

Leveraging Financing and Coverage Benefits: 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*

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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. Use of PrEP is disproportionately low among African American and Latinx people, as well as lower-income populations. Between 2015 and 2016, an estimated 1.14 million Americans were eligible for PrEP, but only 90,000 PrEP prescriptions were filled; only 1 percent of eligible African Americans and 3 percent of eligible Latinos were using PrEP, compared to 14 percent of eligible Whites. Among those who do use PrEP, evidence indicates that some may not be receiving the full set of PrEP clinical services as recommended by the Centers for Disease Control and Prevention (CDC) – such as HIV screening before initiation and quarterly, multisite STI screenings.

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 care and delivery of PrEP medication and clinical services to the Medicaid population. Medicaid's role as insurance for low-income Americans – particularly since the Medicaid expansions authorized under the Affordable Care Act – makes the program a crucial vehicle for expanding access.

To inform this project, this white paper identifies Medicaid benefits and financing mechanisms that could be used to improve uptake and comprehensive delivery of PrEP medication and clinical care. A second white paper describes further ways to leverage the Medicaid program to engage patients and providers in accessing PrEP and utilizing the full suite of recommended PrEP clinical services. The papers will inform a ChangeLab/AcademyHealth convening of Medicaid officials from select states, representatives of managed care organizations (MCOs), public health officials, and patient and provider 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 PrEP and PrEP recommended services and on Medicaid, including the current status of state Medicaid expansions and an overview of models and penetration rates of managed care in Medicaid programs.

It then presents a framework for considering the "levers" in the Medicaid program that could be used to increase and improve PrEP delivery:

- State-level financial policies that can impact PrEP care, including MCO rate-setting and carveouts, as well as other managed care and value-based design approaches;
- Benefit design related to PrEP medication and clinical services, including benefits covered by the state's fee-for-service program, additional benefits that MCOs can offer, contract approaches to aligning benefits across fee-for-service (FFS) and managed care, and the potential impact of the U.S. Preventive Services Task Force (USPSTF) draft recommendation for PrEP;
- **Performance improvement**, based on reporting or incentives at the plan and provider levels;
- Access to PrEP providers in managed care Medicaid, as shaped by state policies on network adequacy and on MCO network decisions; and
- Partnerships with local health departments or communitybased organizations (CBOs), and how states and MCOs can identify and support them.

The paper continues with an overview of Medicaid financing issues for PrEP that are specific to certain types of providers and settings: nurse practitioners and physician assistants, registered nurses (RNs), pharmacists, and federally-qualified and rural health centers. It closes with a discussion of two key overarching considerations: the potential uses of Medicaid claims data to support the use of PrEP medication and clinical care, and the importance of information on PrEP's return on investment (ROI) to effect change within the Medicaid program – at the state level or with specific MCOs.

Every state differs in its HIV epidemic, its resources, its Medicaid program, 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 improving PrEP access through Medicaid. Rather, the goal is to outline in one place the potential tools that state-level stakeholders could use to identify and address barriers in their states, taking into account fiscal and political feasibility. Table 1 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

Medicaid Landscape

What categories of Medicaid eligibility in the state are available to people who are using or are candidates for PrEP?

Has the state expanded Medicaid, facilitating access for a broad set of low-income adults?

Does the state have a Medicaid family planning expansion program. which may facilitate access to some PrEP medication or clinical care services such as sexually transmitted infections (STIs) and HIV screening?

What role do comprehensive MCOs play in the state's Medicaid landscape?

State Level Financial Policies

How can current and projected PrEP uptake be meaningfully reflected in the rates that states pay Medicaid MCOs as well as in the risk-adjustment formula applied?

Is the medication for PrEP carved out of the state's managed care contracts, and if so, how does this influence access to medication and clinical services?

Should the state consider carving the full set of PrEP services out of managed care?

Are there innovative payment models in the state Medicaid program, such as Medicaid health homes, accountable care organizations (ACOs), or others, that could be used or modified to support PrEP?

Benefit Design

What is the state's policy on Medicaid coverage of telehealth, and how might it affect access to and use of PrEP clinical care?

Does the state's Medicaid FFS program apply limits, such as prior authorization requirements, to medication for PrEP? Are they aligned with PrEP care requirements such as confirming ongoing negative serostatus, or do they pose inappropriate barriers to access?

Does the state FFS program pay consistently for PrEP clinical services, including multisite STI testing, as recommended by the CDC?

Does the state FFS program cover optional benefits that could be used to support PrEP, such as targeted case management?

Beyond the benefits in the state Medicaid package, do Medicaid MCOs offer additional services that are relevant to PrEP, such as care coordination services? If so, is PrEP a qualifying condition? Can and should it be?

What approaches can the state use to align coverage policies for PrEP medication and clinical services across the FFS program and MCOs?

Performance Improvement

What programs does the state have to monitor and reward MCO performance, and how could PrEP measures be integrated?

Does the state have a system for performance incentives to Medicaid FFS providers that could be leveraged to support comprehensive PrEP services?

Can support and incentives for offering PrEP clinical services be integrated into existing MCO provider payment models, such as performance incentives or bundled payments? How?

Access to PrEP Providers

How can the state assess the availability of PrEP providers in the Medicaid FFS program?

Are Medicaid MCOs in the state including PrEP providers in their networks? How can the state and MCOs work together to assess and track PrEP provider access?

Partnerships with Local Health Departments and Community-**Based Organizations**

How could the state Medicaid agency work with local health departments and CBOs to promote use of PrEP medication and clinical services?

Could the state require or encourage MCOs to work with local health departments, CBOs or community health workers to promote use of PrEP medication and clinical services? If so, what would this look like?

Specific Considerations Linked to Provider Type and Setting Are nurse practitioners and physician assistants who provide PrEP

able to bill Medicaid for all components of the intervention?

How can the state Medicaid program better support pharmacist engagement in PrEP medication management and clinical service delivery, including through a state Medication Therapy Management (MTM) benefit?

Are public/local health department clinics able to bill Medicaid if they offer PrEP?

Do the state's Medicaid reimbursement rates for Federally-Qualified Health Centers and Rural Health Centers adequately support and incentivize comprehensive provision of PrEP?

Further Considerations

How can Medicaid and public health use existing data to evaluate PrEP access and PrEP uptake, as well as the quality of PrEP care?

What kinds of cost information do Medicaid and MCOs need to inform design of PrEP benefits and delivery?

Table 2: Experts Interviewed for the Project

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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

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 (see Table 2; preliminary interviews conducted by AcademyHealth are marked with an asterisk).

The author then conducted semi-structured interviews with additional experts in Medicaid, PrEP, and patient and provider engagement (see Table 2). 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.

The author also conducted a search of peer-reviewed and "grey" literature on Medicaid and PrEP, as well as on Medicaid financing mechanisms.

AcademyHealth conducted an informal survey of the participants in its Medicaid Medical Directory Network (MMDN) regarding their Medicaid coverage of PrEP medication and clinical care, as well as provider and patient engagement. De-identified responses from 16 states are included in this and the second white paper.

Background

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. This section outlines the components of the full suite of PrEP services, as well as the populations for whom it is indicated, as context for the discussion of the scope and limitations of Medicaid coverage of PrEP.

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. 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 FDA granted ANDA approval to Teva⁸ and Amneal⁹ for generic versions of Truvada in June 2017 and August 2018, respectively. However, neither has yet become available on the U.S. market.

The CDC recommends PrEP be considered as one prevention option for the following people at substantial risk of HIV infection¹⁰:

Men Who Have Sex with Men (MSM) (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 a clinical eligibility criterion, 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.

The discussions of state Medicaid benefits and of Medicaid MCO coverage policies below review key opportunities for, and barriers to, coverage of this set of services.

The Range of Medicaid Policy and Program Environments

Most elements of the Medicaid program – including eligibility, benefits, and financing mechanisms – vary significantly from state to state. This section describes the range of Medicaid policy and program environments, with an emphasis on those features that are relevant to the coverage of PrEP medication and clinical services.

Low-income uninsured patients who do not qualify for Medicaid may be able to access Truvada through the manufacturer's assistance program, which currently offers eligibility up to 500 percent of the federal poverty level for U.S. residents. However, people without insurance may not have a source of assistance to cover PrEP clinical care services and laboratory tests. State and local PrEP assistance programs, such as those offered by Washington State, New York State, and Washington DC, double help fill these gaps but are not widely offered.

Medicaid Eligibility

Eligibility for Medicaid for various populations eligible for PrEP depends on the state and is based on age, household income, and other demographic factors.

Eligibility Categories

Adolescents and pregnant women may be candidates for PrEP; both populations are eligible for Medicaid in all states. In all but two states, children and adolescents through age 18 are eligible for coverage, either through Medicaid or CHIP, up to income levels of at least 200 percent of the federal poverty level (FPL). Approximately two-thirds of states (33 plus DC) cover pregnant women with income levels up to 200 percent FPL or higher; the remainder set eligibility for pregnant women between 138-200 percent of FPL. People with disabilities who are Supplemental Security Income (SSI) beneficiaries are eligible up to thresholds of at least 73 percent in most states.

If a candidate for PrEP is the parent of dependent children, Medicaid may be available, but the income cutoff is quite low in the 19 states that have not expanded Medicaid: in 11 of the 19 non-expansion states, eligibility for parents of dependent children is set lower than 50 percent of the FPL.

Overall, "lawfully present" immigrants may be eligible for Medicaid depending on income level, but in most states non-pregnant adults face a five-year waiting period after obtaining qualified status; in roughly half the states, children and pregnant women face the same waiting period.¹⁸ For the most part, undocumented immigrants are not eligible for Medicaid, other than through a narrow set of exceptions that would not be relevant for most PrEP users.¹⁹ U.S. residents are currently eligible for the manufacturer's assistance program for Truvada, regardless of citizenship status.

Medicaid Expansion

The importance of Medicaid coverage for HIV prevention increased significantly with the Affordable Care Act, which permits states to extend Medicaid eligibility to all adults up to 138 percent of the federal poverty level. As of July 27, 2018, 33 states plus DC had enacted expansions²⁰; on election day in November 2018, three more states (ID, NE, and UT) enacted expansions by ballot initiatives.

State Medicaid expansions have significantly increased rates of insurance coverage overall. By the end of 2016, the 31 states that had expanded Medicaid, along with DC, reported a total of 14.9 million enrollees in the adult expansion group.²¹

Studies have found dramatic increases in Medicaid enrollment in expansion states among populations relevant to PrEP. For example, lesbian, gay and bisexual people experienced an increase in Medicaid enrollment from 7 percent to 15 percent from 2013 to 2016, reflecting an increase of over 500,000 people. Rates of uninsurance among young adults dropped significantly in expansion states, from 34.5 percent to 24.3 percent between 2013 and 2014. Overall, the Medicaid expansion has been found to reduce income- and agebased disparities in insurance coverage; improve some insurance disparities by race and ethnicity; and positively impact access to care across most studies. As a propositive of the proposition of the

Medicaid Family Planning Eligibility Expansions

States have the option to create Medicaid family planning expansion programs that offer coverage of family planning services to people who are not otherwise eligible for Medicaid. These programs cover a narrow range of services, and it does not appear that any state currently covers Truvada itself through a family planning expansion.²⁵ However, the programs can be an important way to reach people with certain PrEP clinical services, including HIV and STI testing and visits, while connecting people to the manufacturer assistance program for the medication.

For example, the Open Arms Healthcare Center in Jackson, Miss., currently has approximately 200 patients on PrEP. For patients who are uninsured, a staff person submits an application to the Medicaid family planning program. For those eligible, the program covers up to four visits a year as well as labs, including STI testing and treatment, therefore reimbursing for several key components of the PrEP intervention.²⁶

As of June 2017, 26 states had expanded Medicaid eligibility for family planning services under either a waiver or a permanent state Medicaid plan provision.²⁷ In 22 of these states, eligibility is based on income, usually set at a threshold around 200 percent FPL.²⁸ Nineteen states cover both men and women, with the remainder covering only women.²⁹

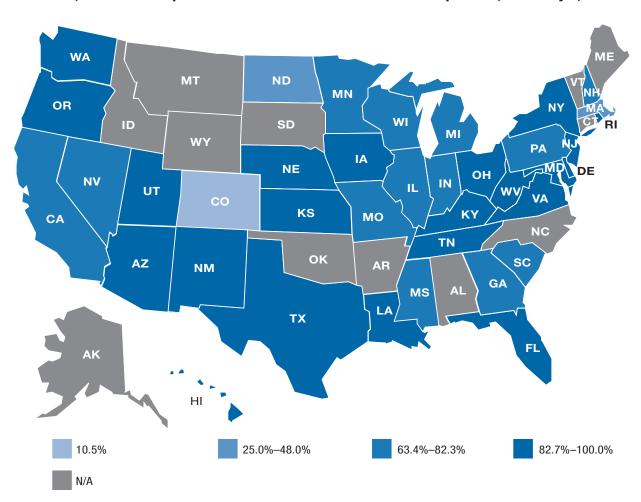


Figure 1: From KFF, Medicaid Comprehensive MCO Penetration Rate: Total Population, as of July 1, 2017

This program may be particularly important for PrEP clinical services in states that have not expanded their overall Medicaid programs. Alabama, Florida, Georgia, Mississippi, North Carolina, Oklahoma, South Carolina, and Wyoming are non-Medicaid expansion states that did have *family planning* expansions as of 2017; all but Florida, Georgia, and Wyoming covered men.³⁰ In addition, even in states with Medicaid expansions, Medicaid family planning programs often cover people up to higher income thresholds, thereby reaching people who are not eligible for full Medicaid.

The scope of services covered by each state's family planning expansion program varies. As of 2009, the most recent year for which survey data was identified, 22 states' Medicaid family planning expansion programs included coverage of STI testing and labwork (though this may not extend to multisite testing or tests at the frequency recommended for PrEP); 11 also covered STI treatment.³¹ Eighteen states reported covering HIV testing.³² Some state family planning expansions also cover condoms, generally with a prescription.³³

Fee-for-Service Medicaid

Fee for service (FFS) describes the traditional model of Medicaid, in which state Medicaid agencies pay physicians or other health care

providers for each service delivered to a Medicaid beneficiary. In most states, at least some enrollees are enrolled in the FFS program (see next section for data on penetration of managed care). As discussed throughout this paper, state Medicaid agencies can have a direct role in implementing financing mechanisms to influence provider behavior through FFS payments and requirements.

Medicaid Managed Care: Landscape

In recent decades, states have significantly expanded their use of managed care approaches within the Medicaid program. Generally, Medicaid managed care refers to a range of arrangements under which states contract with entities that accept a fixed payment to provide a certain set of services to members. To inform potential approaches for bolstering PrEP intervention services, this section provides an overview of comprehensive managed care in Medicaid, and discusses managed care penetration rates – that is, the percent of Medicaid beneficiaries who are comprehensive managed care enrollees – by state.

Comprehensive MCOs

The most common model of managed care in Medicaid is comprehensive "risk-based" managed care. In this model, states contract with plans to cover all or most services to Medicaid enrollees.³⁴

MCOs receive a fixed monthly payment, called a capitation payment, for each enrollee, regardless of which if any services are received that month. Some states "carve out" certain benefits from managed care, continuing to pay for those services on a FFS basis. Regardless of which services are carved out in a given state, MCO enrollees as well as enrollees in other managed care arrangements are entitled by federal regulation to all services available under the state plan, including PrEP medication and all covered PrEP clinical services.³⁵

Comprehensive Medicaid Managed Care Penetration

Because Medicaid managed care poses distinct challenges and opportunities for promoting uptake of PrEP medication and clinical care, it is important for stakeholders to understand how much of their state's Medicaid population is enrolled in managed care. In 2016, approximately two thirds of all Medicaid beneficiaries were enrolled in comprehensive MCOs.³⁶ However, the proportion varies widely by state³⁷:

Managed care enrollment also varies by eligibility category. In a national survey of state Medicaid agencies regarding enrollment in comprehensive MCOs,³⁸ most states reported that managed care penetration among nondisabled, nonelderly, non-pregnant adults was at least as high as that of the total population as reflected in the map above.

There is significant variation in the *number* of MCOs operating in each state with managed care, from one in North Dakota to 23 in New York.³⁹ To the extent different financing ideas discussed in this report would need to be broached with MCOs directly, it would be important to understand how many plans that would entail, as well as, potentially, the number of Medicaid enrollees each covers.⁴⁰

Promoting PrEP Medication and Clinical Care through Medicaid and Medicaid Managed Care

This section explores mechanisms to support the provision of PrEP medication and clinical services within FFS Medicaid and Medicaid managed care. Given the variation in state Medicaid benefits, eligibility, and payment models, no one approach will be appropriate in every state. This section will track the financing and contractual relationships among parts of the Medicaid system to identify potential opportunities for stakeholders to consider in their respective environments.

The chart in Appendix 2 provides a visual framework for considering the key parties and "levers" to promote PrEP in Medicaid.

Role of CMS

As the federal agency administering the Medicaid program, the Centers for Medicare and Medicaid Services (CMS) could potentially play several roles in Medicaid financing of PrEP medication clinical services. CMS's Center for Medicaid and CHIP Services (CMCS) must administer the program within the bounds of federal statute but works closely with states in a variety of ways.

CMCS can send Informational Bulletins or Dear State Medicaid Director letters to all state Medicaid agencies, to inform them of news, obligations, or opportunities in the Medicaid program. In December 2016, CMCS sent a joint Informational Bulletin, along with the Department of Health and Human Services, Health Resources and Services Administration (HRSA), and the CDC, regarding "Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries." The section on PrEP included specific examples of financing approaches states can take to improve access to STI screening and other clinical services:

States have the discretion to establish certain limitations, prior authorization processes or preferred drug lists, on the coverage of PrEP to ensure appropriate utilization when medically necessary; however, we encourage states to take steps to ensure that PrEP is available consistent with USPHS recommendations. For example, neither Colorado nor Washington State subject emtricitabine/ tenofovir to prior authorization processes when it is prescribed for HIV treatment or HIV PrEP. Because regular HIV and STD tests are recommended for persons who initiate PrEP, Washington's Medicaid program also facilitates access to these testing services by covering their receipt on a quarterly basis and in a range of settings that may be more convenient or comfortable for beneficiaries (e.g., family planning clinics, local health departments, or primary care settings). States should ensure that beneficiaries being initiated on PrEP are educated about and provided with sufficient supportive care to ensure adherence to regimens. 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.28

CMS could build on this informational bulletin to help guide state Medicaid agencies, and could consider whether further clarification (e.g. regarding coverage of multisite STI testing) is warranted. In addition, CMS could consider developing technical assistance for states in scaling up PrEP under Medicaid, similar to the work the agency has done to support best practices and models for addressing the opioid epidemic.⁴¹

State-Level Financial Policies

This section describes several key state-level financing decisions that may impact coverage of PrEP medication and clinical care within the Medicaid program: rates paid to MCOs, and how they may (or may not) reflect PrEP costs; decisions about carving components of PrEP care out of managed care; considerations for PrEP in non-comprehensive managed care models; and the potential integration of PrEP into value-based payment models in Medicaid.

Capitation Rates and Risk Adjustment: An Overview

States pay Medicaid MCOs a monthly rate for each enrollee in the plan. Under federal statute and regulations, the rate must be "projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the managed care plan for the time period and the population covered under the terms of the contract."

Within these and further regulatory parameters, states and plans generally develop a base premium by taking into account multiple factors including baseline data, expected trends, state fiscal conditions, services that are carved out of managed care, payments in addition to the base capitation rate, and incentives.⁴³

As a relatively new intervention, the cost of PrEP is likely not fully reflected in current base rates. Therefore, the impact of scaled-up PrEP use on rates could be projected by actuaries and factored into future rates. Ultimately, as PrEP uptake increases and is reflected in utilization data, the cost of the drugs and clinical services would be reflected in the capitated rate.

To reflect variation in actual plan enrollment across MCOs, states apply a risk adjustment based on factors including eligibility category, age, gender, region, and health status. With regard to health status, states vary in the risk adjustment model used, with most relying to some extent on diagnostic codes, several relying on analysis of pharmacy data, and others using a hybrid approach.⁴⁴

Interviewees were not aware of currently available techniques to risk adjust enrollees for PrEP use. Even if PrEP risk adjustment models became available, because PrEP uptake is unlikely to be evenly distributed across plans, states will need to work with specific MCOs to develop payment approaches that meaningfully follow actual PrEP uptake. For example, one interviewee noted that states could budget for increased PrEP uptake and distribute money across plans based on projections, but conduct a "true-up" process at year's end to shift funding to where uptake actually occurred. 45

Another interviewee pointed out that because rates are generally negotiated annually and far in advance of a plan year, there could be a lag between a state's efforts to promote PrEP uptake through

MCOs, and an updated base rate and risk adjustment model that reflects that increase in services. 46 Without reflecting increased PrEP utilization in MCOs' rates in some fashion, MCOs could be reluctant to support outreach and education measures, particularly in states where pharmacy is included in the MCO contract.

Setting MCO Rates Based on Projected PrEP Services Uptake: Case Study of New York's HIV Special Needs Plans

New York State has a specialized type of comprehensive Medicaid MCO called HIV Special Needs Plans, or SNPs, specifically for people living with HIV. The plans cover the same Medicaid benefits as other MCOs in the state, along with enhanced services such as HIV care coordination case management, treatment adherence services, and risk reduction education. All primary care providers in the plan must meet state standards for HIV Specialist designation. The state developed specific capitated rates for HIV special needs plans (SNPs) based on prior utilization and cost data for people living with HIV, resulting in a per member, per month rate of approximately \$5000 (compared to approximately \$800 for general Medicaid managed care plans). 146 There are now three Medicaid HIV SNPs operating in the state.

As of November 2017, all transgender people may enroll in New York's HIV SNPs regardless of serostatus, a change the state made to support access to coordinated, expert services for people at high risk of HIV.¹⁴⁷ Amida Care, the largest HIV SNP, has supported approximately 25 percent of its HIV-negative transgender enrollees in accessing PrEP.¹⁴⁸ Amida is working with the state to expand SNP eligibility to all MSM, regardless of serostatus.

Rate setting for HIV-negative people enrolling in HIV SNPs was based on added costs of PrEP drugs and clinical services, incorporating a projected trended uptake model that estimated the portion of HIV-negative enrollees who would use PrEP.¹⁴⁹

While HIV SNPs are a unique model, other states could look to New York for lessons in adequately setting rates for PrEP use. Specifically, the methods used to project PrEP costs, as well as trended uptake, may be useful in other settings when applied to PrEP users across non-specialized plans.

Medicaid Carveouts

One important contextual consideration for this section is whether in any state it might be advantageous to carve PrEP medication and clinical services out of MCO contracts entirely, keeping payment in the FFS realm. ⁴⁷ Of the 39 states with comprehensive MCOs in 2017, the majority included pharmacy in MCO contracts; only four – Missouri, Tennessee, West Virginia, and Wisconsin – carve pharmacy entirely out of MCO contracts. California, Maryland, and Michigan generally include pharmacy in MCO contracts, but reimburse HIV drugs on a FFS basis. ⁴⁸ Therefore, in those seven states, MCOs would not have financial responsibility for medica-

tion, making them less concerned about the financial impact of utilization. However, MCOs retain responsibility for PrEP clinical services.⁴⁹

This project did not identify any states that have specifically carved PrEP clinical services out of managed care. Arguably, since doing so would remove PrEP entirely from MCOs' cost concerns, such a policy could facilitate beneficiary access, especially if Medicaid claims data or other sources indicate limited access to PrEP through MCOs. However, depending on the details, a carveout might hinder an MCO's ability to coordinate an enrollee's HIV prevention care with their other medical benefits. One potential middle path could involve initially carving out PrEP services, then reversing this policy once the costs and uptake of PrEP within a state are more clearly established and can be incorporated directly into rates.

Addressing PrEP through Non-Comprehensive Managed Care Models

As discussed above, comprehensive managed care offered through MCOs is the dominant form of managed care in Medicaid, but it is not the only model. "Medicaid managed care" can also refer to other financing mechanisms that address a more limited set of benefits or payment arrangements. States with a relevant portion of the population enrolled in limited benefit plans or in primary care case management models can also try to promote PrEP through those frameworks:

- Limited Benefit Plans: Limited benefit plans are arrangements in which states contract with entities to provide a subset of Medicaid services for some or all enrollees. These plans include prepaid inpatient health plans (PIHPs), which frequently focus on mental health or substance use benefits and include responsibility for inpatient behavioral health care. For example, under Michigan's Pre-Paid Inpatient Health Plan, all Medicaid enrollees receive certain behavioral health services, including substance use disorder treatment and counseling for several mental illness, from 10 organizations that receive capitated rates from the state, working with County Health Departments. In states with limited benefit plans, it may be worth identifying whether any of the services related to PrEP would fall under those entities' purview, to identify the need for coordination as well as plan and provider education.
- Primary Care Case Management (PCCM): As of 2017, 15 states had PCCM programs, in which primary care providers are paid monthly case management fees to coordinate care for assigned enrollees; the percentage of Medicaid population enrolled in PCCM in these states varied from 2 to 90 percent.⁵² While the use of PCCMs has been declining and enrollment is generally lower than for comprehensive MCOs, stakeholders in states with significant PCCM enrollment may wish to explore ways to integrate PrEP into provider expectations in the program.

Additional State-Level Value-Based Payment Mechanisms

States can consider building on recent alternative ways of paying for care in Medicaid to support improved provision of PrEP care.

Many states have Patient-Centered Medical Home, or PCMH, initiatives within Medicaid. The PCMH is a model endorsed in 2007 by the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Physicians (ACP), and the American Osteopathic Association (AOA).⁵³ In a PCMH, a primary care physician and care team are responsible for providing or coordinating all of a patient's care across the health care system and community. In 2017, thirty states reported having at least some Medicaid beneficiaries in a Medicaid PCMH model.⁵⁴ Stakeholders can explore whether their state's existing PCMH model would support PrEP use and adherence, or if modifications could be made to increase support of PrEP.

The Affordable Care Act created additional federal funding to support Medicaid Health Homes, a model that builds on the PCMH concept for beneficiaries with chronic conditions. At the core of the financing model are six "health home" services: comprehensive care management, care coordination and health promotion, patient and family support, and referral to community and social support services. ⁵⁵ All of these services could potentially support the use of PrEP for enrollees at high risk of HIV. For example, care coordination and health promotion could include coordination of enhanced HIV and STI screening and counseling; patient support could include PrEP navigation or adherence counseling; and referral to community and social support services could link PrEP users to CBOs or other entities engaged in PrEP support.

Having, or being at risk of, HIV is a potential qualifying condition for a Medicaid health home under federal law, but states have flexibility in determining whether and how to target their programs. A matrix of current state Medicaid health home models, including qualifying conditions and provider eligibility, is available. A state Medicaid agency could identify whether any existing health homes in the state could be used to support PrEP, and consider initiating discussions with other PrEP stakeholders regarding modifications or developing a new model.

Another payment model growing in popularity in Medicaid is the Accountable Care Organization, or ACO. As of February 2018, twelve states have active Medicaid ACO models, and another ten or more states are pursuing them.⁵⁷ In an ACO model, providers share financial risk with regard to their patients, either through a shared-savings formula (usually evolving toward also including shared risk), or through reimbursement on a per-member, permonth basis.⁵⁸

New York's Amida Care MCO currently has an ACO for people living with HIV but is expanding eligibility to HIV-negative people, creating an opportunity for focused efforts to support PrEP for that population.⁵⁹ While this structure may be unique, lessons learned from its development could help inform efforts to address PrEP through less targeted ACOs in other states.

Accountable Health Communities (AHCs) are shared-risk models in which the responsible entity goes further "upstream" than ACOs, and is responsible for addressing the social determinants of health in addition to clinical care and support services. Thirty-one communities are currently participating in CMS's ACH Model for Medicare and Medicaid⁶⁰; other ACH approaches, including multifunder models, are being supported by a range of government and foundation sources.⁶¹ In theory, this model could provide sustainable support for programs that address structural barriers to PrEP and health in general.

Medicaid agencies can work with public health stakeholders to discuss what Medicaid ACO or ACH approaches are already in place in the state, and whether they could be adjusted or expanded to address PrEP.

Benefit Design

While some Medicaid benefit categories are mandatory, states have some discretion to design their FFS coverage packages in ways that may impact whether and how providers offer PrEP clinical services. On the managed care side, Medicaid MCO enrollees are entitled by regulation to all services the state covers. ⁶² However, different restrictions may apply to medication access, and MCOs can cover benefits beyond a state's basic package. This section provides an overview of how states can align benefits across a Medicaid program through MCO contract provisions. It then reviews key benefits that affect PrEP coverage, including clinical visits, medication, clinical services, labs, condoms, and targeted case management. It continues with an overview of billing and coding for PrEP medication and services, and closes with a discussion of how the USPSTF's new recommendation for PrEP could affect Medicaid benefits.

Aligning PrEP Coverage Through MCO Contracts

In some states, it may be feasible to specifically write PrEP standards into MCO contracts – addressing not only medication but also the other benefits discussed in this section. In general, there is considerable variability in the scope and granularity of the coverage requirements that Medicaid programs apply to MCOs by contract. For example, with regard to HIV broadly, a review of selected states' Medicaid MCO model contracts found that three (Florida, New York, and Texas) had detailed contract language regarding HIV clinical services; four (DC, Massachusetts, New Mexico, and Pennsylvania) had minimal specifications; and two (Georgia and

Illinois) did not address HIV clinical services.⁶³ Understanding how prescriptive states have been in their contracts with MCOs is important context for conversations about potential contract requirements related to PrEP.

Even if a state's contracts with MCOs do not explicitly mention PrEP, a state Medicaid agency can reach out to MCOs that are not reimbursing services that the state FFS program would cover to explain why they must bring their policies into alignment. For example, in California, even though HIV is carved out of managed care contracts, claims analysis identified that in some MCOs, fewer enrollees than expected were receiving PrEP. The Medi-Cal program reached out to MCOs, both formally and informally, to discuss making their coverage of PrEP comparable to the FFS benefit. These conversations, typically with a plan's medical director, tended to result in increased PrEP uptake among the plans' enrollees as reflected in claims analyses. ⁶⁴ Similarly, public health officials in Louisiana were able to educate MCOs that multisite STI test claims were neither repeat tests nor errors, but a recommended component of PrEP intervention services. ⁶⁵

State Medicaid agencies, public health agencies and providers can work together to determine approaches to aligning coverage policies across the state program to support comprehensive coverage of PrEP services. Whether to rely on general requirements that MCOs cover all state benefits, or to seek specific benefit requirements in the contract, is a state-specific question that should be discussed with each Medicaid agency.

Access to State Medicaid Contracts

Generally, states have "model" Medicaid contracts. While some may negotiate specific terms differently with different MCOs, these model contracts generally reflect overall state expectations and requirements for participating MCOs. Many states' model contracts are available online; others can be requested directly from the state Medicaid agency. Requestors should ensure that any relevant accompanying documents – such as requests for proposals (RFPs) with provisions to be incorporated in the contracts – are included.

Office Visits and Telehealth

All Medicaid programs cover office visits at various levels of complexity; the National Alliance of State & Territorial AIDS Directors (NASTAD) report described in the billing section of this report offers specific recommendations for visit types to consider using to bill for PrEP initiation, shared medical visits, and counseling.

A growing consideration for PrEP programs is access to telehealth services – clinical services offered where the patient and the practitioner are communicating in real time over a telecommunication.

tions system – to reduce patient burden for the regular screenings and visits recommended for PrEP users. ⁶⁶ States have considerable flexibility to determine whether to cover telehealth services in their Medicaid programs. As of spring 2018, 49 states and DC provide for Medicaid reimbursement of some form of live video telehealth services. ⁶⁷ 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. ⁶⁸

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.⁶⁹ In addition, some multistate Medicaid MCOs provide their enrollees with free access to national telehealth service providers, like Teladoc.⁷⁰ Telehealth providers with specific PrEP programs include Nurx and Plushcare.⁷¹

Stakeholders can try to work within these parameters to promote reimbursement for PrEP and PrEP clinical services, or attempt to change a state's requirements to meet the needs of PrEP patients and providers. Where MCOs are making general services like Teladoc available, the plans could work with public health and clinical partners to explore how any counseling or STI screening facilitated through the service can be coordinated with a patient's other providers as appropriate.

Medication

While states generally have considerable flexibility in Medicaid with regard to coverage of preventive services, they *must* cover Truvada under the Medicaid National Drug Rebate Agreement. Under the terms of the Agreement, manufacturers make drugs available to Medicaid plans with significant rebates, and in turn, states' formularies must include all of those manufacturers' drugs.

However, states can establish their own utilization management techniques to limit use of a drug by FFS enrollees. For example, states can maintain preferred drug lists (setting higher cost sharing for non-preferred drugs); require prior authorization based on certain clinically justified parameters; set limits on use (e.g. quantity limits on the total number of prescriptions per month); or decline to cover off-label uses.

States can choose to eliminate prior authorization on Truvada entirely. Of 16 states responding to an informal AcademyHealth survey of Medicaid Medical Directors, 12 reported having no prior authorization or other utilization management requirements on Truvada for PrEP within their FFS programs.⁷²

A brief prior authorization requirement, for example requiring a physician to confirm that the patient is HIV-negative, may be both medically reasonable and not unduly burdensome.⁷³ However, to the extent a state applies restrictions that increase provider burden (e.g. lengthy prior authorization requirements), provider participation in PrEP – and therefore in PrEP clinical services, could be limited.

State Medicaid agencies should assess any FFS prior authorization requirements for Truvada as PrEP to assess whether they serve as useful clinical tools or unnecessary barriers to care. They could work with providers in the state as well as public health officials to identify an appropriate PA policy for the state FFS program.

In most states, MCOs can place different controls on utilization of covered medications. For example, one interviewee reported that some MCOs in New York State have reportedly applied prior authorization requirements for PrEP that operate as a "speed bump" to access.⁷⁴

Some states apply standardized or "common" Medicaid formularies, requiring MCOs to use the same set of utilization management approaches, either to all pharmacy or to a particular drug or drug class. State Medicaid programs could consider whether to apply this approach for PrEP medication to create consistent access.

STI Testing and Treatment

Medicaid FFS programs typically cover some STI testing as well as the other clinical components of the PrEP intervention, such as HIV screening, pregnancy testing for women, and other lab tests.

However, programs may not formally cover testing on a quarterly basis and may not always cover the multisite STI testing required for some PrEP users. For example, the CDC recommends that for MSM receiving PrEP, quarterly gonorrhea and chlamydia nucleic acid amplification test (NAAT) be conducted on pharyngeal, rectal, and urine specimens ("3-site testing"). The CDC recommends NAAT testing of vaginal specimens for women who engage in vaginal but not anal sex, and of both vaginal and rectal specimens for gonorrhea and chlamydia among women who report engaging in anal sex. Medicaid payment systems may reject multiple claims for tests for the same disease for the same person on the same day, either because of a specific payment policy, or because systems are simply not designed to accept multiple lab claims for one disease in a given day.

In AcademyHealth's informal survey of the Medicaid Medical Director Network regarding PrEP coverage, respondents were asked if their state FFS program would "pose any barriers to coverage of quarterly, multi-site STD testing." Of 15 states with FFS programs

responding, seven stated that the program would not pose barriers; one stated that the program wouldn't pay for a second test on the same day; and seven were indeterminate, with answers including "depends," "I do not believe so," and "probably." These responses suggest that state Medicaid agencies could start by clarifying whether their own policies and systems support multisite, quarterly testing without barriers.

MCO practice also varies with regard to STI claims. For example, Dr. Divya Ahuja of University of South Carolina indicated that among his PrEP patients, he perceives a smoother process for approval of multisite screening for FFS enrollees; MCOs seem to more frequently require one or more calls from a physician or other staffer before approval is granted (though his office had not formally evaluated this pattern). An MCO interviewee suggested that rejections of multisite STI testing claims are more likely to reflect logistical issues like automatic payment systems, rather than specific policies against covering multisite testing.

Challenges associated with claims for multi-site STI testing are not specific to Medicaid. One provider in a non-Medicaid expansion state reported frequent rejections or pushback for multisite STI claims for *privately*-insured patients, as well as significant variation in how private plans manage PrEP-related codes, resulting in a lowered likelihood of additional revenue for billing all components of PrEP. This suggests that multi-payer approaches or alternative payment models could create a more consistent billing and reimbursement environment for PrEP providers.

Lab Validation

Not all labs have undergone validation to support extra-genital (pharyngeal or rectal) site testing, posing a barrier to the multisite testing recommended for most PrEP users. 150 This problem is not unique to Medicaid but must be addressed to allow Medicaid reimbursement. Public health departments and Medicaid agencies could work to ensure that all labs receiving Medicaid reimbursement in the state can conduct validated testing on all types of specimens, or alternatively that enough Medicaid-participating labs are available to meet demand.

State Medicaid agencies and their MCOs can assess their lab reimbursement protocols for STIs to identify and address any barriers to reimbursement of PrEP-associated labs. If needed, the state Medicaid agency and MCOs could work with public health experts to align coverage policies with CDC guidelines. For example, public health officials in Louisiana became aware that the state Medicaid program was rejecting lab claims for multi-site STI tests, only allowing one claim to go through. They were able to work with the office to achieve reimbursement for two sites; the public health staff will be revisiting the issue to confirm if three-site reimbursement is now occurring.⁷⁹

Challenges regarding Medicaid coverage of other tests recommended as part of PrEP, including HIV and hepatitis B tests, as well as renal function tests, have not been identified in the literature or interviews, but could similarly be discussed with state Medicaid agencies and MCOs if problems arise.

Condoms

The CDC's PrEP guidelines note that "[t]he importance of using condoms during sex, especially for patients who decide to stop taking their medications, should be reinforced."80 In many states, Medicaid can reduce financial barriers to condom use. As of July 2015, 27 states of 41 responding to a survey reported covering condoms in their traditional (non-expansion population) Medicaid programs; 18 reported covering condoms for their expansion populations and 18 under their Medicaid family planning expansions waivers or amendments.⁸¹ The majority of states covering condoms require prescriptions for reimbursement.

Because condoms require a prescription to be covered, Medicaid and public health stakeholders should ensure that providers are aware of the appropriate procedures to prescribe condoms for PrEP users to trigger Medicaid reimbursement.

Case Management, Care Coordination, and Peer Support

Services to help coordinate and support care for PrEP users could be implemented as a state benefit or as an "additional" service covered by an MCO.

Targeted Case Management

Targeted Case Management (TCM), an optional Medicaid benefit, allows states to cover enhanced case management services to help certain categories of beneficiaries (or beneficiaries in certain parts of a state) access medical and other services. Because TCM can be developed for specific populations – e.g. adolescents, men who have sex with men – it could be developed in a way that addresses specific barriers to PrEP use and adherence to PrEP medication and clinical services. A number of states' Medicaid programs include targeted case management for people living with HIV. Rhode Island has expanded this concept to make TCM available for certain beneficiaries at high risk of HIV,82 creating a reimbursement mechanism for services around linking people to PrEP and encouraging their adherence to PrEP clinical services.83

Medicaid agencies, public health agencies and PrEP providers could explore whether their states have existing TCM benefits that could be modified to support beneficiaries who are candidates for PrEP and other services, or whether such a benefit can or should be developed.

■ For All Members (as needed) For High-Risk Members Only Not Used For Any Members 1% 1% 8% 8% 14% 25% 41% 34% 24% 54% 55% 74% 61% 58% 58% 46% 36% Chronic Disease CHWs, Peer Interdisciplinary Individualized Care Complex Case Home Visits Mgmt. Support Specialists. Care Teams **Plans** Mgmt. **Health Coaches**

Figure 2: Share of Medicaid MCOs Using Strategies to Promote Coordinated Care

NOTES: "Don't Know" responses not shown. CHW = Community Health Worker. SOURCE: Kaiser Family Foundation Survey of Medicaid Managed Care Plans, 2017.

Peer Support and CHWs

Medicaid regulations permit states to reimburse non-licensed providers for providing preventive services, as long as the services are "recommended by" a licensed provider. This provision would permit states to reimburse community health workers, peer navigators, or similar support workers engaged in the provision of PrEP. To make this change, states would need to submit a state plan amendment to CMS detailing the types of services and providers they propose to reimburse. While uptake of this provision for any kind of preventive service has been limited, Medicaid agency and public health officials could explore whether an amendment to cover non-licensed support providers who offer PrEP would be feasible. If a state implements this option, community health workers (CHWs) could potentially bill for PrEP support services under "Self management education and training"; in some states, CHWs could potentially also be reimbursed for Targeted Case Management (see prior section).84 States could develop specific protocols indicating the amount, scope, and duration of PrEP case management services to be covered.85

State Medicaid agencies could work with other stakeholders to identify existing policies regarding reimbursement of peer support services, and discuss potential reimbursement of PrEP peer supports, navigators, or case managers.

Other MCO Care Coordination Strategies

MCOs can provide care coordination services beyond what's included in a state plan or waivers, at times motivated simply by the identification of a need among their enrollees.⁸⁶ This may include

types of care coordination applicable to PrEP. Currently, as shown in Figure 2, most Medicaid MCOs report using a range of strategies to promote coordinated care⁸⁷:

MCOs could work with other PrEP stakeholders to determine whether and how care coordination for PrEP could be integrated into existing or emerging strategies, for example by including PrEP users as eligible for care coordination services. Partners for such coordination services could include local health departments or CBOs, or those entities could provide training on PrEP to current care coordination providers. MCOs could also consider directly paying for additional staffing at provider facilities with high numbers of enrollees who are PrEP users to conduct care coordination.

To the extent a Medicaid MCO pays for services that go beyond the state's Medicaid benefit package, the MCO must use administrative rather than medical services funds. Regardless, MCOs may be motivated to provide these services to improve their enrollees' health. In addition, quality improvement activities such as care coordination for PrEP, can count toward the numerator of a plan's "medical loss ratio" or MLR. The MLR reflects the proportion of total capitated payments received that are spent on clinical claims and quality improvement. Medicaid MCOs must meet a minimum 85 percent MLR, with most states requiring plans to remit funds to the state if the ratio is not met. Therefore, the inclusion of quality improvement in MLR offers plans an incentive to invest in the kinds of coordination and navigation activities that could support PrEP clinical services.

Table 3: Potential Practice Quality Measures from CDC PrEP Clinical Providers' Supplement, 2017

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

Coding and Billing for PrEP

NASTAD has prepared a detailed guide for providers seeking to bill Medicaid and other payers for PrEP clinical services.⁸⁸ The guide details procedure codes and diagnosis codes for billing key elements of the intervention, including:

- A medical office visit for PrEP initiation;
- Shared medical visits (multiple providers, including at least one physician, APRN, or PA);
- Preventive medicine counseling and/or risk factor reduction intervention, individual or group;
- Labs for PrEP initiation and ongoing monitoring;
- PrEP adherence counseling; and
- High intensity behavioral counseling to prevent STIs.

As discussed in the guide, state Medicaid programs differ in their requirements as to who can provide each service. For example, some permit certain services to be provided by a non-licensed staff number "under the supervision of" a physician, APRN, or PA.

The U.S. Preventive Services Task Force and PrEP

In November 2018, the USPSTF issued a draft "Grade A" recommendation for PrEP for HIV.⁸⁹ If finalized, this recommendation would trigger statutory coverage requirements that the recommended service be covered without cost-sharing by nearly all private issuers, as well as for Medicaid expansion enrollees. In addition, such a recommendation could enhance overall provider

engagement efforts with regard to PrEP. It remains to be seen whether the USPSTF recommendation, if finalized, will explicitly include HIV and STI testing and the other PrEP clinical services in a way that translates into clear coverage requirements for those clinical services.

Performance Improvement

In the Medicaid program, the quality of care covered by MCOs and delivered by providers can be addressed through performance incentives at various levels. This section discusses incentives for improving PrEP care at the plan level, incentives that states can offer providers directly by the state FFS program, and approaches that MCOs apply to reward performance for providers in their networks.

At any level, using performance measures to improve PrEP care requires valid measures. The CDC's 2017 PrEP guidelines include five "Potential Practice Quality Measures" (see Table 3). While none have been tested and validated according to commonly endorsed standards, eventually they – or other nationally developed or state-specific measures – could be used to evaluate the performance of providers and MCOs in offering PrEP medication and clinical services. As an interviewee noted, any discussion of metrics for PrEP clinical services must take place in a broader discussion about PrEP metrics overall, and perhaps incorporate risk adjustments to reflect populations that may be more difficult to reach and retain with consistent PrEP services. 91

Incentives for Plan-Level Quality Improvement

State Medicaid agencies could build specific incentives into their contracts with MCOs to stimulate the provision of recommended services.92 In FY17, the majority of managed care states reported using one or more quality improvement approaches for MCOs: 22 used "pay for performance" bonuses for reaching certain performance thresholds; 29 used "capitation withholds" or penalties for plans not meeting performance thresholds; and 36 required data collection and reporting for quality improvement.⁹³ More states were planning new or expanded quality improvement initiatives. For example, Michigan's "Bonus Template" for Medicaid MCOs involves a total funding withhold; plans can recover 'bonus dollars' for meeting state-set performance goals in areas of population health, health equity, access to care, and community collaboration.94 Tennessee's pay for performance program gives MCOs an additional per member, per month payment when they meet HEDIS performance thresholds, with measures selected by each MCO from among a set of state-identified options.95 While no PrEP-specific performance-based contract provisions were identified in research or interviews, they could be developed and applied.

In addition to financial incentives to MCOs, states can reward high-performing plans with priority for auto-assignment of enrollees who do not select a plan themselves. ⁹⁶ A PrEP measure could be integrated into auto-assignment preferences as well.

States can also require Medicaid MCOs to engage in specific targeted Performance Improvement Projects, or PIPs. A PIP around PrEP coverage and engagement could give MCOs an opportunity, on their own and collaboratively, to closely examine the quality of care and coverage they are providing PrEP users and identify necessary changes.

Medicaid agencies could work with public health officials to identify whether existing MCO quality improvement initiatives could integrate PrEP care. Often, plans are assessed based on HEDIS performance measures, a standard set of plan quality metrics, which do not currently include any PrEP measures. States are not bound by HEDIS or NCQA-approved measures⁹⁷; they could develop their own metrics around PrEP, and pilot models based on them.⁹⁸ However, plans (and providers) may be more likely to resist relatively novel metrics, particularly if linked to penalties or incentives. In addition, states would need to be persuaded that PrEP is a significant enough issue to merit the intensive and complex negotiations around performance measures in MCO contracts.

State Medicaid Agency Direct Financial Incentives to Providers

In states with significant fee-for-service enrollment, state Medicaid agencies could undertake a range of financing policies to directly influence provider behavior regarding PrEP.

One approach is to offer incentives for providers who meet certain standards. Linking incentives to performance would require reliable performance measures linked to PrEP medication and clinical services.

Notably, performance measures could face opposition from providers, who are working with many performance measures and incentive systems across a broad range of health issues. In addition, the relatively small number of PrEP users in any given provider's panel could render performance data unreliable.

While clinic-based quality measures for PrEP services may be a goal, an initial interim step in some contexts could be linking financial incentives to more easily measured provider behavior such as participation in training or academic detailing on PrEP, or in trainings on bias and patient engagement related to PrEP and other sexual health services.

Medicaid agencies and public health officials could identify any existing provider incentive initiatives in their states' FFS programs and determine if PrEP medication and clinical services could be integrated into the model.

MCO Provider Payment Models

Most MCOs pay at least some providers on a fee-for-service basis. However, in nearly all states, MCOs are also using various alternative payment models. 99 In FY17, 93 percent of plans surveyed reporting using "pay for performance" for providers, 38 percent reported using bundled payments and 44 percent reported using other shared-savings or shared risk arrangements. 100

Pay for Performance

Like state FFS programs, MCOs can create incentives linking provider payments to meeting certain standards of performance. As discussed above, this approach for PrEP, as well as for PrEP clinical services, would depend on the development of performance measures acceptable to both plans and providers. The feasibility would also depend on whether the relevant performance information could be gleaned from claims data, or whether it would require information from medical records or other sources. Offering payment incentives for appropriate provision of PrEP clinical services could be tailored to specific specialties (e.g. infectious disease, internal medicine, or family practice) within an MCO's network.

Bundled Payments

The term "bundled payments" does not have a single meaning in payment policy – rather, it can be used in different contexts to describe a broad range of payment types, including:

- A single payment for a particular type of office visit;
- An "episode-based" payment, such as paying a health system for a patient's knee surgery and all related services prior and in followup to it; and
- "Global" payments (e.g. per member, per month (PM/PM) to a group or system in return for providing a certain type of care).
 This is sometimes referred to as "subcapitation."

One PrEP provider interviewed stated that a per-visit bundled rate from Medicaid MCOs for PrEP would be ideal, but anticipated that in most cases providers will have to continue to get as much as possible out a standardly-reimbursed visit.¹⁰¹ It is also important to note that in much of the literature, the "success" of bundled payments is discussed in terms of financial savings, though measures are typically put in place to maintain quality.¹⁰² PrEP stakeholders should therefore consider both the feasibility and value of pursuing bundled MCO payments to providers for PrEP.

Shared Savings or Shared-Risk Models

Shared savings models are structured in a way that allows providers to benefit if the quality of patient services yields savings; shared-risk models can also include providers' accepting "downside" risk if costs are higher than anticipated. Overall, many practices may not be ready to engage in risk-sharing, particularly down-side risk, for PrEP or for care provision in general. In addition, PrEP may not generate enough costs, or savings, to rise to the level of warranting a shared savings model.

Access to PrEP Providers

Patients can only access PrEP medication and clinical care if they have access to care providers.

States with significant FFS enrollment should work with public health stakeholders and providers to ensure that PrEP providers are participating in the program and accepting new Medicaid patients. If not, they should work to identify barriers and potential solutions.

Comprehensive Medicaid MCOs contract with a specific network of providers – including clinicians, health care facilities, and laboratories – to provide care to their enrollees. Generally, a provider must be part of a specific MCO's network to receive reimbursement for services provided to that MCO's enrollees.

Current federal law and regulations require states that use managed care to develop "network adequacy" standards for certain provider

Lessons from MCO Support of Medication-Assisted Treatment for Opioid Addiction

A recent report for the Association for Community Health 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. Like PrEP, MAT is an evidence-based tool that has been underutilized within Medicaid programs and more generally. However, MAT has taken on increased urgency because of the national opioid epidemic, and the ways MCOs have approached its scaleup could help inform PrEP efforts.

The authors of the report identified provider barriers 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. 152

MCOs profiled in the report used a variety of approaches to engage new MAT providers and to support and maintain existing providers. Examples of strategies that used financial incentives include the following:

- UPMC (Pa.) offers performance-based payments for providers who meet multiple MAT-related quality indicators. The payments can be used to hire social workers or nurse care managers, or to otherwise strengthen treatment services.
- Inland Empire Health Plan (Calif.) will be including payment for out of office MAT training time in its provider contracts.
- Partnership Health Plan (Calif.) gives financial incentives to primary care providers who are willing to take MAT referrals and conduct specific monitoring activities.
- Geisinger Health Plan (Pa.) provides bundled payment for MAT prescribers to reduce provider administrative burden. The payment is a per member, per month amount that includes an initial visit; initiation of MAT, stabilization, and maintenance (drugs are reimbursed separately). Providers send a weekly list of MAT patients to the plan; the model does not currently include quality requirements, but Geisinger is considering their inclusion.¹⁵³

categories, which are not PrEP- or HIV-specific. ¹⁰³ However, states can choose to develop further standards; in theory, a state Medicaid agency could by contract require MCOs in the state to include PrEP providers in their network.

MCOs can also go further to ensure that their networks meet the needs of their enrollees. In addition to considering statewide PrEP network adequacy standards, MCOs could work with public health stakeholders to evaluate their networks and identify PrEP providers to meet their members' HIV prevention needs.

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 could inform first steps in determining an MCO's network adequacy with regard to PrEP. Such efforts could be paired with ensuring that MCO networks includes STI clinics, other public health clinics, and infectious disease doctors, thereby reaching a slate of providers who may be more likely to offer PrEP services.

Partnerships with Local Health Departments and Community-Based Organizations

Local health departments (LHDs) or CBOs could, in some cases, serve as quality providers of PrEP clinical services or support services. Public health stakeholders could, through a formal "certification" or informally, help identify public or community-based entities in the region that are qualified to support PrEP users and providers.

This section describes how state Medicaid agencies could support LHD and CBO engagement in PrEP directly or by encouraging or requiring MCO engagement, as well as how MCOs could support LHD and CBO engagement.

State Medicaid Agencies Directly Supporting Local Health Departments or CBOs

State Medicaid agencies could reimburse local health department STD or primary care clinics or community-based providers that offer PrEP and/or PrEP clinical services for Medicaid enrollees.

Health-department-run clinics, including STD clinics, are important sites for initiating PrEP medication and clinical services or, for some clinics, maintaining patients on PrEP. Health department clinics that do not currently have or intend to have the capacity to initiate or deliver PrEP also serve a crucial role in actively referring patients to providers in the community.

A 2015 survey from NACCHO (National Association of County and City Health Officials) of local health departments (LHDs) that provide or contract out HIV or STI screenings found that almost one third were engaged in some way in PrEP. Those that directly provided services or ran STD clinics were more likely to be engaged in PrEP. "Engagement" varied, with 74 percent making referrals to PrEP providers, and only 9 percent delivering PrEP, though almost a third of LHDs who were at all engaged with PrEP saw direct provision as an "optimal" role for LHDs. 105 While these figures may have increased in the intervening years, one interviewee reported that an increasing number of LHDs see their role as initiating patients on PrEP and working to transition them to other primary care providers, if that is an option. 106

When LHDs do engage in providing PrEP medication, clinical care, and support services, Medicaid might not always be billed. The NACCHO survey found that only 47 percent of respondent LHDs – all of which were directly providing STI or HIV services – reported billing Medicaid at all. ¹⁰⁷ In some states, public STD clinics are legally prohibited from billing insurance, including Medicaid. ¹⁰⁸ When asked if their state Medicaid program pays for PrEP, 75 percent of respondents in the NACCHO survey selected "Don't know." ¹⁰⁹

These data are consistent with a concern expressed by a member of the steering committee that public clinics may be serving PrEP patients without receiving reimbursement, even when those patients have Medicaid coverage. 110 This could be due to a range of factors, including confidentiality concerns (particularly for adolescents or young adolescents who share an address with their parents), or visits being conducted by nonbillable providers (e.g. RNs). In addition to being a non-optimal use of health department funds, this potential pattern could make it difficult to identify problems when billing Medicaid for STI services because Medicaid is not, in fact, being billed (for PrEP or for any services). A further concern is a potential lack of coordination/communication between providers offering different components of the PrEP service suite.

Stakeholders could explore whether Medicaid reimbursement for LHD provision of PrEP and related clinical care is being maximized within the parameters of their state's laws and payment policies. Within this assessment, stakeholders could also determine if eligible public primary care or STD clinics in the state are in fact participating in the 340B program, which requires Medicaid-participating pharmaceutical manufacturers to offer deep discounts on drugs to certain categories of registered safety net providers, including STD clinics.¹¹¹

For non-clinical CBOs, State Medicaid agencies could develop contracts or agreements to offer PrEP support services. Because support of non-clinical CBOs is not a traditional role for Medicaid in all states, public health agencies can help identify opportunities for this engagement.

MCO Collaboration with LHDs or CBOs

On the managed care side, MCOs could also establish contracts or memoranda of understanding (MOUs) with local health departments to offer PrEP medication and/or clinical services to enrollees. MCOs may undertake such actions based on their members' needs; stakeholders could also explore whether current state MCO contract language could encourage or require MCOs to engage with LHDs and CBOs, for PrEP or more broadly.

In addition to reimbursing LHDs for clinical care, MCOs also have the flexibility to consider more novel ways of incorporating LHD services into PrEP care. For example, Medicaid MCOs could help support Disease Intervention Specialists (DIS), funding them in a way comparable to CHWs, to serve the STI tracking and care coordination needs of their enrollees. This approach would extend beyond PrEP, and involve engaging MCOs in understanding the benefits of LHD and DIS involvement with STIs for their communities' health and their financial bottom line.

MCOs could also work with non-clinical CBOs to support PrEP users. For example, in a model that could be considered for PrEP support, AIDS Foundation of Chicago (AFC) contracts with two Medicaid MCOs. Under the "Reach and Engage" service package, AFC conducts outreach to members deemed "unable to locate" to connect and re-engage them with primary care providers. 112 One MCO pays a flat monthly rate; another pays on a PM/PM basis. Members assigned to AFC include some who are HIV-positive as well as others who are at high risk of HIV. This type of model could be useful in the PrEP arena; for example, a non-clinical CBO could propose to work with MCOs to support various parts of PrEP, such as linking PrEP users to a range of clinical services.

AIDS United has developed a set of webinars and resources to support CBOs in approaching MCOs. 113 The Association for Community Affiliated Plans also has multiple resources, including a factsheet highlighting of range of examples of Medicaid MCO partnerships with local organizations. 114

MCOs can similarly engage with community health workers, on their own initiative or under a state contractual requirement. For example, Michigan's Medicaid MCOs are required by contract to support CHWs. ¹¹⁵ Priority Health, a Medicaid MCO and integrated delivery system, employs CHWs and additionally contracts with a vendor to directly address enrollee needs in a specific portion of the state. ¹¹⁶ CHWs both within and outside the plan help identify and address enrollees' social determinants of health. ¹¹⁷ Medicaid agencies and MCOs could work with public health agencies to explore supporting qualified CHWs as PrEP navigators.

Specific Considerations Linked to Provider Type and Setting

PrEP scaleup may in many contexts rely on the engagement of providers other than physicians, and settings other than a traditional clinical setting. This section reviews certain considerations related to Medicaid reimbursement for non-physician providers, as well as issues related to pharmacy reimbursement, federally-qualified health centers and rural health centers.

Nurse Practitioners and Physician Assistants

Within a given state, engagement of nurse practitioners (NPs) and physician assistants (PAs) in PrEP would depend on both scope of practice and reimbursement. Scope of practice issues are not specific to Medicaid, but Medicaid and public health stakeholders need to understand the opportunities and limitations for these providers at the state level. In 26 states, NPs have prescribing authority only within the bounds of a relationship with a physician; in 11 states NPs must complete a transition period toward full prescribing authority; and in 13 states plus DC, NPs have full prescribing authority (see www.scopeofpracticepolicy.org for details by state). 118 For PAs, who generally work with a supervising physician, in most states prescriptive authority is determined by agreement between the PA and that physician. 119

Nurse practitioner (NP) visits can be billed to Medicaid¹²⁰ as long as services provided are within the state's scope of practice laws. State FFS programs generally reimburse NPs at between 75 and 100 percent of the physician reimbursement rate.¹²¹ A NP interviewed stated that she generally bills her PrEP visits as a Level 3 established office visit, which allows for counseling and risk reduction.¹²²

All Medicaid programs offer reimbursement for services provided by Physician Assistants operating within their scope of practice, but in some states reimbursement may be through the supervising physician. The rate may be lower than that paid for services provided by physicians or the same, depending on the state.¹²³

Services Provided by Registered Nurses

As noted by one infectious disease doctor interviewed for this project, one way to reduce the burden of repeated STI testing on prescribers would be to task-shift the testing to RNs. 124 Jason Farley, a PrEP provider and researcher and the immediate-past President of the Association of Nurses in AIDS Care, maintains that non-prescribing RNs could in fact run a PrEP clinic under standing orders, with the nurse conducting clinical monitoring and the patient self-swabbing for STIs. 125 In this model, a prescribing provider could be consulted for specific cases such as seroconversion, nonadherence, or a diagnosed STI in need of treatment. Lyn Stevens of New York State's Department of Health echoed the belief that some ongoing PrEP services and visits could be conducted by RNs. 126

However, multiple interviewees noted that visits with *only* a registered nurse are not reimbursable in their specific settings. ¹²⁷ Reimbursement of RN visits should be assessed at the state level to determine what PrEP clinical services can be supported under this model.

Pharmacies and Pharmacists

Pharmacies and pharmacists can play key roles not only in dispensing PrEP medication but also in supporting adherence to PrEP and to PrEP clinical services through various models.

In pharmacies with clinics that employ health care providers with prescribing authority, providing PrEP is relatively straightforward. For example, at certain Walgreens sites, health care clinic providers are able to prescribe PrEP, along with conducting STI and HIV screenings. 128

Pharmacists may also be able to provide most or all PrEP services directly, depending on the practice arrangements permitted under state law. For example, in Seattle, the Kelley-Ross Pharmacy runs a "One-Step PrEP" clinic under a collaborative drug therapy agreement. Pharmacists conduct initial meetings, sexual histories, lab testing, and education, in addition to dispensing medication. An estimated 20 percent of the clinic's PrEP patients are Medicaid enrollees, most enrolled in MCOs. The pharmacists can bill visits on the same terms as other providers based on level of service, and can conduct all necessary lab testing with Medicaid reimbursement.

In Iowa, collaborative practice agreements between MDs and PharmDs allow the pharmacists to provide expanded PrEP services. ¹³² Providers conduct an initial PrEP visit through either telehealth or an LGBTQ+ clinic, and pharmacists do monitoring and follow-up visits. ¹³³

For pharmacies acting within more traditional bounds of practice, Medicaid reimburses for drugs and pays pharmacists a small dispensing fee. However, in some states, Medicaid will reimburse pharmacists for enhanced medication therapy management, or MTM services. ¹³⁴ In theory, MTM eligibility could be extended to persons on PrEP and include enhanced counseling and reminders about renewals.

Stakeholders could explore their states' pharmacist practice agreements and Medicaid financing models for pharmacies, including whether their state Medicaid program has an MTM model that could be applied to pharmacist engagement in PrEP.

Federally-Qualified Health Centers and Rural Health Centers

As community-based providers of comprehensive and coordinated primary care services, ¹³⁵ federally-qualified health centers (FQHCs) should be an important locus for the provision of PrEP medication and clinical services. FQHCs receive federal funding from the Bureau of Primary Health Care within HRSA to offer care; they serve both uninsured and insured patients, including Medicaid enrollees. FQHCs' unique Medicaid reimbursement

structure creates both opportunities and challenges for provision of PrEP medication and clinical services.

Under federal law, state Medicaid programs pay FQHCs under a prospective payment system (PPS), using a set, per-visit rate based either on cost reporting or on local averages. This per-visit rate includes all services provided during a visit with a licensed provider, encompassing not only the primary encounter but, for example, any nurse or lab services provided in the visit. Some states have "unbundled" certain services from the PPS rate in order to incentivize their provision; for example, some states reimburse FQHCs the actual acquisition costs for long-acting reversible contraceptives, on top of the PPS rate. 137

Medicaid MCOs are not required under federal law to pay FQHCs the PPS rate, but must pay at least what they would pay a non-FQHC provider for the same services. However, FQHCs must *receive*, in the aggregate, at least the amount they would have earned under the PPS payment. Therefore, states must make "wraparound" payments to FQHCs if the MCO reimbursement is in fact lower, in the aggregate, than the PPS.

Under federal law, similar Medicaid payment provisions apply to Rural Health Centers, which are certain facilities in "nonurbanized," underserved areas.¹³⁸

Whitman-Walker Health, an FQHC in Washington DC, provides PrEP intervention services to approximately 2,000 people, an estimated 30-35 percent of whom are Medicaid enrollees. As an FQHC, Whitman-Walker serves many vulnerable patients, requiring wraparound care to meet patients' health needs. Therefore, the cost reporting on which the clinic's PPS rate is based includes not only clinical services but also support services, including such as care navigator and retention manager. The resulting enhanced rate, higher than the typical commercial reimbursement Whitman-Walker receives for the clinical services only, still falls short of covering all PrEP-related services the clinic offers. Importantly, FQHC reimbursement rates can vary by state and by facility. House Because PPS rates are only negotiated every few years, they are often not reflective of current year expenses, and may not reflect the costs of emerging technologies or newer services like PrEP.

Whitman-Walker has been able to establish a specific PrEP clinic which to date has seen approximately 200 of their PrEP patients. The patients see both a nurse and phlebotomist in a brief visit to streamline their receipt of PrEP clinical services. These patients do not otherwise come to the center frequently for other medical care (though the patients do see a clinical provider at least once per year, for annual wellness visits, per 340B program requirements). Other

than the lab work, the visits are not reimbursable by Medicaid or other insurance because the patients do not see a Medicaid-reimbursable clinical provider in this visit. However, Whitman-Walker reports that it is worth it to use clinic funds to support this immediate PrEP access option so that this subset of patients receive PrEP adherence support and STI testing on demand.¹⁴¹

FQHCs, like STD clinics, are eligible for the 340B drug pricing program. An FQHC with its own pharmacy, or that contracts with pharmacies in the community under 340B, can buy drugs at the 340B discounted rate.

Stakeholders can work to promote provision of PrEP medication and clinical services at FQHCs, at the local, state, and federal levels. Locally, public health agencies can determine if FQHCs are providing PrEP and work to identify barriers, including those related to Medicaid reimbursement. At the state level, the Medicaid agency can work with public health stakeholders to analyze FQHC reimbursement and whether modifications can be made to adequately support PrEP medication and clinical services. Federally, HRSA can work with CMS and the CDC to identify opportunities, such as developing ongoing training opportunities or clinical practice resources for FQHC staff. While these queries and approaches focus on the Medicaid lens, they could serve to identify broader barriers and opportunities to PrEP at FQHCs.

Further Considerations for Medicaid Benefits and Financing

A number of additional opportunities and challenges should be considered at the state level to help optimize Medicaid support of PrEP intervention services.

Leveraging Medicaid Data to Increase Access

Multiple interviewees agreed that Medicaid claim data should be leveraged to improve provision of PrEP clinical services to current PrEP users, as well as to increase PrEP uptake and adherence. Because Medicaid agencies do not always have staffing or resources to spare for new analyses, 142 public health stakeholders may need to develop or expand existing data sharing agreements with state Medicaid agencies, or work together to identify a third party that could conduct the analyses. 143

For benefit design and financing purposes, 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, to help optimize how the benefit is structured and financed;
- Tracking the provision of clinical services to current PrEP users, in part to inform calculations of value, potentially for valuebased payment approaches; and

 Identifying candidates for PrEP, based on STI-related claims or other indicators from Medicaid data, to consider the potential impact of broad, population-based models for improving PrEP coverage and uptake.

Developing an ROI for PrEP

Multiple experts on the steering committee noted the importance of developing return on investment (ROI) data on PrEP to help inform benefit and financing discussions among State Medicaid agencies, MCOs, and other PrEP stakeholders.

ROI can be conceptualized at two levels: the ROI for PrEP overall, and the marginal ROI for optimal PrEP care that includes all recommended clinical services. The former is important for consideration of overall PrEP uptake; the latter may be useful in promoting policy changes to specifically ensure that Medicaid programs and MCOs are covering STI labs and other clinical PrEP services. In addition, information about the likely timeline in which ROI would be realized would help Medicaid agencies and MCOs understand if they are likely to see the savings themselves.

An important factor to consider in PrEP ROI is that a high proportion of PrEP users are likely to be "expansion enrollees" for whom the vast majority of Medicaid costs are borne by the federal government. For these adults, the federal government pays an FMAP starting at 100 percent and ramping down to 90 percent. For most states, this is far higher than the usual FMAP. Therefore, from the state perspective, the marginal costs of PrEP medication and clinical services are likely to be heavily discounted for expansion enrollees. ¹⁴⁴ Of course, any financial savings from PrEP would be similarly discounted for the state.

MCOs, receiving fixed rates from the state per enrollee, would also be concerned about ROI. In states where one issuer dominates the Medicaid MCO market, cost-effectiveness arguments might be particularly effective because that issuer is more likely to see any savings achieved. As noted above, in states where pharmacy or HIV drugs are carved out of MCO contracts, the ROI for PrEP would be less relevant for MCOs.

The financial ROI for PrEP may evolve over time, both as generics becomes available and as more information emerges regarding intermittent use models.

Conclusion

The Medicaid program is complex, offering a broad range of both challenges and opportunities for delivery of PrEP medication and clinical services. The levers and examples discussed in this white paper, along with the accompanying paper on Medicaid patient and provider engagement, should serve as a starting point for conversations about how Medicaid agencies and MCOs can work with public health to increase access, reduce HIV transmission, and promote the health of PrEP users.

Appendix 1: Project Steering Committee

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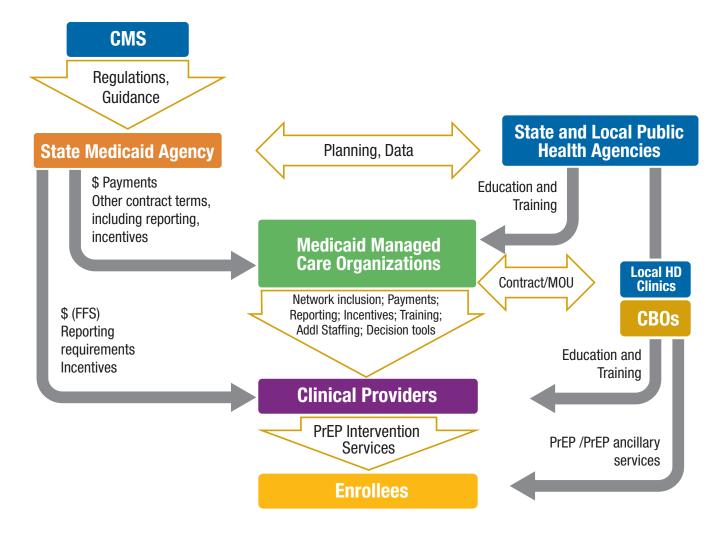
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Appendix 2: Schematic of Medicaid Financing Levers



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