

# SB 79: HIV pre- and post-exposure prophylaxis dispensation



## Executive Summary

In Missouri, over 12,000 people live with HIV, and over 500 new HIV infections are diagnosed each year. Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) medications are highly effective methods of blocking HIV infection in individuals who are at high risk of exposure, or who have been recently exposed. Currently in Missouri, clinicians may prescribe and dispense PrEP and PEP as long as the individual seeking the medication meets eligibility criteria set by the provider, such as injection drug use or sexual contact with an HIV-positive partner. In addition, Washington University in St. Louis currently collaborates with the Missouri Department of Health and Senior Services to operate pharmacy-based PrEP care, the only program of its type in the state. SB 79 would authorize licensed pharmacists to independently dispense a thirty-day supply of PrEP and a complete course of PEP. In order to dispense these medications, pharmacists must first complete a training program. Dispensation of these medications is also subject to several restrictions: those seeking PrEP must test negative for HIV, receive counseling related to the treatment, and notify their health care provider of prophylaxis treatment. Similar laws are currently in effect in Colorado, Oregon, and California.

## Highlights

- PrEP and PEP are **highly effective medications (up to 90% effective with proper adherence)** for preventing HIV infection.
- There is **no evidence of severe negative health effects** due to PrEP or PEP.
- PEP has only been demonstrated to be **effective when administered within 72 hours of a potential exposure to HIV**, so rapid access to PEP is necessary for it to be a useful treatment.
- **Black and Hispanic Missourians are disproportionately affected by HIV** but are less likely to receive therapeutics.

## Limitations

- Due to the ethics of withholding potentially life-saving medication and the difficulty of recruiting large populations, there are no randomized controlled trials demonstrating the efficacy of PEP. Instead, researchers rely on results from animal models, cases involving pregnant women, and studies of healthcare workplace exposures to HIV.
- Similar legislation has been in effect in CO, OR, and CA for under two years, so it is difficult to conclusively assess the effect this policy has had elsewhere.

## Research Background

### PrEP and PEP prevent HIV infection

Human immunodeficiency virus (HIV) is a type of virus that, if left untreated, can severely weaken the immune system's ability to fight off other infections. This condition is known as acquired immunodeficiency syndrome (AIDS), and leads to about 150 deaths in Missouri per year.<sup>1</sup> HIV can be transmitted through blood or sexual contact; common transmission routes also include sharing used needles and childbirth. Most HIV cases in Missouri are disproportionately located in St. Louis and Kansas City, and affect Black and Hispanic Missourians at rates that are 9.3 and 3.4 times greater than White populations, respectively.<sup>1</sup> Currently, medications known as antiretrovirals are available to treat HIV infections by decreasing the amount of virus present, and slowing or preventing the development of AIDS.

Since 2012, pre-exposure prophylaxis (PrEP) medication has been approved by the FDA as a means of reducing the risk of new HIV infections. Currently two similar drugs (brand names Truvada® and Descovy®) are available as pills that can be taken daily to prevent HIV infection. These prescriptions are intended for people who do not have HIV but are at a high risk of exposure, such as injection drug users or those with HIV-positive sexual partners. Many large-scale, placebo-controlled studies demonstrate the efficacy of PrEP in reducing the risk of HIV infection across many different scenarios (e.g., sexual exposure, injection drug use, incidental exposure). Across demographic groups and contexts, PrEP has consistently been demonstrated to provide a 50 to 90% reduction in the risk of contracting HIV (efficacy can vary based on type of exposure and drug resistance properties of the particular HIV strain, for example), but proper adherence to dosing schedules is necessary for achieving high efficacy.<sup>2,3,4</sup> There is not evidence that taking PrEP leads individuals to engage in riskier behaviors that would offset the benefits of PrEP.<sup>3</sup>

Another pharmaceutical intervention to prevent HIV infection is post-exposure prophylaxis (PEP). This medication is a short-term (typically ~28 day) regimen that reduces the risk of HIV infection if administered shortly after exposure. Crucially, PEP is most effective (as high 80%) when administered within 36 to 72 hours of exposure, and when the drug regimen is adhered to fully.<sup>5</sup> Much of the evidence for PEP's effectiveness comes from animal studies and observational case studies due to the ethical concerns of withholding PEP for a placebo-controlled study. Notably, infants born to mothers with HIV who are administered PEP within 48 hours of delivery contract HIV at lower rates than infants who did not receive PEP, and healthcare workers who experience occupational exposure but receive PEP are less likely to contract HIV than workers who did not receive treatment.<sup>5</sup>

Both PrEP and PEP are safe for repeated use, as the most common side effects are nausea and gastrointestinal irritation. There is a small risk of reversible kidney toxicity in people who use PrEP for several years, so patients receiving PrEP treatment are often required to have their kidney function monitored at regular intervals.<sup>4</sup>

## Barriers to PrEP and PEP access

Despite the demonstrated efficacy of PrEP and PEP and the at-risk population in Missouri, Missouri's uptake of these drugs remains lower than average. In Missouri, there are only 51 PrEP users per 100,000 residents, compared to the U.S. average of 68.<sup>6</sup> This low uptake rate persists despite the fact that the CDC has identified Missouri as at-risk for HIV outbreaks, and has identified 13 MO counties as being in the top 5% of U.S. counties most vulnerable to HIV outbreaks. Nationally, the CDC estimates that only 18% of people who are candidates for PrEP treatment have received it. Males and White populations are more likely than females and Black or Hispanic populations to receive PrEP, indicating that barriers to access persist.<sup>6</sup>

Survey data indicate that barriers such as stigma, cost, drug availability, and information availability prevent patients from receiving PrEP and PEP treatment. Many individuals report that they are uncomfortable discussing their sexual behavior or orientation with primary care providers, and are less likely to ask for PrEP if they have an HIV-positive partner.<sup>7</sup> Although most private insurers and Medicaid cover prescription and testing costs, the time costs associated with follow-up appointments and monitoring may prevent some people from accessing PrEP, particularly if they do not have a provider located nearby.<sup>4</sup> A collaborative practice telemedicine program in Iowa (called PrEPIOWA) was launched in 2017 to allow pharmacists to prescribe PrEP remotely, providing a potential pathway to removing geographic access barriers.<sup>8</sup> Finally, many individuals are simply unaware of PrEP/PEP, and healthcare providers may be resistant to recommending or prescribing these medications.<sup>9</sup>

## References

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