# SB355\_NCPA\_fav.pdf Uploaded by: Belawoe Akwakoku Position: FAV



February 10, 2022

The Honorable Paul G. Pinsky, Chairman
The Honorable Cheryl Kagan, Vice-Chairwoman
Education, Health and Environmental Affairs Committee
Miller Senate Office Building
11 Bladen Street, Room 2 West Wing
Annapolis Maryland, MD 21401

#### RE: NATIONAL COMMUNITY PHARMACISTS ASSOCIATION IN SUPPORT OF SB355

Dear Chair Pinsky, Vice Chair Kagan and committee members:

I am writing to you on behalf of the National Community Pharmacists Association in support of **SB 355**. This legislation would increase patient access to human immunodefiency virus (HIV) pre-exposure (PEP) and post-exposure (PEP) medications, and result in HIV related cost saving while combating the spread of the virus by identifying the virus early and preventing disease progression.

NCPA represents the interest of American's community pharmacists, including owners of more than 19,400 independent community pharmacies acoss the United States and 395 independent pharmacies in Maryland. These Maryland pharmacies filled over 22 million prescriptions last year, impacting the lives of thousands of patients in your state.

Over 90% of Americans live within five miles of a community pharmacy<sup>1</sup>. More than any other segment of the pharmacy industry, independent community pharamcists are often located in the most nderserved rural and urban areas and are frequently the most accessible healthcare providers in many communities and are critical for the provision of immunizations and other preventatieve care service in the community.. in addition, community pharmacists are proud to play a vital role in Maryland's efforts to increase access to PrEP and PEP medications statewide. Access to pharmacy care services along with HIV PrEP and PEP medications will play a critical role in combating the HIV epidemic and staving off costly downsteream medical interventions.

NCPA applauds the mandatory coverage language in SB355. Mandatory coverage provisions for pharamcists provided preventative health care services is paramount to the intended success of SB355. NCPA emphasizes that pharmacists undergo a minimum of six years of comprehensive undergraduate and professional education. Pharmacists' training in clinical services, disease state management, interpretation of lab data will be appropriately utilizied and compensated for recognizing pharamacists as a competent arm in cobating the HIV epidemic and improving patient's lives within the state of Maryland.

100 Daingerfield Road Alexandria, VA 22314-2888 703.683.8200 PHONE 703.683.3619 FAX

<sup>&</sup>lt;sup>1</sup> NCPDP Pharmacy File, ArcGIS Census Tract File, NACDS Economics Department.

Like other medical professions, the pharmacy profession has evolved from dispensing and product reimbursement based industry to a profession with the *training* and patient *relationships* to provide outcomes-based services and participate in care coordination efforts. <sup>2</sup> NCPA supports SB 355 required the Maryland Board f Pharmacy to adopt an approved pharmacists training program for PrEP and PEP medications and services. The training program will aim to address the challenges and knowledge gaps, including but not limited to, counseling unique populations, recommending appropriate vaccinations, understanding HIV disease state, HIV medications along with how and when to exercise appropriate patient follow-up, and refering the patient to necessary resources and healthcare providers.

Such a training program will optimize efforts in supporting all facets of the patient's experience relating to PrEP and PEP services and ensure a high standard of care in carring out the responsibilities aligned with lowering rates of HIV infection throughout the state.

SB 355 would increase patient access to HIV PrEP and PEP medications and aid in reducing spending related to HIV care while challenging the progression of the disease. To protect Marylanders, we respectfully ask you to support SB 335. If you have any questions about the information contained in this letter or wish to discuss the issue in greater detail, please do not hesitate to contact me at <a href="mailto:belawoe.akwakoku@ncpa.org">belawoe.akwakoku@ncpa.org</a> or (703) 600-1179.

Sincerely,

Belawoe Akwakoku

State Government Affairs Manager

Belowe ahwakaku

**National Community Pharmacists Association** 

<sup>&</sup>lt;sup>2</sup> Troy Trygstad, *Payment Reform Meets Pharmacy Practice and Education Transformation*, 78 North Carolina Med. J. 3 at 173 -176 (May-June 2017), available at <a href="http://www.ncmedicaljournal.com/content/8/3/173.full.pdf+html">http://www.ncmedicaljournal.com/content/8/3/173.full.pdf+html</a>

# LAM\_SB0355\_FAV.pdf Uploaded by: Clarence Lam Position: FAV

#### CLARENCE K. LAM, M.D., M.P.H.

Legislative District 12
Baltimore and Howard Counties

Education, Health, and Environmental Affairs

Committee

Chair, Environment Subcommittee

Chair, Environment Subcommittee

Executive Nominations Committee

Joint Committee on Ending Homelessness

Senate Chair

Joint Audit and Evaluation Committee Joint Committee on Fair Practices and State Personnel Oversight

Vice Chair

Baltimore County Senate Delegation

Chair

Howard County Senate Delegation

Chair

Asian-American & Pacific-Islander Caucus



## THE SENATE OF MARYLAND Annapolis, Maryland 21401

Miller Senate Office Building 11 Bladen Street, Room 420 Annapolis, Maryland 21401 410-841-3653 · 301-858-3653 800-492-7122 Ext. 3653 Clarence.Lam@senate.state.md.us

### SB 355 - HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements

#### **Background**

- Human immunodeficiency virus (HIV) is a virus that attacks the body's immune system and can lead to Acquired Immunodeficiency Syndrome (AIDS) if left untreated.
- SB355 is an ammended reintroduction of SB 828 which was first introduced in 2021 with updated language drafted upon consultation with stakeholders and advocates.

#### Why SB 355 is Needed

- In 2020, there were 31,676 people living with diagnosed HIV in Maryland, including 724 patients newly diagnosed that year.
- Compared to other states, Maryland has high rates of new HIV infections.
  - Maryland was ranked 8th among states in adult and adolescent HIV diagnosis rates in 2019.<sup>1</sup>
  - Of those living with HIV in the state, 67% have suppressed viral loads and 77% are engaged in treatment for their HIV.
- Medications for pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are effective at preventing the transmission of HIV; the Centers for Disease Control (CDC) estimates that, when taken as directed, PrEP can reduce the risk of sexual transmission by greater than 90%.

<sup>&</sup>lt;sup>1</sup> Maryland Department of Health

- Accessing these medications can be difficult for people without a primary care physician or those living in rural areas. PEP is most effective when taken within 72 hours of an exposure; the inability to see a provider within that time window in order to secure a prescription may prove to be highly consequential.
- The COVID-19 pandemic has greatly disrupted access to PrEP and PEP. One study in Boston found a 72% reduction in PrEP initiation and a 191% increase in PrEP refill lapses in just four months.<sup>2</sup>
- Community pharmacists are not only accessible for patients but they are highly well-regarded health care professionals. Given approximately 90% of Americans live within five miles of a pharmacy, pharmacists have a unique ability to expand preventive services and medication accessibility.<sup>3</sup>

#### What SB 355 Does

- SB 355 authorizes pharmacists to prescribe up to a 60-day supply of PrEP to HIV-negative individuals with subsequent prescriptions needing to be prescribed from a physician.
- SB 355 authorizes pharmacists to prescribe a complete course of PEP to individuals screened to have been exposed to HIV within the past 72 hours consistent with CDC.
- In each case, patients will undergo post encounter counseling at the pharmacy to be appraised of treatment protocols and the importance of phsylician-based continuum of care.
- Pharmacists will notify the patient's primary care physician (PCP).
- Patients without a PCP or or those unwilling to identify one will be provided a list of providers within their area including a list of Ryan White endorsed clinics which are specialized in preventing the spread of HIV care.
- Patients with eligible health plans will not be subject to any cost-share for either PrEP or PEP within this pathway.

#### What SB 355 Accomplishes

- SB 355 would improve public health by facilitating increased access points to PrEP and PEP by allowing pharmacists to prescribe and dispense limited supplies.
- California, Oregon, and Colorado permit pharmacists to prescribe and dispense PrEP and PEP<sup>4</sup>
- SB 355 expands accesspoints to therapeutic medication to mitigate the contraction and spread of HIV.
- SB 355 trains pharmacists on how to properly prescribe and administer PrEP and PEP.

<sup>&</sup>lt;sup>2</sup> Mascolini M. COVID-19 disrupts PrEP starts, refills, HIV/STI testing in Boston clinic. AIDS 2020, 2020.

<sup>&</sup>lt;sup>3</sup> Qato DM, Zenk S, Wilder J, Harrington R, Gaskin D, Alexander GC. The availability of pharmacies in the United States: 2007-2015. *PLoS One*. 2017;12(8):e0183172. Published 2017 Aug 16. doi:10.1371/journal.pone.0183172

<sup>&</sup>lt;sup>4</sup> Zhao A, Dangerfield DT 2nd, Nunn A, et al. Pharmacy-Based Interventions to Increase Use of HIV Pre-exposure Prophylaxis in the United States: A Scoping Review [published online ahead of print, 2021 Oct 20]. *AIDS Behav.* 2021;1-16. doi:10.1007/s10461-021-03494-4

## **SB 355 - Annapolis Pride - Statement of Support -** Uploaded by: Eric Lund

Position: FAV



### SB 335 - HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements

#### **Education, Health, and Environmental Affairs**

**Position: SUPPORT** 

We, the board of directors of Annapolis Pride, support SB 0335, The HIV Prevention Act. Annapolis Pride is a grassroots organization that advocates for the LGBTQ+ county residents, their families, and allies.

It was not that long ago that a diagnosis of HIV was a death sentence. Medical professionals, researchers, advocates, and activists have worked hard to change that stark diagnosis. Although no longer terminal, it is still a chronic condition to be managed throughout one's lifetime.

Maryland has made good strides in reducing the number of yearly HIV infections but there are still challenges to be met. At the end of 2020, there were 31,676 people aged 13+ living with diagnosed HIV in Maryland. Maryland was ranked 8th among states and territories in adult/adolescent HIV diagnosis rates (per 100,000) in 2019.

As the Covid-19 numbers decrease and we emerge from the pandemic and isolation, it is not unreasonable to expect an increase in other infection rates as we begin to return to more socialization. But there are existing medications to help prevent an increase in HIV infections. Much of the challenge in preventing the spread of HIV is access to these simple treatments. By extending certain prescribing privileges to pharmacists, we will help streamline access to patients that might otherwise find it difficult to navigate the usual healthcare process.

This also opens the door to directly engage and educate patients through local and trusted pharmacists already in the community.

Through this bill we would allow people easier access to this life saving medication and treatments and help build a healthier Maryland.

We respectfully urge this committee to issue a favorable report for SB 355.

## SB0355 2022-02-08 Testimony of FreeState Justice t Uploaded by: Ian Bravo

Position: FAV



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www.freestate-justice.org

February 8, 2022

The Honorable Paul G. Pinsky Senate Education, Health, and Environmental Affairs Committee Miller Senate Office Building Annapolis, Maryland 21401

#### **Testimony of FreeState Justice**

#### IN SUPPORT OF

#### SB355: HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements

To the Honorable Chair Paul Pinsky, Vice Chair Cheryl Kagan, and esteemed members of the Education, Health, and Environmental **Affairs Committee:** 

FreeState Justice is Maryland's lesbian, gay, bisexual, transgender, and queer (LGBTQ) civil rights advocacy organization. Each year, we provide free legal services to dozens, if not hundreds, of LGBTQ+ Marylanders who could not otherwise be able to afford an attorney, as well as advocate more broadly on behalf of the LGBTQ+ community.

We write today in support of Senate Bill 355, which expands access to HIV prevention medications by expanding insurance coverage, limiting the ability of insurers to require pre-authorization before medication can be dispensed, and permitting pharmacists to dispense initial prescriptions of HIV prevention medications under limited circumstances. We strongly believe these provisions will help to minimize the spread of HIV in Maryland.

Antiretroviral drugs have been used since the late 1980s as a form of treatment for people living with AIDS. Beginning in the 1990s, antiretrovirals have also been used preemptively to prevent the

#### LEADERSHIP STAFE

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Dylan Burns

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Jave Yarbrough

transmission of HIV, first in the form of post-exposure prophylaxis (PEP), and more recently as pre-exposure prophylaxis (PrEP).

PEP is often prescribed to individuals who have been unintentionally or unknowingly exposed to HIV, and, when begun within 72 hours of exposure, can significantly reduce the risk of contracting HIV. While PEP was initially used primarily occupationally by healthcare providers who were exposed to HIV or to prevent transmission to infants at the time of birth, the Department of Health and Human Services has recommended the non-occupational use of PEP in a variety of circumstances since 2005, including condom breakage, unprotected sex with an anonymous partner, or needle sharing. Although it is typically easy to obtain a PEP prescription for its original occupational uses (as they take place within a healthcare setting), the 72 hour time limit to start PEP can be a significant barrier in non-occupational situations.

PrEP, on the other hand, is an antiretroviral medication that, when taken in advance of exposure, significantly reduces the likelihood the individual will contract HIV. When taken as prescribed, PrEP can reduce the risk of contracting HIV by 99%, virtually eliminating new HIV cases. The first PrEP medication, Truvada, was approved by the Food and Drug Administration in 2012, with other medications following over the past decade, including most recently Apretude, an extended-release injectable that patients need to take only once every two months instead of daily.

While both PEP and PrEP dramatically decrease the risk to users of contracting HIV, significant barriers prevent their uptake. In addition to requiring a physician's prescription, PEP and especially PrEP often require insurance pre-authorization. The delays brought about by these barriers can cause at-risk individuals to miss their critical 72 hour window to take PEP or to miss out on the protection of PrEP before unintentional exposure. By limiting the ability of insurers to require pre-authorization for the use of PEP and PrEP, Senate Bill 355 ensures Marylanders will not miss out on their protection simply because they are waiting for a decision.

Furthermore, Senate Bill 355 also expands access to PEP and PrEP by reducing the barriers to obtaining an initial prescription. Under SB355, pharmacists may dispense an initial 60-day prescription of PEP or PrEP without a physician's prescription, in a method similar to how Maryland pharmacists may prescribe emergency contraception behind the counter. Pharmacies are significantly more accessible to individuals without primary care providers, have more flexible hours than many medical provider offices, and generally do not require appointments in advance, something that is especially critical where individuals are unable to make an appointment with a physician in timely manner or where time is of the essence, such as during the 72 hour window for PEP.

Significant protections remain in place, however, to ensure that individuals are not prescribed PEP or PrEP inappropriately and that they follow up with a physician. In addition to requiring extensive, non-waivable counseling on taking the medication (including side effects, the importance of following the medication regimen precisely, and the need for continued testing for a variety of sexually-transmitted infections), Senate Bill 355 also requires pharmacists to verify that the patient is not already HIV+, either by submission of a test done within the prior 7 days or by doing an instant test at point of service. In the event that the individual tests positive, the pharmacist is to provide them with a list of referrals to health care providers specialized in the treatment of HIV/AIDS. Together with the 60 day limit on pharmacist prescriptions, these provisions ensure that individuals will not be able to obtain long-term access to medication without a doctor's oversight.

By authorizing pharmacists to prescribe and dispense PEP and PrEP to patients, SB355 taps into the under-recognized potential of pharmacists' roles in HIV prevention and contributes greatly to public health through expanding patients' accessibility to life changing medication, and allowing PEP and PrEP to reach a broader population of community members.

For these reasons, FreeState Justice urges a favorable report on Senate Bill 355.

## **HIV - pharmacists - testimony - senate - 2022 - S** Uploaded by: Lisae C Jordan

Position: FAV



#### Working to end sexual violence in Maryland

P.O. Box 8782 Silver Spring, MD 20907 Phone: 301-565-2277 Fax: 301-565-3619 For more information contact: Lisae C. Jordan, Esquire 443-995-5544 www.mcasa.org

#### Testimony in Support of Senate Bill 355 Lisae C. Jordan, Executive Director & Counsel February 10, 2022

The Maryland Coalition Against Sexual Assault (MCASA) is a non-profit membership organization that includes the State's seventeen rape crisis centers, law enforcement, mental health and health care providers, attorneys, educators, survivors of sexual violence and other concerned individuals. MCASA includes the Sexual Assault Legal Institute (SALI), a statewide legal services provider for survivors of sexual assault. MCASA represents the unified voice and combined energy of all of its members working to eliminate sexual violence in the State of Maryland. We urge the Education, Health & Environmental Affairs and Finance Committees to report favorably on Senate Bill 355.

#### Senate Bill 355 – Preventing HIV for Rape Survivors, Sex Workers, and Others

This bill expands availability of nPEP (post-exposure treatment to prevent HIV infection) and nPrEP (preventative treatment to prevent HIV infection) by permitting pharmacists to dispense the medication. Critically, this bill also prohibits insurance companies from requiring preauthorization in order to provide insurance coverage. SB355 would help rape survivors, sex workers, and others prevent HIV infection.

One of the risks faced by rape survivors is HIV infection.<sup>1</sup> Studies of HIV transmission have been based on consensual sexual activity, and do not account for the violence of rape, so it is unclear what the risk level is, however, 91.9% of rape victims reported some degree of initial fear or concern for contracting HIV and 72.6% reported extreme fear or concern for contracting HIV.<sup>2</sup> However, the cost of medication along with the short window to start effective treatment can be a major deterrent to receiving care.<sup>3</sup> Treatment must begin within 72 hours of the assault and the cost of a full treatment regimen can range from \$1,500 to over \$3,000 depending on health insurance coverage.<sup>4,5</sup>

In response, since 2019, rape survivors have been provided with access to medication to prevent HIV infection after a sexual assault. Criminal Procedure Article §11-1008. Upon request of a rape victim, and with a prescription from his or her medical provider, the State will pay for the full course of HIV prevention treatment known as non-occupational post exposure prophylaxis (nPEP). Follow-up care for

<sup>&</sup>lt;sup>1</sup> Draughon, J. (2012). Sexual Assault Injuries and Increased Risk of HIV Transmission.

<sup>&</sup>lt;sup>2</sup> Resnick, H., Monnier, J., Seals, B., Holmes, M., Walsh, J., Acierno, R., Kilpatrick, D., (2002). Rape-Related HIV Risk Concerns Among Recent Rape Victims.

<sup>&</sup>lt;sup>3</sup> Draughon Moret, J.E., Sheridan, D.J., Wenzel, J.A. (2021) "Reclaiming Control" Patient Acceptance and Adherence to HIV Post-Exposure Prophylaxis Following Sexual Assault. *Global Qualitative Nursing Research*, 8.

<sup>&</sup>lt;sup>4</sup> Center for Disease Control and Prevention (2016). *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV*. Retrieved from: https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf

<sup>&</sup>lt;sup>5</sup> Maryland Sexual Assault Evidence Kit Policy & Funding Committee (2019). *Annual Report: 2019*. Retrieved from: https://www.marylandattorneygeneral.gov/Pages/Groups/2019\_SAEK\_Committee\_Annual\_Report.pdf Daiber, D. (2018).

patients taking nPEP is also provided. This successful project is set to sunset this year and Senate Bill 331/House Bill 245 have been introduced to continue the project permanently.<sup>6</sup>

Senate Bill 355 would enhance the current nPEP for Rape Survivors project if it is continued by providing survivors with another point of access. Many survivors choose not to go the hospital following the trauma of rape, and SB355 would expand HIV prevention for these survivors. Training for pharmacists regarding responding to rape survivors can be provided by MCASA and is similar to existing training for nurses and other health care professionals.

Eliminating preauthorization requirements is a critical component of SB355. When the State fails to protect its people from crime, the least it can do is provide medication to prevent health and life destroying infections. Under the current nPEP for Rape Survivors program, patients have the option of using their insurance or not in order to protect their privacy. Survivors who decline to provide their insurance information are provided with nPEP through the criminal injuries compensation fund administered by the Governor's Office of Crime Prevention, Youth & Victim Services. Last year, a survivor presented for treatment and gave her insurance information to the health care provider. The sexual assault was recent, but the patient was nearing the end of the treatment window (72 hours).

The Medicaid provider declined to cover the nPEP medication because the rape survivor did not get preauthorization. The survivor did not get treatment. It is not known whether she now has an HIV infection.

Maryland's public policy should support rape survivors following an assault, not impose bureaucratic barriers to treatment. Insurance companies, including Medicaid providers, should be prohibited from requiring preauthorization for nPEP.

Expanded access to n-PrEP will respond to sex workers, including victims of sex trafficking.

Those engaged in trading sex are at higher risk of exposure to HIV and n-PrEP can be important to prevention of HIV infection. Condom use to prevent HIV may be refused by customer or thwarted through stealthing, the practice of removing a condom without a partner's consent and continuing to engage in sexual activities. One in three women and one in five men reported being victims of stealthing, with the women reporting being stealthed more likely to be a sex worker. Senate Bill 355 will reduce barriers to obtaining n-PrEP and also increase education about STIs and other health risks for this population.

The Maryland Coalition Against Sexual Assault
urges the
Education, Health & Environmental Affairs and Finance Committees
to report favorably on Senate Bill 355

<sup>&</sup>lt;sup>6</sup> For more information, see, Report on the Operation and Results of the Pilot Program (HIV Postexposure Prophylaxis), http://dlslibrary.state.md.us/publications/Exec/GOCPYVS/CP11-1008(e)\_2021.pdf

<sup>&</sup>lt;sup>7</sup> https://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0209779

# SB355 Written Testimony\_NSP.pdf Uploaded by: Neha Pandit Position: FAV





Associate Professor School of Pharmacy 20 N. Pine Street, PHN 417 Baltimore, MD 21201 410-706-2997 npandit@rx.umaryland.edu

February 1, 2022

The Honorable Paul G. Pinsky
Chair, Education, Health, and Environmental Affairs Committee
2 West Miller Senate Office Building
11 Bladen Street
Annapolis, MD 21401

Support: SB355 HIV Prevention Drugs- Prescribing and Dispensing by Pharmacists and Insurance Requirements

Dear Chairman Pinsky and Members of the Committee:

My name is Dr. Neha Sheth Pandit and I have been an HIV clinical pharmacist for close to 15 years. I am an Associate Professor and Vice Chair for Research and Scholarship at the University of Maryland Baltimore School of Pharmacy. I am a board-certified pharmacotherapy specialist and credentialed with the American Academy of HIV Medicine. I currently practice at the University of Maryland Midtown Campus, the THRIVE Program which cares for over 2300 people living with HIV and provides pre-exposure and post exposure HIV prophylaxis to those at risk for infection.

In 2012, the first medication for pre-exposure prophylaxis (PrEP) was approved by the Food and Drug Administration. By 2018, despite advances in the science, the uptake of PrEP use was riddled with disparities by geography, gender and other demographics. In the state of Maryland there is a disproportionate need for PrEP in females and those less than 25 and greater than 55 years of age who are at risk for HIV.<sup>1</sup>

There are significant barriers to PrEP uptake including lack of awareness and knowledge, low perception of HIV risk, social stigma, provider bias and medical distrust, lack of access, and financial barriers.<sup>2</sup> The approval of SB355 would be one of many positive steps for Maryland to overcome these barriers and to move one step closer to Ending the HIV Epidemic.

Studies have shown that pharmacists see their patients between 1.5 to 10 times more frequently than they see primary care physicians. The increased accessibility of community pharmacists will greatly improve the process for PrEP uptake. For post-exposure prophylaxis (PEP), time to antiretroviral initiation is imperative to reduce HIV risk. The accessibility of initial medications for PEP at local pharmacies would not only help educate patients of the necessity to start treatment within 72 hours but also allow patients the ability to schedule an appointment with prescribers with ease by providing appropriate resources.

Pharmacists have shown their abilities to appropriately provide these services with administration of immunizations, naloxone and oral contraceptive dispensing, in addition to administration of point of care testing. In the past year of an unprecedented pandemic, pharmacists sustained their accessibility for patients to ensure continuity of healthcare services. This policy supports the idea that pharmacists are often the first line of health care services for patients and allows for a smooth transition to a prescriber.

Lastly, SB355 provides additional support for the financial barriers for PEP and PrEP. This policy begins to ensure the cost of these medications are not prohibitive for the prevention of HIV. SB355 presents an opportunity for the State of Maryland to improve access to care, extend the public health role of trained pharmacists, and to educate the general public.

I hope that each of you will help increase the access to PrEP and PEP for Maryland constituents by issuing a favorable report on SB355.

Sincerely,

Neha Sheth Pandit, PharmD, AAHIVP, BCPS

Neha South Poundit

**Associate Professor** 

University of Maryland Baltimore School of Pharmacy

- 1. AIDSVu 2021: <a href="https://aidsvu.org/local-data/united-states/south/maryland/#prep">https://aidsvu.org/local-data/united-states/south/maryland/#prep</a>
- 2. Mayer KH, et al. Adv Ther 2020:37(5):1778-1811. Doi: 10.1007/s12325-020-01295-0.

## **2022 ACNM SB 355 Senate Side.pdf** Uploaded by: Scott Tiffin

Position: FAV



#### Support

### Senate Bill 355 – HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements

Senate Education, Health, and Environmental Affairs Committee February 10, 2022

The Maryland Affiliate of the American College of Nurse-Midwives supports *Senate Bill 355 – HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements*. The bill permits pharmacists to dispense post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) to prevent HIV in certain circumstances.

ACNM supports this legislation as a public health initiative for the following reasons:

- **Dispensing of PEP is Time Sensitive:** To be effective in preventing HIV, an individual needs to take PEP within 72 hours of potential exposure to HIV. In some circumstances, pharmacists may be in a better position to provide PEP within this time period;
- Pathway to Primary Care: Pharmacists may only provide up to 60 days of PrEP if patients meet certain clinical requirements. Then, the pharmacist must transition care to a primary care provider. This arrangement will increase the number of people who obtain PrEP and who are under the care of a primary care provider.
- Improved Insurance Coverage: Federal law requires insurance companies cover PrEP with no cost share. This bill ensures that the ancillary services patients need as part of being on PrEP are also covered.

We ask for a favorable report on this legislation. If we can provide any additional information, please contact Scott Tiffin at (443) 350-1325 or stiffin@policypartners.net.

# **2022 MNA SB 355 Senate Side.pdf**Uploaded by: Scott Tiffin Position: FAV



To: Senate Education, Health, and Environmental Affairs Committee

Bill: Senate Bill 355 – HIV Prevention Drugs - Prescribing and Dispensing by

**Pharmacists and Insurance Requirements** 

Date: February 6, 2022

**Position:** Support

The Maryland Nurses Association (MNA) supports Senate Bill 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements. The bill permits pharmacists to dispense post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) to prevent HIV in certain circumstances and improves insurance coverage for PEP and PrEP.

MNA supports this legislation because there is a compelling public health need to increase access to PEP and PrEP. This bill increases access to this life saving medication by using pharmacists to "quick start" the drug regimen and then transition care to primary care providers so that it can be managed by a patient's health care provider. The bill has well-developed safeguards to ensure that pharmacists are only dispensing these medications in the most clinically appropriate situations.

MNA also strongly supports the insurance provisions of this bill. Under federal law, insurance companies are required to cover PrEP without cost share. However, there is a lack of clarity over whether insurance companies have to cover the PrEP related ancillary services without cost sharing. If a patient is unable to access these ancillary services they are not going to be able to be prescribed PrEP.

We ask for a favorable report on this legislation. If we can provide any additional information, please contact Scott Tiffin at (443) 350-1325 or stiffin@policypartners.net.

# SB0355 testimony 20220208.pdf Uploaded by: Stephen Berry Position: FAV

#### Stephen A. Berry, MD PhD

Vice-Chair for Quality and Safety, Department of Medicine Associate Professor of Medicine Johns Hopkins School of Medicine

#### **Division of Infectious Diseases**

725 N. Wolfe St / Office 217 Baltimore, MD 21205 443-287-4841 / Fax 410-502-5029 sberry8@jhmi.edu



#### **February 8, 2022**

Dear Senators,

Preventing the spread of HIV remains a critical public health problem in Maryland, particularly for persons with limited access to healthcare providers. Urban communities and rural communities in Western Maryland and on the Eastern Shore may be the most impacted.

Pre-exposure (PrEP) and post-exposure prophylaxis (PEP) are powerful tools to prevent HIV transmission, but the success of these tools is limited by accessibility. Like all preventive health tools, people will be more inclined to use PrEP and PEP if they can be initiated conveniently and quickly. A long drive or bus ride to a clinic with a wait to be seen by a provider is a high barrier for someone who is healthy and busy working and/or raising a family.

In the case of HIV prevention tools, privacy is also essential. HIV clinics, which often prescribe PrEP and PEP to persons who do not have HIV, are known by name in the community. During my fifteen years-experience as an HIV provider, many patients have told me how they avoided first coming to an HIV clinic for years because they worried others would find out.

Allowing pharmacists to prescribe and dispense PrEP and PEP may greatly expand the number of access points in communities throughout the state. People go to pharmacies for all number of reasons, and can thus feel their privacy will be protected.

The medicines used for PrEP and PEP in 2022 are very safe. Moreover, pharmacists have a decades-long track record of prescribing and monitoring other medications under appropriate standards. A good example is the anti-coagulation drug warfarin, which, from a medical standpoint, carries much more risk than do PrEP and PEP medicines.

Senate Bill 0355 will provide an important way to expand access and use of HIV PrEP and PEP in Maryland. I urge the General Assembly to adopt this bill.

Sincerely,

Stephen A. Berry, MD PhD Associate Professor of Medicine

## SB355\_MACDS\_FWA.pdf Uploaded by: Sarah Price

Position: FWA





# SB355 – HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and Insurance Requirements Education, Health, and Environmental Affairs Committee February 10, 2022

**Position:** Support with Amendments

The Maryland Association of Chain Drug Stores (MACDS) and the National Association of Chain Drug Stores (NACDS) appreciate the opportunity to express support for broad access to convenient quality care for Marylanders by leveraging community pharmacies. We thank Senator Lam for introducing this bill and urge the Committee to recognize pharmacists as qualified healthcare professionals, more than capable of providing enhanced access to lifesaving therapy. SB355 authorizes pharmacists to initiate and dispense Human Immunodeficiency Virus (HIV) prevention medications. Successful passage of this bill is imperative to ensure Marylanders have additional healthcare destinations and necessary patient choice and convenience to receive the timely care they deserve to prevent HIV infection and spread.

#### **Broaden Pharmacist Authority to Ensure Increased Access for Marylanders**

HIV prevention has transformed in recent years because of increased access to and use of effective prevention medications including Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP). As one of the most frequently visited and trusted members of a patient's healthcare team, pharmacists are well-positioned to safely and conveniently link patients to essential care, such as HIV prevention services, within various communities across Maryland. Nearly 90% of Americans live within 5 miles of a pharmacy and evidence shows that patients visit pharmacies 10 times more frequently than other healthcare providers, demonstrating that pharmacists can fill gaps in patient care and support the healthcare team.

In 2019, nearly 1.2 million people in the United States aged 13+ were living with diagnosed or undiagnosed HIV infection. In Maryland, among people living with HIV in 2019, it was estimated that nearly 90% had been diagnosed, while an estimated more than 3,500 people with HIV in Maryland remain undiagnosed. Currently, approximately 12 states recognize pharmacists' ability to provide HIV prevention services, in addition to community pharmacy models and pilot studies noting expanded access by leveraging pharmacists within the community. Most recently, Virginia pharmacists were granted authority to initiate and dispense HIV prevention medications. Virginia pharmacies' enhanced accessibility and convenience within the community, especially for timely services such as HIV prevention, SB355 would similarly allow pharmacists the ability to help those affected by HIV, especially those who may not have the appropriate resources to seek care elsewhere.

#### **Recommended Amendments**

- 1. As medication experts of the healthcare team, pharmacists have adequate background and training to confirm and dispense the appropriate medication for a patient, along with monitoring and counseling on potential side effects. As such, pharmacists are fully capable of initiating and dispensing a 60-day supply versus only a 30-day supply to patients, as appropriate. Furthermore, extending this authority for pharmacists without burdensome restrictions will also provide patients an avenue to receive uninterrupted care, especially as some patients may not have a primary care provider at the time of their pharmacy visit. Creating extra administrative requirements will only impact the patient as it takes away pharmacists' time with patients.
- 2. Certain requirements within SB355 limit pharmacists from providing the proposed service, which ultimately prevents patients from receiving the care they require. As a standard, pharmacists offer patients the opportunity to receive counseling and consultation regarding their new and existing medications. However, requiring pharmacists to refuse provision of HIV prevention services due to patients' not accepting the offer for consultation could prove to be a dangerous precedent for any medication. Pharmacists have the necessary technology and infrastructure to document their offer to counsel the patient and the patient's refusal within the electronic system and thus, should still be able to offer the service if the patient is eligible and in need of the service.
- 3. Finally, successful implementation of this care service is vital to expanding access for Marylanders, and sustainability of this service is an important component for uptake by both patients and pharmacies. Implementation of HIV prevention measures, including the utilization of life-saving prevention medications such as PrEP, can lead to healthcare cost-savings. According to the Centers for Disease Control and Prevention (CDC), HIV prevention efforts conducted between 2008 to 2017 have resulted in 10,000 fewer HIV infections per year and saved \$4.58 billion. Additionally, studies have shown that HIV prevention implementation can lead to estimated healthcare savings of nearly \$230,000 per person and have noted the use of PrEP to be a cost-effective measure. Thus, appropriate reimbursement and coverage for pharmacy care should be implemented to support patient access, especially those in rural and medically underserved areas, and sustain the provision of quality, affordable pharmacy care throughout Maryland communities.

#### Conclusion

The COVID pandemic has clearly demonstrated that pharmacies are critical partners in providing access to care. Maryland boasts more than 800 pharmacies that have been open and operational during the pandemic to provide patients with community-based healthcare, while allowing physicians to focus on providing more specialized care to COVID patients. Pharmacies' accessibility and integration in communities across the state, their doctorate-level clinical training, and their ability to ensure patients have access to the supportive care measures they need make them well-positioned to provide HIV prevention services. Thus, MACDS and

NACDS support passage of SB355 with our recommended amendments to provide vulnerable Marylanders who are at-risk of HIV with the option to receive the care they deserve in the setting they feel most comfortable. We appreciate the tremendous efforts already taken by the General Assembly to enhance healthcare access and welcome the continued opportunity to work to with you and your constituents.

i \*studied in Medicaid patient population\* Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full

 $<sup>\</sup>hbox{$^{\text{ii}}$ $https://health.maryland.gov/phpa/OIDEOR/CHSE/SiteAssets/Pages/statistics/Maryland-HIV-Fact-Sheet-2021.pdf}$ 

https://www.japha.org/article/S1544-3191(20)30039-X/fulltext

https://www.dhp.virginia.gov/pharmacy/docs/protocols/PrEPCombinedProtocol12-22-2021.pdf

<sup>&</sup>lt;sup>v</sup> CDC. CDC's HIV Work Saves Lives and Money. Feb 2020. <a href="https://www.cdc.gov/nchhstp/budget/infographics/hiv.html">https://www.cdc.gov/nchhstp/budget/infographics/hiv.html</a>

<sup>&</sup>lt;sup>vi</sup> Schackman BR, Fleishman JA, Su AE, et al. The lifetime medical cost savings from preventing HIV in the United States. Med Care. 2015.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4359630/#:~:text=Results,lifetime%20cost%20estimate%20is%20%2496%2C700.

vii Ouellet E, Durand M, Guertin JR, LeLorier J, Tremblay CL. Cost effectiveness of 'on demand' HIV pre-exposure prophylaxis for non-injection drug-using men who have sex with men in Canada. Can J Infect Dis Med Microbiol. 2015 <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4353265/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4353265/</a>

## **SB 355\_PEP and PrEP\_OAA.pdf**Uploaded by: Allison Taylor

Position: UNF



Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc 2101 East Jefferson Street Rockville, Maryland 20852

February 10, 2022

The Honorable Paul G. Pinsky Senate Education, Health, and Environmental Affairs Committee 2 West, Miller Senate Office Building 11 Bladen Street Annapolis, Maryland 21401

#### **RE:** SB 355 – Oppose Unless Amended

Dear Chair Pinsky and Members of the Committee:

Kaiser Permanente respectfully opposes SB 355, "HIV Prevention Drugs – Dispensing by Pharmacists and Insurance Requirements." While we support expanding access to both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), we believe this proposal would need substantial amendments to address the concerns outlined below.

Kaiser Permanente is the largest private integrated health care delivery system in the United States, delivering health care to over 12 million members in eight states and the District of Columbia. Kaiser Permanente of the Mid-Atlantic States, which operates in Maryland, provides and coordinates complete health care services for approximately 800,000 members. In Maryland, we deliver care to over 460,000 members.

PrEP is not just a medication, but a comprehensive program to prevent HIV. Our clinical experts are concerned that authorizing direct access to PrEP at a pharmacy could inhibit overall HIV prevention efforts and could negatively impact patient care. A pharmacist-driven program to help expand access and utilization to PrEP can be valuable and effective if done right. There are effective pharmacy-based PrEP programs that operate under a physician's direction and include the various, critical elements of a PrEP program, including screening and monitoring labs, risk-reduction counseling, STI screening, and clinical follow-up. In many of our locations at Kaiser Permanente, we have trained clinical pharmacists providing PrEP through such programs, including appropriate screening for other sexually transmitted diseases and referral to substance use programs, and it works well because physicians are an integral part of the care. We are not comfortable allowing a pharmacist to independently furnish PrEP outside of a comprehensive PrEP program, which is highly specialized and requires extensive time and training.

<sup>&</sup>lt;sup>1</sup> Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc., the nation's largest not-for-profit health plan, and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 650 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente's members.

Kaiser Permanente Comments on SB 355 February 10, 2022

PrEP is not recommended for all patients, regardless of risk of acquiring HIV. The U.S.

Preventive Services Task Force recommends that clinicians offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition, which is outlined in recent guidance. This legislation includes no guardrails to ensure that the appropriate population receive this medication, which we think would be important given the medication's high cost. We also question whether community pharmacists will have the time to do appropriate counseling and monitoring of labs and adherence during ongoing PrEP and whether they have the clinical skillset to interpret an HIV test to distinguish an acute HIV seroconversion, in which case starting PrEP could lead to HIV drug resistance.

Maryland Medicaid already pays for PrEP and PEP. Coverage for PrEP and PEP was carved into coverage through the HealthChoice program on January 1, 2020. Therefore, there is no need to amend section 15-103 of the Health – General Article to mandate coverage.

The State may already have a funding source to help defray insurance costs associated with PrEP and PEP. Chapter 46 of the Acts of 2016 established a Special Fund consisting of "any rebates received by the [Maryland Department of Health] from the Maryland AIDS Drug Assistance Program as a result of State General Fund expenditures," to be used only for "State-identified priorities for HIV prevention, surveillance, and care services." As noted in the fiscal note for that legislation, MDH intended to use this fund to defray costs associated with PrEP for high-risk HIV-negative individuals. At that time, DLS estimated that a one-time General Fund expenditure of \$100,000 would generate over \$3.7 million in rebates by 2021. The General Assembly should understand whether this Special Fund is adequately covering the cost of PrEP for eligible Marylanders before prohibiting a carrier from imposing a cost-sharing requirement.

Thank you for the opportunity to comment. Please feel free to contact me at Allison. W. Taylor@kp.org or (202) 924-7496 with questions.

Sincerely,

Allison Taylor

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**Director of Government Relations** 

Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.

## **5c - SB 355 - EHEA - Bd. of Pharm - LOC.docx.pdf** Uploaded by: Heather Shek

Position: UNF



## Board of Pharmacy

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

Jennifer L. Hardesty, Board President - Deena Speights-Napata, Executive Director

February 10, 2022

The Honorable Paul G. Pinsky Chair, Senate Education, Health, and Environmental Affairs Committee 2 West Miller Senate Office Building Annapolis, MD 21401

### RE: Senate Bill 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements

Dear Chair Pinsky and Committee Members:

The Maryland Board of Pharmacy (the Board) is submitting this letter of concern for Senate Bill (SB) 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements.

SB 355 would authorize a Maryland-licensed pharmacist to prescribe and dispense preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP) for HIV prevention to patients under certain circumstances. SB 355 would require the Board to approve and/or develop a training program on the use of PrEP and PEP, and require a pharmacist to complete the training program prior to prescribing and dispensing PrEP or PEP. SB 355 would also require the Board to adopt regulations mandating a pharmacist to create and disseminate information regarding a federal program.

The Board of Pharmacy is supportive of the appropriate expansion of the practice of pharmacy; however, the Board has concerns regarding provisions contained in SB 355.

SB 355 would require the Board to develop and/or approve an appropriate training program on the use of PrEP and PEP that includes information regarding financial assistance programs. *See* § 12–514(D)(2). While the Board provides guidance regarding the practice of pharmacy, it is not an educational institution. The Board ensures that pharmacy is practiced safely, but it is not equipped to develop a training program on the use of PrEP and PEP. The Board submits that a pharmacist should receive education regarding the use of all pharmaceuticals, including PrEP and PEP, under the supervision of a qualified instructor at a school of pharmacy.

SB 355 would require a Maryland-licensed pharmacist to complete an additional training program on the use of PrEP and PEP prior to prescribing and dispensing the aforementioned HIV prevention pharmaceuticals. See § 12–514(D)(1)(I). The Board understands that healthcare practitioners must be highly skilled and qualified to ensure public safety; however, requiring a pharmacist to complete an additional training program to engage in a task covered as part of their

core curriculum is unnecessary to protect public health and neglects to value the competence that a pharmacist has demonstrated by obtaining a degree from a school of pharmacy, completing an internship, and passing the NAPLEX and MPJE. The Board suggests removing the mandatory training provision from SB 355, as Maryland-licensed pharmacists are required to complete a rigorous curriculum and achieve certain testing criteria prior to successfully obtaining a license from the Board.

The Board would like to inform the Committee that certain Maryland-licensed pharmacists manage drug therapy pursuant to a prescriber-pharmacist agreement, drug therapy protocol, and therapy management contract. *See* Md. Code Ann., Health Occ., §§ 12-6A-01 – 12-6A-10; COMAR 10.34.29. Many pharmacists that practice pharmacy pursuant to a drug therapy protocol have obtained postgraduate education and training in specialized areas, including infectious diseases. The Board requires a pharmacist that desires to practice pursuant to a drug therapy protocol to possess a (1) Doctor of Pharmacy or Bachelor of Science in Pharmacy combined with additional clinical training, (2) Board of Pharmacy Specialties certificate, American Society of Consultant Pharmacist's Certified Geriatric Practitioner certificate, or complete a residency offered by a body accredited by the Accreditation on Pharmacy Education, and (3) experiential learning hours. The Board submits that Maryland-licensed pharmacists that have been approved to practice pharmacy pursuant to a drug therapy protocol are highly competent and should be exempt from additional training requirements.

SB 355 would allow a pharmacist to order an HIV test. See § 12–514(B)(3)(I)(2). The Board notes that a Maryland-license pharmacist does not have the ability to order an HIV test currently. It is the Board's understanding that the Laboratories Administration of the Maryland Department of Health would need to approve and supply testing materials. The Board would suggest that SB 355 is amended to include a provision for access to testing materials.

SB 355 would require a dispensing pharmacist to maintain records regarding a patient and limit subsequent prescriptions without documentation of a physician's visit. See §§ 12–514(B)(1)(III)(2), 12–514(B)(1)(IV), 12-514(B)(2)(II). The Board is concerned that SB 355 would not prevent a patient from obtaining PrEP and/or PEP from multiple pharmacists, as the legislation does not include a requirement or mechanism to monitor and share the information with other health care professionals.

Finally, SB 355 would require the Board to adopt regulations mandating a pharmacist to create and disseminate information regarding the operations of a healthcare facility with which they are not freely associated. See §§ 12–514(B)(1)(VI), 12–514(B)(3)(II)(2), 12–514(C)(1)(IV)(2), 12–514(D)(1)(II), 12–514(E). SB 355 would require a dispensing pharmacist to provide certain patients "with a list of physicians, clinics, or other health care providers in the area that receive funding...from the Ryan White HIV/AIDS Program...." The requirement to maintain current information regarding the operations of a different healthcare provider and provide patients with a list of healthcare options may be burdensome to an individual pharmacist. The Board would suggest that a pharmacist could include general information, in the form of a link to QR code, regarding the Ryan White HIV/AIDS Program on the copy of the medical record that is provided to the patient or provide verbal notice. The Board does not support regulations that would create unnecessary administrative burdens in the practice of pharmacy.

If you would like to discuss this further, please do not hesitate to contact <u>deena.speights-napata@maryland.gov</u> / (410) 764-4753.

Sincerely,

Jennifer L. Hardesty,

PharmD, FASCP

President

## MMCOA SB355 02 10 2022.pdf Uploaded by: Jennifer Briemann

Position: UNF



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### Senate Bill 355 – HIV Prevention Drugs – Dispensing by Pharmacists and Insurance Requirements

#### **OPPOSE**

#### Senate Education, Health, and Environmental Affairs Committee Senate Finance Committee

#### February 10, 2022

Thank you for the opportunity to submit testimony in opposition to Senate Bill 355 – HIV Prevention Drugs – Dispensing by Pharmacists and Insurance Requirements.

The Maryland Managed Care Organization Association (MMCOA), which is comprised of all nine MCOs that serve Medicaid, is committed to ensuring access to the prescription drugs and devices that our members depend on for their health. Maryland's nine MCOs serve over 1.5 million Marylanders through the Medicaid HealthChoice program.

While we support efforts to improve member access to care, this bill may increase costs to the Health Choice program through the limitation of which drug is administered under the bill's provisions.

In addition, we believe the legislation presents clinical concerns for our members by eliminating the provider/patient education and evaluation that is critical, based on the patient's medical history and current needs. We do not support elimination of prior authorization and step therapy for PrEP. Furthermore, we would also want to encourage more communication on generic equivalency as part of the testing for HepC and HIV.

For these reasons, we respectfully oppose Senate Bill 355.

The MMCOA looks forward to continued collaboration with the State as we work to identify ways to improve access to affordable high-quality care for all Medicaid participants.

Please contact Jennifer Briemann, Executive Director of MMCOA, with any questions regarding this testimony at jbriemann@marylandmco.org.

## SB0355\_UNF\_MedChi, MDAAP, MACHC\_HIV Prevention Dru Uploaded by: Steve Wise

Position: UNF



Maryland Chapter

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Specifing for Maryland Kide!



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TO: The Honorable Paul G. Pinsky, Chair

Members, Senate Education, Health, and Environmental Affairs Committee

The Honorable Clarence K. Lam

FROM: J. Steven Wise

Pamela Metz Kasemeyer Danna L. Kauffman Christine K. Krone

DATE: February 10, 2022

RE: **OPPOSE** – Senate Bill 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and

Insurance Requirements

On behalf of the Maryland State Medical Society, the Maryland Chapter of the American Academy of Pediatrics, and the Mid-Atlantic Association of Community Health Centers, we submit this letter of **opposition** for Senate Bill 355. Senate Bill 355 would authorize pharmacists to dispense certain HIV prevention drugs to a patient without a prescription. While the above-named organizations appreciate the intent of the legislation is to facilitate access to both pre- and post-exposure prophylaxis HIV medications in order to enhance HIV prevention, they have a number of concerns with this proposal, some of which may have unintended consequences and therefore would undermine the presumed objectives of the legislation.

First, the bill creates definitions of pre- and post-exposure prophylaxis which both allow the Board of Nursing, Board of Pharmacy, and Board of Physicians to define drug combinations that can be used for these purposes. However, these professional regulatory boards do not define treatments on drug combinations for illnesses and are not established to do so. The portion of the definition relying on the Centers for Disease Control to define these drug combinations is more appropriate.

Second, the bill allows a pharmacist to dispense a 30-day supply, but no more than a 60-day supply, of pre-exposure prophylaxis without a prescription under certain circumstances. There is concern that patients will pharmacy shop and continue to receive these incremental supplies instead of seeking needed medical care from a physician or other provider. Furthermore, a provider would not know how many 30-60 day supplies of pre-exposure prophylaxis a patient has received, because maintaining electronic medical records is not part of a pharmacists' normal protocols, and these drugs are not subject to the Prescription Drug Monitoring Program.

Further, the inclusion of post-exposure prophylaxis in the medications that a pharmacist is authorized to dispense without a prescription is also of concern. The recommended medical care, counselling, and other services that should be provided post-exposure differ from those required for pre-exposure and are not within the scope of practice of a pharmacist.

Finally, the bill allows a pharmacist to order an HIV test for a patient after the pharmacist "screens" the patient. Pharmacists are not normally permitted under their scope of practice to order tests without a prescription from a prescriber and are not trained to "screen" patients in the way that physicians are. The above-named organizations will continue to work with the sponsor on this legislation, but in its current form they have the above concerns and based on those concerns ask the Committee for an unfavorable report.

#### For more information call:

J. Steven Wise Pamela Metz Kasemeyer Danna L. Kauffman Christine K. Krone 410-244-7000

**5a - SB 355 - EHEA - BON - LOI.docx.pdf**Uploaded by: Maryland Department of Health Office of Governmental Affairs

Position: INFO



## Board of Nursing

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

February 10, 2022

The Honorable Paul G. Pinsky Chair, Senate Education, Health, and Environmental Affairs Committee 2 West, Miller Senate Office Building Annapolis, MD 21401-1991

RE: SB 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements – Letter of Information

Dear Chair Pinsky and Committee Members:

The Maryland Board of Nursing (the Board) respectfully submits this letter of information for Senate Bill (SB) 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements. This bill authorizes pharmacists to prescribe and dispense pre-exposure prophylaxis and post-exposure prophylaxis for HIV prevention to patients under certain circumstances. This bill requires the Maryland Medical Assistance Program to provide drugs that are approved by the United States Food and Drug Administration (FDA) for HIV prevention.

The Board believes it is necessary to expand access to prophylaxis medications for HIV prevention to individuals who are truly in need of this service. The Board, however, is not in favor of restricting certain practitioners, by way of additional training or administrative burden, from prescribing these medications. The pandemic has placed incredible limitations on healthcare practitioners' ability to provide adequate and timely care. Patients are unable to receive expeditious treatment, and, in turn, their illnesses are left aggravated. There has, however, been a collective response by the legislature related to expanding certain scopes of practice to address the current obstacles in the healthcare field.

The Board believes pharmacists are educationally prepared and competent to prescribe and dispense prophylaxis medications for HIV prevention. To practice in Maryland, pharmacists must: (1) complete a rigorous four-to-six year education and residency program; (2) successfully pass the national certification test; and (3) obtain a license in good standing from the Board of Pharmacy. Pharmacists are noted to be one of the most readily accessible healthcare practitioners in the community. Most Marylanders live within a few minutes' walk or drive of a pharmacy. Additionally, individuals often do not need an appointment to consult a pharmacist on their prescribed medication. The Board of Nursing respectfully defers to the Board of Pharmacy for their thoughts and expertise.

For the reasons discussed above, the Board of Nursing respectfully submits this letter of information for SB 355.

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I hope this information is useful. For more information, please contact Iman Farid, Health Policy Analyst, at (410) 585 – 1536 (<u>iman.farid@maryland.gov</u>) or Rhonda Scott, Deputy Director, at (410) 585 – 1953 (<u>rhonda.scott2@maryland.gov</u>).

Sincerely,

Gary N. Hicks Board President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

**5b - SB 355 - EHEA - MDH - LOI.docx.pdf**Uploaded by: Maryland Department of Health /Office of Governmental Affairs

Position: INFO



Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

February 10, 2022

The Honorable Paul Pinsky Chair, Senate Education, Health and Environmental Affairs Committee 2 West Miller Senate Office Building Annapolis, MD 21401-1991

### RE: SB 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements – Letter of Information

Dear Chair Pinsky and Committee Members:

The Maryland Department of Health (MDH) respectfully submits this letter of information on Senate Bill (SB) 355 – HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements.

SB 355 authorizes pharmacists to prescribe and dispense pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) drugs, requires the Maryland Medical Assistance Program (Maryland Medicaid) to provide HIV prevention drugs, and prohibits managed care organizations (MCOs), insurers, non-profit health service plans, and health maintenance organizations (HMOs) from requiring prior authorization, step therapy, or cost-sharing for both drugs.

PEP and PrEP medications are integral to meaningful HIV prevention. PrEP is a daily medication for people at risk of acquiring HIV infection. PrEP is an as-needed medication that has been shown to reduce HIV transmission by 80 percent if taken within 72 hours of exposure. SB 355 would enhance access to these treatments for Marylanders with limited access to healthcare.

The Maryland Medicaid program currently provides coverage of the following PrEP drugs: Truvada, Descovy, generic forms of these drugs, and Apretude. Costs for these drugs through the fee-for-service (FFS) program to MDH range from \$72.90 to \$3,699.99 for a 30-day supply. The following PEP regimens are also covered as a combination with brand or generic Truvada: Isentress, Tivicay, Prezista, Ritonavir, and Stribild. These are 28-day courses that range in cost to MDH from \$80.10 to \$3,759.30.

<sup>&</sup>lt;sup>1</sup> https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html

<sup>&</sup>lt;sup>2</sup> Bamberger JD, Waldo CR, Gerberding JL, Katz MH. Postexposure prophylaxis for human immunodeficiency virus (HIV) infection following sexual assault. Am J Med. 1999 Mar. 106 (3):323-6

All HIV drugs for Maryland Medicaid's FFS program and for the managed care program (HealthChoice) have a \$1 copay for Medicaid participants. This copay is waived for pregnant women and children. If a participant cannot afford to pay the copay, the pharmacist is required to dispense the medication without collecting the copay. In Calendar Year (CY) 2021, copays related to HIV/AIDs drugs amounted to \$4,748 in the FFS program and \$140,624 in HealthChoice. These copays are considered revenue for MDH.

Benefits covered for HealthChoice participants are subject to the requirements of The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). Compliance with MHPAEA includes an assessment of financial requirements, such as copays, placed on medical/surgical drugs (M/S) in comparison with those in place for mental health/substance use disorder benefits. Exempting certain M/S drugs from copays would require ongoing monitoring by MDH to ensure ongoing compliance with MHPAEA, and could have implications for MDH's ability to collect behavioral health drug copays in future years if additional M/S drugs are exempt from copays. In CY 2021, copays for behavioral health drugs amount to \$3.6 million, all in the FFS program.

Finally, MDH notes that Federal Ryan White HIV/AIDS funding dollars are not currently authorized for application to PrEP coverage or ongoing care. MDH also notes that while "The Maryland Center for HIV Services" is named in SB 355, HIV prevention services are housed under the Infectious Disease Prevention and Health Services Bureau within the Prevention and Health Promotion Administration.

If you have any questions, please contact Heather Shek, Director of Governmental Affairs, at <a href="heather.shek@maryland.gov">heather.shek@maryland.gov</a> or (443) 695-4218.

Sincerely,

Dennis R. Schrader

Dennis R. Shadan

Secretary