March 2019
ISSUE BRIEF

amfAR
MAKING AIDS HISTORY
The Foundation for AIDS Research

Expanding Access to Pre-Exposure Prophylaxis (PrEP) for Adolescents and Young Adults: Models for Addressing Consent, Confidentiality, and Payment Barriers

In May 2018, the U.S. Food and Drug Administration (FDA) approved the once-daily oral medication Truvada as pre-exposure prophylaxis (PrEP) for adolescents, in combination with safer sex practices, for reducing the risk of acquiring HIV.[1] Previously, Truvada was approved as PrEP only for adults aged 18 and older. Adolescents and young adults bear a disproportionate HIV burden. In 2016, youth aged 13 to 24 made up 21% of all new HIV diagnoses in the United States.[2] Of these diagnoses in youth, most (81%) occurred among young gay and bisexual men, with Black and Latinx gay and bisexual men disproportionately affected.[3] Young Black gay and bisexual men account for 54% of all new HIV diagnoses among young gay and bisexual men, while young Latinx gay and bisexual men account for 25% of new diagnoses among this population.[4] Ensuring that adolescents and young adults at risk for HIV can access PrEP is a key step toward reducing the number of HIV diagnoses.

Now that one barrier to PrEP has been eliminated, it is important to systematically assess and address other barriers to PrEP for adolescents and young adults. Questions arise about whether minors can consent to receiving PrEP without parental notification or consent, whether young people can count on their personal health information remaining confidential, and whether payment sources exist to enable young people, acting independently of their parents or guardians, to obtain the financial resources to access PrEP and related monitoring services, either through insurance, public programs, or other sources.

This report offers a brief examination of how three jurisdictions consider and address policy issues that arise related to consent, confidentiality, and payment barriers: Colorado, New York, and California. Each of them is discussed in the context of highlighting successful HIV efforts to reform public health laws or adopt programs specific to the adolescent and young adult populations. It is important to note that the examples and case studies are included in this report for the purpose of identifying key insights and opportunities, which may or may not be completely relevant

Common Lessons to Facilitate Adolescent and Young Adult Access to PrEP

As more jurisdictions grapple with how to expand access to PrEP for adolescents and young adults, they may need different strategies to build consensus for legal and policy reform. While the specific path or statutory language may vary, many jurisdictions must address:

Consent: Long before PrEP came along, most states had enacted laws and policies to permit unemancipated minors to consent to HIV and STI screenings and treatment. These laws did not anticipate the availability of a preventive medication. Therefore, many jurisdictions must find the most salient approach to updating these laws to also permit these minors to consent to PrEP access without parental consent.

Confidentiality: A standard practice for accountability and fraud prevention is for health plans to mail an explanation of benefits (EOB) to policyholders whenever the policyholder or covered dependents access services. This can impede PrEP access if it results in disclosure to a parent or guardian. Therefore, jurisdictions should consider ways to establish patient rights to direct where and in what format an EOB is sent, so that it goes to the recipient of the service, not the policyholder.

Payment: Payment for PrEP medications and related monitoring services can be a barrier for many people, including young people. Just as the AIDS Drug Assistance Program (ADAP) is a critical component of the HIV care system enacted to ensure that uninsured and underinsured individuals with HIV can access treatment, several states have established, and more should consider establishing, ADAP-like PrEP access programs. Additionally, local and state discretionary funds, patient assistance programs offered by pharmaceutical companies, and charitable resources play important roles in creating a patchwork financing system to enable all young people to access PrEP.

in the context of other jurisdictions. These examples and case studies do not cover and are not intended to cover all of the policy and program initiatives undertaken around PrEP for adolescents and young adults in these jurisdictions.

Background

PrEP involves HIV-negative individuals taking a daily pill containing two antiretrovirals to prevent becoming infected with HIV. Introduced within the last decade, PrEP remains a new intervention that has proven to be both safe and highly effective for preventing HIV infection. Although the annual number of HIV diagnoses in the United States decreased from 2011 to 2015, the number of diagnoses did not decline among youth.[5] More concerning, HIV diagnoses increased by 19% among young Latinx gay and bisexual men during this period.[6] Young Latinx gay and bisexual men experienced the largest increase in HIV diagnoses of all racial/ethnic groups, while young Black gay and bisexual men remain most heavily impacted and account for the majority of all new HIV diagnoses among young gay and bisexual men. These numbers clearly demonstrate a need for effective HIV prevention services to reduce the number of HIV diagnoses among these communities of adolescents and young adults.

Although the annual number of HIV diagnoses in the United States decreased from 2011 to 2015, the number of diagnoses did not decline among youth.

Expanded FDA approval of Truvada for PrEP has eliminated a major impediment to providing PrEP for adolescents at significant risk for HIV. While some health care providers previously prescribed Truvada for PrEP off label to adolescents, many providers were hesitant or unwilling to prescribe in the absence of FDA approval for this population. Despite the recent FDA approval, adolescents still face many obstacles to accessing PrEP. One challenge is that in most states adolescents under age 18 cannot access PrEP on their own without parental consent. This can be a significant barrier for adolescents most at risk for HIV because they may not have disclosed their sexual orientation or risk behaviors to their parents and may fear the repercussions of disclosure. State laws generally authorize testing and treatment of minors for sexually transmitted infections (STIs) and, in many cases, HIV, without parental notice or consent, but most state laws do not specifically authorize *prevention* of STIs. (Minors are defined as those who have not yet reached the age of majority, which varies from state to state, but in most states is 18.)

Additionally, a significant concern of many adolescents and young adults who are on their parents' health insurance is the standard practice (required under many state laws) of providing notice of any coverage decision to the primary insured policyholder. This notice may be referred to as an explanation of benefits, or EOB. Many young people are reluctant for their parents to receive notice of their use of a drug related to sexual activity, particularly if they are gay or bisexual. Yet another challenge adolescents and young adults face is limited payment options to access PrEP.

In November 2018, the U.S. Preventive Services Task Force (USPSTF) issued a draft "Grade A" recommendation for PrEP, urging that health care providers offer PrEP to people at high risk for HIV.[7] The recommendation will help address affordability and improve access to PrEP. If finalized, the recommendation would trigger statutory coverage requirements that PrEP be covered without cost sharing by nearly all private health plans, including employer plans and those offering coverage through Affordable Care Act (ACA) marketplaces. All state Medicaid programs currently cover PrEP, but the recommendation would require that, for Medicaid expansion enrollees, any cost sharing be lowered to zero. Some states also apply zero cost sharing for USPSTF recommendations to traditional Medicaid enrollees. Even if traditional Medicaid enrollees face cost sharing, for most services it is limited to nominal amounts. Moreover, the ACA incentivizes states to cover Grade A and B recommended services without cost sharing in traditional Medicaid. It is not clear what the USPSTF recommendation, if finalized, will mean for coverage of components of PrEP care beyond the medication itself, such as provider visits and laboratory tests.

Addressing issues of consent, confidentiality, and payment that pose barriers to PrEP for adolescents and young adults has been one of the top priorities in various jurisdictions within the United States. As policymakers and HIV community stakeholders consider options for improving access to PrEP and supporting effective HIV prevention for adolescents and young adults, it is important for them to understand the policy and program approaches undertaken in other jurisdictions so they can identify best practices and learn from the challenges faced by others. This brief report is a collection of select examples of how three jurisdictions have sought to overcome consent, confidentiality, and payment barriers to PrEP access for adolescents and young adults.

Colorado

Minor Consent

In May 2016, the Colorado General Assembly approved legislation to modernize statutes related to STIs.[8] The legislation, Senate Bill 146 (SB 146), was signed by Colorado Governor John Hickenlooper on June 6, 2016. SB 146 repealed two HIV criminalization statutes, reformed another HIV criminalization statute, and standardized and modernized

<table>
<tr><th colspan="3">Colorado Statutes on Minor Consent for HIV and STI Testing, Treatment, and Prevention</th></tr>
<tr><td></td><td>Before July 1, 2016</td><td>After July 1, 2016</td></tr>
<tr><td>HIV Testing and Treatment</td><td>“Any county, district, or municipal public health agency, state institution or facility, medical practitioner, or public or private hospital or clinic may examine and provide treatment for HIV infection for any minor if such physician or facility is qualified to provide such examination and treatment. The consent of the parent or guardian of such minor shall not be a prerequisite to such examination and treatment.”</td><td rowspan="3">“(1) (a) A health care provider or facility, if consulted by a patient who is a minor, shall perform, at the minor’s request, a diagnostic examination for a sexually transmitted infection. The health care provider or facility shall treat the minor for a sexually transmitted infection, if necessary; discuss prevention measures, where applicable; and include appropriate therapies and prescriptions.”

“(2) The consent of a parent or legal guardian is not a prerequisite for a minor to receive a consultation, examination, or treatment for sexually transmitted infections. For the purposes of this section, health care provided to a minor is confidential, and information related to that care must not be divulged to any person other than the minor; except that the reporting required pursuant to the “Child Protection Act of 1987,” part 3 of article 3 of title 19, C.R.S., still applies. . . .”</td></tr>
<tr><td>STI Testing and Treatment</td><td>“Any physician . . . with the consent of the minor patient, may make a diagnostic examination for sexually transmitted infection and may prescribe for and treat the minor patient for sexually transmitted infection without the consent of or notification to the parent or guardian . . . .”</td></tr>
<tr><td>HIV and STI Prevention, including PrEP</td><td>Not specified.</td></tr>
</table>

statutory language addressing STIs, including HIV. While initial versions of what ultimately became SB 146 were focused on reforming Colorado’s HIV criminalization laws, the final enactment was broader and contained provisions that allow minors to consent to HIV and STI services, including prevention services such as PrEP. The Colorado Mod Squad (“mod” is short for modernization), a decriminalization task force led by the Positive Women’s Network–USA Colorado and formerly known as the HIV Decriminalization Task Force, conceived of and helped to develop SB 146, advocating for the inclusion of minor consent language. At least one member of the Mod Squad was at the General Assembly every single day of the 2016 legislative session to support the passage of the legislation, highlighting the need for consistent advocacy to achieve policy change.

Prior to the 2016 legislation, the law in Colorado expressly allowed minors to consent to HIV testing and treatment services but did not mention prevention services. Under the old law, HIV was dealt with under statutory provisions separate from other STIs, which at the time the law defined as not including HIV. The 2016 legislation first redefined STIs to include HIV along with chlamydia, syphilis, gonorrhea, and other infections, and then added statutory language to allow minors to consent to PrEP without the consent and notification of a parent. It specifies that, where applicable, a health care provider shall discuss prevention measures with a minor and include appropriate therapies and prescriptions. The new law took effect on July 1, 2016.

Confidentiality

While advocacy around consent and PrEP generally focuses on minors, issues related to confidentiality and PrEP also arise for young adults who are able to consent to receive PrEP. Like minors, young adults who are covered by their parents’ health insurance worry about breaches of confidentiality if insurance companies mail an EOB or other documents to their parents. This is particularly relevant because the Affordable Care Act (ACA) permits young adults up to age 26 to remain on their parents’ health insurance plans.

Prior to the 2016 legislation, the law in Colorado expressly allowed minors to consent to HIV testing and treatment services but did not mention prevention services.

Protecting confidentiality comes down to a mixture of federal and state laws. Federal law provides some mechanisms for protecting confidentiality. For example, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule establishes that health care providers or insurers may deny a personal representative access to medical records if a patient, including a minor, may be subjected to domestic violence, abuse, or neglect by the representative.[9] The HIPAA privacy rule also allows patients, including minors who have consented to their own care, to

Lessons Learned: Colorado Legislation Allowing Minors to Consent to PrEP and Other Prevention Services

Efforts to reform minor consent laws can be complex and time intensive. While there is no blueprint for success, policymakers and HIV community stakeholders in other jurisdictions may consider potential lessons learned from the successful effort in Colorado:

- **Framing the Issues:** Legislation enacted in Colorado was framed in terms of public health modernization. Allowing minors to consent to prevention services, which include PrEP, was part of the legislation but was not the sole or main focus. Such an omnibus legislation approach may make it easier for some legislators to vote for proposals that they would have a hard time justifying to their constituents if each proposal was voted on separately. Proposals may be less likely to attract critical attention if placed in a broader context.
- **Navigating Points of Contention:** One disadvantage of the omnibus legislation approach is that continuous issues could potentially threaten the entire legislation. In the context of PrEP, as well as more generally, the notion of minor consent without parental consent is contentious. For many Colorado legislators, it was more controversial than modernizing HIV criminalization laws. Prior to the 2016 legislation, minors in Colorado could be tested and treated for HIV without the consent of or notification to a parent or guardian, but some legislators had been uncomfortable with that aspect of the existing law—even before any move to further liberalize it.
- **Bridging the HIV-STI Divide:** Many people considered HIV and sexually transmitted infections (STIs) to be completely separate issues in the past, and some people still think of them separately today. The responses to HIV and STIs evolved along separate paths, with different affected populations, workforces, and funding streams, as well as different statutory and regulatory provisions. This divide has changed over time, creating opportunities to integrate HIV and STI provisions and avoid challenges related to reforming minor consent laws for HIV only or for STIs only.
- **Engaging People Living with HIV:** It is important to have HIV community stakeholders at the table and leading the advocacy. The legal reform in Colorado was achieved with the meaningful involvement of people living with HIV in a coalition of grassroots activists, community leaders, lobbyists, medical experts, and other stakeholders.
- **Fostering Bipartisan Allies:** Colorado is often considered to be a “purple” state, where voters do not predominantly choose either the Republican Party or the Democratic Party. At the time the Colorado legislation was approved, Democrats controlled the state House of Representatives and Republicans controlled the state Senate. This required advocates to work with members of both parties.
- **Building Broad Support:** The Colorado Department of Public Health and the Colorado Organizations Responding to AIDS (CORA) supported legal reform in Colorado. Obtaining buy-in from health officials and organizations could be crucial to expanding access to PrEP for adolescents and young adults in other jurisdictions.

request that health care providers and insurers place certain restrictions on disclosure of their protected health information.[10] Although health care providers and insurers are not required to agree to these requests, if they do agree, they must comply and honor the request if the health care has been fully paid for by anyone other than the insurer.[11] Moreover, the HIPAA privacy rule requires that health care providers accommodate reasonable requests by patients to receive protected health information “by an alternative means or at alternative locations” and that insurers do the same if the patient clearly states that the disclosure of all or part of that information could endanger him or her.[12] Many young people receive services funded by government programs. Additional protections for confidentiality are contained in federal statutes and regulations governing the Title X Family Planning Program, Medicaid, and other programs.

Beyond HIPAA and other basic protections contained in federal statutes and regulations, state law provides the primary mechanism for protecting the confidentiality of health information. As part of its laws, Colorado has specific statutes governing EOBs, which are relevant to confidentiality related to PrEP access for young adults. The Colorado Division of Insurance has issued regulations requiring an insurance carrier in the state to ensure confidential communication between the carrier and a covered adult child of a policyholder.[13] The regulations state that information may not be sent to the policyholder without prior consent of the covered adult child.[14] This is a striking development to give young adults on their parents’ insurance plans control over access to EOBs and other confidential information.

The Colorado insurance regulation is not without its shortcomings. First and foremost, the regulation only applies to adult children of policyholders and provides no confidentiality protections for non-adult children, i.e., those under the age of 18. While minors in Colorado can consent to PrEP, they still face the risk that an insurer could mail an EOB to their parents. Second, since many covered adult children may have the same address as their parents, there is still some possibility that breaches of confidentiality could occur even if the EOB is

not addressed to parents. One potential solution is to require or support insurers to allow electronic communications as well as to make necessary technical changes to redirect communications to alternative locations. Third, a regulation is only as effective as its implementation and enforcement. Litigation may be needed when insurers in Colorado violate the regulation. Even in jurisdictions without a regulation like Colorado's, insurers often have their own confidentiality policies that could be the basis for litigation if they are not followed.

New York

Minor Consent

Amendments to New York State health regulations allow minors to consent to their own HIV treatment and prevention services, such as PrEP, without parental involvement.[15] On December 14, 2016, the New York State Department of Health published proposed amendments to health regulations to allow minors to consent to the treatment and prevention of HIV infection. These amendments were in furtherance of Governor Andrew Cuomo's plan to end HIV/AIDS in New York State by 2020, and followed a series of activities, including a statewide forum on PrEP for adolescents, hosted by the New York State Department of Health AIDS Institute in November 2015.[16] The amendments went into effect on April 12, 2017.

The old law treated HIV differently from STIs, and minors could not consent on their own to HIV treatment and PrEP.

Prior to the new amendments, minors in New York State could consent on their own to the provision of reproductive and sexual health care, including medical treatment to diagnose, prevent, and manage STIs. But the old law treated HIV differently from STIs, and minors could not consent on their own to HIV treatment and PrEP. One amendment changed the regulations to include HIV on the Group B list of STIs along with human papillomavirus (HPV) and genital herpes simplex. The regulations were also amended to include prevention services within the definition of treatment for persons who are infected or are suspected to be at risk of being infected with an STI. The impact of the amendments was that minors under the age of 18 became able to consent to treatment and prevention services for HIV as well as for other Group B STIs. So now under New York State law, a health care provider may prescribe HIV treatment or PrEP to a minor without the consent of the minor's parent, and medical and billing records cannot be released to a parent without the minor's permission.

Payment

A range of payment options now exist for adolescents and young adults in New York State to access PrEP, but more policy reform and education may be needed to inform young people and facilitate access to PrEP.[17] New York State Medicaid, through its fee-for-service program and Medicaid managed care plans, covers PrEP for adults and adolescents, including PrEP medication costs, medical appointments, and lab tests. Fee-for-service Medicaid does not issue EOBs, so this program avoids the risk of confidentiality breaches for adolescents and young adults. However, Medicaid managed care plans do send notice upon a service or claim denial, so adolescents and young adults on these plans should be advised to work with their plans or providers to arrange for notices to be sent to an alternative address.

Outside of Medicaid, the PrEP Assistance Program (PrEP-AP) in New York State serves adolescents and adults who reside in the state, are uninsured or underinsured, and have been prescribed PrEP. PrEP-AP covers the cost of medical appointments and lab tests, but does not cover the cost of PrEP medication. While Gilead Sciences—the manufacturer of Truvada, the only FDA-approved medication for PrEP—offers patient assistance programs to help cover prescription costs, minors may find it difficult to access and use these programs. For individuals under the age of 18, a patient representative may need to attest or sign on the minor's behalf, which may present a barrier for those who have not disclosed their sexual orientation or risk behaviors to their parents. In such cases, providers at adolescent and young adult specialized care centers funded by the New York State Department of Health can provide information and assistance in navigating payment options. There are also other options for low-cost access to PrEP in New York City.

California

Confidentiality

In California, a minor who is 12 years of age or older may consent to medical care related to the prevention of HIV and other STIs.[18] Disclosure of this confidential health information to parents is not permitted without the signed consent of the minor. Effective January 1, 2015, the Confidential Health Information Act (CHIA), which amended California's Confidentiality of Medical Information Act, requires that health plans allow enrollees who are legally authorized to consent to care to request an alternative method to receive EOBs, including having the EOBs sent to an alternative mailing address or be made available electronically to the enrollee.[19,20] CHIA requires health plans to allow patients or clinicians to further request that EOBs not be sent to policyholders for sensitive services, such as HIV and STI services, including PrEP, if the disclosure of this information could endanger the patient.

Payment

San Francisco created an "Emergency Youth Truvada Fund" to help overcome cost barriers.[21] The Emergency Youth Truvada Fund is available to youth aged 15–24 in San Francisco who otherwise would be unable to access PrEP. The fund is available to youth under the age of 15 on a case-by-case basis. This funding is limited, however, and is not sufficient to meet long-term needs. Additional sources of funding are necessary to ensure that adolescents and young adults can have access to PrEP.

Conclusion

This report has discussed a number of examples and case studies from different jurisdictions related to overcoming consent, confidentiality, and payment barriers that adolescents and young adults face in accessing PrEP. As more jurisdictions seek to improve access to PrEP for adolescents and young adults, it is important to identify and share best practices and lessons learned for reforming laws and policies.

Prepared for amfAR by Sean E. Bland
O'Neill Institute for National and Global Health Law, Georgetown Law, March 2019

This issue brief was developed independently of, but informed by, an expert consultation meeting held in Washington, DC, in December 2016. The meeting brought together approximately 30 diverse stakeholders, including youth, adolescent providers, child psychologists, people living with HIV, HIV medical and non-medical providers, researchers, lawyers, ethicists, and policy experts. The author thanks and acknowledges all those who participated in the meeting.

REFERENCES

1. National Institutes of Health. Item of Interest: FDA Approves PrEP Therapy for Adolescents at Risk for HIV. https://www.nichd.nih.gov/newsroom/releases/051618-PrEP. Published May 16, 2018. Accessed October 10, 2018.
2. Centers for Disease Control and Prevention. HIV Among Youth. https://www.cdc.gov/hiv/group/age/youth/index.html. Published April 20, 2018. Accessed October 10, 2018.
3. Ibid.
4. Ibid.
5. Ibid.
6. Ibid.
7. U.S. Preventive Services Task Force. Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis. https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. Published November 2018. Accessed March 7, 2019.
8. Law V. Activists win legislative overhaul of Colorado's HIV criminalization laws, await governor's signature. *The Body*. http://www.thebody.com/content/77636/activists-win-legislative-overhaul-of-colorados-hi.html. Published May 24, 2016. Accessed October 10, 2018.
9. *See* 45 C.F.R. §164.502(g).
10. 45 C.F.R. §164.522(a)(1).
11. Ibid.
12. 45 C.F.R. §164.522(b)(1).
13. 3 Colo. Code Regs. §702-4:4-2-35, Sec. 6.
14. Ibid.
15. 10 N.Y. Codes R. & Regs. Part 23.
16. Hansen MB. *PrEP for Adolescents: Successes, Challenges, & Opportunities.* https://cdn.hivguidelines.org/wp-content/uploads/20160825080651/HIVG_AdolescentPrep_Meeting-report_final_02-18-20161.pdf. Published November 18, 2015. Accessed October 10, 2018.
17. New York State Department of Health AIDS Institute. *Payment Options for Adults and Adolescents for Pre-Exposure Prophylaxis (PrEP).* https://www.health.ny.gov/diseases/aids/general/prep/docs/prep_payment_options.pdf. Published August 2018. Accessed October 10, 2018.
18. Cal. Fam. Code §6926.
19. Cal. Civ. Code §56.107.
20. Kahn L. *New California Health Privacy Law Goes into Effect.* https://www.insideprivacy.com/health-privacy/new-california-health-privacy-law-goes-into-effect/. Published January 9, 2015. Accessed October 10, 2018.
21. Land E. *Teen PrEP Program Ramps Up in San Francisco.* https://betablog.org/teen-prep-program-ramps-san-francisco/. Published May 10, 2017. Accessed October 10, 2018.

amfAR

MAKING AIDS HISTORY

amfAR, The Foundation for AIDS Research
www.amfar.org

Public Policy Office
1100 Vermont Avenue, NW
Suite 600
Washington, DC 20005
USA
+1.202.331.8600