



MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

November 30, 2018

The Honorable Edward J. Kasemeyer
Chair, Senate Budget and Taxation Committee
3 West Miller Senate Office Bldg.
Annapolis, MD 21401-1991

The Honorable Maggie McIntosh
Chair, House Appropriations Committee
121 House Office Bldg.
Annapolis, MD 21401-1991

RE: 2018 Joint Chairmen's Report (Page 79) – Prophylactic HIV Therapy – M00F03.01

Dear Chair Kasemeyer and Chair McIntosh:

In keeping with the requirements of the 2018 Joint Chairmen's Report (Page 79), the Maryland Department of Health (the Department) submits this report on:

the number of victims that seek sexual assault forensic exams who would be eligible for a full course of non-occupational post-exposure prophylaxis (nPeP) HIV therapy under the current guidelines of the [Centers for Disease Control and Prevention]; the number of individual sexual assault victims who receive, and who are denied, the full course of nPeP HIV therapy under the State's current policies; the cost to the State if an individual contracts HIV due to sexual assault and who did not receive the full course of nPeP HIV therapy; the barriers for victims in accessing nPeP HIV therapy; and mechanisms to cover associated costs of providing nPeP HIV therapy to victims of sexual assault. In making cost estimates, MDH should take into account assumptions regarding how many victims will decline nPeP HIV therapy, including because the victim ascertains the HIV status of their perpetrator or reevaluates their risk, and how many patients will decline to take the full course of nPeP HIV therapy because they cannot tolerate the medication.

If you should have any questions or comments, please do not hesitate to contact Webster Ye, Deputy Chief of Staff, at (410) 767-6480 or at webster.ye@maryland.gov.

Sincerely,

Robert R. Neall
Secretary



MARYLAND
Department of Health

**Joint Chairmen's Report
Prophylactic HIV Therapy (pg. 79)**

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Governor

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Lt. Governor

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Executive Summary

Preventing the spread of human immunodeficiency virus (HIV) continues to be a public health priority for the State of Maryland. HIV has long-term health and social consequences, including expensive healthcare treatments, lost productivity, and social stigmatization. For victims of sexual assault, the additional burden of acquiring HIV can be overwhelming.

Fortunately, medication has improved and can even reduce the risk of infection after a potential exposure. Non-occupational post-exposure prophylaxis (nPEP) HIV therapy is a 28-day course of antiretroviral medication that, when initiated within 72 hours of a potential exposure, can reduce the risk of HIV infection. Ensuring immediate access to this medication is a key strategy to reducing HIV incidence.

The Sexual Assault Reimbursement Unit (SARU) reimburses physicians and hospitals for costs related to conducting forensic examinations and collecting evidence for a victim of sexual assault. Health-General §15-127 states that a hospital providing services to a victim of sexual assault or abuse must do so without charge to the individual. In cases where the risk of HIV infection is high, SARU provides a 3-7 day supply of nPEP HIV therapy in order to ensure treatment is initiated within 72 hours of a potential exposure. Approximately 20 such claims are approved each year.

SARU could be expanded to (1) provide the full 28-day course of nPEP HIV therapy instead of a starter pack, and (2) broaden the guidelines to align with those set by the Centers for Disease Control and Prevention for nPEP HIV therapy. This two-pronged approach may increase access to nPEP HIV therapy, but at a significant cost to the State.

While the Maryland Department of Health recognizes the importance of access to nPEP HIV therapy for victims of sexual assault, additional work is warranted to assess if an unmet need exists and the most effective strategy to address any needs. Neither the Department nor SARU are aware of the various strategies used by hospitals and healthcare providers to ensure access to nPEP HIV therapy. Additional education and outreach to those hospitals within the State designated as Sexual Assault Forensic Examination Centers may be a more appropriate and cost-effective first step towards understanding and addressing barriers to nPEP HIV therapy.

How nPEP HIV therapy costs are covered for victims of sexual assault is a complex issue that will require the collaborative efforts of the Governor's Office of Crime Control and Prevention (where SARU is now housed), healthcare providers, hospitals, advocates for victims of sexual assault, the Planning Committee to Implement Improved Access to Sexual Assault Medical Forensic Examinations in Maryland, and the General Assembly of Maryland.

Introduction

Following the 2018 legislative session, the Joint Chairmen’s Report (JCR) directed the Maryland Department of Health (the Department), in consultation with the Governor’s Office of Crime Control and Prevention (GOCCP), to report on the provision of non-occupational post-exposure prophylaxis (nPEP) human immunodeficiency virus (HIV) therapy to victims of sexual assault. This report provides the best-available information to estimate the scope of the issue and identify possible courses of action to protect the health and safety of victims of sexual assault.

Background

HIV as a Public Health Priority

Victims of sexual assault are at risk for acquiring sexually-transmitted infections, including HIV. Initiating and completing a 28-day course of nPEP HIV therapy (antiretroviral medication) can lower, but not eliminate, an individual’s risk of HIV infection after the potential exposure. Ensuring access to this therapy within 72 hours of the potential exposure is a key public health strategy for preventing HIV infection.

Maryland’s Sexual Assault Reimbursement Unit

Until recently, the Sexual Assault Reimbursement Unit (SARU) was housed within the Department. SARU provides reimbursement for hospitals, physicians, and laboratories providing emergency medical treatment and evidence collection examinations for alleged victims of sexual assault. SARU was established under Health-General §15-127 and regulated under the Code of Maryland Regulations (COMAR) 10.12.02, *Rape and Sexual Offenses – Physician and Hospital Charges*. HB 247 (Chapter 442 of the Acts of 2018) transferred SARU to the newly-created Victim Services Unit within GOCCP as of July 1, 2018.

Current Reimbursement Policies and Practices

Current Guidelines

In most cases, SARU follows the U.S. Department of Justice National Protocol for Sexual Assault Medical Forensic Examinations in referring the victim to the appropriate or confidential and free HIV counseling and testing site.¹ In cases where there was a high risk for HIV infection, SARU provided reimbursement for a starter pack of nPEP HIV therapy to victims of sexual assault. Specifically, claims were paid when 1) the assailant was a known HIV carrier or IV drug user, 2) there was anal penetration, or 3) there were multiple assailants.

A starter pack is generally a 3-7 day supply whereas a full course regimen is 28 days. Starter packs are provided in order to initiate treatment within 72 hours of exposure, giving the victim time to assess their risk and obtain a full course of treatment, often through insurance if covered or through pharmaceutical company patient assistance programs (see [Mechanisms to Cover nPEP HIV Therapy Costs](#)).

Under these guidelines, SARU paid 20 claims for starter packs in 2017 and 21 claims in 2016. It is

¹ Littell, K. (2004). A national protocol for sexual assault medical forensic examinations: Adults/adolescents. NCJ, 228119. Accessed 8/7/2018 at <https://nicic.gov/national-protocol-sexual-assault-medical-forensic-examinations-adultsadolescents-second-edition>.

important to note that SARU's data come from a claims database which does not capture personal information about the victim. Currently SARU does not track the number of claims for nPEP that have been denied. In cases when the victim does not meet SARU's current reimbursement criteria, hospitals may seek reimbursement through another mechanism. The Department does not have any information on claims related to nPEP that were not submitted to the Department.

CDC Guidelines

The Centers for Disease Control and Prevention (CDC) recently updated their guidelines for providing nPEP HIV therapy.² According to these guidelines, nPEP HIV therapy is not recommended when administered over 72 hours after exposure or when there is negligible risk for HIV acquisition. When the exposure was within 72 hours, nPEP HIV therapy is recommended if the source patient (in the case of sexual assault, the assailant) is known to be HIV-positive and is made on a case-by-case basis when the HIV status of the source patient is not known. CDC recommends that patients who meet the guidelines should receive treatment for 28 days.

The Planning Committee to Implement Improved Access to Sexual Assault Medical Forensic Examinations in Maryland has expressed interest in aligning current policies with the CDC's updated guidance. The Department was working with the Committee to re-examine current eligibility and reimbursement policies prior to the transfer of SARU to GOCCP.

While the JCR requested a comparison to the guidelines from the Clinical Consultation Center at the University of California at San Francisco, this report will use the CDC guidelines for comparison. CDC standards are national standards or guidance that are intended for public health agencies such as the Department, and are the most appropriate standard for state-level health policy.

Scope of Issue

Number of Sexual Assaults per Year

According to the Maryland Uniform Crime Report (UCR), there were 1,691 forcible rapes and 124 attempted rapes reported in 2016, the latest year for which data are available. This is up slightly from 1,628 forcible rapes in 2015. In 2015 the National Uniform Crime Reporting program changed the definition of rape, so statistics prior to 2015 are not comparable.

The Maryland UCR only captures cases that are reported to law enforcement and may underestimate the total number of cases of sexual assault. Not all incidents of sexual assault may be reported. A study by the U.S. Department of Justice found that 77% of rapes go unreported. Using this figure there would have been over 7,900 rapes in 2016.³ Even if a victim of sexual assault presents to a hospital, the victim is not required to report the assault to the police in order to receive a medical forensic examination and emergency treatment. Adult rape is not a reportable offense for medical providers and other mandated reporters. The Department has no additional information on the number of victims of sexual assault who may seek forensic exams or nPEP HIV therapy.

² Centers for Disease Control and Prevention. (2016). Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016. *Annals of Emergency Medicine*, 68(3), 335-338.

³ Morgan, R. E., & Kena, G. (2017). *Criminal Victimization, 2016*. U.S. Department of Justice, Office of Justice Programs, NCJ 251150. Accessed 24 October 2018 at <https://www.bjs.gov/content/pub/pdf/cv16.pdf>.

Prescriber Options for Initiating nPEP HIV Treatment

The 2016 CDC Guidelines summarize many of the considerations for choosing whether to prescribe the full 28-day course of nPEP HIV therapy or a 3-7 day starter pack.² Adherence may improve when the entire 28-day nPEP medication supply is provided at the initial visit, especially if the victim has difficulty returning for multiple follow-up visits. A starter pack may be prescribed when a full course of antiretroviral medications is not stocked or immediately available at the healthcare facility. A starter pack may also be prescribed while determining the perpetrator's HIV status or to assess tolerance to the medication before prescribing the full course of treatment. If the victim is pregnant, a child, or has renal dysfunction, a specialist may need to be consulted to modify the medication regimen. If not immediately available at the initial visit, a starter pack may be initiated and the treatment regimen modified as necessary at a future visit with the specialist.

Managing side effects, counseling the patient, and performing follow-up laboratory testing can help improve adherence to nPEP HIV therapy. This may require frequent and early follow-up visits. In cases of sexual assault, the victim is likely under considerable emotional distress when first seeking care after a possible HIV exposure and may not have been attentive to all details presented before making a decision regarding nPEP HIV therapy.

Cost Estimates

Starter Pack

In State fiscal year 2017, SARU provided reimbursement for twenty (20) nPEP starter packs at a total cost of \$10,261.40. Average costs per claim were:

Baseline laboratory tests:	\$236.71
<u>nPEP starter pack:</u>	<u>\$276.36</u>
Total cost per person:	\$513.07

These costs are derived from the SARU claims database and were an average of the costs for nPEP HIV therapy obtained from itemized bills submitted by hospitals seeking reimbursement from SARU. Baseline laboratory tests are used to assess current HIV status. Hospitals often only billed the Department for 1 day of therapy, suggesting hospitals covered the cost of these medications by other means.

Full Course

The following are the estimated costs for a full course of nPEP HIV therapy:

Baseline laboratory tests:	\$236.71
28-day nPEP medication:	\$3,111.00
<u>Follow-up testing:</u>	<u>\$205.44</u>
Total cost per person:	\$3553.15

The baseline laboratory tests are the same as for the starter pack and are based on previous SARU claims. The 28-day supply of antiretroviral medication is based on the actual wholesale cost based on the most recent Medicaid price for the three most frequently prescribed nPEP HIV therapy regimens.

Beyond the additional nPEP medication costs, a full course of treatment requires additional follow-up tests for creatinine function and liver function to ensure continuation of treatment is not contraindicated. The cost of these follow-up tests is based on the American Medical Association's 2017 Clinical Diagnosis Laboratory Fee Schedule.

Expanded Eligibility

In addition to the increased costs associated with providing a 28-day full course of treatment, aligning SARU's reimbursement eligibility criteria to the CDC's guidelines would greatly expand the number of victims of sexual assault who would be eligible for nPEP HIV therapy. Unless treatment would be initiated over 72 hours after exposure (where treatment is not recommended) or the assailant is a known HIV carrier (where treatment is recommended), the CDC guidelines largely leave the treatment decision up to the provider and victim on a case-by-case basis. Because SARU is the payer of first resort, expanding eligibility guidelines would greatly increase the costs to the program.

The Department does not have data on the proportion of victims of sexual assault who present to a healthcare provider over 72 hours after exposure or the proportion of cases in which the assailant is a known HIV carrier. The Department does not have data on the number of victims of sexual assault for whom, according to CDC guidelines, a full-course of nPEP HIV therapy would be recommended. For illustrative purposes, if a full course of nPEP HIV therapy were provided to every reported victim of sexual assault in 2016, the cost to the State would be approximately \$6 million for treatment alone. SARU would need one additional nurse auditor to handle the additional work load, at an annual cost of \$55,000. While nPEP HIV therapy may not be indicated in each of these cases (such as if it would be initiated 72 hours or more after exposure), it is also probable that the total number of sexual assaults as reported by the Maryland UCR is an undercount of the total number of cases.

Cost to State of HIV Infection

The CDC estimates that the average costs of HIV care are \$23,000 per year and \$379,668 over the course of the patient's lifetime (in 2010 dollars). In Maryland, approximately 1,400 new HIV diagnoses are made per year at a total lifetime cost of \$514 million.⁴

These costs are not specific to HIV contracted as a result of sexual assault. These costs represent healthcare costs only and do not include other costs, such as loss of productivity. The proportion of these costs borne by the State is not known. The Department does not have the data necessary to assess the costs to the State if an individual did not receive the full course of nPEP HIV therapy and contracts HIV due to sexual assault.

Assumptions and Limitations

Not all victims of sexual assault may initiate or complete nPEP HIV therapy. A 2015 meta-analysis of 54 studies sought to estimate the rate of initiation and adherence for participants who were prescribed either a starter pack or full 28-day course of nPEP HIV therapy.⁵ The researchers evaluated the quality of the evidence, and thus the reliability of their findings, as "very low." At this time, the Department does not believe there is sufficient evidence to estimate the proportion of survivors who would decline or fail to comply with treatment.

⁴ <https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html>

⁵ Ford, N., Venter, F., Irvine, C., Beanland, R. L., & Shubber, Z. (2015). Starter packs versus full prescription of antiretroviral drugs for postexposure prophylaxis: a systematic review. *Clinical Infectious Diseases*, 60 (suppl_3), S182-S186.

Some victims of sexual assault may discontinue treatment due to intolerance of the medication. In these cases, the costs of follow-up laboratory testing may not apply. However, the full cost of the medication would be billed when the prescription is filled, so the majority of costs are not recoverable. If a known assailant tested negative for HIV, this would be another reason why a victim would discontinue treatment. As stated above, if the victim received the full pack of medication initially, the vast majority of the costs would already be paid and the only savings would be from not having the follow-up laboratory tests. Additionally, some individuals may simply choose to stop taking the medication. Again, the same considerations regarding costs would apply.

It is possible a victim of sexual assault may know the assailant is a carrier of HIV. However, it cannot be definitively known that an assailant is *not* a carrier of HIV. In some cases, the assailant may not know themselves that they are a carrier of HIV. HIV status can only be known through a recent and reliable laboratory test.

The lack of accurate data on these and other issues make cost estimates difficult. For these reasons it is appropriate to use a conservative estimate of costs in order to ensure the SAFE program is able to serve all victims.

Barriers to Accessing nPEP HIV Therapy

A 2017 meta-analysis of six studies found the proportion of sexual assault patients who were offered nPEP HIV therapy ranged widely from 19% to 100%.⁶ The study found that while some of the variation could be attributed to factors associated with the sexual assault patient (including race, insurance status, age, and presence of injuries), differences between hospital policies or even providers may account for much of the different rate of nPEP HIV therapy being offered. Sexual assault victims often first seek care at an emergency department where staff may not be familiar with nPEP HIV therapy guidelines or have limited experience. Sexual assault nurse examiners or forensic nurses often have more extensive training and education in caring for sexual assault patients, but even in these settings nPEP HIV therapy is not consistently offered to all sexual assault patients.

In a 2017 study, healthcare providers for victims of sexual assault reported mixed levels of comfort providing nPEP HIV therapy, a lack of clear protocols in place for prescribing, and provider knowledge of key pieces of the prescribing guidelines ranging from 40-90%.⁷ Provider discomfort, largely stemming from lack of knowledge and clear protocols at sites, seemed to be the major barrier to offering nPEP HIV therapy.

Additionally, some Maryland programs have received anecdotal information that indicates other reasons for not accessing nPEP HIV therapy could include provider discomfort or unwillingness to prescribe, patient belief that the medication will be too expensive, and lack of provider time to help patients access assistance programs for those without insurance.

⁶ Scannell, M., Kim, T., & Guthrie, B. J. (2018). A Meta-Analysis of HIV Postexposure Prophylaxis Among Sexually Assaulted Patients in the United States. *Journal of the Association of Nurses in AIDS Care*, 29(1), 60-69.

⁷ Straub, D. M., & Suggs, V. (2017). nPEP Provision by Sexual Assault Providers: Why Aren't They Prescribing it?. *Journal of Adolescent Health*, 60(2), S86.

Mechanisms to Cover nPEP HIV Therapy Costs

SARU as Payer of First Resort

Health-General §15-127 states that a hospital providing services to a victim of sexual assault or abuse must do so without charge to the individual. COMAR 10.12.02 further clarifies that a provider may not charge a victim, a victim's family, or insurance carrier. In essence, SARU is the payer of first resort for covered services (as outlined in statute and regulations). Billing the victim's insurance carrier would create concerns about confidentiality among victims and advocates. While the Health Insurance Portability and Accountability Act (HIPAA) requires personal health information be treated as confidential, HIPAA may be insufficient to ensure privacy when family members share the same health insurance plan (for example, a college student on her parents' plan, the victim has a company sponsored plan, etc.). SARU is the payer of first resort to ensure no statement of medical services information is sent to the victim or his/her family or employer, violating confidentiality.

Expanding covered services to include the full course of nPEP HIV therapy would likely result in shifting costs from hospitals, insurance companies, the State and Federal Medicaid program, and pharmaceutical companies to the State. By only covering a starter pack, SARU does not limit the ability of other funding mechanisms to cover the costs of nPEP HIV therapy. While other mechanisms may be available to cover the costs of nPEP HIV therapy (discussed below), statutory changes may be necessary to use alternative funding mechanisms.

Maryland Medical Assistance Program

For those who qualify for the Maryland Medical Assistance Program (also known as Medicaid), nPEP HIV therapy medications are covered with a \$1 copay if participants obtain a prescription and are not on any other HIV medication. The Department does not have any information on the proportion of sexual assault victims who qualify for Medicaid.

Pharmaceutical Company Patient Assistance Programs

The CDC recommends a treatment regimen of Truvada with a secondary medication such as Tivicay or Isentress. Gilead has a patient assistance program for the medication Truvada. For the uninsured with incomes below 500% federal poverty level, Gilead provides immediate access once in a patient's lifetime. The patient is enrolled via telephone after the provider faxes a letter of medical necessity, and the patient is provided a bank identification number, processor control number, and prescription number to facilitate payment at the pharmacy. Tivicay, manufactured by Viiiv, can be obtained through the exact same process through phone enrollment but must be done by an advocate. Isentress can only be obtained via a paper enrollment form with medications sent overnight, but this is not ideal given the short 72 hour window to initiate nPEP, so Truvada with Tivicay is the preferred regimen for the uninsured.

Conclusion

The primary function of SARU is to reimburse hospitals, physicians, and laboratories for the examination and collection of forensic evidence of victims of sexual assault. In cases where the victim is at a high risk of HIV infection, SARU provides reimbursement for a starter pack of nPEP HIV therapy to ensure therapy is initiated within the critical 72 hour window after a potential exposure. To date, SARU reimburses about 20 of these claims each year.

It is likely that when a victim of sexual assault does not meet SARU's current criteria for reimbursement for nPEP HIV therapy, hospitals pursue other options for obtaining and initiating treatment. Without additional information, it is not possible for the Department to accurately determine if there is an unmet need for access to nPEP HIV therapy. The Department recognizes the critical importance of immediate access to antiretroviral medication, but expanding eligibility guidelines and coverage for the full 28-day course of nPEP HIV therapy could greatly escalate costs, threatening SARU's ability to provide its core services. Increasing provider knowledge of nPEP HIV therapy guidelines and coverage options and encouraging hospitals to have clear prescribing policies may be cost-effective ways to increase access to nPEP HIV therapy.

Other areas that should be explored before expanding the current nPEP programs include possible sources of State and federal funding, negotiating with pharmaceutical companies regarding drug pricing, partnering with a pharmacy regarding drug pricing, determining whether there is a way to eliminate or reduce privacy concerns regarding use of individual insurance, ensuring that vouchers for drugs are fully used, and determining whether there is a current State prescription drug program that could assist in managing the costs of the drugs. It may be that a combination of these items can be used to reduce costs and ensure greater availability of nPEP HIV therapy.