

Enhancing Provider and Patient Engagement and Education: Medicaid Strategies to Deliver PrEP Intervention Services

Prepared for the CDC, ChangeLab and AcademyHealth as part of the Medicaid Strategies to Implement Comprehensive PrEP Intervention Services project *Naomi Seiler, JD*

January 2019

Table of Contents

INTRODUCTION	.3
BACKGROUND	
PREP AND THE CDC'S GUIDELINES	
OVERVIEW OF BARRIERS TO PATIENT ENGAGEMENT	
OVERVIEW OF BARRIERS TO PROVIDER ENGAGEMENT	. 8
LEVERAGING THE MEDICAID PROGRAM TO ENGAGE PATIENTS AND PROVIDERS	.9
PATIENT AND PROVIDER EDUCATIONAL RESOURCES AND OPERATIONAL TOOLS.	
Patient and provider educational resources	.9
Operational support tools for patients and providers	.9
CONDUITS FOR ENGAGING PATIENTS AND PROVIDERS THROUGH THE MEDICAID PROGRAM.	11
CMS level	11
State Medicaid agencies	
Medicaid MCOs	
Partnering with provider organizations	
USING MEDICAID DATA TO TARGET PREP RESOURCES AND EDUCATION	
Measuring current PrEP use in the Medicaid program.	
Tracking provision of clinical services to current PrEP users	
Finding candidates for PrEP	
LEVERAGING MEDICAID BENEFITS FOR PATIENT AND PROVIDER ENGAGEMENT	-
PrEP and telehealth in Medicaid	
Additional Medicaid benefits to support PrEP Users.	
Engaging pharmacists to support patients and providers	
Linking providers to CBOs to support comprehensive care for patients	
FURTHER CONSIDERATIONS.	
Cultural competency in Medicaid programs	
Assisting patients with PrEP adherence through enrollment changes	
Privacy for adolescent minors and other PrEP users in State Medicaid programs	
PrEP and Substance Use.	
CONCLUSION	20

Thank you to all of the experts who participated in interviews for this project, as well as to those who generously reviewed a draft: Jeffrey Crowley at the O'Neill Institute at Georgetown Law; and Pedro Alonso Serrano, Hektoen Institute. Any mistakes or omissions are the author's.

Funding for this paper was made possible by the Centers for Disease Control and Prevention and ChangeLab Solutions under Cooperative Agreement NU380T000141. The findings and conclusions of this paper are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Introduction

Pre-exposure prophylaxis, or PrEP, is a highly effective HIV prevention intervention that is dramatically underused, with one recent analysis suggesting that fewer than 1 in 10 people with indications for PrEP in the U.S. are receiving it.¹ Use of PrEP is disproportionately low among African American and Latinx people, as well as lower-income populations.^{2,3,4} Between 2015 and 2016, an estimated 1.14 million Americans were eligible for PrEP, but only 90,000 prescriptions for Truvada for PrEP were filled. What's more, utilization showed significant racial and ethnic disparities in use. Though African Americans represent over 45 percent of people with indications for PrEP use in the U.S.,⁵ they accounted for only 11.2 percent of PrEP users in 2016.⁶ Regional disparities in the HIV epidemic are reflected in lower PrEP use as well: the South accounted for over half of new HIV diagnoses in 2016, but fewer than 30 percent of PrEP users.⁷

Among those who do use PrEP, some may not be receiving the Centers for Disease Control and Prevention's (CDC) full set of recommended PrEP clinical services – such as HIV screening before initiation and quarterly, multisite sexually transmitted infection (STI) screenings. A recent study of providers in San Francisco Public Health Primary Care Clinics found that when initiating PrEP, providers failed to order HIV tests in nearly a quarter of patients, and failed to order STI tests in nearly a fifth of patients.⁸ Once patients were on PrEP, providers ordered STI testing in only 72 percent of follow-up intervals.⁹

As part of its work to address these challenges, the CDC is supporting a project, led by AcademyHealth and ChangeLab, to identify ways to improve delivery of PrEP medication and clinical services to the Medicaid population. Medicaid's role as insurance for lowincome Americans – particularly since the Medicaid expansion authorized under the Affordable Care Act – makes the program a crucial vehicle for expanding access. Extensive research and practice is underway to try to engage providers in offering, and patients in accessing, the full suite of PrEP medication and clinical services. However, there is little information available on how to drive engagement with and through state Medicaid programs in ways that optimally address provider and patient barriers.

To inform this project, this paper seeks to identify a "menu" of ways to leverage the Medicaid program to educate patients and providers about PrEP and support them in adherence to the medication and clinical services. A separate white paper discusses specific Medicaid financing mechanisms that could be used to improve uptake and comprehensive delivery of PrEP; these include mechanisms to incentivize provider engagement, and the papers should be considered jointly. The papers will inform an AcademyHealth and ChangeLab convening of Medicaid officials from select states, representatives of Medicaid managed care organizations (MCOs), public health officials, and other stakeholders in January of 2019 to consider which of the approaches discussed may be appropriate for their policy environments.

This paper begins with background information on patient and provider barriers to use of PrEP medication and clinical services. It then identifies specific types of educational resources and operational support tools that experts report would be most helpful in promoting engagement, and describes opportunities for dissemination of these resources by Centers for Medicare and Medicaid Services (CMS), State Medicaid agencies, and MCOs, including through partnering with professional societies.

The paper then reviews potential uses of Medicaid claims data to track current PrEP use, assess the provision of clinical services to PrEP users, and identify potential new users. It describes how this data could be combined with surveillance data and other information to help target and shape PrEP education and outreach efforts.

The next section discusses specific Medicaid benefits that may promote provider and patient engagement, including telehealth and medication therapy management by pharmacists. It also describes how some PrEP services could be offered by community-based organizations to support patients and prescribers, and discusses how Medicaid programs and MCOs could support those organizations.

The last section addresses several further considerations for patient and provider engagement through Medicaid, including leveraging cultural competency initiatives in state Medicaid programs, assisting PrEP users experiencing enrollment "churn," creating PrEP linkages for Medicaid-eligible people leaving the corrections system, and parsing privacy issues for adolescent minor PrEP users in Medicaid. It concludes with a discussion of considerations around promoting PrEP for people who inject drugs.

States differ in their HIV epidemics, resources, Medicaid programs, and the relationship between the HIV/public health community and the Medicaid agency. This paper does not present a one-size-fits all answer to promoting PrEP engagement through Medicaid. Rather, the goal is to outline in one place the potential tools that state-level stakeholders could use to better engage and support Medicaid providers and patients through the full PrEP intervention suite. Table 1, below, contains a high-level summary of issues to consider at the state level, based on the topics covered in this paper. After the convening in January 2019, condensed versions of the white papers will be developed as an additional tool to help stakeholders at the state level identify key action items.

Table 1: High-Level Issues to Consider at the State Level

Barriers to Patient and Provider Engagement

Is there state-level data on patient uptake of PrEP medication and clinical services, within Medicaid or overall? Are there quantitative or qualitative assessments of patient barriers to PrEP within the state?

How many and what kind of providers in the state are currently prescribing PrEP, overall and within the Medicaid program? Is there state-level evidence on barriers to provider engagement in PrEP?

Patient and Provider Outreach and Education

What general and state-specific resources would be useful for educating Medicaid enrollees in the state about PrEP?

What resources would be useful for educating current and potential PrEP providers?

What operational tools could help support both patients and providers in uptake of and adherence to PrEP medication and clinical services?

How does the state Medicaid agency communicate with enrollees and with providers?

How do Medicaid MCOs in the state communicate with enrollees and providers?

What opportunities exist for one-time and ongoing inclusion of resources related to PrEP through these communication channels?

Which professional societies would be useful partners for engaging in provider outreach within the state? Which organizations might be willing to work with Medicaid and public health stakeholders to strengthen access to and delivery of PrEP medication and clinical care among Medicaid beneficiaries?

Medicaid Data-Sharing to Target PrEP Resources and Education

What do Medicaid claims data, alone or combined with surveillance or other data, show about current PrEP use in the state? Could Medicaid claims data be used to monitor receipt of PrEP clinical services among current PrEP users?

Could Medicaid claims data be used to inform outreach to potential PrEP users based on indicators such as STI treatment?

Is there an existing data agreement between public health and Medicaid in the state? If not, could the Medicaid agency, or a third party, run analyses related to PrEP? Are there opportunities for collaborating with specific Medicaid MCOs on analysis of their own claims data?

Using other Medicaid Benefits for Patient and Provider Engagement

How can the state's Medicaid telehealth payment policies be leveraged to expand access to PrEP medication and clinical services for enrollees? What are potential pros and cons of PrEP telehealth models for patients and providers?

Does the state Medicaid program include benefits that could be specifically leveraged to support current PrEP users, such as targeted case management or nonemergency medical transportation?

Does the state have a medical therapy management (MTM) benefit that could be used to pay pharmacists to support current PrEP users and providers? Does the state allow advanced pharmacy practice in a way that would allow further pharmacist engagement in PrEP?

Could community-based organizations (CBOs) provide some PrEP services to make them more accessible to PrEP users and reduce the burden on prescribing providers? If yes, could the CBOs be Medicaid providers or otherwise receive financial support from Medicaid agencies or MCOs?

Further Considerations

How does the state promote cultural competency in its Medicaid program and in partnership with MCOs? Could PrEP and related issues of sexual orientation, gender identify, and race be incorporated into these activities?

Are PrEP providers and users able to navigate shifting Medicaid status, including loss of insurance, changing to private coverage, or switching among MCOs?

Could screening for PrEP eligibility be included in any formal or informal processes for facilitating Medicaid enrollment for people leaving the criminal justice system?

What privacy concerns do the state's Medicaid policies present, particularly for adolescent PrEP users?

How can the provision of PrEP medication and clinical services be integrated into existing services in the state for people who inject drugs, and into new initiatives to address the growing opioid epidemic?

Methodology

AcademyHealth conducted initial discussions with the project Steering Committee (see Appendix 1) to identify the appropriate scope for this white paper. AcademyHealth staff then conducted preliminary interviews with a set of key informants to begin to develop key themes and topics for the convening and white papers. The author then conducted semi-structured interviews with additional experts in Medicaid, PrEP, and patient and provider engagement (see Table 2, below; preliminary interviews conducted by AcademyHealth are marked with an asterisk and all others were conducted by the author).

Interviews of multiple staff at the same organization or agency were combined. All interviews were conducted for the overall project, with insights from the experts incorporated into both white papers.

Table 2: Experts Interviewed for the Project

Divya Ahuja, MD, University of South Carolina Associate Professor of Clinical Internal Medicine

Jennifer Babcock, MPH, Vice President for Medicaid Policy and Director of Strategic Operations, Association for Community Affiliated Plans

Laura Beauchamps, MD, University of Mississippi Medical Center, Assistant Professor Infectious Disease; Medical Director, Open Arms Healthcare Center

Sean Bland, JD, Senior Associate, O'Neill Institute, Georgetown Law*

Sarah Calabrese, PhD, Assistant Professor of Psychology, George Washington University

John Carlo, MD, Member, American Medical Association (AMA) Council on Science and Public Health; CEO, Prism Health North Texas

Stephen Cha, MD, Chief Medical Officer of UnitedHealthcare Community & State

Megan Coleman, FNP, Director of Community Based Research, Whitman-Walker Health, DC

Edwin Corbin-Gutiérrez, MA, Senior Manager, Health Systems Integration, National Alliance of State and Territorial AIDS Directors*

Jeffrey S. Crowley, MPH, Distinguished Scholar and Program Director of Infectious Disease Initiatives, O'Neill Institute, Georgetown Law*

Vanessa Diaz, MD, MSCR, Medical University of South Carolina

Jason Farley, PHD, MPH, ANP-BC, AACRN, FAAN, Co-Director Clinical Core, Hopkins Center for AIDS Research; Immediate-Past President, Association of Nurses in AIDS Care (ANAC)

Douglas Fish, M.D., Medical Director, Division of Program Development & Management, New York State Department of Health*

Andrea Gelzer, MD, MS, FACP, Senior Vice President & Corporate Chief Medical Officer, Amerihealth/Caritas

DeAnn Gruber, PhD, MSW, Director of the Bureau of Infectious Diseases, Louisiana Department of Health*

Elizabeth Hacker, MPH, PrEP Coordinator, Detroit Public Health STD Clinic

Chad Hendry, Director of Sexual and Reproductive Health, Howard Brown Health

Kristin Keglovitz-Baker, PA-C, Chief Operating Officer and Certified Physician Assistant, Howard Brown Health

Amy Killilea, JD, Director, Health Systems Integration, National Alliance of State and Territorial AIDS Directors

Douglas Krakower, MD, Research Scientist, The Fenway Institute; Assistant Professor of Medicine and Population Medicine, Harvard Medical School; Harvard Medical Faculty Physician at Beth Israel Deaconess Medical Center

Leighton Ku, PhD, MPH, Professor and Director of the Center for Health Policy Research, George Washington University School of Public Health

Paul Loberti, MPH, Administrator for Medical Services, Project Director Health System Transformation, Project Director HIV Provision of Care & Special Populations Unit, Health & Human Services, State of Rhode Island*

Erin Loubier, JD, Senior Director for Health and Legal Integration and Payment Innovation, Whitman-Walker Health, DC

Juan Carlos Loubriel, Director of Community Health and Wellness, Whitman-Walker Health, DC

Kathryn Macomber, MPH, Director, Division of HIV/STD Programs, Michigan Department of Health and Human Services*

Kathy McNamara, RN, Associate Vice President, Clinical Affairs, National Association of Community Health Centers (NACHC)

David Neff, MD, Chief Medical Director, Michigan Department of Health and Human Services*

Sable Nelson, Esq, Policy Analyst, NMAC

Marty Player, MD, Medical University of South Carolina

Daniel Raymond, Deputy Director of Planning and Policy, Harm Reduction Coalition

Catherine Reid, MD, Office of Medical Affairs, Michigan Department of Health and Human Services*

Sandra Robinson, MBA, Chief, ADAP Branch, Office of AIDS, California Department of Public Health

Sara Rosenbaum, JD, Harold and Jane Hirsh Professor of Health Law and Policy and Founding Chair of the Department of Health Policy, George Washington University School of Public Health

David Rzeszutko, MD, Medical Director, Priority Health (Michigan)

Matt Salo, Executive Director, National Association of Medicaid Directors

Bellinda Schoof, MHA, CPHQ, Division Director, Health of the Public and Science, American Academy of Family Physicians (AAFP)

Lyn Stevens, MS, NP, ACRN, Medical Director, AIDS Institute, New York State Department of Health; Past President, Association of Nurses in AIDS Care (ANAC)*

Donna Sweet, MD, MACP, AAHIVS, Director, KU Wichita Internal Medicine Midtown and Ryan White Programs; Director and Principal Investigator, Kansas AIDS Education and Training Center

Elyse Tung, PharmD, BCACP, Kelley-Ross Pharmacy Group, Seattle

Gretchen Weiss, MPH, Director of HIV, STI, and Viral Hepatitis, National Association of County and City Health Officials (NACCHO)

Melody Wilkinson, DNP, APRN, FNP-BC, Member, American Association of Nurse Practitioners (AANP); Program Director of the Family Nurse Practitioner Program and Assistant Professor, Georgetown University

Doug Wirth, MSW, President and CEO, Amida Care (NY)

Mike Wofford, PharmD., Chief Medi-Cal Pharmacy Policy, CA Department of Healthcare Services

* Interviewed by AcademyHealth staff in preliminary interviews

The author also conducted a search of peer-reviewed and "grey" literature on Medicaid and PrEP.

Finally, AcademyHealth conducted an informal survey of the participants in its Medicaid Medical Director Network (MMDN) regarding their FFS Medicaid coverage of PrEP medication and clinical care, as well as provider and patient engagement. Deidentified responses received from 16 states are included.

Background

This section provides an overview of the CDC's guidelines for PrEP medication and clinical services, including potential PrEP users and the schedule of recommended services. It then gives a brief overview of patient and provider barriers to engagement – not an exhaustive discussion of the literature, but an outline of key issues. For both patients and providers, it is important to note that knowledge and attitudes may have changed considerably even in the few years since PrEP was formally approved in the U.S. A state-specific assessment could help provide more targeted and current understanding of barriers to be addressed.

PrEP and the CDC's Guidelines

Pre-exposure prophylaxis for HIV, or PrEP, refers to the daily use of a medication by people who are HIV-negative to reduce the risk of seroconversion. Trials have demonstrated effectiveness of over 90 percent for consistent use among those at risk of sexual transmission, and over 70 percent for people who inject drugs.¹⁰ This section outlines the components of the full suite of PrEP services, as well as the people for whom it is indicated, as context for the discussion of engaging patients and providers through Medicaid.

There is only one drug currently approved by the FDA for PrEP in the US: a fixed-dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg, sold by Gilead as Truvada. FDA granted ANDA approval to Teva¹¹ and Amneal¹² for generic versions of Truvada in June 2017 and August 2018, respectively. However, neither has yet become available on the U.S. market.

All states must cover Truvada for PrEP in their Medicaid programs, but there is variation across and within states in whether barriers to access exist.

The CDC recommends PrEP be considered as one prevention option for the following people at substantial risk of HIV infection¹³: Men Who Have Sex with Men (MSMs) (including those who inject drugs)

- HIV-positive sexual partner
- Recent bacterial STI (gonorrhea, chlamydia, syphilis)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work

Persons Who Inject Drugs

- HIV-positive injecting partner
- Sharing injection equipment

Heterosexual Women and Men (including those who inject drugs)

- HIV-positive sexual partner
- Recent bacterial STI (gonorrhea, syphilis)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work
- In high HIV prevalence area or network

In order to determine clinical eligibility, the guidelines recommend a documented negative HIV test result; an assessment to rule out signs or symptoms of acute HIV infection; a renal function test (estimated creatinine clearance); and assessment of current medications to rule out contraindications. While not part of the clinical eligibility criteria, documentation of Hepatitis B infection and vaccination status is recommended prior to initiating PrEP. The CDC recommends that once on PrEP, people receive a follow-up visit at least quarterly for an HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, and STI symptom assessment. Renal function testing is recommended at 3 months and every 6 months thereafter. Overall, bacterial STI testing is recommended every 3-6 months for both sexually active men and women. The CDC recommends nucleic acid amplification (NAAT) STI testing at sites of potential sexual exposure including pharyngeal and rectal testing for MSM, as well as rectal testing for women who report engaging in anal sex. Providers should offer pregnancy tests and discussion of pregnancy intent with women every six months, and people who inject drugs should have access to clean needles and drug treatment services.

Overview of barriers to patient engagement

Many factors may hinder patient engagement along the "PrEP care continuum."¹⁴ Key barriers identified in the literature and in interviews for this project include:

- Lack of awareness: Since Truvada was approved for PrEP in 2012, public awareness has increased overall.¹⁵ However, there are still some people who could benefit from PrEP who are not aware that the option exists.¹⁶ In the years since PrEP approval, studies have found gaps in PrEP awareness among a range of populations at high risk of HIV. For example:
 - In 2016, over 17 percent of new HIV diagnoses were among young MSM.¹⁷ A study of young MSM across the US (median age 24) between 2013 and 2015 found that roughly a third were unaware of PrEP.¹⁸
 - In 2016, Black MSM were the most-affected subpopulation in the U.S., representing a quarter of all new HIV diagnoses.¹⁹ It has been estimated that over one half of Black transgender women are living with HIV.²⁰ However, a study of substanceusing black MSM and transgender women in New York City from 2012 through 2015 found that only 18.2 percent were aware of PrEP.²¹
 - Women accounted for 19 percent of new HIV diagnoses in 2016,²² but less than 5 percent of PrEP users from 2014 to 2016.²³ Focus groups conducted in 2014 with at-risk women in six US cities found that nearly none had been aware of PrEP prior to the focus group.²⁴

Awareness may be increasing among these and other groups, but it cannot be assumed that all potential PrEP users are aware of the option.

- Affordability concerns: Potential PrEP users may have heard about the costs of PrEP, particularly the medication for people without insurance.^{25,26,27} Truvada has an average acquisition cost (the price pharmacies charge without insurer discounts) of approximately \$1,600 per month.²⁸ Though cost sharing in Medicaid is nominal, these concerns may be shared by Medicaid enrollees, particularly if they are unaware that the medication and most clinical services should be covered by their program with minimal cost sharing. Fear of costs can be exacerbated when patients become aware of the additional visits and monitoring, leading to lost work hours and travel costs.
- *Concerns about side effects or drug interactions:* Patients may be concerned about side effects of taking a medication, especially for preventive purposes. However most PrEP users experience no side effects, and among the 8-10% who do (headache, upset stomach), they last only a few days. Concerns about PrEP reduc-

ing the effects of hormone therapy have been reported among transgender women.²⁹ To date, there are no substantive data available to corroborate these concerns. However, preliminary data do suggest that hormone therapy for transgender women can lower the efficacy of PrEP.³⁰

- *Geographic barriers:* Multiple interviewers cited geography as a barrier for patients, particularly in rural settings.³¹ Patients are unable to travel long distances to PrEP providers in cities, particularly for quarterly visits for monitoring and testing. Transportation can also be a barrier to regular visits for PrEP users in urban settings.³²
- Lack of relationship with a trusted provider who offers PrEP: Some potential PrEP users may not have a relationship with a trusted provider who could prescribe PrEP. For example, a study of MSM in Oklahoma noted that a combination of geographic barriers and a dearth of "affirming providers" were commonly reported as barriers by MSM.³³ One interviewee who offers PrEP navigation at a public STD clinic noted that some transgender and MSM patients express not feeling comfortable discussing PrEP or sexual history with some prior providers.³⁴ For women, family planning clinics may be their primary or only source of trusted health care, and these providers do not always offer or discuss PrEP.³⁵ As discussed later in this paper, though people who inject drugs accounted for 10 percent of new HIV diagnoses in 2016, many substance use treatment providers also do not offer PrEP.
- *Perceived provider stigma:* Lack of a relationship with a trusted provider is related to perceived (and often real) provider stigma or bias. One study based on online focus groups with MSM from different parts of the country found that "[w]hen participants were asked if they would feel comfortable discussing PrEP with their own primary care physicians (PCPs), most indicated discomfort due to embarrassment or fears of being judged."³⁶ Stigma is multifactorial and will likely vary based on setting and other factors; for example, a study that compared focus groups of White MSM in Boston with Black MSM in Jackson found that the latter group were more likely to report provider stigma around HIV and sexual orientation.³⁷
- *Internal stigma:* Potential PrEP users may also have internal biases against PrEP use. For example, in one study surveying black MSM and transgender women at a pride event in 2015 in a large southeastern city, 23 percent stated that PrEP was "for individuals who are promiscuous"; this belief was associated with lack of interest in using PrEP.³⁸ Similarly, a study of heterosexual, HIV-negative women who are Planned Parenthood patients in three high-prevalence Connecticut cities found:

Participants commonly perceived PrEP-user stereotypes, with many believing that others would regard them as promiscuous (37%), HIV-positive (32%), bad (14%), or gay (11%) if they used PrEP. Thirty percent would feel ashamed to disclose PrEP use. Many participants expected disapproval by family (36%), sex partners (34%), and friends (25%).³⁹

The study found these perceptions to be negatively associated with comfort discussing PrEP with a provider and intention to use PrEP.⁴⁰

Upcoming Resources on Barriers to Patient Engagement in PrEP

Four NIH-funded national cohort studies of cis, trans and gender non-conforming young men, women, and others, ages 13 and older, will begin releasing data in 2019.¹⁸¹ These studies will provide further information on barriers to engagement in PrEP among these populations, helping inform national and state solutions.

Overview of barriers to provider engagement

Based on the literature and interviews conducted for this project, key barriers to provider engagement with PrEP overall include:

• *Awareness:* Since the approval of Truvada for PrEP in 2012, provider awareness has grown, but many providers are still not fully informed about PrEP. For example, one 2015 survey of academic primary care physicians found that while nearly all were aware of PrEP, two-thirds of them had not prescribed it; of these non-adopters, over 55 percent rated their knowledge of PrEP as poor or fair, and over 65 percent rated their knowledge of PrEP side effects as poor or fair.⁴¹ In the study, self-rated knowledge of PrEP was associated with prescribing it; another study found that *actual* knowledge of PrEP (as measured with a 5-question test) was also associated with prescribing as well as intent to prescribe in the future.⁴²

Knowledge of PrEP among primary care physicians is, predictably, lower than among HIV specialists. An online survey of primary care physicians and HIV physicians found that primary care physicians were less likely to have heard of PrEP (76 percent vs. 98 percent) or to report familiarity with prescribing it (28 percent vs. 76 percent).⁴³ A more recent survey of primary care physicians in a university health system in North Carolina found low rates of PrEP prescribing, with "lack of knowledge" being the largest reported barrier.⁴⁴

• *Lack of skills/experience:* Some providers may lack the skills to comfortably elicit sexual histories. For example, the study comparing primary care physicians and HIV experts found that fewer primary care physicians reported feeling "somewhat or completely comfortable" discussing sexual activities (75 percent

vs. 94 percent).⁴⁵ Primary care providers may also be reluctant to begin prescribing antiretroviral medications,⁴⁶ a class with which few have experience. However, interviewees stated that overall, PrEP is a relatively simple intervention for primary care providers to manage,^{47,48} and that efforts to engage more providers should not overstate the necessary skills.

- *Confusion regarding scope of guidelines:* One interviewee noted that the current CDC PrEP guidelines still leave ambiguity regarding patient criteria, and that they could potentially exclude patients who would in fact benefit from PrEP.⁴⁹ An alternative approach would be the "routinizing" of PrEP making it a routine discussion with all adult patients.⁵⁰ In addition to preventing under-reach, this approach could help reduce the impact of bias in provider decisionmaking regarding PrEP. However, depending on implementation, this could add further burden to provider swith limited time with patients.
- *Time/capacity:* Multiple interviewees noted that even when providers have the skills and willingness to counsel patients about PrEP, they may lack the time in a primary care visit with multiple other health issues to address.⁵¹ One interviewee reported that the CDC-recommended guidelines for ongoing STI testing may be daunting for primary care providers.
- *Concerns about unintended consequences:* Across multiple studies, providers report concerns about the unintended consequences of PrEP, including the development of resistance; potential lack of adherence; and the possibility of risk compensation, i.e. PrEP users increasing risky behaviors.^{52,53,54,55}
- *Questions about cost and reimbursement:* Some providers are unaware of how to seek reimbursement for PrEP, or how to assist patients in accessing PrEP without burdensome cost sharing.⁵⁶
- Lack of clear sense of responsibility for PrEP: Many HIV specialists believe that scale-up of PrEP needs to occur in the primary care setting where most persons without HIV infection get care, yet many primary care providers believe they lack the time and expertise to offer PrEP, a dilemma described by Krakower et al. as the "purview paradox."⁵⁷ Meanwhile, while STD clinics may be seen as a logical place to reach people at high risk of HIV, a lack of funding and capacity may be challenges. One interviewee noted that STD clinics may aim to start patients on PrEP and transition them to a primary care provider⁵⁸, but that referrals could lead to lower persistence in PrEP use.⁵⁹

Overall, there was consensus among interviewees that more providers need to offer PrEP services, and most interviewees for this project concurred that uptake among primary care providers is crucial.⁶⁰ However, one interviewee opined that in a practice with only a handful of PrEP-eligible patients, it may make more sense to refer them to providers with substantial numbers of PrEP patients than to manage them directly.⁶¹ • *Stigma and Bias:* Provider resistance to engaging in PrEP can be rooted in conscious or subconscious bias based on race, sexual orientation, gender identity, sexual behavior, socioeconomic factors, or a combination. For example, one study that presented medical students with a vignette involving an MSM patient seeking PrEP found that participants reflecting higher levels of heterosexism were more likely to anticipate adherence problems and risk compensation, leading to lower intention to prescribe.⁶² Another study of medical students found greater belief that a hypothetical black patient would engage in risk compensation compared to a white patient, a factor that again was associated with reported lower likelihood to prescribe.⁶³ Studies of MSM in varied geographic settings have found perceived provider stigma to be a barrier to asking about PrEP or discussing relevant sexual behaviors.^{64,65}

Bias may be an issue among other staff in medical settings. Implicit (or explicit) bias among receptionists, nurses and other staff can affect patients' willingness to utilize or even ask about PrEP.

Providers and PrEP: the Information-Motivation-Behavioral Skills Model

The Information-Motivation-Behavioral Skills, or IMB, model, could be one framework for considering provider engagement in PrEP.¹⁸² Information would involve making providers aware of PrEP and addressing misconceptions. Motivation could be extrinsic (e.g. CME requirements, set protocols) and intrinsic (getting provider buy-in, based on PrEP's unique benefits, such as being user-controlled, private, effective for both PWID and sexual risk, and effective for discordant couples, including those who wish to conceive). Finally, behavioral skills can be developed through concrete guidelines and resources, including checklists, scripted language, hands-on training and education materials (see below for further discussion of specific materials and resources).

Leveraging the Medicaid program to engage patients and providers

This section provides an overview of resources to educate patients and providers about PrEP and of operational tools to support adherence to the medication and clinical services. It then describes how these resources could be disseminated in the Medicaid program by three potential "messengers": CMS, state Medicaid agencies, and Medicaid MCOs. State Medicaid agencies or MCOs can work with public health stakeholders to identify the appropriate set of resources, messages and communication channels for distribution within a given state or region.

Patient and provider educational resources and operational tools

This section describes the scope of resources that could be used to educate and inform patients and provider about PrEP, and the operational tools that could help support continued engagement in PrEP among provider and adherence among PrEP users.

Patient and provider educational resources

There are a wide range of resources that could be shared with patients and providers to educate them about PrEP. In collaboration with Medicaid agencies and MCOs, public health agencies may play a role in the development of any new or specifically tailored materials. Existing examples of many of these resources are available, for example through Project Inform at www.projectinform.org/prep/.

For patients, information could include:

- Culturally competent and accessible information about PrEP services.
- State-specific information on how Medicaid covers PrEP medication and clinical services.
- PrEP locator information (i.e. a url for a site for finding PrEP providers). The existing website https://preplocator.org is a searchable directory of clinics and providers who offer PrEP. It is not exhaustive relying on direct submissions or confirmations from providers but may be a good starting point. Some health departments have developed their own PrEP provider directories, using the central preplocator tool or their own maps.⁶⁶ Optimally, a directory would include information on how to find a PrEP provider participating in the Medicaid program (as included in the directory provided by the North Carolina AIDS Education and Training Center)⁶⁷ or in specific Medicaid MCO networks.

For providers, based on the literature review and interviewees, the following educational resources could be considered for dissemination through the avenues described in this section.

- The CDC's PrEP guidelines and provider education tools. Multiple interviewees noted that providers would consider the CDC's existing guidelines to be a trusted source of information. While some providers – or patients – may find their way to the guidelines online or through other sources, they and any future updates should remain a key component of provider outreach, along with the CDC's PrEP education resources and tools for providers.⁶⁸
- State-specific information. Multiple interviewees noted that providers would benefit from state-specific information. This could include:
 - Any relevant recommendations or guidelines from the state DOH. For example, DC has developed a provider guide with District-specific PrEP and PEP information and guidelines.⁶⁹

- Information about the state's Medicaid program and parameters for coverage of PrEP medication and clinical services, including billing and coding information.
- Education on taking sexual histories. One interviewee noted that sexual histories should be part of routine medical care, beyond just a screening tool for PrEP⁷⁰; similarly, another noted that discussing sexual history can be useful for some patients even if they are not ready for PrEP.⁷¹ Resources for providers could include materials on taking sexual histories, such as SIECUS's guide to taking sexual histories for providers serving LGBT youth.⁷²
- Continuing education on PrEP. Providers should be made aware of continuing education (CE) resources on HIV prevention, including PrEP. In general, CE is available for physicians as well as nurse practitioners, physician assistants, and registered nurses. CE on PrEP could increase knowledge while allowing providers to meet their state-level requirements.
- Availability of PrEP academic detailing. A number of states and cities have developed "academic detailing" programs on PrEP, offering training to providers to increase adoption of PrEP prescribing as well as of CDC-recommended clinical services.^{73,74,75} Providers could be informed of the availability of any such opportunities in their state or region.
- **PrEP Locator Resources**. As an interviewee noted, the Preplocator.org directory or state-specific directories may be useful not only for patients but also for providers, allowing prescribers who are new to PrEP to contact other providers in the area with initial questions or for ongoing peer support.⁷⁶

The U.S. Preventive Services Task Force

A positive recommendation from USPSTF could represent an important opportunity for engaging patients and providers, both through and outside the Medicaid program.

First, within Medicaid, the elimination of some cost-sharing for expansion enrollees could be an important shift. While Medicaid cost sharing is generally "nominal" and in most states must be waived by providers and pharmacies if requested, even small out-of-pocket costs can be a deterrent to care. In addition, the perceived cost of PrEP may be a barrier to patient access, even though costs for Medicaid enrollees would be relatively modest. To the extent PrEP can be advertised as entirely free for Medicaid patients, concerns about cost could be reduced as a barrier for Medicaid enrollees.

Second, many interviewees agreed that a positive USPSTF recommendation for PrEP could encourage more providers, particularly primary care providers, to offer the service. Therefore, a positive recommendation could help address the "purview problem" by specifically validating PrEP as an intervention that belongs (though not exclusively) in the primary care setting.

Operational support tools for patients and providers

In addition to educational materials about PrEP, both providers and patients could benefit from a range of operational "tools" and resources to support ongoing provision of, and adherence to, PrEP medication and clinical services. While some of these supports would be specifically provider-facing – such as workflow models for PrEP delivery – others, such as text platforms, could support both patients and providers by facilitating reminders and communication.

- Workflow sheets or algorithms. Providers, particularly those new to PrEP, could benefit from a workflow model or algorithm that walks through the steps of PrEP offer, initiation, and ongoing monitoring.^{77,78,79} For example, the New York State Department of Health developed quick reference cards for PrEP that could be attached to provider lanyards for clinical use.⁸⁰ One interviewee described educational materials she developed for Planned Parenthood's PrEP provider training program, which included scripted language for patient encounters.⁸¹
- Standardized prior authorization form. It may be appropriate to develop clear, standard prior authorization (PA) forms for PrEP medication to simplify requests on the provider side. While PA can in theory pose a barrier to access to PrEP, a simple form linked to relevant clinical information (e.g. demonstrated HIV-negative status at initiation) may be less of a barrier.
- **Consumer communication tools.** One interviewee, a PrEP navigator, reported that her calls to current PrEP users to remind them of followup visits or to check on patients who miss visits help promote compliance with ongoing monitoring.⁸² She noted that a texting program for PrEP users could also be helpful, possibly for medication reminders or allowing questions by text. As noted in the textbox below, the VA's toolkit for PrEP engagement includes PrEP-specific messages in the system's text messaging system. A text message platform for youth PrEP users was recently found to increase PrEP adherence among youth at high risk of HIV acquisition⁸³; the tool will be integrated into larger demonstration projects.⁸⁴
- Patient screening tools. Interviewees noted that both patients and providers would benefit from simple patient screening tools. Multiple interviewees recommended disseminating question-naires that patients could complete on their own, either before a visit or while waiting in the waiting room or exam room.^{85,86} These tools could make some patients more comfortable answering questions related to sexual history. In addition, they would save provider time, and address the barrier of discomfort taking sexual histories for some providers. Such tools are already available; for example, the CDC has developed a six-question MSM risk index for PrEP and a seven-question risk index for people who inject drugs.⁸⁷ The Stigma Project has developed the CDC guidelines into a user-friendly screening tool.⁸⁸

- **Patient counseling supports.** Providers and patients could benefit from tools to help PrEP users remain engaged. For example, the Integrated Next Step Counseling model, developed for the iPrEx study, guides providers through a patient-centered discussion of PrEP, with an emphasis on PrEP adherence.⁸⁹
- National Clinical Consultation Center. The National Clinician Consultation Center at UCSF, funded by the CDC as part of the Health Resources and Services Administration's (HRSA) AIDS Education and Training Center (AETC) program, has a provider warmline (PrEPline) offering free phone consultations to provide clinical advice on PrEP.⁹⁰ Medicaid programs and MCOs could also disseminate information on training opportunities from other AIDS Education and Training Centers.⁹¹
- Other expert consults. One interviewee noted that it would be helpful to have some kind of reimbursement for PrEP "peer support" for primary care providers.⁹² Another interviewee who is an infectious disease doctor serves as a peer consult on PrEP within the clinical network that employs him, offering support usually via email. These consults are not reimbursed by Medicaid or other payers.⁹³ Similarly, a different interviewee conducts a Project ECHO-type consultation model for PrEP for primary care providers within his state; participants get CME credit, but no reimbursement.⁹⁴

Conduits for engaging patients and providers through the Medicaid program

This section discusses how PrEP education resources and operational support tools could be disseminated by CMS, state Medicaid agencies, and MCOs. It also describes potential partnerships with professional societies to amplify provider engagement efforts.

CMS level

CMS administers the Medicaid program at the federal level. Generally, the agency is fairly removed from direct interaction with Medicaid patients and providers, communicating instead with state Medicaid agencies through Dear State Medicaid Director Letters, Informational Bulletins, and other guidance documents.⁹⁵ However, CMS did mention provider PrEP education in a 2016 joint informational bulletin with HHS, HRSA, and the CDC:

Additional strategies states may consider to ensure that utilization management techniques are not designed or implemented in ways that amount to denial of access to PrEP among persons for whom it is indicated include 1) provider education, 2) development of clear policies and procedures for assessing and making determinations about indications for PrEP, and 3) careful review and monitoring of Medicaid FFS and managed care benefits and coverage.⁹⁶

Veterans Health Administration: PrEP Materials and Resources for Patients and Providers

The VA convened a National PrEP Working Group in 2017 to develop targets for PrEP uptake.¹⁸³ To begin to meet these goals, the VA developed a set of products to increase uptake and awareness across the system; these included a PrEP awareness communication tool, PrEP training modules for providers, a VA blog on PrEP, and AIDSVu reports showing regional HIV risk. Further materials included academic detailing training modules and virtual PrEP training for clinical pharmacists. To facilitate targeting of PrEP to high-risk groups, the VA developed clinical support tools to identify candidates for PrEP, telehealth protocols for PrEP, and social media awareness campaigns.

- The VA also developed a set of clinical support tools to specifically address the quality of ongoing clinical care for PrEP users, including lab monitoring. These tools include:
- a set of clinical considerations, aligned with the CDC's guidelines;
- a "PrEP clinical criterion check list";
- other clinical support tools, including prepopulated EHR templates and order menus for PrEP initiation and monitoring; and
- PrEP-related texts in the VA's text-messaging system, to support adherence, appointment attendance, tracking, and patient education.¹⁸⁴

Building on items 1 and 2, the CDC could ask CMS to consider disseminating materials to inform specific provider education at the state level, as well as tools for developing clear procedures for providers to help them make determinations about which patients are candidates for PrEP. These provider capacity assessment and support tools could be modeled on the approach CMS has taken with regard to substance use disorder, offering clinical resources guides, a national workshop, and a range of webinars, both live and archived.⁹⁷

The CDC could also collaborate with HRSA's Bureau of Primary Health Care (BPHC) to address patient and provider issues at FQHCs.

State Medicaid agencies

State Medicaid agencies could disseminate PrEP resources through a range of communication channels, identified through interviews for this project as well as AcademyHealth's informal survey of its Medicaid Medical Director Network (MMDN).⁹⁸ For patients, states could include brief information about PrEP in initial enrollment materials and ongoing mailings to enrollees. Some respondents to the MMDN survey also reported using enrollee emails and automated calls.⁹⁹ An important caveat noted by two MMDN respondents is that in states with high managed care enrollment, states might not communicate directly with enrollees.

State Medicaid agencies could use their agency websites to highlight key PrEP resources both for patients and providers, including specific information on coverage for both, as well as on billing and coding details for providers. Some states may have specific sites for information related to pharmacy; for example, California Medi-Cal's Drug Use Review program has an educational intervention component regarding drug-specific therapy issues.¹⁰⁰

State Medicaid agencies can also reach providers through a range of approaches:

- *Provider manuals.* Provider manuals can lay out service standards for provision of PrEP medication and clinical services, as well as links to resources for further education and support.
- *Emails and/or newsletters to providers.* Most state Medicaid agencies have regular communiques to providers noting updates such as formulary or billing changes, or highlighting certain key policies. For example, New York State's Medicaid program sends a monthly update to providers, largely focused on billing and policy issues.¹⁰¹ These communications may be electronic; five of the sixteen respondents to AcademyHealth's survey specifically noted email as an effective way to reach providers.¹⁰²
- Some newsletters may be read more often by administrative staff than by providers themselves and therefore may be appropriate outlets for highlighting and providing links to key PrEP billing and coding resources.
- *Direct letters to providers* regarding PrEP. The State Medicaid agency could send letters to all Medicaid providers in the state, or to targeted subsets, specifically highlighting PrEP resources.
- State Medicaid agencies could also use "all-plan letters" to encourage MCOs to share PrEP information with participating providers and with enrollees.

Examples of State Medicaid Outreach to Medicaid Providers

In December 2017, California's Department of Health Care Services sent a notice to all Medi-Cal providers regarding erroneous delays and denials of PrEP and PEP, and clarifying that both are covered services available through Medi-Cal.¹⁸⁵

In New York, the Department of Health (DOH) learned of provider confusion over Medicaid coverage of PrEP and PEP in Fee for Service Medicaid. DOH developed a document for distribution to all Medicaid FFS providers to clarify coverage policies.¹⁸⁶

Lessons from MCO Provider Engagement Efforts Related to Medication-Assisted Treatment for Opioid Addiction

A recent report for the Association for Community-Affiliated Plans detailed the strategies that several Medicaid MCOs are using to support and engage primary care physicians in prescribing Medication-Assisted Treatment (MAT) for opioid use disorder.

The authors of the report identified provider barriers to offering MAT that in several ways echo those involved with PrEP: a lack of provider education, the additional management burden of MAT practice, and stigma related to the patient population and to the underlying risk behavior.

Medicaid MCOs profiled in the report used a variety of approaches to engage new MAT providers and to support and maintain existing providers. For example:

- UPMC (Pa.) supports educational sessions in medical schools, as well as training opportunities for providers, including webinars, conferences, and on-site presentations.
- UPMC supports physicians who are on call at all hours to answer questions from prescribing physicians, as well as a 24-hour care management services for patients and providers.
- Community Health Network of CT offers a two-day conference on addiction, opioid use disorder and MAT, with 16 free CME credits, for its providers. It also offers online toolkits for primary care providers and emergency room-based providers.
- Inland Empire Health Plan (CA) has a payment structure that support out-of-office time for trainings related to MAT.
- Multiple MCOs support Project ECHO models related to opioid use. For example, Passport Health Plan (Ky.) is engaged in a Project ECHO collaborative to support buprenorphine prescribing, particularly for rural providers; and Partnership Health Plan (Calif.) uses the ECHO model to train primary care providers on treating chronic pain. Partnership Health Plan has also engaged a MAT provider who visits network practices to support MAT implementation.
- Three health plans Inland, Passport, and UPMC are developing consistent screening processes to identify patients with opioid use disorder. Geisinger Health Plan uses ICD codes to identify candidates for targeted outreach.
- Geisinger Health Plan conducted an internal survey of its physicians regarding addiction in SUD, in part to identify and address provider bias and stigma.

It is important to note that state Medicaid agencies may be concerned that patient or provider outreach will drive a demand for PrEP that the state cannot afford to meet.

Medicaid MCOs

MCOs can provide information directly to their own enrollees. Enrollee MCO manuals could include basic information on PrEP and how to learn more, as well as information on finding a PrEP provider specifically within that MCO's network. MCOs could also send information about PrEP to all members or to specific zip codes, targeted based on Medicaid claims data analysis and/or state surveillance data. 103

Medicaid MCO websites usually have both enrollee and provider interfaces. The enrollee website could link to basic consumer information about PrEP and how to access it; the provider interface, targeted to in-network providers, could highlight provider resources on PrEP.

MCOs can reach out to providers through additional channels:

- *Provider manuals*: Provider manuals can lay out service standards for provision of PrEP medication and clinical services, as well as links to resources for further education and support.
- *Provider mailings:* Like state Medicaid agencies, MCOs routinely send regular or special communications to providers on key coverage or policy issues, which could highlight PrEP resources. This outreach could be targeted based on Medicaid claims data analysis and/or state surveillance data.¹⁰⁴
- *CME*: Medicaid MCOs can highlight, sponsor, or otherwise promote CME for their providers. MCOs could work with public health agencies to incorporate PrEP-related provider education into these opportunities.
- Medical Affairs: MCOs' Medical Affairs offices can reach out directly to providers for informational engagement on a range of clinical topics,¹⁰⁵ and could consider including PrEP in the scope of this outreach.

Finances are a crucial consideration for MCOs. MCOs may be hesitant to engage in patient and provider outreach if they are concerned that the rates they receive from the state would not adequately reimburse any ensuing uptake in PrEP medication and clinical services.

Partnering with provider organizations

Multiple interviewees cited the CDC as a primary source of trusted information for providers, including primary care providers, reinforcing the idea that Medicaid programs could add value simply by highlighting the CDC's PrEP guidelines and resources. However, interviewees also noted a range of other professional societies to which providers turn for information. Of 16 state Medicaid Medical Directors responding to AcademyHealth's informal survey for this project, five specifically noted the important role of medical professional societies in helping reach providers.¹⁰⁶ Medicaid agencies, MCOs, and public health agencies could reach out to these professional organizations at the national, state, and/or local levels to identify opportunities for promoting PrEP engagement and education among providers.¹⁰⁷ Provider organizations could also work closely with Medicaid agencies and MCOs to help assess and strengthen policies related to coverage of PrEP medication and clinical services. Alternative financing opportunities may be more likely to come to fruition if providers, as well as public health stakeholders, are engaged in the process.

Multiple interviewees noted that providers often trust information developed at the state level as particularly responsive to their and their patients' needs. This would include state-level chapters of the organizations discussed below, as well as information from respective State Departments of Health.

Several organizations already have longstanding relationships with the CDC's Division of HIV/AIDS and could be strong partners in continued work to promote PrEP access within Medicaid. The National Medical Association represents more than 50,000 African American physicians and their patients, and promotes professional education and scholarship as well as responsive health policy and consumer education.¹⁰⁸ The National Hispanic Medical Association represents 50,000 Hispanic physicians in the U.S. and also engages in provider and patient engagement as well as policy work.¹⁰⁹ The American College of Physicians serves a similar role with regard to internal medicine specialists and subspecialists.¹¹⁰

Other professional societies could represent further opportunities for reaching and supporting new PrEP providers and patients. Affiliates of three, the AMA, AAFP, and AANP, were interviewed for this project:

• American Medical Association (AMA): The AMA is a professional organization for all physicians, both MDs and DOs, as well as medical students. In 2016, the AMA adopted a policy supporting improved provider education on PrEP for HIV, noting that a 2015 survey had found that 34 percent of primary care physicians and nurses had never heard of the intervention.¹¹¹ The AMA simultaneously endorsed policies in support of full insurance coverage of the costs associated with PrEP as well as the development of policies to provide PrEP for free to high-risk individuals.¹¹²

Nationally, the AMA has several member groups, or "Sections," that may be particularly interested in PrEP; these include the Advisory Committee on LGBTQ Issues and the Minority Affairs Section.¹¹³ The AMA also maintains a "Federation of Medicine" directory of state-level medical associations, including specialty associations. The directory includes society names, leadership, contact information, and websites.¹¹⁴ Stakeholders could use this resource to identify state-level physician societies and discuss ways to work together to promote AMA's policy on PrEP education.

The American Academy of Family Physicians (AAFP): The ۲ AAFP is a membership organization for family physicians who serve patients of all ages in a wide variety of settings, including offices, hospitals, community health centers, urgent care centers, and emergency rooms.¹¹⁵ It currently has 131,400 members, including medical students and residents.¹¹⁶ The AAFP develops practice guidelines for family physicians. These are often based on US Preventive Services Task Force recommendations: the AAFP reviews all USPSTF clinical preventive services recommendations and develops its final recommendations based on the evidence base from the USPSTF. AAFP's current policy on "Prevention and Control of Sexually Transmitted and Blood Borne Infections" states that "[f]amily physicians should counsel and when appropriate prescribe PrEP as a routine part of STI prevention."117

The AAFP has 55 constituent chapters that are involved in education, messaging and promotion for family physicians within the state. They often follow national priorities, but can engage on specific issues independently, and may be open to approach for collaboration on PrEP issues.¹¹⁸ Stakeholders should consider reaching out to their states' AAFP chapters regarding statespecific opportunities for increasing PrEP access in the state's Medicaid program and overall.

- The American Academy of Nurse Practitioners (AANP): The AANP is a national provider organization for Nurse Practitioners across all specialties, as well as nursing students. AANP is viewed as a key source of education and information driving NP practice, including by hosting CME and other educational materials on its website.¹¹⁹
- The AANP also maintains an online directory of state, local, and regional organizational members.¹²⁰ Stakeholders could reach out to relevant organizations in the state to discuss potential collaboration on PrEP education and promoting PrEP through Medicaid.

Other professional societies to consider including in PrEP planning and engagement efforts include, but are not limited to, state primary care associations and state chapters of the American Academy of Physician Assistants and the American Academy of Pediatrics. In addition to professional societies, stakeholders should consider partnering with organizations that represent specific types of facilities. For example, NACCHO, the National Association of County and City Health Officials, has an educational series on PrEP for local health departments.¹²¹

Using Medicaid data to target PrEP resources and education

Multiple interviewees agreed that Medicaid claims and encounter data could be leveraged to increase PrEP uptake and adherence and to improve provision of PrEP clinical services to current PrEP users. Because Medicaid agencies do not always have staffing or resources to spare for new analyses,¹²² public health stakeholders could develop or expand existing data sharing agreements with state Medicaid agencies, or work together to identify a third party, such as a university,¹²³ that could conduct the analyses.¹²⁴

In an important caveat, two interviewees noted that "real-time" use of Medicaid claims data is generally not feasible,¹²⁵ due in part to lags in claims processing.¹²⁶ Despite this limitation, Medicaid claims data could potentially be used in at least three ways:

- Identifying the current rate of PrEP use in the Medicaid program, including stratification by certain populations;
- Tracking the provision of clinical services to current PrEP users;
- Identifying candidates for PrEP, based on STI-related claims or other indicators from Medicaid data.

These analyses and any related outreach to providers or patients would need to be conducted in line with existing privacy agreements as well as community expectations.

Measuring current PrEP use in the Medicaid program

First, Medicaid claims data can be used to identify who is receiving PrEP. New York State's AIDS Institute applied an algorithm to state Medicaid pharmacy and diagnosis data to identify enrollees who were on Truvada for more than 30 days,¹²⁷ excluding those with an HIV diagnosis.¹²⁸ In California, a recent analysis of PrEP uptake among Medi-Cal beneficiaries looked at changes in utilization from 2013 to 2016, stratifying data by age, gender, race, ethnicity and region to assess patterns and disparities that could help guide public health efforts to promote uptake.¹²⁹

Similar analyses in other states could help establish a baseline for PrEP use among Medicaid enrollees and allow tracking of the impact of Medicaid-specific or statewide promotion efforts. The CDC's recent paper estimating the number of adults with PrEP indications includes figures by state and includes stratification by transmission risk group and race/ethnicity,¹³⁰ making it a useful tool for comparing PrEP access in the Medicaid program to estimated need. Identifying active PrEP prescribers in Medicaid can help states determine if communities with high PrEP need – e.g. with high STI rates – have sufficient access. Stakeholders may also wish to explore potential integration of Medicaid claims data with AIDSVu data on PrEP use.¹³¹ An important limitation is that data on race is often missing from Medicaid claims. In addition, claims data do not capture gender identify or sexual orientation, limiting the ability to answer certain key access questions.¹³² This is one effect of an overall lag in SOGI (sexual orientation and gender identity) data collection in Medicaid programs, posing a challenge for assessment of baseline need and progress in reaching people with PrEP and other services.¹³³

A further limitation is the lookback period could result in somewhat outdated utilization counts. Nonetheless, such an analysis would offer some important baseline information about how well a state Medicaid program is reaching enrollees with PrEP.

Tracking provision of clinical services to current PrEP users

Medicaid claims data could also be used to track whether people currently using PrEP are also receiving appropriate clinical services. For enrollees identified as PrEP users based on the type of analysis described above, a *lack* of claims for STI screening or other components of PrEP services could indicate that appropriate clinical services are not being provided.¹³⁴

Claims-based analyses would only identify services reimbursed by Medicaid, omitting, for example, screenings obtained at a non-billing STI clinic.¹³⁵ However, this approach could at least flag patterns (by region or provider) of potential non-receipt of appropriate services. Such an analysis could potentially be utilized to inform targeted provider outreach, either by Medicaid agencies or public health counterparts.

Finding candidates for PrEP

Medicaid claims data could also be used to identify enrollees who are candidates for PrEP. For example, certain STI diagnoses within Medicaid claims might indicate patients whose providers could be encouraged to offer information about PrEP. Such information could also potentially be found in state surveillance data¹³⁶; for example, Michigan's "Data to PrEP" program uses surveillance data to identify and conduct PrEP outreach to HIV-negative men with a single rectal gonorrhea infection, two urethral or pharyngeal gonorrhea infections, or syphilis. Incorporating Medicaid claims data into such initiatives might help fill gaps left by incomplete reporting to departments of health.

Medicaid Claims Data and MCOs

Generally, State Medicaid agencies have access to all claims data for their enrollees, whether FFS or managed care. However, MCOs receive their own payment data first, and may have relatively sophisticated analysis capacity.¹⁸⁷ In some states, it may make sense for MCOs to conduct PrEP-related data analysis for their own covered populations. In all states with MCO enrollment, Medicaid agencies, MCO, and public health stakeholders can work together to ensure reporting of those elements of encounter data that are important for PrEP analysis.

Leveraging Medicaid benefits for patient and provider engagement

This section describes specific Medicaid benefits that could be leveraged to better engage patients and/or providers in the full PrEP intervention suite. The section reviews PrEP and telehealth in Medicaid; as well as additional Medicaid benefits, like nonemergency medical transportation, that could assist PrEP users. It also discusses how Medicaid can support both pharmacists and nonclinical CBOs in bolstering patient and provider engagement.

PrEP and telehealth in Medicaid

Telehealth options for accessing PrEP could increase patient access, mitigating both geographic and other barriers to care.

As of spring 2018, 49 states and DC provide for Medicaid reimbursement of some form of live video telehealth services.¹³⁷ Roughly half of states specify a specific set of facilities that can serve as "originating sites" where the patient may be; only ten states permit a patient's home to be the originating site.¹³⁸ Telehealth coverage in Medicaid can vary by service type. Among MCOs, for example, a 2017 survey found that 37 percent of Medicaid MCOs use telemedicine for mental health or SUD counseling, along with 20 percent for chronic disease management; 32 percent did not use telemedicine.¹³⁹ In addition, some multistate Medicaid MCOs provide their enrollees with free access to national telehealth service providers, such as Teladoc.¹⁴⁰

Several telehealth models for PrEP exist. For example, in New York State, the AIDS Institute identified rural counties with limited PrEP access.¹⁴¹ They then worked with an FQHC in the region that had engaged in HIV treatment telehealth to establish a system for PrEP telehealth. The FQHC reached out to clinics in the underserved communities to begin providing PrEP to patients at those clinics, with the local providers present in the room so they could become comfortable with PrEP provision themselves.

Louisiana recently launched a Tele-PrEP program. Via a HIPAA compliant video platform, patients can use a computer, tablet, or smartphone to interact with a nurse practitioner located in New Orleans; a tele-PrEP navigator connects the patients to lab services.¹⁴² For patients with Medicaid, Medicaid will pay for the drugs.

In one current trial of telehealth vs. standard PrEP, patients see a provider on camera, and HIV and STI kits are sent to the home for self-swabbing and finger sticks.¹⁴³ Subjects' insurance pays for the telehealth encounters, but study funds are being used to purchase the home test kits. If such a model is identified as an effective approach more broadly, it may be important to identify an avenue for Medicaid or alternative reimbursement of at-home test kits.

Additional Medicaid benefits to support PrEP Users

A number of additional Medicaid benefits could be leveraged to promote patient access to PrEP by addressing barriers to access and adherence:

- Targeted Case Management: Medicaid programs can support Targeted Case Management for specific groups of enrollees. Rhode Island has expanded this concept to make TCM available for certain beneficiaries at high risk of HIV,¹⁴⁴ creating a reimbursement mechanism for services around linking people to PrEP and encouraging their adherence to PrEP clinical services.
- Care Coordination: Many Medicaid MCOs conduct a range of care coordination activities for enrollees, including chronic disease management; community health workers, peer support specialists, and health coaches; individualized care plans; and home visits. These approaches could be tailored toward supporting PrEP users in adherence and receiving clinical services, potentially via PrEP navigators.¹⁴⁵ For example, MCOs could work with public health agencies to develop models for supporting PrEP navigation counselors at the plan or provider level.
- Non-Emergency Medical Transportation (NEMT) Benefit: Nonemergency medical transportation is a Medicaid benefit that covers transportation to non-emergency, Medicaid-covered care. By federal regulation, state Medicaid plans must "[s]pecify that the Medicaid agency will ensure necessary transportation for beneficiaries to and from providers; and [d]escribe the methods that the agency will use to meet this requirement."¹⁴⁶ States have considerable latitude in how they implement this requirement, and several states have implemented waivers of the requirement for certain categories of beneficiaries. Stakeholders could review their respective states' NEMT benefits to determine what, if any, transportation resources are available to PrEP-eligible enrollees and include information about the availability of free transportation in PrEP outreach materials.

In addition to these specific benefits, funding models such as PCMHs, Medicaid health homes and ACOs could provide care coordination services to help support PrEP users in adhering to the full PrEP intervention.

Engaging pharmacists to support patients and providers

Increasing pharmacist engagement in various elements of PrEP delivery could help improve patient access and engagement. A recent synthesis of evidence on models for PrEP delivery noted several benefits of pharmacy engagement in PrEP, including the possibility of evening and weekend hours (not always available at providers' office), and pharmacists' ability to review and respond to refill gaps to address nonadherence.¹⁴⁷ In some states, Medicaid reimburses pharmacists for enhanced medication therapy management, or MTM, services.¹⁴⁸ For example, Mississippi Medicaid's "Pharmacy Disease Management" program reimburses pharmacists for counseling enrollees with a range of diseases including diabetes, asthma, and hyperlipidemia.¹⁴⁹ States with a Medication Therapy Management benefit in their Medicaid programs could explore the possibility of reimbursing pharmacists for providing enhanced counseling and reminders for patients using PrEP.¹⁵⁰

In addition to engaging patients, an MTM benefit could reimburse for pharmacist engagement with prescribers. For example, a pharmacist who notes that a patient didn't pick up her PrEP prescription could reach out to the prescriber to flag the issue.¹⁵¹ Conversely, a pharmacist who notices that a patient has multiple refills on their PrEP medication could reach out to the prescriber to ensure that there is a mechanism for the patient to receive required STI, HIV, and other screenings as needed each quarter.¹⁵²

Some pharmacists may be able to conduct HIV testing¹⁵³ and possibly collect specimens and forward to a laboratory for other PrEPrelated tests (e.g. STI tests with patients self-swabbing). In states that allow advanced pharmacist practice or collaborative practice agreements with clinical practices, pharmacists may be able to actually prescribe PrEP *and* offer clinical services, offering patients the full range of PrEP services at one site. For example, pharmacists at Kelley-Ross Pharmacy in Seattle can prescribe PrEP and offer the full range of CDC-recommended clinical services, receiving Medicaid reimbursement from the Medicaid MCOs with which they contract¹⁵⁴

Linking providers to CBOs to support comprehensive care for patients Providers can partner with community-based organizations to reduce barriers for patients and facilitate provider provision of PrEP, either by offering PrEP navigation or other services like medication adherence support.

For example, clinicians at Open Arms Health Care Center in Jackson, Miss., provide PrEP. Open Arms is affiliated with My Brother's Keeper, a CBO with satellite sites in Hattiesburg and near the Coast. Patient can go to My Brother's Keeper for rapid HIV tests and bloodwork, combined with a telehealth visit with a provider at Open Arms. This reduces transportation time and costs for patients.¹⁵⁵

At the Medical University of South Carolina (MUSC), the Department of Family Medicine partners with Palmetto Community Care (formerly Low Country AIDS Services) in the provision of PrEP.¹⁵⁶ Palmetto Community Care refers patients to MUSC, where providers can conduct initial assessments and prescribe PrEP. Patients can then return to PCC for regular labwork, the results of which are shared with the prescribing provider at MUSC. This relationship makes labwork and PrEP adherence support more accessible for patients, while relieving the primary care clinic of some of the work of ongoing monitoring.¹⁵⁷

Stakeholders should determine whether these relationships exist or could be fostered. To the extent possible, if CBOs are staffed in a way that makes them eligible Medicaid providers, they could be reimbursed for services offered. Non-clinical CBOs could attempt to develop contractual relationships (or MOUs) with state Medicaid agencies or MCOs to help support the provision of services.

NMAC's HIV and PrEP Navigation Program

NMAC's "Linking Communities to Care through HIV and PrEP Navigation" provides capacity building for non-clinical CBOs and health care organizations to offer PrEP and HIV care navigation services.¹⁸⁸ The program focuses on recruitment, linkage, and retention for people of color, focusing on communities most affected by HIV risk. Online resources include a landscape assessment on HIV and PrEP Navigation as well as a guide on motivational interviewing for HIV and PrEP.

Further considerations

This section addresses additional considerations for engaging patients and providers in PrEP medication and care through the Medicaid program:

- State and MCO cultural competency requirements as a potential nexus for efforts to address various forms of stigma surrounding PrEP;
- The importance of recognizing Medicaid "churn" and guiding consumers through eligibility changes while continuing to adhere to the PrEP intervention suite;
- Mechanisms for coordinating PrEP for people returning to the community from the corrections system; and
- Adolescent minors and privacy within Medicaid.

It closes with a discussion of addressing PrEP for people who use drugs, particularly in light of heightened attention to the opioid epidemic.

Cultural competency in Medicaid programs

Federal regulations require state Medicaid programs to develop methods to promote culturally competent services:

Access and Cultural Considerations. The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.¹⁵⁸

Further, regulations require all Medicaid MCOs – as well as limited benefit Medicaid managed care plans called Prepaid Inpatient Health Plans (PIHPs) and Prepaid Ambulatory Health Plans (PAHPs) – to participate in these state activities:

Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity.¹⁵⁹

States could identify existing Medicaid and MCO activities to promote cultural competency, and explore opportunities to incorporate information related to PrEP, as well as to broader education to address stigma and bias related to race, sexual orientation, and gender identity.

Assisting patients with PrEP adherence through enrollment changes

An individual's Medicaid status is not static. For example, people may lose eligibility for Medicaid because of increases in income, becoming eligible instead for subsidized coverage through state-level marketplaces under the Affordable Care Act. In non-Medicaid expansion states, people who are eligible for Medicaid under very low income thresholds could lose eligibility at a slightly higher income level and become uninsured. In all states, people may lose eligibility for administrative reasons such as failing to complete paperwork in a timely fashion.

Churning can have serious impacts on access to care. A recent study of 2015 data in three states found that almost 1 in 4 lowincome adults reported a change in coverage during the prior year, with half of those reporting a *gap* in coverage.¹⁶⁰ The study found significant disruptions of care for "churners," including a third reporting skipping doses or stopping taking prescribed medications¹⁶¹ While not PrEP-specific, the study's findings raise concerns regarding PrEP adherence through coverage changes.

Providers whose PrEP patients lose Medicaid eligibility should be prepared to help navigate continuous access to PrEP medication and clinical services, whether under new insurance or through patient assistance programs and other funding streams. For example, one interviewee, a PrEP Navigator at a public health STD clinic, noted that she has helped people sign up for the Gilead patient assistance program as a stopgap when faced with interruptions in public or private insurance coverage.¹⁶² Medicaid agencies could consider collaborating with public health agencies to develop resource guides that educate providers and patients on other sources of PrEP coverage if eligibility changes. It is also important to note that in states with multiple Medicaid MCOs, beneficiaries could retain coverage but switch plans. Alignment across MCOs, including utilization management approaches and coverage policies for STI screening and other clinical services, would help smooth the transition for patients using PrEP.

Facilitating PrEP access for Medicaid-eligible people leaving the corrections system

Some people returning to the community after being incarcerated may be candidates for PrEP. Most states suspend, rather than terminate, Medicaid enrollment for individuals while they are incarcerated, in part to facilitate restarting coverage upon release.¹⁶³ The majority of states also have initiatives to facilitate Medicaid enrollment before release.¹⁶⁴ As part of the pre-release process, states can identify patients with heightened health or social needs. For example, Louisiana's state Medicaid agency begins planning nine months before release, and the process includes identification of "high needs" people such as those with serious mental illness, substance use disorder, or multiple morbidities.¹⁶⁵ States could explore whether Medicaid pre-release coordination processes in their state could address PrEP eligibility and include appropriate education and referrals.

Privacy for adolescent minors and other PrEP users in State Medicaid programs

While Truvada has been used off-label for PrEP in adolescents prior to this year, FDA recently formally extended the drug's PrEP indication to adolescents weighing at least 35 kg (approx. 77 pounds).¹⁶⁶ A recently published study surveying a subset of members of the Society of Adolescent Health and Medicine found that a vast majority of respondents (93.2 percent) had heard of PrEP, and that 35.2 percent

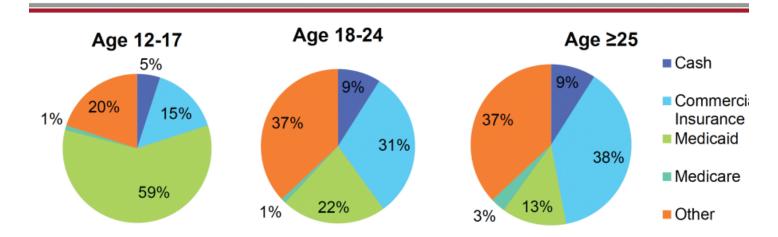
PrEP as a Conduit to Medicaid or Other Insurance Coverage

To maximize Medicaid support of PrEP medication and clinical services, both clinical PrEP providers and non-clinical CBOs engaged in PrEP should engage in routine insurance screening and/or referral. Patients are not always aware of their eligibility for Medicaid, and these programs could help identify the eligible unenrolled. Insurance assistance could also help PrEP users navigate Medicaid administrative requirements to avoid gaps in coverage and access. Two interviewees noted that their intake processes for PrEP patients include counseling on Medicaid and other benefit eligibility as well as assistance with enrollment.^{189,190}

A further reason for robust insurance assistance is that linking PrEP-eligible people to Medicaid or other insurance improves access to a broad range of services, including mental health and substance use disorder treatment services, further improving overall health and reducing HIV risk factors. In addition, identifying Medicaid-eligible people can help conserve funding in state and local PrEP assistance programs, such as those offered by Washington State,¹⁹¹ New York State,¹⁹² and Washington DC.¹⁹³

had prescribed it. However, overall young people are not accessing PrEP in proportion to the HIV risk experienced in this age group. Data presented by Gilead at the 2018 International AIDS Conference showed that 15 percent of people who had ever used Truvada were under age 25; only 1.5 percent were teenagers (and over 83 percent of the teenagers were girls).¹⁶⁷

Among 12-17 year-olds, the data reflected that Medicaid was the most significant payer¹⁶⁸:



Payment Methods for FTC/TDF for PrEP by Age Category

Benefit-wise, since PrEP medication is approved for adolescents, Medicaid and CHIP programs should be expected to cover PrEP medication and clinical services for adolescents on the same terms as for adults. However, adolescent use can raise heightened questions about privacy. Federal law requires state Medicaid programs to have a process for confirming that beneficiaries in fact received the services billed. To comply with this requirement, some states send "explanation of benefit" (EOB) notices to beneficiaries after services are delivered, though this approach is not required. In addition, federal law requires Medicaid MCOs to send written notices of denials, or partial denials, of requests.

In a related issue for adolescents that is not Medicaid-specific, only some states' laws explicitly permit minors to independently consent to PrEP. The CDC's compilation of minor consent laws regarding HIV and STI services offers a starting point for state-level identification of any potential barriers for minor consent.¹⁶⁹

State Medicaid agencies can identify how their EOB and privacy policies would apply to adolescents and other enrollees using PrEP and related services, and whether any suppression policy extends to denial notices. Pediatricians, adolescent health providers, and others who may offer PrEP or discuss it with adolescents should be made aware of what Medicaid privacy protections apply in their respective states.

PrEP and Substance Use

The key randomized trial of PrEP use among people who inject drugs, or PWID, found a reduction in HIV incidence of 49.8 percent compared to the placebo arm; for patient with high levels of adherence, the risk reduction was 73.5 percent.¹⁷⁰

PWID may be willing to use PrEP but experience a range of barriers. Some studies have found extremely low rates of PrEP awareness among PWID in the US.¹⁷¹ However, a number of studies have found fairly high *willingness* to use PrEP once information is shared. For example, in a study of PWID using a mobile syringe exchange service in Camden, NJ, 88.9 percent of women and 71.0 percent of men expressed willingness to use PrEP.¹⁷² However, respondents also reported multiple barriers to PrEP use, including "feeling embarrassed (45.0%) or anxious (51.6%) about taking PrEP, nondisclosure to partners (51.4%), limited engagement with health care providers where PrEP might be provided (43.8%), and lacking health insurance (32.9%)."¹⁷³

Meanwhile, substance use treatment providers may experience their own barriers to engaging in PrEP provision. For example, one study identified multiple barriers to PrEP provision among substance use treatment providers in six New York City outpatient programs.¹⁷⁴ At the time (2014), very few study respondents were aware of PrEP. Response was generally positive, but provider concerns about implementation included lack of medical staff to prescribe and monitor PrEP, questions about cost and reimbursement (including via Medicaid), and the need for training to help providers educate patients.¹⁷⁵ In addition, as noted by one interviewee, adherence concerns have historically led providers to hesitate to prescribe medication, such as ART or HCV treatment, to people who use drugs.¹⁷⁶

Stakeholders could take a number of steps to explore the benefits and challenges of trying to improve access to PrEP medication and clinical services for people who inject drugs. A number of complex issues should be considered.¹⁷⁷

- What do the epidemiologic data show in the state regarding people at high risk of HIV based on injection drug use? What about use of other drugs, which may impact sexual risk? What is the overlap of this group with Medicaid eligibility in the state?
- Are substance use treatment providers, including those offering medication-assisted treatment for opioid use, offering PrEP for prevention of sexual acquisition or of injection transmission in the case of relapse of injection drug use? Can or should these services be bundled with other SUD services?
- Are adequate syringe exchange programs (SEPs) currently in place? SEPs are highly effective at preventing the transmission of HIV by injection, as well as other viruses and bacteria. If an SEP is already providing high levels of HIV protection, what added level of risk protection, such as against sexual risk, would PrEP services offer? Are there other potential outreach approaches to reach people at risk of HIV who are *not* clients of SEPs? Could PrEP be instituted as an interim approach while SEPs are being established in the wake of significant HIV events in injection drug use, like the outbreak in Scott County, Indiana?
- How does injection drug use or the use of other drugs overlap with sexual risk factors for HIV? Among people with multiple risk factors, how many identify (internally or to their providers) as people who inject or use drugs? Would programs targeting PWID reach these populations?
- What is the ROI for PrEP for PWID? A 2016 study modeled evaluated the cost-effectiveness of providing adult U.S. PWID with PrEP, PrEP with frequent screening, and PrEP with ART for those who seroconvert.¹⁷⁸ The analysis found that the third scenario, PrEP + screening + ART, would offer the best outcome, averting 26,700 new infections.¹⁷⁹ However, it would cost \$253,000 per QALY, compared to \$4500-\$34,000 per QALY in an SEP.¹⁸⁰

Multiple interviewees noted that the current public health and political concern about the opioid epidemic is driving resources toward helping people who use drugs, including injection drugs. Therefore, to the extent stakeholders are interested in expanding PrEP access among people who inject or otherwise use drugs, they could identify opportunities for incorporating PrEP within and beyond the Medicaid program.

Conclusion

Scaling up the full PrEP intervention suite will require extensive patient and provider education and support efforts. As generic PrEP drugs and, potentially, long-acting injectables become available, the role of biomedical prevention will be even more important. The Medicaid program offers important opportunities to reach providers, as well as many of the patients who could most benefit from PrEP. The approaches outlined in this paper can serve as a starting point to identify next steps to seize these opportunities at the state level.

Appendix 1: Project Steering Committee

Members:

Douglas Fish, Medical Director, New York State Department of Health

Lisa Glenn, Associate Medical Director, Medicaid/CHIP, Texas Health and Human Services Commission

DeAnn Gruber, Director, Louisiana Office of Public Health Bureau of Infectious Diseases

Kathryn Macomber, Director, Division of HIV/STD Programs, Michigan Department of Health and Human Services

Jill Morrow-Gorton, Acting Chief Medical Officer, MassHealth, Office of Clinical Affairs, Commonwealth Medicine, University of Massachusetts Medical School

Dave Rzeszutko, Medical Director, PriorityHealth

John Wiesman, Secretary, Washington State Department of Health and President, Association of State and Territorial Health Officials (ASTHO)

Doug Wirth, CEO, Amida Care

Patricia Witherspoon, Assistant Medical Director, South Carolina Department of Health and Human Services

Laura H. Bachmann, Chief Medical Officer, Clinical Team Lead, Program Development and Quality Improvement Branch, Division of STD Prevention, Centers for Disease Control and Prevention

Ex Officio Members:

Josh Hardy, Health Insurance Specialist, Division of Quality and Health Outcomes, Children and Adults Health Programs Group, Centers for Medicare and Medicaid Services **Priya Jakhmola, MS,** Lead Health Scientist, Division of HIV/AIDS Prevention (DHAP), Centers for Disease Control and Prevention

AcademyHealth Staff:

Susan Kennedy, Senior Manager, AcademyHealth

Enrique Martinez-Vidal, Vice President, AcademyHealth

Rachel Ruback, Research Assistant, AcademyHealth

Samantha Smith, Senior Manager, AcademyHealth

ChangeLab Solutions:

Hannah Sheehy, Senior Policy Analyst, ChangeLab Solutions

CDC Staff:

Ijeoma Ihiasota, Public Health Analyst, Office of Policy, Planning, and Communications, Division of HIV/AIDS Prevention, Centers for Disease Control and Prevention

Dan Lentine, Partnerships Liaison, Office of Policy, Planning, & External Relations, Division of STD Prevention, Centers for Disease Control and Prevention

William Pearson, Health Scientist, Health Services Research and Evaluation Branch, Division of STD Prevention, Office of Infectious Disease, Centers for Disease Control and Prevention

Raul A. Romaguera, DMD, Deputy Director, Division of STD Prevention, Centers for Disease Control and Prevention

Abigail Viall, Program and Performance Improvement Office, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention

Endnotes

- Siegler AJ, et al., The prevalence of pre-exposure prophylaxis use and the pre-exposure prophylaxis to-need ratio in the fourth quarter of 2017, United States, Annals of Epidemiology (2018), https://doi.org/10.1016/j.annepidem.2018.06.005
- 2 CDC, "HIV prevention pill not reaching most Americans who could benefit – especially people of color" (Mar. 2018). www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html
- 3 See, e.g., California HIV/AIDS Research Program, "Addressing PrEP Disparities Among Young Gay and Bisexual Men in California" (Sep. 2016). https://aplahealth.org/wp-content/uploads/2016/09/APLA_PrEP_FullReport_WEB.pdf
- 4 Goldstein et al., "Being PrEPared Preexposure Prophylaxis and HIV Disparities." New England Journal of Medicine (Sept. 19, 2018). www.nejm.org/doi/ full/10.1056/NEJMp1804306?query=TOC
- 5 Smith et al., "Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015" Annals of Epidemiology xxx (2018) 1-8.
- 6 Huang et al., "HIV Preexposure Prophylaxis, by Race and Ethnicity United States, 2014–2016." MMWR Morb Mortal Wkly Rep. 2018 Oct 19; 67(41): 1147–1150.
- 7 AIDSVU, "Deeper Look: PrEP." https://aidsvu.org/resources/deeper-look-prep/
- 8 Spinelli et al., "Provider Adherence to Pre-exposure Prophylaxis Monitoring Guidelines in a Large Primary Care Network" Open Forum Infectious Diseases, Volume 5, Issue 6, 1 June 2018, ofy099, https://doi.org/10.1093/ofid/ofy099
- 9 Id.
- 10 CDC, "PrEP" (Updated Aug. 23, 2018). www.cdc.gov/hiv/basics/prep.html
- ANDA Approval Letter from FDA to Teva Pharmaceuticals USA, Inc. (June 8, 2017). www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090894Orig1s 000ltr.pdf
- 12 Id.
- 13 CDC, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update: A Clinical Practice Guideline." " (Published online Mar. 2018). https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
- 14 Nunn et al., "Defining the HIV pre-exposure prophylaxis care continuum." AIDS. 2017 Mar 13;31(5):731-734. doi: 10.1097/QAD.000000ubach0000001385.
- 15 Strauss et al., "Exploring Patterns of Awareness and Use of HIV Pre-Exposure Prophylaxis Among Young Men Who Have Sex with Men." AIDS Behav. 2017 May;21(5):1288-1298. doi: 10.1007/s10461-016-1480-0.
- 16 Interview with Liz Hacker, October 5, 2018.
- 17 CDC, "HIV Among Youth." https://www.cdc.gov/hiv/group/age/youth/index. html.
- 18 Strauss et al., "Exploring Patterns of Awareness and Use of HIV Pre-Exposure Prophylaxis Among Young Men Who Have Sex with Men." AIDS Behav. 2017 May;21(5):1288-1298. doi: 10.1007/s10461-016-1480-0.
- 19 CDC, "HIV and Gay and Bisexual Men." https://www.cdc.gov/hiv/group/msm/ index.html
- 20 CDC, "HIV Among Transgender People." https://www.cdc.gov/hiv/group/gender/transgender/index.html
- 21 Garnett et al., "Limited awareness of pre-exposure prophylaxis among black men who have sex with men and transgender women in New York City." AIDS Care. 2018 Jan;30(1):9-17. doi: 10.1080/09540121.2017.1363364. Epub 2017 Aug 9.
- 22 CDC, "HIV Among Women." https://www.cdc.gov/hiv/group/gender/women/ index.html
- 23 Huang et al., "HIV Preexposure Prophylaxis, by Race and Ethnicity United States, 2014–2016." MMWR Morb Mortal Wkly Rep. 2018 Oct 19; 67(41): 1147–1150.
- 24 Auerbach et al., "Knowledge, Attitudes, and Likelihood of Pre-Exposure

Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV." AIDS Patient Care STDS. 2015 Feb 1; 29(2): 102–110.

- 25 Wood et al., "Young Transgender Women's Attitudes Toward HIV Pre-Exposure Prophylaxis." J Adolesc Health. (2017) May; 60(5): 549–555.
- 26 Auerbach et al., "Knowledge, Attitudes, and Likelihood of Pre-Exposure Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV." AIDS Patient Care STDS. 2015 Feb 1; 29(2): 102–110.
- 27 Interview with Kristin Keglovitz-Baker and Chad Hendry, September 27, 2018.
- 28 Data.Medicaid.Gov, "National Average Drug Acquisition Cost" Database. https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d
- 29 Guerrero, "Myth Busted! PrEP Does Not Lower HRT Levels In Trans Women." Plus (July 30, 2018). https://www.hivplusmag.com/prevention/2018/7/30/ myth-busted-prep-does-not-lower-hrt-trans-women
- 30 Hiransuthikul et al., "Drug-drug interactions between the use of feminizing hormone therapy and pre-exposure prophylaxis among transgender women: The iFACT study." Presented at the 22nd International AIDS Conference (2018). https://programme.aids2018.org//PAGMaterial/eposters/13177.pdf
- 31 See also Hubach et al., "Barriers to and Adoption of Pre-Exposure Prophylaxis for the Prevention of HIV Among Men Who Have Sex with Men (MSM) in a Relatively Rural State" AIDS Education and Prevention, 29(4), 315–329, 2017.
- 32 Interview with Liz Hacker, October 5, 2018.
- 33 Hubach et al., "Barriers to and Adoption of Pre-Exposure Prophylaxis for the Prevention of HIV Among Men Who Have Sex with Men (MSM) in a Relatively Rural State" AIDS Education and Prevention, 29(4), 315–329, 2017.
- 34 Interview with Liz Hacker, October 5, 2018.
- 35 Seidman et al., "Family planning providers' role in offering PrEP to women." Contraception 97 (2018) 467–470.
- 36 Maloney et al., "Culturally Competent Sexual Healthcare as a Prerequisite for Obtaining Preexposure Prophylaxis: Findings from a Qualitative Study." LGBT Health (2017); Volume 4, Number 7.
- 37 Cahill et al., "Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts." AIDS Care. 2017 Nov; 29(11): 1351–1358.
- 38 Eaton et al., "Stigma and Conspiracy Beliefs Related to Pre-exposure Prophylaxis (PrEP) and Interest in Using PrEP Among Black and White Men and Transgender Women Who Have Sex with Men." AIDS Behav. 2017 May; 21(5): 1236–1246.
- 39 Calabrese et al., "HIV Pre-Exposure Prophylaxis Stigma as a Multidimensional Barrier to Uptake Among Women Who Attend Planned Parenthood." JAIDS: September 1, 2018 - Volume 79 - Issue 1 - p 46–53doi: 10.1097/ QAI.00000000001762.
- 40 Id.
- 41 Blackstock et al., "A Cross-Sectional Online Survey of HIV Pre-Exposure Prophylaxis Adoption Among Primary Care Physicians" J Gen Intern Med (2016) 32(1):62–70.
- 42 Blumenthal et al., "Knowledge is Power! Increased Provider Knowledge Scores regarding Pre-exposure Prophylaxis (PrEP) are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP." AIDS Behav. 2015 May ; 19(5): 802–810. doi:10.1007/s10461-015-0996-z.
- 43 Petroll et al., "PrEP Awareness, Familiarity, Comfort, and Prescribing Experience among US Primary Care Providers and HIV Specialists." AIDS Behav. 2017 May; 21(5): 1256–1267. doi:10.1007/s10461-016-1625-1.
- 44 Clement et al., "An educational initiative in response to identified PrEP prescribing needs among PCPs in the Southern U.S.," AIDS Care, 30:5,650-655, DOI: 10.1080/09540121.2017.1384534.
- 45 Petroll et al., "PrEP Awareness, Familiarity, Comfort, and Prescribing Experience among US Primary Care Providers and HIV Specialists." AIDS Behav. 2017 May; 21(5): 1256–1267. doi:10.1007/s10461-016-1625-1.

46 Interview with Donna Sweet, August 16, 2018.

47 Id.

- 48 Interview with Erin Loubier, Juan Carlos Loubriel, and Megan Coleman, August 7, 2018.
- 49 Interview with Sarah Calabrese, August 21, 2018.
- 50 Calabrese, Krakower, and Mayer, "Integrating HIV Preexposure Prophylaxis (PrEP) Into Routine Preventive Health Care to Avoid Exacerbating Disparities." American Journal of Public Health December 2017, Vol 107, No. 12.
- 51 Interview with Doug Krakower, August 9, 2018.
- 52 Blumenthal et al., "Knowledge is Power! Increased Provider Knowledge Scores regarding Pre-exposure Prophylaxis (PrEP) are Associated with Higher Rates of PrEP Prescription and Future Intent to Prescribe PrEP." AIDS Behav. 2015 May ; 19(5): 802–810. doi:10.1007/s10461-015-0996-z.
- 53 Wood et al., "Knowledge, Practices, and Barriers to HIV Preexposure Prophylaxis Prescribing Among Washington State Medical Providers." Sexually Transmitted Diseases (July 2018) Volume 45, Number 7.
- 54 Blackstock et al., "A Cross-Sectional Online Survey of HIV Pre-Exposure Prophylaxis Adoption Among Primary Care Physicians" J Gen Intern Med (2016) 32(1):62–70.
- 55 Calabrese et al., "Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care. PLoS ONE (2016) 11(6): e0157324. doi:10.1371/journal.pone.0157324
- 56 See, e.g., Wood et al., "Knowledge, Practices, and Barriers to HIV Preexposure Prophylaxis Prescribing Among Washington State Medical Providers." Sexually Transmitted Diseases (July 2018) Volume 45, Number 7.
- 57 Krakower et al., "HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings: A Qualitative Study." AIDS Behav. 2014 September ; 18(9): 1712–1721. doi:10.1007/s10461-014-0839-3
- 58 Interview with Gretchen Weiss, August 17, 2018.
- 59 Hoover et al., "Human Immunodeficiency Virus Prevention With Preexposure Prophylaxis in Sexually Transmitted Disease Clinics." Sexually Transmitted Diseases Volume 43, Number 5, May 2016.
- 60 See, e.g., Interview with Doug Krakower, August 9, 2018; interview with Donna Sweet, August 16, 2018.
- 61 Interview with John Carlo, August 6, 2018.
- 62 Calabrese et al., "A Closer Look at Racism and Heterosexism in Medical Students' Clinical Decision-Making Related to HIV Pre-Exposure Prophylaxis (PrEP): Implications for PrEP Education." AIDS and Behavior (2018) 22:1122–1138. https://doi.org/10.1007/s10461-017-1979-z
- 63 Calabrese et al., "The Impact of Patient Race on Clinical Decisions Related to Prescribing HIV Pre-Exposure Prophylaxis (PrEP): Assumptions About Sexual Risk Compensation and Implications for Access." AIDS Behav. (2014) February; 18(2): 226–240. doi:10.1007/s10461-013-0675-x.
- 64 Raifman et al., "Healthcare Provider Contact and Pre-exposure Prophylaxis in Baltimore Men Who Have Sex With Men" Am J Prev Med. 2017 January; 52(1): 55–63. doi:10.1016/j.amepre.2016.07.031.
- 65 Hubach et al., "Barriers to and Adoption of Pre-Exposure Prophylaxis for the Prevention of HIV Among Men Who Have Sex with Men (MSM) in a Relatively Rural State" AIDS Education and Prevention, 29(4), 315–329, 2017.
- 66 See, e.g., District of Columbia Department of Health, "Explore your Options: PrEP," https://doitrightdc.com/prep/prep-locator/
- 67 North Carolina AIDS Education and Training Center, "Consumers Interested in or Currently Taking PrEP." https://www.med.unc.edu/ncaidstraining/clincianresources/prep/prep-for-consumers/
- 68 CDC, "Prescribe HIV Prevention." https://www.cdc.gov/actagainstaids/campaigns/prescribe-hiv-prevention/index.html
- 69 D.C. Department of Health, "PrEP Handbook: PrEP is DC's Key HIV Preven-

tion Practice." https://doh.dc.gov/sites/default/files/dc/sites/doh/service_content/attachments/DC%20Providers%20PrEP%20Handbook.pdf

- 70 Interview with Melody Wilkinson, August 22, 2018.
- 71 Interview with Kristin Keglovitz-Baker and Chad Hendry, September 27, 2018.
- 72 See, e.g., SIECUS, "PrEP Education for Youth-Serving Primary Care Providers Toolkit: Clinical Tools Section 1.7: Taking A Sexual History" (2018) https:// siecus.org/wp-content/uploads/2018/07/1.7-Taking-A-Sexual-History.pdf
- 73 Decker, "Academic detailing as an intervention to increase PrEP knowledge and best prescribing practices among providers in San Francisco" (July 20, 2017). www.nastad.org/sites/default/files/Mega-Meeting-Slides/opportunities_to_engage_clinical_providers_-alyson_decker.pdf
- 74 AcademyHealth Interview with Deann Gruber, May 23, 2018.
- 75 AcademyHealth interview with Lyn Stevens, June 5, 2018.
- 76 Interview with Player and Diaz, August 28, 2018.
- 77 Id.
- 78 Interview with Sarah Calabrese, August 21, 2018.
- 79 Interview with Melody Wilkinson, August 22, 2018.
- 80 New York State Department of Health AIDS Institute, "Clinical Education Initiative" www.surveymonkey.com/r/BG38MH5.
- 81 Interview with Sarah Calabrese, August 21, 2018.
- 82 Interview with Liz Hacker, October 5, 2018.
- 83 Liu et al., "Randomized Controlled Trial of a Mobile Health Intervention to Promote Retention and Adherence to Preexposure Prophylaxis Among Young People at Risk for Human Immunodeficiency Virus: The EPIC Study," Clinical Infectious Diseases (2018). https://doi.org/10.1093/cid/ciy810
- 84 Email from Pedro Serrano, Oct. 26, 2018.
- 85 Interview with Player and Diaz, August 28, 2018.
- 86 Interview with Bellinda Schoof, August 29, 2018.
- 87 CDC, "Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update – Clinical Providers' Supplement" (Published online Mar. 2018). www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-providersupplement-2017.pdf
- 88 The Stigma Project, www.ispreprightforme.org.
- 89 Amico et al., "Integrated Next Step Counseling (iNSC) for Sexual Health and PrEP Use Among Young Men Who Have Sex with Men: Implementation and Observations from ATN110/113." AIDS Behav (2018). https://doi.org/10.1007/ s10461-018-2291-2
- 90 UCSF Clinical Consultation Center, "PrEP: Pre-Exposure Prophylaxis" (2018). Available at https://nccc.ucsf.edu/clinician-consultation/prep-pre-exposureprophylaxis/
- 91 AETC National Coordinating Resource Center, "Directory of AIDS Education and Training Centers" (2018). https://aidsetc.org/directory
- 92 Interview with Erin Loubier, Juan Carlos Loubriel, and Megan Coleman, August 7, 2018.
- 93 Interview with Douglas Krakower, August 8, 2018.
- 94 Interview with Diva Ahuja, August 9, 2018.
- 95 Interview with Stephen Cha, August 6, 2018; www.medicaid.gov/federal-policy-Guidance/index.html
- 96 CMS, "Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries" (Dec. 2016). www.medicaid.gov/federal-policyguidance/downloads/cib120116.pdf
- 97 CMS, "Medicaid.gov: Substance Use Disorder Tools & Resources." www. medicaid.gov/state-resource-center/innovation-accelerator-program/programareas/reducing-substance-use-disorders/tools-and-resources/index.html
- 98 AcademyHealth survey of MMDN, October 2018.

99 Id.

- 100 California Department of Health Care Services, "DUR: Educational Articles" http://files.medi-cal.ca.gov/pubsdoco/dur/edarticles.asp
- 101 New York State Department of Health, "DOH Medicaid Update." www.health. ny.gov/health_care/medicaid/program/update/main.htm
- 102 AcademyHealth survey of MMDN, October 2018.
- 103 Interview with Doug Wirth, September 17, 2018.
- 104 Id.
- 105 Interview with David Rzeszutko, August 14, 2018.
- 106 AcademyHealth survey of MMDN network, October 2018.
- 107 Interview with Stephen Cha, August 6, 2018.
- 108 National Medical Association, "About Us." https://www.nmanet.org/page/ About_Us
- 109 National Hispanic Medical Association, "About NHMA." http://www.nhmamd. org/about/about-nhma/
- 110 American College of Physicians, "About ACP." https://www.acponline.org/ about-acp
- 111 AMA, "AMA Urges More Physician Education on Use of Once-A-Day HIV Prevention" (June 2016). www.ama-assn.org/ama-urges-more-physician-education-use-once-day-hiv-prevention
- 112 Id.
- 113 AMA, "Member Groups (Sections)." www.ama-assn.org/about/membergroups-sections
- 114 AMA, "AMA Federation Directory." https://federationdirectory.ama-assn.org/ federations
- 115 AAFP, "Family Medicine Facts." www.aafp.org/about/the-aafp/family-medicinefacts.html
- 116 AAFP, "Table 1: 2018 AAFP Membership Category" www.aafp.org/about/theaafp/family-medicine-facts/table-1.html
- 117 AAFP, "Prevention and Control of Sexually Transmitted and Blood Borne Infections" (2016). www.aafp.org/about/policies/all/prevention-control.html
- 118 Interview with Bellinda Schoof, August 29, 2018.
- 119 Interview with Melody Wilkinson, August 22, 2018.
- 120 AAFP, "Browse Directory." https://my.aanp.org/Directories/BrowseBy.aspx
- 121 Interview with Gretchen Weiss, August 17, 2018.
- 122 Interview with Leighton Ku, September 5, 2018.
- 123 For example, the State-University Partnership Learning Network (SUPLN) fosters collaboration between state governments and state university research centers to conduct research on the Medicaid program. https://www.academyhealth.org/SUPLN.
- 124 Interview with Leighton Ku, September 5, 2018.
- 125 Id.
- 126 Interview with Doug Wirth, September 17, 2018.
- 127 To distinguish between PrEP and post-exposure prophylaxis, which involves 28 days of medication.
- 128 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. www.cdc.gov/mmwr/preview/mmwrhtml/ mm6446a5.htm
- 129 California HIV/AIDS Policy Research Centers. Examining PrEP Uptake among Medi-Cal Beneficiaries in California: Differences by Age, Gender, Race/ Ethnicity and Geographic Region (Feb. 2018). http://www.californiaaidsresearch.org/files/PrEP_Brief_2.8.18.pdf
- 130 Smith et al., "Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015" Annals of Epidemiology xxx (2018) 1-8.

- 131 Email from Pedro Serrano, Oct. 26, 2018.
- 132 Interview with Leighton Ku, September 5, 2018.
- 133 NASTAD, "Modernizing Programs to Collect Sexual Orientation and Gender Identity Data." www.nastad.org/sites/default/files/sogi.issue_.brief_.final_.pdf
- 134 Interview with Doug Krakower, August 8, 2018.
- 135 Interview with Leighton Ku, September 5, 2018.
- 136 AcademyHealth Interview with Michigan officials, May 24, 2018.
- 137 Center for Connected Health Policy, "50 State Scan of Telehealth Reimbursement Laws and Medicaid Policies – Factsheet" (2018). www.cchpca.org/sites/default/files/resources/50%20State%20Factsheet%20Spring%202018%20FINAL. pdf
- 138 Id.
- 139 Kaiser Family Foundation, Medicaid Managed Care Plans and Access to Care: Results from the Kaiser Family Foundation 2017 Survey of Medicaid Managed Care Plans" (Mar. 2018). www.kff.org/report-section/medicaid-managed-careplans-and-access-to-care-provider-networks-and-access-to-care/
- 140 Peter Wehrwein, "Q&A: A Conversation with Henry DePhillips, MD: The Doctor in the Teladoc House" (April 2017). www.managedcaremag.com/archives/2017/4/conversation-henry-dephillips-md-doctor-teladoc-house
- 141 AcademyHealth interview with Lyn Stevens, June 5, 2018.
- 142 AcademyHealth Interview with Deann Gruber, May 23, 2018; www.louisianahealthhub.org/teleprep
- 143 Interview with Jason Farley, August 9, 2018.
- 144 NASTAD, "Financing HIV Prevention Services: Collaboration and Innovation between Public Health and Medicaid Agencies; Case Study: Rhode Island" (Feb. 2016). www.nastad.org/sites/default/files/resources/docs/NASTAD-HIV-Prevention-Rhode-Island-Case-Study.pdf
- 145 Interview with Erin Loubier, Juan Carlos Loubriel, and Megan Coleman, August 7, 2018.
- 146 42 CFR 431.53 Assurance of transportation.
- 147 Mayer et al., "Evolving Models and Ongoing Challenges for HIV Preexposure Prophylaxis Implementation in the United States" J Acquir Immune Defic Syndr (2018);77:119–127.
- 148 National Conference of State Legislatures, "Medication Therapy Management: Pharmaceutical Safety and Savings" (Updated Oct. 2016). http://www.ncsl.org/ research/health/medication-therapy-management.aspx
- 149 Mississippi Division of Medicaid, "Mississippi Medicaid Provider Reference Guide: Part 214: Pharmacy Services" (2014). https://medicaid.ms.gov/wpcontent/uploads/2014/01/Provider-Reference-Guide-214.pdf
- 150 Interview with Elyse Tung, September 7, 2018.
- 151 Id.
- 152 Id.
- 153 Interview with Laura Beauchamps, August 16, 2018.
- 154 Interview with Elyse Tung, September 7, 2018.
- 155 Interview with Laura Beauchamps, August 16, 2018.
- 156 Interview with Player and Diaz, August 28, 2018.
- 157 Id.
- 158 42 CFR § 440.262 Access and cultural considerations.
- 159 42 CFR 438.206 Availability of services.
- 160 Sommers et al., "Insurance Churning Rates For Low-Income Adults Under Health Reform: Lower Than Expected But Still Harmful For Many." Health Affairs 35, No. 10 (2016).
- 161 Id.
- 162 Interview with Liz Hacker, October 5, 2018.

163 Kaiser Family Foundation, "Medicaid Moving Ahead in Uncertain Times: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2017 and 2018" (Oct. 2017). http://files.kff.org/attachment/Report-Results-from-a-50-State-Medicaid-Budget-Survey-for-State-Fiscal-Years-2017-and-2018

164 Id

165 Id

- 166 Letter from FDA to Gilead (May 15, 2018). www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/021752Orig1s055ltr.pdf
- 167 Ryan, "Just 15% of Those Who've Started PrEP Are Younger Than 25." Poz (July 30, 2018). www.poz.com/article/just-15-whove-started-prep-younger-25
- 168 Data from Gilead, reproduced in Ryan, "Just 15% of Those Who've Started PrEP Are Younger Than 25." Poz (July 30, 2018). https://www.poz.com/article/just-15-whove-started-prep-younger-25
- 169 CDC, "Minors' Consent Laws for HIV and STI Services" (Updated June 2018). www.cdc.gov/hiv/policies/law/states/minors.html
- 170 Choopanya et al. "Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): A randomised, double-blind, placebo-controlled phase 3 trial." Lancet 2013; 381:2083–2090.
- 171 See, e.g., Stein et al., "Willingness to use HIV pre-exposure prophylaxis among opiate users" AIDS Behav (2014); 18:1694–1700; finding PrEP awareness of 7.4 percent among opioid users entering detox.
- 172 Roth et al., "An Exploration of Factors Impacting Preexposure Prophylaxis Eligibility and Access Among Syringe Exchange Users." Sexually Transmitted Diseases (April 2018) 45: 4.

173 Id.

174 Spector et al.," PrEP in substance abuse treatment: a qualitative study of treatment provider perspectives." Substance Abuse Treatment, Prevention, and Policy (2015) 10:1. www.substanceabusepolicy.com/content/10/1/1

175 Id.

176 Interview with Daniel Raymond, October 4, 2018.

177 Id.

178 Bernard et al., "Cost-Effectiveness of HIV Preexposure Prophylaxis for People Who Inject Drugs in the United States." Ann Intern Med. ;165:10–19. 179 Id.

- 181 See https://grants.nih.gov/grants/guide/rfa-files/rfa-ai-16-031.html
- 182 Interview with Sarah Calabrese, August 21, 2018; Walsh and Petroll, "Factors Related to Pre-exposure Prophylaxis Prescription by U.S. Primary Care Physicians." Am J Prev Med 2017 Jun;52(6).
- 183 Chartier et al., "Accessibility and Uptake of Pre-Exposure Prophylaxis for HIV Prevention in the Veterans Health Administration." Fed Pract. 2018 March;35(2):S42-S48.

184 Id.

- 185 California Department of Health Care Services, "Erroneous Treatment Delays and Denials for HIV PrEP and PEP" (Dec. 11, 2017). http://files.medi-cal. ca.gov/pubsdoco/newsroom/newsroom_26539.asp.
- 186 New York State Department of Health, "Truvada (emtricitabine and tenofovir DF) Medicaid Fee-for-Service." www.health.ny.gov/diseases/aids/general/prep/ truvada.htm
- 187 Interview with Leighton Ku, September 5, 2018.
- 188 NMAC, HIV and PrEP Navigation Program: Linking Communities to Care through HIV and PrEP Navigation. www.nmac.org/programs/capacity-building/hiv-prep-navigation-program/
- 189 Interview with Laura Beauchamps, August 16, 2018.
- 190 Interview with Liz Hacker, October 5, 2018.
- 191 Washington State Department of Health, "Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)." www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIV/Prevention/PrEPDAP
- 192 New York State Department of Health, "PrEP Patient Assistance Program (PrEP-AP)." www.health.ny.gov/diseases/aids/general/prep/prep-ap_provider. htm
- 193 DC Department of Health, "Pre Exposure Prophylaxis Drug Assistance Program (PrEP DAP)." https://dchealth.dc.gov/DCPrEPDAP

¹⁸⁰ Id.