with and at risk for HIV. This is an important strategy to improve access to care and outcomes and overcome health disparities. Unfortunately, we know that certain comorbidities “cluster” among people living with HIV, and that these comorbidities can both increase the risk of poor outcomes and serve as barriers to treatment. New guidance must include updated recommended strategies to address syndemics and other health needs that are more likely to impact the HIV community.

Improve Access to Viral Hepatitis Screening and Treatment

Over 20% of people living with HIV in the United States are estimated to be co-infected or to have been previously infected with hepatitis C (HCV),³⁶ and 5-10% of people living with HIV are estimated to be co-infected with hepatitis B (HBV).³⁷ HHS should reference clinical guidelines that recommend HCV and HBV screening for all people who test positive for HIV, as well as HBV vaccination for individuals who screen negative.³⁸

Particular challenges currently exist around access to HCV treatment in many state Medicaid programs. In order to ensure that individuals who are HIV-HCV co-infected are able to receive effective treatment for all of their medical needs and achieve positive health outcomes, Medicaid beneficiaries must have the opportunity to be prescribed a range of hepatitis C medications. Many state Medicaid programs inappropriately restrict access to care, including through sobriety restrictions and prior authorization requirements that directly impede access to individuals at highest risk for HCV infection.³⁹ Furthermore, co-infected individuals must have the opportunity to be prescribed medications beyond what may be available on a state's Medicaid preferred drug list, in the case that such a prescription is necessary to manage potential drug interactions. We applaud CMS' continued efforts to promote the importance of access to HCV treatment, and we encourage HHS to emphasize access to HCV medication as a priority for HIV-HCV co-infected individuals in an updated version of the HIV Bulletin.

Improve Access to Substance Use Disorder Treatment and Mental Health Services

HHS included important information in the 2016 HIV Bulletin about the need for states to improve access to substance use disorder (SUD) treatment and mental health services, especially in light of the impact of the opioid crisis and the risk that it poses for people living with or at risk for HIV. Since then, the impacts of the opioid crisis have grown exponentially. Although all states provide some form of medication-assisted therapy (MAT) to treat SUD, access may be limited through benefit design limits and other constraints. In 2018, SAMHSA published a report entitled "Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose," highlighting considerations for state Medicaid programs, best practices, and examples of states covering MAT.⁴⁰ We encourage HHS to reference this resource in an updated version of the HIV Bulletin. Additionally, the provision of harm reduction services are critically important to limit transmission of HIV and viral hepatitis, and to provide support to people using injection drugs. HHS should provide direct recommendations as to how states can effectively cover harm

³⁶ CDC, People Coinfected with HIV and Viral Hepatitis, available at <https://www.cdc.gov/hepatitis/populations/hiv.htm>.

³⁷ HHS, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, Hepatitis B Virus/HIV Coinfection, available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hepatitis-b-virus-hiv-coinfection>.

³⁸ *Id.*; HHS, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, Hepatitis C Virus/HIV Coinfection, available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/hepatitis-c-virus-hiv-coinfection>.

³⁹ Hepatitis C: The State of Medicaid Access, available at <https://stateofhepc.org/>.

⁴⁰ SAMHSA, Medicaid Coverage of Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose, available at https://store.samhsa.gov/sites/default/files/d7/priv/medicaidfinancingmatreport_0.pdf.

reduction services through their Medicaid programs, including examples of other states that have done so.⁴¹ Further, we encourage HHS to provide guidance on appropriate access to mental health services. Such services are crucially important for people living with HIV, who are at increased risk for certain mental health conditions and can find ART adherence more difficult due to unmet mental health needs.

Improve Access to Gender Affirming Care

Medicaid serves as an important access point to care for many transgender and gender non-conforming people. Current federal guidelines highlight the well-documented connection between the provision of gender affirming care, improving mental health and well-being among transgender and gender non-conforming people, and facilitating HIV care engagement.⁴² Yet, coverage for gender affirming care varies widely across state Medicaid programs.⁴³

As part of an updated HIV Bulletin, HHS should make clear that all medically necessary gender affirming care must be provided to Medicaid beneficiaries. We strongly recommend that such guidance make explicit the full scope of medically necessary gender affirming care, including but not limited to hormone therapy, surgical care, mental health services, all necessary ancillary services, and primary and preventive care that is provided in a gender affirming, non-discriminatory manner. Currently, most state Medicaid programs do not provide the full range of medically necessary gender affirming services. We recommend that HHS look to standards of care developed by leading professional organizations that specialize in the provision of gender affirming care, including but not limited to those developed by the World Professional Association for Transgender Health (WPATH).⁴⁴ Of particular note, we emphasize that such care requirements should include:

- All necessary care, including primary and preventive care, without barriers as a result of gender marker requirements.⁴⁵ Coding coverage of services to be linked to certain gender markers can create serious barriers to care, especially considering the cost of changing names and gender markers on government documents, onerous and discriminatory surgical requirements, and the unavailability of accurate gender markers (e.g., limited availability of “X” gender markers);⁴⁶

⁴¹ New York Department of Health, Medicaid Harm Reduction Services Benefit, available at https://www.health.ny.gov/diseases/aids/consumers/prevention/medicaid_harm_reduction.htm.

⁴² HHS, Panel's Recommendations Regarding Transgender People with HIV, available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/transgender-people-hiv>; see also HHS Notice and Guidance on Gender Affirming Care, Civil Rights, and Patient Privacy, available at <https://www.hhs.gov/sites/default/files/hhs-ocr-notice-and-guidance-gender-affirming-care.pdf>.

⁴³ Movement Advancement Project, Healthcare Laws and Policies, available at https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/medicaid.

⁴⁴ WPATH, Standards of Care Version 7, available at <https://www.wpath.org/publications/soc>.

⁴⁵ Currently, some Medicaid services are unavailable to beneficiaries who need them because their gender marker does not match the state Medicaid requirement to access that service. Robin J. Kempf, Nicole M. Elias & Alonso J. Rubin-DeSimone, Transgender and Gender Non-Binary Healthcare Coverage in State Medicaid Programs: Recommendations for More Equitable Approaches, *J. Health Human Servs. Admin.* 2021;44(1):86-108.

⁴⁶ National Center for Transgender Equality, Identity Documents Center, available at <https://transequality.org/issues/health-hiv>.

- Hair removal services inclusive of electrolysis, which may be necessary for individuals with darker skin or hairs that otherwise do not respond to other forms of hair removal.⁴⁷ This coverage is necessary to ensure that Medicaid policies do not exacerbate existing racial disparities in access to care for gender affirming services;⁴⁸
- Appropriate care transitions and effective continuity of care for individuals entering or exiting carceral settings. Transgender and gender non-conforming people are disproportionately likely to be involved in the criminal justice system, and navigating access to gender affirming care is generally challenging. Transgender and gender non-conforming people require particular support during these transitions of care;⁴⁹ and
- Parity between fee-for-service and MCO and ACO coverage options. Parity is necessary to ensure equal access, and ensure that managed care plans are not applying onerous prior authorization requirements to gender affirming care that are not otherwise applied to services used to treat non-gender dysphoric diagnoses.

As part of these efforts, we strongly recommend that CMS explicitly prohibit categorical exclusions to gender affirming care, such as those for minors.⁵⁰ We also recommend that CMS include network adequacy requirements to ensure that Medicaid beneficiaries are able to access care from providers competent in providing care to transgender and gender non-conforming people. This is necessary, considering the high rates of discrimination faced by transgender and gender non-conforming people in healthcare settings.⁵¹

Improve Access to Tenancy Supports for People Living with HIV

Safe and stable housing is vital for people living with HIV. In 2015, CMCS released a bulletin for states outlining ways to cover housing-related activities for people with disabilities.⁵² For people living with HIV who are experiencing homelessness or unstable housing, states should explore covering Individual Housing Transition Services to help individuals find housing. Individual Housing & Tenancy Sustaining Services help people stay housed. When bundled and braided with HOPWA or HUD homeless funds, Medicaid-funded transition and tenancy support

⁴⁷ Cecily Reeves, Madeline B. Deutsch & Jeannine Wilson Stark, UCSF, Transgender Care: Hair Removal, June 17, 2016, available at <https://transcare.ucsf.edu/guidelines/hair-removal>.

⁴⁸ National Center for Transgender Equality, The Report of the 2015 U.S. Transgender Survey, 2016, at 98, available at <https://transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf> (“People of color, including multiracial (42%), American Indian (41%), Black (40%), and Latino/a (37%) respondents, were more likely to not have seen a doctor or other health care provider due to cost in the past year.”).

⁴⁹ National Center for Transgender Equality, LGBTQ People Behind Bars: A Guide to Understanding the Issues Facing Transgender Prisoners and Their Legal Rights, available at <https://transequality.org/sites/default/files/docs/resources/TransgenderPeopleBehindBars.pdf>.

⁵⁰ In 2021, the State of Arkansas passed “The Arkansas Save Adolescents from Experimentation (SAFE) Act,” banning gender affirming medical procedures for transgender people under age 18. A.R. Legis. Assemb. Act 626. Reg. Sess. 2021-2022 (2021).

⁵¹ *Supra* note 49, at 96 (“[O]ne-third (33%) [of those surveyed] reported (having at least one negative experience with a doctor or other health care provider related to being transgender, including having to teach the provider about transgender people in order to receive appropriate care (24%), being asked invasive or unnecessary questions about being transgender not related to the reason for the visit (15%), or being refused transition-related health care (8%)”).

⁵² CMCS Informational Bulletin, Coverage of Housing-Related Activities and Services for Individuals with Disabilities, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-26-2015.pdf>.

services can help funding that pays for rents go further. HHS should encourage states to take advantage of the waiver flexibilities outlined in the 2015 bulletin.

Thank you for the opportunity to provide these recommendations and for your consideration of these comments. If you have further questions, please do not hesitate to contact us.

Respectfully Submitted,

Maryanne Tomazic
Center for Health Law and Policy Innovation
Harvard Law School
mtomazic@law.harvard.edu

Rachel Klein
The AIDS Institute
rklein@taimail.org