

ORAL v3 Testimony Gaydos for SB0634.pdf

Uploaded by: Charlotte Gaydos

Position: FAV

ORAL Testimony for SB0634: Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

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Thank you for allowing me to testify today

The Problem: As most of you know, sexually transmitted infections are epidemic in the U.S. and in Maryland. CDC estimates there one million cases occur per day in the US.

In MD there were nearly 38,000 cases of chlamydia, 11,500 cases of gonorrhea and 800 cases of syphilis in 2019, as well as 724 people diagnosed with HIV infection in 2020.

These infections are associated with severe sequelae.

Considerations: New molecular diagnostics have permitted individuals to collect their own specimens in a clinic, or even at home.

Please differentiate between **home-testing**, which is performance of the test at home (HIV) and **home-collection**, which is for collection of urogenital swabs at home for mail-in to a laboratory for testing.

SOLUTIONS: Many (>10) commercial companies have developed on-line recruitment of individuals to collect urogenital samples for STIs or blood for HIV tests. These services are not covered by insurance.

Some Universities like our IWANTTHEKIT at Hopkins developed such programs which are offered as public health testing for free. We have tested over **20,000** genital, rectal, and oropharyngeal specimens from **>10,000 participants 14 years** and older since **2004**.

IWTK has been funded by NIH grants, occasionally by the State of MD, and recently (2019) by the Baltimore City Health Department. Baltimore residents can also order a free home test-yourself HIV test. Tests are not covered by insurance. Sustainability is a future issue.

During COVID-19 (221.3) compared to pre-COVID-19 (29.7) IWTK increased **645%**. **In the last 30 days we performed 1,016 tests from 714 kits.**

In Conclusion: Making these tests collected outside of a clinic billable to insurance by law would be game changing.

Passing SB 0634 will enable more persons with insurance to get tested for STIs.

Testimony v2 for SB0634 STI insurance Gaydos Writt

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Testimony for SB0634: Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

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The Problem:

- One million new cases of Sexually Transmitted Infections (STIs) per day in the U.S.
- Cases reported to the CDC are at an all-time high: 1.8 million cases of chlamydia (19% increase since 2015) and 616,392 cases of gonorrhea (56% increase). Syphilis and congenital syphilis have increased dramatically.
- STIs are associated with severe sequelae such as HIV acquisition, pelvic inflammatory disease, infertility, low birthweight, and adverse birth outcomes.
- Cases and Rates in Maryland: (2019 Latest available) Chlamydia: 37,779 cases, 624.9/100,000 population; Gonorrhea: 11,598 cases, 191.8/100,000; Syphilis: 868 cases, 14.4/100,000.
- Adolescents and young adults bear most of the burden of STIs.

Diagnostic Advances:

- In the last 15 years molecular methods have allowed more accurate tests, as well as more obtainable sample types to be used, such as vaginal swabs, urine, penile meatal swabs, and dried blood spots.
- Companies have obtained FDA clearance for self-collected urogenital swabs for these STI tests.
- Some companies (e.g., 247 Lab Kit, Everywell, Let's Get Checked, My Lab Box, Nurx, Planned Parenthood, Verisana, iDNA, Alpha Medical, binx Health, Virtuwel) are offering internet-recruited individuals the ability to collect samples at home for mail in to testing sites for performance of molecular tests for chlamydia and gonorrhea. These are expensive and not covered by insurance.
- Universities (e.g., Johns Hopkins University's program, IWANTTHEKIT (IWTK) also offer public health screening for home collected urogenital samples for free.
- The OraQuick® (Orasure) home test for HIV antibodies is the only test in the US thus far that can be purchased at a pharmacy over-the-counter (OTC) or for mail out to individuals for performance by the individual at home. It is expensive.

Terminology and Other Considerations:

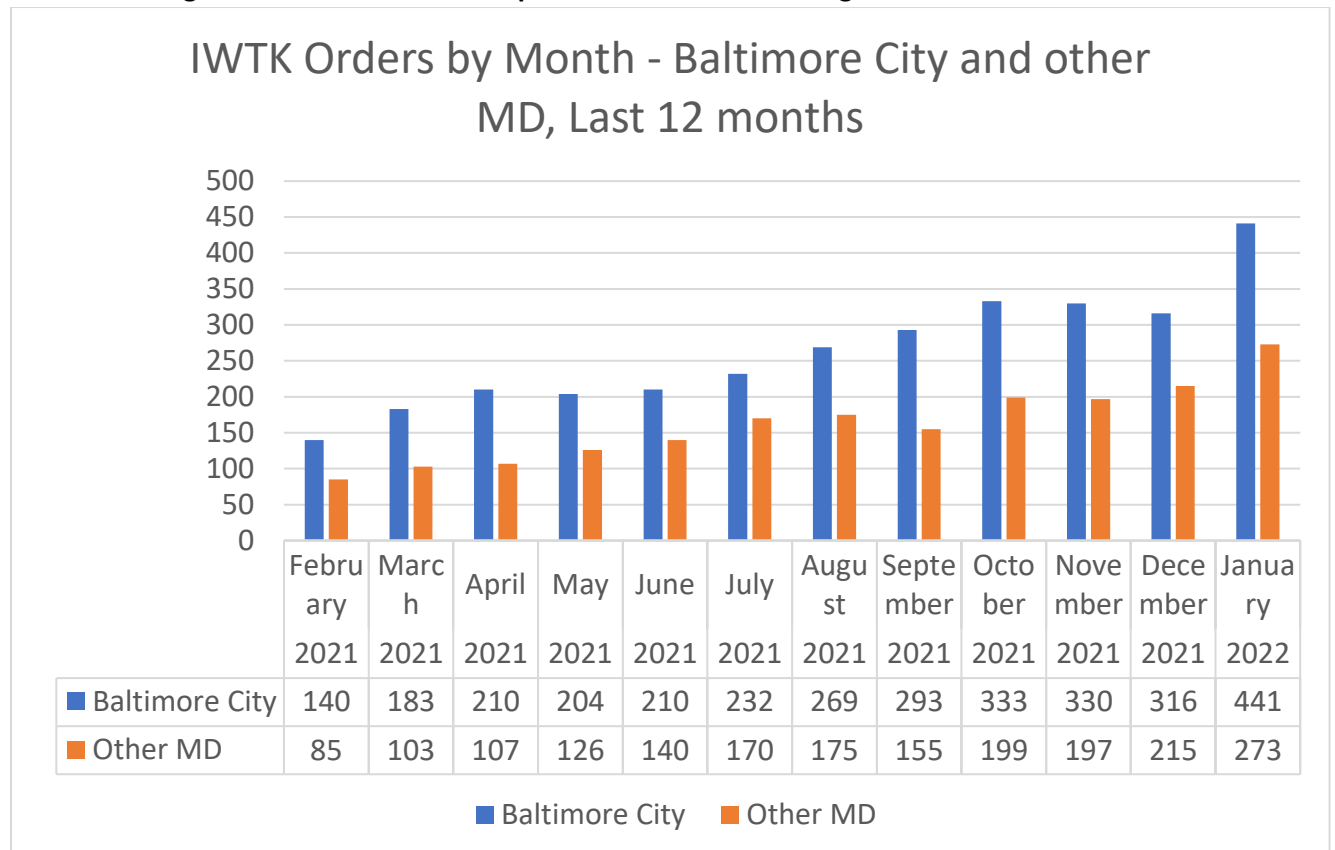
- It is necessary to distinguish between **home-collection** of specimens at home for mailing (e.g., chlamydia and gonorrhea) and **home-tested** samples that are self-performed (e.g., HIV).
- Surveys have shown that women prefer self-collected vaginal swabs and men are willing to self-collect penile-meatal swabs at home or in a clinic. Many prefer collection at-home for convenience, and issues of privacy and stigma.
- New point-of-care (POC) tests have been developed recently that can be obtained by doctors' offices and clinics, tested by a health care worker, and provide results in 30 min at the clinical encounter. This makes it possible to treat patients before they leave the clinic. Thus far, there are two such POC tests. Adoption and insurance coverage will help the STI epidemic. In the future, it might be possible for them to be performed by individuals at home.

Solutions:

- Many online companies, who offer testing for specimens collected at home and mailed to a testing site, charge high prices (e.g., \$50-300), but these tests are not covered by insurance. **Making these tests billable to insurance by law would be game changing.**
- IWANTTHEKIT (IWTK) is good public health practice and is free but not billable by insurance. Funding is an issue for the future.
- We opened IWTK in 2004, which provides **free and confidential home-collection, mail-in STI testing** to residents of Maryland. Our program has tested over 20,000 genital, rectal, and oropharyngeal specimens from >10,000 female, male, and non-binary gender-identifying users for individuals 14 years and older. It has been funded by NIH grants, occasionally by the State of MD, and recently (2019) by the Baltimore City Health Department. Baltimore residents can also order a free home test-yourself HIV test. Sustainability is a future issue. **Making these tests covered by insurance is important.**
- IWTK users obtain test results on the HIPAA-secure IWTK website; positive results are also sent to the clinic pre-selected by the user for follow-up treatment. Treatment success is high.
- The **monthly average** of IWTK testing kits requested **during COVID-19** (221.3) compared to pre-COVID-19 (29.7) **increased 645%. In January, 2022, we performed 1,016 tests from 714 kits.**
- Home collection and testing provide a reliable, convenient, and private method to access STI/HIV diagnostics, obviating the need for in-person clinic visits where the risk of COVID-19 exposure may be high.

Conclusions:

- **Passing SB 0634 will enable more persons with insurance to get tested for STIs.**



SB0634_with_933025_1.rtf.docx.pdf

Uploaded by: Clarence Lam

Position: FAV

UNOFFICIAL COPY OF SENATE BILL 634

SENATE BILL 634

J5

2lr2480

By: **Senator Lam**

Introduced and read first time: February 3, 2022

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance - Home Test Kits for Sexually Transmitted Diseases -**
3 **Required Coverage**

4 FOR the purpose of requiring certain health insurance policies and contracts to provide
5 coverage for the purchase of home test kits to test for sexually transmitted diseases
6 and related laboratory costs if the home test kit is ordered by ~~an in-network~~ a provider
7 under certain circumstances; and generally relating to health insurance coverage for
8 home test kits to test for sexually transmitted diseases.

9 BY adding to
10 Article - Insurance
11 Section 15-857
12 Annotated Code of Maryland
13 (2017 Replacement Volume and 2021 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
15 That the Laws of Maryland read as follows:

16 **Article - Insurance**

17 **15-857.**

18 **(A) IN THIS SECTION, "HOME TEST KIT" MEANS A PRODUCT THAT:**

19 **(1) IS USED BY AN INDIVIDUAL TO SELF-COLLECT SPECIMENS TO**
20 **TEST FOR SEXUALLY TRANSMITTED DISEASES, INCLUDING THE HUMAN**
21 **IMMUNODEFICIENCY VIRUS, AT A LOCATION THAT IS NOT A CLINICAL SETTING;**

22 **(2) IS RECOMMENDED BY:**

UNOFFICIAL COPY OF SENATE BILL 634

2
1 (I) THE FEDERAL CENTERS FOR DISEASE CONTROL AND
2 PREVENTION GUIDELINES; OR

3 (II) THE UNITED STATES PREVENTATIVE SERVICES TASK
4 FORCE; AND

5 (3) (i) HAS A CLINICAL LABORATORY IMPROVEMENT
6 AMENDMENT WAIVER;

7 (ii) IS CLEARED OR APPROVED BY THE FEDERAL FOOD AND
8 DRUG ADMINISTRATION; OR

9 (iii) IS DEVELOPED BY A LABORATORY IN ACCORDANCE WITH
10 ESTABLISHED REGULATIONS AND QUALITY STANDARDS.

11 (B) THIS SECTION APPLIES TO ~~EACH INDIVIDUAL, GROUP, OR BLANKET~~
12 ~~HEALTH INSURANCE POLICY OR CONTRACT THAT IS ISSUED OR DELIVERED IN THE~~
13 ~~STATE BY AN INSURER OR A NONPROFIT HEALTH SERVICE PLAN :~~

(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS ON AN EXPENSE-INCURRED BASIS UNDER HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

14 (c) A POLICY OR CONTRACT SUBJECT TO THIS SECTION SHALL PROVIDE
15 COVERAGE FOR:

16 (1) THE PURCHASE OF A HOME TEST KIT IF:

17 (i) ~~AN IN-NETWORK~~ A PROVIDER DETERMINES THE HOME TEST
18 KIT IS MEDICALLY NECESSARY OR APPROPRIATE AND ORDERS THE TEST KIT FOR AN
19 INSURED OR ENROLLEE; OR

20 (ii) ~~AN IN-NETWORK~~ A PROVIDER ISSUES A STANDING ORDER FOR
21 THE TEST KIT FOR USE BY AN INSURED OR ENROLLEE BASED ON CLINICAL
22 GUIDELINES AND THE INDIVIDUAL HEALTH NEEDS OF THE INSURED OR ENROLLEE;
23 AND

24 (2) LABORATORY COSTS FOR PROCESSING THE HOME TEST KIT.

25 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all
26 policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or
27 after January 1, 2023.

28 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
29 January 1, 2023.

SB0634-933025-01.pdf

Uploaded by: Clarence Lam

Position: FAV



SB0634/933025/1

AMENDMENTS
PREPARED
BY THE
DEPT. OF LEGISLATIVE
SERVICES

21 FEB 22
10:44:18

BY: Senator Lam
(To be offered in the Finance Committee)

AMENDMENTS TO SENATE BILL 634
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in line 6, strike “an in–network” and substitute “a”.

AMENDMENT NO. 2

On page 2, strike beginning with “EACH” in line 11 down through “PLAN” in line 13 and substitute “:

(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS ON AN EXPENSE–INCURRED BASIS UNDER HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE”;

and in lines 17 and 20, in each instance, strike “AN IN–NETWORK” and substitute “A”.

SB634_LAM_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

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



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THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

Support SB 634:

Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

Background Information:

- Not all diseases begin with infections, however Sexually Transmitted Diseases (STDs) first begin as Sexually Transmitted Infections (STIs).
- STIs are considered STDs when the individual begins to show symptoms; some STIs like gonorrhea and chlamydia can be asymptomatic.
- STIs are infections that pass from one person to another through sexual/physical contact.
- There are more than 20 types of STIs, which include chlamydia, genital herpes, gonorrhea, pubic lice, trichomoniasis, and HIV/AIDS, amongst others.
- STIs can be caused by bacteria, viruses, or parasites.
- STIs are associated with serious health consequences, especially if untreated.
- An individual with an undiagnosed STI poses a serious public health concern as they are often asymptomatic and can unknowingly continue to spread it from person to person.
- An STI home test kit can typically screen for one or more STIs via a urine sample, blood sample, or superficial genital swab. After the sample is collected, an individual can package and send it away for results using an envelope included in the kit.
- In 2022, California became the first state to mandate health insurance coverage for home STI test kits.
- Studies have shown that home testing for STIs has the potential to save costs when compared to the direct and indirect costs of a clinic visit.^{1 2}

¹ [Cost Comparisons between Home- and Clinic-Based Testing for Sexually Transmitted Diseases](#)

² [Cost-Effectiveness Analysis of Chlamydia trachomatis Screening](#)

The Issue:

- Maryland has seen rising rates of multiple STIs. The total number of cases of chlamydia, gonorrhea, and syphilis reported in Maryland increased 51 percent from 2010 to 2019.³
- In 2015, Maryland ranked 7th among the 50 states in the number of HIV diagnoses, 10th in rates of syphilis, 23rd in chlamydial infections, and 24th in gonorrheal infections.⁴
- The rising rate of syphilis infections among women of reproductive age is particularly concerning as it increases the risk of congenital syphilis (when a pregnant woman transmits the syphilis infection to the fetus). This can lead to fetal or infant death, or devastating lifelong developmental abnormalities and delays.

What does SB 634 do?

- SB 634 mandates health insurance coverage for STI test kits that can collect specimens outside of a clinical setting.
- Eligible insurance plans that are captured by this bill will require that the test and associated laboratory processing fees are considered a covered benefit.
- Home STI test kits must have the recommendation of the Centers for Disease Control or the U.S. Preventive Services Task Force in addition to being approved by the Federal Food and Drug Administration.

What does SB 634 accomplish?

- SB 634 increases access to important tools for diagnosing STIs.
- Given that many STIs are asymptomatic, testing and diagnosing the infection is an essential first step to reducing the rising rates of STIs in the state of Maryland.
- Minority populations are at higher risk of contracting STIs and face more barriers to accessing health care, making home test kits an important tool for reducing disparities in health care.⁵
- SB 634 enables individuals to utilize their existing health insurance benefits to mitigate the costs of these tests.

Sponsor Amendment SB0634/933025/1:

- Ensures that existing network coverages are maintained, so that the bill does not mandate coverage that is inconsistent with an insurance product's network allowances.
- Clarifies that this bill only applies to plans that provide hospital, medical, and surgical benefits, as opposed to plans such as dental where this benefit would be inappropriate.

³ [Maryland Department of Health: Sexually Transmitted Infections 2019 Annual Report](#)

⁴ [CDC: Maryland - 2015 State Health Profile](#)

⁵ [Maryland Department of Health: Sexually Transmitted Infections 2019 Annual Report](#)

SB0634_FAV_MedChi, MACHC_HI - Home Test Kits STDs

Uploaded by: Danna Kauffman

Position: FAV



MID-ATLANTIC ASSOCIATION OF
COMMUNITY HEALTH CENTERS

The Maryland State Medical Society
1211 Cathedral Street
Baltimore, MD 21201-5516
410.539.0872
Fax: 410.547.0915
1.800.492.1056
www.medchi.org

TO: The Honorable Delores G. Kelley, Chair
Members, Senate Finance Committee
The Honorable Clarence K. Lam

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Christine K. Krone

DATE: February 23, 2022

RE: **SUPPORT** – Senate Bill 634 – *Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage*

On behalf of the Maryland State Medical Society and the Mid-Atlantic Association of Community Health Centers, we submit this letter of **support** for Senate Bill 634. Senate Bill 634 requires an insurer to provide coverage for the purchase of an approved home test kit used for the testing of sexually transmitted diseases (STDs) if an in-network provider determines the home test kit is medically necessary or appropriate and orders the test kit for an insured or enrollee or if an in-network provider issues a standing order for the test kit for use by an insured or enrollee based on clinical guidelines and the individual health needs of the insured or enrollee. An insurer must also cover the laboratory costs for processing the home test kit.

Recently, through the 2019 STD Surveillance Report, the federal Centers for Disease Control and Prevention reported that annual cases of STDs in the United States have climbed for the sixth consecutive year, hitting racial and ethnic minority groups, gay and bisexual men, and youth the hardest.¹ Specifically, the report showed a 30% increase in chlamydia, gonorrhea, and syphilis (the three most commonly reported STDs) between 2015 and 2019, with the sharpest increase in cases of syphilis among newborns (nearly quadrupling). In all three STD categories, Maryland ranks above the United States average – 11th for chlamydia; 20th for gonorrhea; and 12th for primary and secondary syphilis. Preliminary data for 2020 points to these trends continuing, which may be the result of disruptions to STD testing and treatment services due to the COVID-19 pandemic.

Beginning on January 1st of this year, California became the first state to require insurers to cover at-home tests for STDs. Maryland must also examine and implement new ways to control this rising trend. Senate Bill 634 provides another path for STD testing while still maintaining the provider-patient relationship to ensure necessary treatment if a test is positive. For these reasons, we urge a favorable vote on Senate Bill 634.

For more information call:

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

¹ Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2019*. Atlanta: U.S. Department of Health and Human Services; 2021

SB 634-FIN-FAV.pdf

Uploaded by: Elizabeth Gilliams

Position: FAV



BRANDON M. SCOTT
MAYOR

*Office of Government Relations
88 State Circle
Annapolis, Maryland 21401*

SB 634

February 23, 2022

TO: Members of the Finance Committee

FROM: Natasha Mehu, Director of Government Relations

RE: Senate Bill 634 – Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

POSITION: Support

Chair Kelley, Vice Chair Feldman, and Members of the Committee please be advised that the Baltimore City Administration (BCA) **supports** Senate Bill (SB) 634.

Sexually transmitted infection control is a public health emergency in Maryland. In Maryland's most recent report on sexually transmitted infections (STIs), the total number of cases of gonorrhea, chlamydia, and primary and secondary syphilis increased 51% from 2010 to 2019. While Maryland has made steady progress to reduce rates of new HIV diagnoses, every tool is needed in our kit to drive this rate to zero.

Access to testing is the catalyst to diagnose, treat, and prevent the onward spread of STI's. In high prevalence populations, over 50% of gonorrhea and chlamydia infections have no symptoms at all, underlining the need for screening tests. Undiagnosed and untreated STIs can lead to serious health consequences, including infertility, pregnancy complications, birth defects, and infant blindness. Furthermore, the presence of an STI can increase the risk for HIV acquisition and transmission.

SB 634 promises to enable increased access to HIV and STI testing by moving it out of the four walls of a clinic. At home testing has been shown to be a safe, effective, and patient-centered model, and is promoted by the CDC. At home testing overcomes the barriers of time, transportation, and stigma of seeking facility-based testing. Lastly, SB 634 will lessen a cost burden that currently makes at home testing unfeasible for many. At home HIV/STI tests currently can cost over \$100 out of pocket.

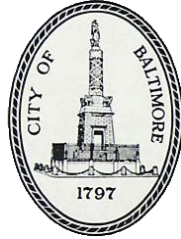
COVID-19 has spurred the rapid expansion of at-home testing, and demand has not declined even with restoration of sexual health services.

We respectfully request a **favorable** report on Senate Bill 634.

SB0634-FIN-FAV.pdf

Uploaded by: Natasha Mehu

Position: FAV



BRANDON M. SCOTT
MAYOR

*Office of Government Relations
88 State Circle
Annapolis, Maryland 21401*

SB 634

February 23, 2022

TO: Members of the Senate Finance Committee

FROM: Natasha Mehu, Director, Office of Government Relations

RE: Senate Bill 634 – Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

POSITION: SUPPORT

Chair Kelley, Vice Chair Feldman, and Members of the Committee please be advised that the Baltimore City Administration (BCA) **supports** Senate Bill (SB) 634.

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COVID-19 has spurred the rapid expansion of at-home testing, and demand has not declined even with the restoration of sexual health services.

We respectfully request a **favorable** report on SB 634.

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SB634_MdPHA_FAV

Uploaded by: Raimee H. Eck

Position: FAV



Mission: To improve public health in Maryland through education and advocacy **Vision:** Healthy Marylanders living in Healthy Communities

SB 634

Hearing Date: 2/23/22

Committee:

Position: Favorable

Chairperson Kelley and members of the Finance Committee: The Maryland Public Health Association (MdPHA) would like to offer favorable testimony regarding SB 634.

Home test kits allow a person to perform a test privately and conveniently in their own home. It can eliminate the need for long wait times for a doctor's appointment and potentially alleviate the stress of not knowing their condition. Follow up after a positive test is then necessary for treatment, but it may reduce unnecessary visits under emergency care for a negative test.

We urge a favorable report.

The Maryland Public Health Association (MdPHA) is a nonprofit, statewide organization of public health professionals dedicated to improving the lives of all Marylanders through education, advocacy, and collaboration. We support public policies consistent with our vision of healthy Marylanders living in healthy, equitable, communities. MdPHA is the state affiliate of the American Public Health Association, a nearly 145-year-old professional organization dedicated to improving population health and reducing the health disparities that plague our state and our nation.

support of senate bill 634.pdf

Uploaded by: Roanna Kessler

Position: FAV

Senate Bill 634 - Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

Sponsor Testimony

Roanna Kessler, MD

Chief Medical Director, Johns Hopkins University, Student Health & Well-Being

February 23, 2022

Chair Kelley and Vice Chair Feldman:

My name is Roanna Kessler and I am the Chief Medical Director for Johns Hopkins University Student Health & Well-Being. I oversee the campus primary care services for all of Johns Hopkins University students and learners. Today I am testifying in my professional capacity in support of Senate Bill 634. The views expressed here are my own and do not necessarily reflect the policies or positions of Johns Hopkins University/Johns Hopkins Health System.

The most recent CDC data (from 2018) estimates that on any given day 1 in 5 people in the U.S. have a sexually transmitted infection (STI). Almost half of new infections were among people aged 15-24 which is why this bill is particularly relevant to the college-aged population and the college health centers that serve them. Our providers know that many STIs are asymptomatic and would not be detected if there was no routine screening. Furthermore, if left untreated & undetected these infections continue to spread in the community and can lead to chronic medical issues.^{1,2}

STI rates have been increasing nationwide over the last decade and the Maryland state data reflects the same trend.³ According to the American College Health Association Sexual Health Services Survey, college health centers have also noticed upward trends in STI testing positivity, especially for Gonorrhea & Syphilis.⁴

In a typical year about 10% (over a 1,000) of our Homewood health center visits are STI related (this includes screening, symptoms, and treatment). There are probably many more students who never come through our doors because of stigma associated with STIs and fear of invasive exams to collect specimens. Many of our students would certainly prefer the privacy of testing from home. This is especially salient to our transgender & non-binary community who often avoid seeking healthcare due concerns about discrimination, resulting in postponement or avoidance of healthcare, and poor physical and mental health outcomes.⁵

We know the scope and consequences of the STI epidemic are significant, and efforts to date to address this have been insufficient. The COVID-19 pandemic has accelerated some innovative approaches to healthcare delivery such as increased use of telehealth, home test kits, and alternate settings for treatment.⁶ By insurance covering the cost of at-home STI testing, Senate Bill 634 would reduce systemic



and financial barriers to receiving STI screening which aligns with the vision of the U.S. Department of Health and Human Services Sexually Transmitted Infections National Strategic Plan for the United States:

“The United States will be a place where sexually transmitted infections are prevented and where every person has high-quality STI prevention, care, and treatment while living free from stigma and discrimination. This vision includes all people, regardless of age, sex, gender identity, sexual orientation, race, ethnicity, religion, disability, geographic location, or socioeconomic circumstance.”⁶

On behalf of myself and other college health providers, I respectfully urge you to pass Senate Bill 634.

Thank you for your kind attention and I will be happy to answer any questions you may have.

References:

1. <https://www.cdc.gov/std/statistics/STI-Estimates-Dear-Colleague-Letter.pdf>
2. Kreisel, Kristen M. PhD*; Spicknall, Ian H. PhD*; Gargano, Julia W. PhD†; Lewis, Felicia M.T. MD*,‡; Lewis, Rayleen M. MPH†; Markowitz, Lauri E. MD†; Roberts, Henry PhD§; Johnson, Anna Satcher MPH¶; Song, Ruiguang PhD¶; St. Cyr, Sancta B. MD*; Weston, Emily J. MPH*; Torrone, Elizabeth A. PhD*; Weinstock, Hillard S. MD* Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2018, Sexually Transmitted Diseases: April 2021 - Volume 48 - Issue 4 - p 208-214. doi: 10.1097/OLQ.0000000000001355
3. <https://health.maryland.gov/phpa/OIDPCS/CSTIP/CSTIPDocuments/Reports/STI%202019%20Annual%20Report%20Maryland.pdf>. The 2019 Maryland STI Annual Report
4. ACHA 2020 SEXUAL HEALTH SERVICES SURVEY. Survey Report Issued: November 15, 2021
5. Kcomt L, Gorey KM, Barrett BJ, McCabe SE. Healthcare avoidance due to anticipated discrimination among transgender people: A call to create trans-affirmative environments. *SSM Popul Health*. 2020;11:100608. Published 2020 May 28. doi:10.1016/j.ssmph.2020.100608
6. U.S. Department of Health and Human Services. 2020. Sexually Transmitted Infections National Strategic Plan for the United States: 2021–2025. Washington, DC

SB0634 home STI and HIV testing berry 20220223.pdf

Uploaded by: Stephen Berry

Position: FAV

Requiring insurers to pay for home sexually-transmitted infection (STI) and HIV test materials makes sense medically and will likely reduce STIs and HIV

The disease burden is high

- Similar to national trends, bacterial STIs including gonorrhea and chlamydia have been steadily increasing in Maryland since 2010 with approximately 38,000 chlamydia cases and 12,000 gonorrhea cases reported in 2019 (last year with data available)
- In the past 10 years, HIV incidence has been decreasing in Maryland, with 724 new diagnoses reported in 2020; unfortunately, this is still far from zero

Self-collecting samples at home is simple and accurate

- The collection process has no need for a healthcare provider
- Gonorrhea and chlamydia
 - In a clinic, providers apply a swab (gently rub a fiber-tipped device that looks like a Q-tip) to the throat, vagina, rectum, or penis to collect a sample
 - Providers then mail the swab to a lab for PCR-type testing within several days
 - Test results are extremely accurate (>95% sensitivity and specificity; more accurate than PCR tests for SARS-CoV-2)
 - People self-collect swab specimens identically to how providers do
 - Self-collected swabs capture samples equally as well as provider-collected swabs
 - People generally prefer self-collection to provider-collection
 - Mailing swabs from home has proven simple and reliable for over a decade in publicly-funded services such as *I Want The Kit* (<https://iwantthekit.org/>)
 - Persons receiving positive results at home reliably seek treatment
- HIV
 - FDA-approved home kit uses saliva and provides a result within 15-20 minutes on a device that resembles a home COVID test or pregnancy test
 - Results with 92% accuracy

Increased sample collection at home will likely break transmission chains and reduce the long-term consequences of bacterial STIs and HIV

- Analogous to using testing to interrupt COVID transmission
- All three infections are asymptomatic the majority of the time, and transmission generally occurs while people are asymptomatic
- Gonorrhea and Chlamydia
 - In women and men can progress to cause pain at the local site of infection
 - In some women lead to devastating consequences including tubal abscesses, acute or chronic pelvic pain, and infertility
 - Diagnosing infections and getting cured prevent transmission to others and progression to these severe outcomes in women

- HIV
 - Untreated, will progress to severe immunodeficiency and death
 - Treated, it is not transmissible via sex, and people can expect to live a normal, healthy life

Insurance coverage for home kits can be expected to increase testing at home

- Analogous to free or low-cost home COVID testing
- Providing free home HIV test kits increases overall testing and HIV case detection in publicly-funded research programs (*JAMA Intern Med* 2020;180(1):117-125)
- People know when they have potentially been exposed and want to access testing
- Time and stigma are major barriers to making a clinic visit according to surveys (*MMWR* Sep 24, 2021, 70(38):1322-1325) and in my own experience as a provider
- Out-of-pocket cost (generally \$50 - \$300 per test) is currently a major barrier for people to use home kits

Manabe Written Testimony for SB0634_22Feb2022.pdf

Uploaded by: Yukari Manabe

Position: FAV

Testimony for SB0634: Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

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I am an infectious diseases clinician and medical director of the Johns Hopkins Hospital John G Bartlett Specialty Practice that provides HIV and primary care to more than 3000 people living with HIV. We also offer pre-exposure prophylaxis (PrEP) to a group of patients at high risk for HIV. Both of these groups of patients require routine STD screening. Giving patients more options for testing that include self-collection as well as mail-in options will increase timely screening, treatment and help to address the STD epidemics.

Statement of the Problem

- In 2019 (most recent available data), there were 37,778 cases of chlamydia, 11,597 cases of gonorrhea; the rates of both infections have been increasing year on year since 2015.
- The majority of cases of chlamydia are asymptomatic so many of these infections go undiagnosed and untreated. Gonorrhea can also be asymptomatic in women with genital infection and in both sexes with rectal infection.
- Both infections can have severe consequences including pelvic inflammatory disease which can lead to infertility and ectopic pregnancy, and infection in babies born to infected mothers which can lead to blindness and pneumonia
- Without testing, patients cannot know their status in order to get treated and prevent transmitting STIs to others.
- Stigma and inconvenience of coming to static clinics are both barriers to routine screening.

Why this bill will address the problem of STIs including HIV

- ‘Home test kit’ refers to home self-collection of specimens that can be tested in a reference lab after being dropped off or mailed in.
- There is no difference in the accuracy of testing with self-collected compared to clinician-collected samples.
- We know that a significant proportion of patients prefer to self-collect samples for STD testing in the privacy of their own homes.
- Maryland will be only the second state in the country to be so forward thinking in passing legislation that will expand the access to non-clinic-based self-collected samples for STD testing in reference labs. The legislative mandate that insurers pay for this kind of innovative screening approach will increase access and uptake of testing

Why now?

- The COVID-19 pandemic massively disrupted STD testing and clinical care and access to essential services including testing due to closure of STD clinics and massively reduced in-person services.
- During that time, the State of Maryland referred clients to I Want the Kit, an on-line program where users could receive self-collection kits in the mail, and then return swabs to our College of American Pathologists-certified lab for high quality testing. There was a 645% increase in orders for this testing during COVID which has been sustained and continues to increase.
- Providers should be able to order and have insurers pay for similar services to make these kinds of alternatives sustainable.

In summary, I applaud the timely introduction of this bill. Creative approaches for reaching people and allowing them to take control over their own sexual health may change the disturbing trends in STD rates. Without testing to find asymptomatic infection, the continually increasing rates of STIs cannot be reversed.