CENTER *for* HEALTH LAW *and* POLICY INNOVATION
HARVARD LAW SCHOOL

November 7, 2021

Submitted by email to HHSPlan@hhs.gov

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation, Strategic Planning Team
Attn: Strategic Plan Comments
200 Independence Avenue, SW, Room 434E
Washington, DC 20201

Re: Draft HHS Strategic Plan FY 2022 – 2026

Dear Acting Assistant Secretary Haffajee,

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) appreciates the opportunity to provide comments on the Draft HHS Strategic Plan FY 2022 – 2026. CHLPI advocates for reforms to improve the health of systemically marginalized individuals, and we appreciate and share the Department's commitment to protecting and strengthening health care access for underserved populations. We write specifically in regard to ways the proposed Strategic Plan can be strengthened (1) to protect the health care rights of transgender and gender nonconforming individuals fully, (2) to ensure adequate access to prescription drugs for people enrolled in Medicaid, (3) to address barriers to care for people living with chronic conditions who are enrolled in Marketplace plans, and (4) to align with the goals of the Ending the HIV Epidemic in the U.S. (EHE) initiative, and (5) to ensure accountability and measurable progress through the use of robust performance goals and community feedback .

1. Protect the health care rights of transgender and gender nonconforming individuals fully.

Protection of health care rights for transgender and gender nonconforming individuals is crucial, as these individuals face both heightened discrimination by the health care system and severe health disparities compared to the general population.[1] In a 2010 survey, 70% of transgender and gender nonconforming respondents reported experiencing discrimination in the health care system,[2] and in 2015, 23% of transgender individuals reported that they did not see a doctor when they needed to because of fear of being mistreated.[3] CHLPI recommends the following additions to the Strategic Plan to ensure and guide effective protection of health care rights for transgender and gender nonconforming individuals.

[1] Transgender people are up to five times more likely than the general population to be living with HIV/AIDS, are more likely to live with psychological distress, and are nine times more likely to have attempted suicide in their lifetimes than the general population. *See* Transgender Legal Defense & Education Fund, Comment Letter on 2019 Proposed Rule at 3–19 (Aug. 13, 2019), available at https://www.regulations.gov/document/HHS-OCR-2019-0007-149238.
[2] *See* Planned Parenthood Fed'n of Am., Comment Letter on 2019 Proposed Rule at 7 (Aug. 13, 2019), Available at https://www.regulations.gov/document/HHS-OCR-2019-0007-154878.
[3] *See* Sandy E. James et al., *The Report of the 2015 U.S. Transgender Survey* 5 (Dec. 2016), https://perma.cc/N3XP-QH4S.

a. *Enforce Section 1557 to its fullest extent.*

Building on President Biden's Executive Order 13988[4] and the Department's announcement that it will interpret and enforce Section 1557's prohibition of discrimination on the basis of sex to include discrimination on the basis of gender identity,[5] the Department should clarify its commitment to fully enforcing Section 1557 by incorporating the following language into the Strategic Plan:

> "Fully enforce Section 1557 of the Affordable Care Act to protect the rights of individuals experiencing discrimination on the basis of race, color, national origin, age, disability, and sex (including on the basis of gender identity, sexual orientation, and pregnancy termination), and recognize the private right of individuals and entities to bring claims under Section 1557, including under a disparate impact theory."

We recommend that this language be included as a Strategy under Objective 1.3 (Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health); Objective 3.4 (Increase safeguards to empower families and communities to prevent and respond to neglect, abuse, and violence, while supporting those who have experienced trauma or violence); or Objective 4.1 (Improve the design, delivery, and outcomes of HHS programs by prioritizing science, evidence, and inclusion).

b. *Strengthen the Marketplace by enforcing nondiscrimination requirements for Qualified Health Plans.*

Qualified Health Plans (QHPs) have employed plan designs that exclude coverage of gender-affirming care[6] and that engage in adverse tiering, placing certain drugs used to treat chronic conditions on the highest cost-sharing tiers.[7] Community-led enforcement has not been a sufficient substitute for rigorous QHP certification processes that identify discriminatory practices up front.[8] The Department can work towards achieving adequate enforcement by incorporating the following language into the Strategic Plan:

> "Strengthen nondiscrimination protections in the Qualified Health Plan certification process by flagging and addressing discriminatory practices, such as coverage exclusions for gender-affirming care and adverse tiering of prescription drugs, prior to open enrollment."
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> "Fully implement and enforce nondiscrimination protections for Qualified Health Plans through prospective enforcement by the Office for Civil Rights (OCR) and through coordination among

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[4] Exec. Order No. 13988, 86 Fed. Reg. 7023 (Jan. 20, 2021).
[5] Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 Fed. Reg. 27984 (issued May 10, 2015) (codified at 45 C.F.R. pt. 86).
[6] OUT2ENROLL, *Summary of Findings: 2021 Marketplace Plan Compliance with Section 1557* (2021), https://perma.cc/6JJ9-NGBW.
[7] CENTER FOR HEALTH LAW AND POLICY INNOVATION, *Georgia Marketplace 2019 QHP Assessment* (2019), https://perma.cc/DL4M-AF24; *see also CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, CHLPI BLOG (2016), https://perma.cc/F5J6-NC5V.
[8] For example, in 2016 CHLPI, along with partners in seven states, filed fourteen formal administrative complaints with HHS' Office of Civil Rights. *See CHLPI Launches Groundbreaking Campaign to Enforce Health Care Rights for People Living With HIV In Seven States*, CHLPI BLOG (2016), https://perma.cc/ZP5K-MRBR. We received minimal information about the status of our complaints until 2019, when at least nine were closed without conclusion because the insurer ceased offering QHPs on the Marketplace. Efforts to obtain information through the Freedom of Information Act relevant to community-led enforcement has also been ineffective, with five requests still open from 2018 and 2019. Our complaints were filed against plans that engaged in adverse tiering practices.

OCR, the Center for Consumer Information and Insurance Oversight, and state regulators to delineate clear, public lines of enforcement responsibilities."

We recommend that both Strategies be included under Objective 1.1 (Increase choice, affordability, and enrollment in high-quality healthcare coverage) or Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).

c. *Prioritize enforcement of OCR complaints that do not undermine civil rights protections*.

The creation of the OCR Conscience and Religious Freedom Division has enabled entities to use religious freedom as a basis to discriminate against LGBTQ+ people and people seeking reproductive care.[9] The Department can protect against this by incorporating the following language into the Strategic Plan:

> "Effectively utilize the enforcement capacity of the Office for Civil Rights (OCR) by dismissing with care complaints that use religious freedom as a pretext for discrimination, while prioritizing complaints that do not undermine the civil rights protections of LGBTQ+ people and people seeking reproductive care."

We recommend this language be included as a Strategy under Objective 5.2 (Sustain strong financial stewardship of HHS resources to foster prudent use of resources, accountability, and public trust).

d. *Commit to realizing Strategic Objectives for transgender and gender nonconforming individuals by using specific language to highlight the needs of this community.*

We appreciate the explicit inclusion of transgender persons in the definition of "underserved populations" used by the Strategic Plan, as well as the specific inclusion of transphobia as a target for education modules in Objective 1.5 (Bolster the health workforce to ensure delivery of quality services and care). Specifically naming transgender and gender nonconforming persons as a group to consider in implementing these strategies helps to highlight their important but often overlooked health needs.

To more fully incorporate the needs of transgender and gender nonconforming persons in the Strategic Plan, we recommend the Strategic Plan develop and adopt a definition of "culturally-competent care" that explicitly encompasses trans-competent care.

Additionally, the Department should consider adjusting language in existing Strategies to acknowledge the health needs of transgender and gender nonconforming persons. Changes, marked by underlines, that can be made directly to the Draft Strategic Plan include:

Objective 1.1 (Increase choice, affordability, and enrollment in high-quality healthcare coverage):

> "Build the capacity of organizations to navigate the changing health care landscape to better support their clients to access and use their health coverage to improve health outcomes, including the use of client navigators for gender-affirming care."

Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs):

[9] Caroline Medina et al., *Improving the Lives and Rights of LGBTQ People in America*, CENTER FOR AMERICAN PROGRESS (2021), https://perma.cc/DK9M-S65S.

> "Improve health care quality by defining and tracking progress on core clinical measures that target high-priority health conditions and services, such as cancer, chronic disease, prenatal care, gender-affirming care, HIV screening, antimicrobial resistance, and immunizations."

Objective 1.3 (Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health):

> "Ensure the provision of safe, culturally-competent care and services for birthing people, with dedicated focus on African American/Black and American Indian/Alaska Native women, transgender and gender nonconforming people, and people with lower incomes, during maternal, perinatal, prenatal, and postpartum periods of life, including raised awareness of pregnancy-related risk factors and available benefits."

Objective 2.3 (Enhance promotion of healthy behaviors to reduce occurrence and disparities in preventable injury, illness, and death):

> "Support partnerships and collaborations to enhance the promotion of interpersonal and emotional skills among children, youth, and adolescents to prevent adverse childhood experiences, suicide, substance use, and youth violence in communities by supporting the implementation and evaluation of evidence-based programs, including interventions related to health promotion, socioemotional learning, homophobia and transphobia, and teen pregnancy."

Objective 3.4 (Increase safeguards to empower families and communities to prevent and respond to neglect, abuse, and violence, while supporting those who have experienced trauma or violence):

> "Facilitate and support access to health care and behavioral health services for anyone who is surviving domestic violence, dating violence, family violence, gender-based violence, and sexual violence, including 24-hour confidential hotline, shelters and programs, and a network of state coalitions and national technical assistance providers.

2. Ensure adequate access to prescription drugs for people enrolled in Medicaid.

Approximately one in four people in the United States has reported difficulty affording prescription drugs due to high out-of-pocket costs.[10] The financial burden created by high out-of-pocket costs causes many people to delay needed drug treatment, take drugs less frequently than prescribed, or cease drug treatment earlier than recommended.[11] CHLPI is acutely concerned with the barrier to access posed by high drug prices, and we support HHS' commitment to exploring innovative strategies to reduce beneficiary spending on prescription drugs.[12] We further appreciate HHS' emphasis that cost reductions must "improve quality and beneficiary health."[13] In line with this commitment, HHS should make clear in the Strategic Plan that

[10] *What are the recent and forecasted trends in prescription drug spending?*, PETERSON-KFF HEALTH SYSTEM TRACKER (Feb. 20, 2019), https://perma.cc/R989-7HP3.
[11] *See Catastrophic Out-of-Pocket Health Care Costs: A Problem Mainly for Middle-Income Americans with Employer Coverage*, THE COMMONWEALTH FUND (Apr. 17, 2020), https://perma.cc/J62M-BHZP.
[12] *See Draft Strategic Plan FY 2022 – 2026, Strategic Goal 1, Objective 1.2*, U.S. Department of Health and Human Services, https://perma.cc/SB4N-VJ7L ("Foster innovation by supporting public-private research and prioritizing payment and service delivery models that test ways to reduce program and beneficiary spending on prescription drugs, support increased utilization of biosimilars and generic drugs, and lower overall spending while improving quality and beneficiary health.").
[13] *Id*.

closed formularies, which restrict Medicaid enrollees' access to needed medicines, are not an appropriate means to contain costs. We recommend that HHS include the following language in the Strategic Plan:

> "Support innovative strategies that reduce the cost of prescription drugs within the Medicaid program, while ensuring continued access to a broad range of drugs within each therapeutic class."

We recommend that this language be included as a Strategy under Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).

Currently, Medicaid covers nearly all drugs approved by the Food & Drug Administration (FDA) from manufacturers who have entered into agreements with HHS under the Medicaid Drug Rebate Program.[14] In contrast, some state Medicaid programs have proposed implementing a "closed formulary," where the state would cover only specific drugs in each therapeutic class.[15] In 2021, CMS approved Tennessee's application for a Section 1115 waiver to "implement a 'commercial-style' closed drug formulary."[16] In 2017, CMS rejected a similar request from Massachusetts.[17]

Closed formularies impose a heavy burden on individuals living with chronic and complex conditions.[18] For example, Medicaid provides health insurance coverage for 42% of nonelderly adults with HIV in regular care.[19] People living with HIV rely on complex treatment regimens developed by their physicians based on individualized factors, such as drug interactions, coexisting conditions, side effect profiles, and concerns with patients' medication adherence. If physicians are unable to prescribe a range of drugs in a therapeutic class, they cannot respond adequately to patients' individualized needs. Additionally, requiring people to switch to alternative treatments can have an adverse impact on adherence to therapy, which drives poorer health outcomes and may ultimately increase overall health care costs.[20]

While states can and do use strategies such as preferred drug lists to incentivize physicians to prescribe more cost-effective drugs where clinically appropriate, states should not eliminate Medicaid enrollees' access to needed drugs by implementing closed formularies. An exceptions process to a closed formulary, such as the process included in Tennessee's Section 1115 waiver,[21] does not resolve this issue. With an exceptions process, gaining access to medically necessary drugs will be more burdensome and time-consuming than under current law, delaying access to treatment and potentially deterring people from engaging in the exceptions process, forgoing appropriate treatment entirely.

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[14] *Understanding the Medicaid Prescription Drug Rebate Program*, KAISER FAMILY FOUNDATION (Nov. 12, 2019), https://perma.cc/Q9JN-PMX7.
[15] *Id*.
[16] *CMS Approves Innovative Tennessee Aggregate Cap Demonstration to Prioritize Accountability for Value and Outcomes*, CENTERS FOR MEDICARE AND MEDICAID SERVICES (Jan. 08, 2021), https://perma.cc/D3FK-TRPU.
[17] *See* The Chronic Illness & Disability Partnership, Comment Letter on Massachusetts 1115 Demonstration Request (Oct. 20, 2017), https://perma.cc/2Z26-PQQK.

[18] Over half of Medicaid enrollees have one or more chronic conditions. *Identifying the Most Prevalent and Costly Chronic Conditions in Medicaid*, AM. J. MANAGED CARE (Nov. 28, 2017), https://perma.cc/95Y3-GCHF.

[19] *10 Things to Know about Medicaid: Setting the Facts Straight*, KAISER FAMILY FOUNDATION (Mar. 6, 2019), https://perma.cc/DF2E-6ZS2.
[20] *See The Effect of a Closed Formulary on Prescription Drug Use and Costs*, INQUIRY – BLUE CROSS AND BLUE SHIELD ASSOCIATION (Winter 1999/2000), https://www.jstor.org/stable/29772863.
[21] *CMS Approves Innovative Tennessee Aggregate Cap Demonstration to Prioritize Accountability for Value and Outcomes*, CENTERS FOR MEDICARE AND MEDICAID SERVICES (Jan. 08, 2021), https://perma.cc/D3FK-TRPU.

Finally, the current Medicaid Drug Rebate Program secures rebates that are significantly lower than those negotiated by Medicare Part D insurers who use closed formularies for non-protected therapeutic classes, and it does so while ensuring that Medicaid enrollees have access to the prescription drugs that they need.[22] If states were to negotiate for lower drug prices using a closed formulary as leverage, they would be unlikely to secure lower prices than the current rebate program offers. Thus, any savings would come from undue restrictions in coverage rather than lower prices. Innovative strategies to reduce drug costs must preserve access to care for vulnerable populations.

3. Address barriers to care for people living with chronic conditions who are enrolled in Marketplace plans.

CHLPI strongly recommends the Department include clear strategies to ensure people with chronic conditions have affordable health insurance with access to necessary providers and life-saving prescription drugs. To meet the Strategic Plan's goal of protecting and strengthening equitable access to high quality and affordable health care, it is crucial that the needs of vulnerable communities with more intensive health care needs are met.[23] To this end, we applaud the provisions that promote equitable access to affordable health care, and suggest some new language for areas that can be expanded to achieve these goals.

a. *Promote adequate access to necessary services and providers for people living with chronic conditions.*

Health insurance plans place inappropriate limits on provider networks which can discourage enrollment of people living with complex or chronic conditions. This practice leaves fewer options for people living with HIV and other chronic conditions and can be a barrier to accessing health care. We applaud HHS' commitment to "increase choice, affordability, and enrollment in high-quality health care coverage."[24] Further, we suggest that strengthening network adequacy requirements for QHPs be included as a Strategy and propose the following language:

> "Create robust network adequacy standards for Qualified Health Plans in order to provide equitable access to health care for people living with HIV and other chronic conditions."

We recommend that this language be included as a Strategy under Strategic Objective 1.1 (Increase choice, affordability, and enrollment in high-quality healthcare coverage).

Inclusion of this language closely aligns with HHS' stated goal of health equity.[25] For example, people living with HIV often have trouble finding high quality in-network providers.[26] More robust network adequacy requirements would help create more equitable access to medically necessary care for all QHP enrollees. Specifically, we encourage HHS to improve network adequacy standards by strengthening requirements to contract with essential community providers (ECPs) and by prohibiting plans from limiting who can serve as a primary care provider (PCP). ECPs improve access to quality of health care for people with chronic conditions. Furthermore, insurers that limit who can serve as a PCP (e.g., by prohibiting

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[22] *Pricing and Payment for Medicaid Prescription Drugs*, KAISER FAMILY FOUNDATION (Jan. 23, 2020), https://perma.cc/47EB-6TL8.
[23] *To End HIV Epidemic, We Must Address Health Disparities*, NATIONAL INSTITUTES OF HEALTH (Feb. 19, 2021), https://perma.cc/Z3XT-WCTW.
[24] *Draft Strategic Plan FY 2022 - 2026, Strategic Goal 1, Objective 1.1*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/3CD7-PPKH.
[25] *See id*.
[26] *Health Insurance Coverage for People with HIV Under the Affordable Care Act: Experiences in Five States,* KAISER FAMILY FOUNDATION (Dec. 19, 2014), https://perma.cc/7P48-LPMZ.

specialists from serving as PCPs) often create plans that force people living with HIV and other chronic illnesses to forgo their providers who are trusted and experienced in treating their complex care needs. By committing to address network adequacy in these ways, HHS can further show its commitment to health equity for people with HIV and other chronic conditions.

b. *Improve access to prescription drugs for people living with chronic conditions.*

Access to affordable prescription drugs is critical to the health of consumers living with chronic conditions and disabilities, including HIV, cancer, and multiple sclerosis. Unfortunately, these critical and life-saving drugs can be prohibitively expensive both because of high drug prices and lack of insurance coverage. We applaud HHS' commitment to "reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs" in Strategic Objective 1.2.[27] We are excited about how these goals could help people living with chronic conditions, particularly with equitable access to prescription drugs; however we note that many of the cost-reducing strategies for drugs rely on biomedical innovation and new drugs on the market, rather than ensuring that prescriptions are adequately covered by insurance plans. People with chronic conditions often struggle with exorbitant costs for drugs because of coverage gaps or prohibitive cost-sharing obligations. Health plans with insufficient coverage for medically necessary prescription drugs leave people with chronic conditions to either pay substantial costs for prescription drugs or go without necessary treatment. We recommend adding the following Strategy to Objective 1.2 to ensure insured individuals with chronic conditions are not priced out of accessing prescription drugs:

> "Ensure that Qualified Health Plans provide affordable coverage of necessary prescription drugs for people with chronic illnesses."

We recommend that this language be included as a Strategy under Strategic Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).

Additionally, QHPs are currently permitted to make mid-year formulary changes, allowing them to stop covering necessary prescription drugs for people with chronic illnesses part way through the year, or to place those drugs on a higher cost-sharing tier. The result is that insured individuals with chronic disease may have a significantly higher financial responsibility for their care than they had anticipated. In order to further HHS' goal of access to case, we recommend that HHS include the following language in the Strategic Plan:

> "Ensure continuous access to medically necessary prescriptions by prohibiting adverse mid-year formulary changes in Qualified Health Plans."

We recommend that this language be included as a Strategy under Strategic Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).

c. *Strengthen protections through standardized plan options.*

Affordability continues to be a major challenge for individuals living with HIV and other chronic conditions due to high deductibles and prescription drug cost-sharing requirements. For example, when a plan requires co-insurance, rather than a co-pay, in its coverage of prescription drugs, individuals face unpredictable out-of-pocket costs and may be required to pay a large amount of their health care costs upfront, instead of spreading out costs over the plan year. Standardized plan option designs can address these problems by eliminating coinsurance and ensuring that coverage of prescription drugs are not subject to a deductible.

[27] *Draft Strategic Plan FY 2022 - 2026, Strategic Goal 1, Objective 1.2*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/EY28-QGS2.

We believe such standardized plan options would support HHS' commitment to "promote available and affordable health care coverage to improve health outcomes in our communities" under Strategic Objective 1.1. We also recommend that HHS include the following language in the Strategic Plan:

> "Enhance safeguards for consumers by implementing standardized plan designs for Qualified Health Plans that improve predictability and affordability for enrollees."

We recommend that this language be included as a Strategy under Strategic Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).

4. Align with the goals of the Ending the HIV Epidemic in the U.S. initiative.

As part of HHS' Strategic Plan, CHLPI strongly recommends that the Department include clear strategies to address the HIV epidemic by promoting prevention, testing, and treatment efforts, in line with HHS' ongoing Ending the HIV Epidemic in the U.S. (EHE) initiative.[28] Despite exciting and innovative advancements in HIV prevention and treatment technology, reductions in the number of new infections have plateaued in recent years,[29] and severe disparities in HIV infection and access to care persist.[30] A comprehensive and aggressive response is needed to achieve the initiative's goals of substantially reducing the number of new HIV infections and scaling up access to prevention and treatment services. We applaud HHS' inclusion of specific Strategies to monitor key clinical measures for individuals living with HIV[31] and to promote HIV education and linkage to care services for people who test positive for HIV.[32] We include additional recommendations, here, that would further HHS' stated goals.

a. *Ensure access to HIV prevention and treatment services for Medicaid beneficiaries.*

People living with HIV are disproportionately likely to receive their health care through Medicaid.[33] This makes Medicaid a critically important piece of the infrastructure that supports HIV treatment and prevention in this country. Although there have been exciting innovations in testing, biomedical prevention, and treatment in recent years, coverage of these technologies is often inconsistent across Medicaid programs. For example, new long-acting injectable treatment (Cabenuva) has been approved by the FDA, but some Medicaid programs are imposing prior authorization requirements beyond what is required by federal clinical guidelines or the FDA label, creating barriers to care. HHS should commit to ensuring consistent and equitable access to HIV testing, prevention, and treatment services through clear guidance

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[28] *What is Ending the HIV Epidemic in the U.S.?*, HIV.GOV, https://perma.cc/XC6A-V52R.
[29] *CDC Data Confirm: Progress in HIV Prevention Has Stalled,* CENTERS FOR DISEASE CONTROL AND PREVENTION (Feb. 27, 2019), https://perma.cc/AD6L-4YCX.
[30] *To End HIV Epidemic, We Must Address Health Disparities*, NATIONAL INSTITUTES OF HEALTH (Feb. 19, 2021), https://perma.cc/Z3XT-WCTW.
[31] *See Draft Strategic Plan FY 2022 - 2026, Strategic Goal 1, Objective 1.2*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/EY28-QGS2 ("Improve healthcare quality by defining and tracking progress on core clinical measures that target high-priority health conditions and services, such as cancer, chronic disease, prenatal care, HIV screening, antimicrobial resistance, and immunizations.").
[32] *See Draft Strategic Plan FY 2022 - 2026, Strategic Goal 1, Objective 1.3*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/YW9G-9L6D; *Strategic Plan FY 2019 – 2022, Strategic Goal 2, Objective 2.3*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/9NG5-H75P ("Promote partnerships to implement programs and outreach that focus on raising awareness and rapidly linking affected individuals to relevant care and treatment services, including persons harmed by substance use disorders and persons with HIV.").
[33] *Medicaid and HIV*, KAISER FAMILY FOUNDATION (Oct. 1, 2019), https://perma.cc/C37W-Y29X ("Medicaid is the largest source of insurance coverage for people with HIV, estimated to cover 42% of the adult population, compared to just 13% of the adult population overall").

to state Medicaid programs and enforcement of federal requirements and protections, and by including the following language in the Strategic Plan:

> "Improve full and equitable access to HIV testing, prevention, and treatment services for Medicaid beneficiaries, in alignment with clinical best practices, through policy development, issuance of guidance, and enforcement."

We recommend that this language be included as a Strategy under Objective 1.3 (Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health).

b. *Increase access to pre-exposure prophylaxis.*

Pre-exposure prophylaxis (PrEP) is a highly effective, although underutilized,[34] prevention tool that is understood to be an important lever in achieving HHS' EHE objectives. In addition to ensuring access to PrEP under private health insurance plans and state Medicaid programs, in line with the recent USPSTF Grade A rating,[35] HHS should commit to supporting wider access to PrEP, regardless of insurance status. HHS is already scaling up efforts to provide no-cost PrEP through the Ready. Set. PrEP. program, for qualifying individuals without prescription drug coverage.[36] In line with these efforts, we recommend that HHS include the following language in the Strategic Plan:

> "Expand access to low- or no-cost HIV prevention tools, including pre-exposure prophylaxis, to ensure access for all people, regardless of insurance status."

We recommend that this language be included as a Strategy under Objective 1.3 (Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health); Objective 2.2 (Protect individuals, families, and communities from infectious disease and non-communicable disease through development and equitable delivery of effective, innovative, readily available diagnostics, treatments, therapeutics, medical devices, and vaccines); or Objective 2.3 (Safeguard and Improve National and Global Health Conditions and Outcomes).

c. *Address disparities in HIV transmission and access to care.*

The HIV epidemic disproportionately affects historically marginalized people and communities, including Black communities, Latinx communities, women, people who use injection drugs, and LGBTQ+ communities.[37] In order to fulfill HHS' stated commitment to health equity, addressing disparities in HIV transmission and remedying unequal access to prevention and treatment must be priorities. HHS is already

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[34] *PrEP Use Across the U.S. at the County-Level*, AIDSVU (April 14, 2020), https://perma.cc/QXM5-XMD8.
[35] In June 2019, The U.S. Preventive Services Task Force (USPSTF) issued a Grade A for PrEP, 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. *Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV): Preexposure Prophylaxis*, U.S. PREVENTIVE SERVICES TASK FORCE (Jun. 11, 2019), https://perma.cc/8AWR-9X6S. HHS, the Department of Labor, and Treasury further clarified that required coverage of PrEP under the ACA includes relevant ancillary services, including requisite lab tests, medical visits, and adherence counseling. *FAQs About the Affordable Care Act Implementation Part 47*, U.S. DEPARTMENTS OF HEALTH AND HUMAN SERVICES, LABOR, AND THE TREASURY (Jul. 19, 2021), https://perma.cc/6GMA-AFMZ.
[36] *Ready, Set, PrEP*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/G23Y-FJ7Q.
[37] *To End HIV Epidemic, We Must Address Health Disparities*, NATIONAL INSTITUTES OF HEALTH (Feb. 19, 2021), https://perma.cc/Z3XT-WCTW.

responding to this need through geographically focused efforts as part of the EHE initiative.[38] In order to further respond to this need, we recommend that HHS include the following language in the Strategic Plan:

> "Address disparities in HIV transmission and access to care by focusing resources in those communities most severely impacted by the HIV epidemic and supporting community-led strategies to improve access to care for historically underserved populations."

We recommend that this language be included as a Strategy under Objective 1.3 (Expand equitable access to comprehensive, community-based, innovative, and culturally-competent healthcare services while addressing social determinants of health) or Objective 2.2 (Protect individuals, families, and communities from infectious disease and non-communicable disease through development and equitable delivery of effective, innovative, readily available diagnostics, treatments, therapeutics, medical devices, and vaccines).

5. Ensure accountability and measurable progress through the use of robust performance goals and community feedback.

HHS recognizes that ongoing performance management and institutional accountability are necessary for meaningful improvement over time.[39] A commitment to accountability requires that progress be measurable and responsive to public feedback. In order to guide and measure progress over the next four years, we recommend the following approaches.

a. *Include measurable Performance Goals that prioritize underserved populations for each Strategic Objective*.

The GPRA Modernization Act of 2010 requires that agency strategic plans include performance goals and descriptions of how those goals contribute to the general objectives of the strategic plan.[40] These goals are identified in Annual Performance Plans.[41] The inclusion of measurable goals is key to ensuring that departments and agencies achieve material progress and can demonstrate that progress to community stakeholders. We strongly recommend HHS adopt Performance Goals, such as those listed below, that prioritize underserved populations as part of a comprehensive effort to achieve its Strategic Objectives.

> "Increase the rate of treatment among people in underserved communities who are living with cancer, chronic disease, prenatal care, gender-affirming care, HIV screening and prevention, and immunizations" for Objective 1.2 (Reduce costs, improve quality of healthcare services, and ensure access to safe medical devices and drugs).
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> "Reduce the number of Qualified Health Plans that require co-insurance for prescription drug coverage" and "Increase the number of health insurance plans that provide robust coverage of gender-affirming care" for Objective 1.1 (Increase choice, affordability, and enrollment in high-quality healthcare coverage)

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[38] *Ending the HIC Epidemic in the U.S.*, HEALTH RESOURCES AND SERVICES ADMINISTRATION, https://perma.cc/2XH2-VQ8N.

[39] *FY 2021 Annual Performance Plan and Report - Executive Summary*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://perma.cc/TE6G-TMH4 ("Performance goals and measures are powerful tools to advance an effective, efficient, and productive government, while being accountable for achieving program outcomes.").

[40] GPRA Modernization Act of 2010, Pub. L. No. 111-352, 124 Stat. 3866 (2010).

[41] *Frequently Asked Questions*, GENERAL SERVICES ADMINISTRATION & THE OFFICE OF MANAGEMENT AND BUDGET, https://perma.cc/E9AS-8FVE.

CHLPI recommends that HHS track and quantify progress on these Performance Goals as part of the Department's Annual Performance Report.

b. *Solicit feedback from the public as part of each HHS Annual Performance Report*.

We recommend the Department hold a period for public comment each year before the final publication of the Annual Performance Report and incorporate this feedback into its self-assessment. By creating an opportunity for public comment, HHS will gain important information about successes and places for improvement in pursuit of the Strategic Goals. Public comment will also facilitate enhanced accountability and dialogue between the Department and stakeholders. As part of these efforts, the Department should proactively outreach to underserved communities and the organizations that serve them, to better understand how the Department's efforts are impacting them and identify areas of improvement.

Thank you again for the opportunity to comment on the Draft Strategic Plan. Please reach out via e-mail (mtomazic@law.harvard.edu) with any questions or requests for additional resources.

Sincerely,

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