



**Department  
of Health**

# Post-Exposure Prophylaxis in NYS

**June 13, 2017**

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**Office of the Medical Director, AIDS Institute**

**Health Home Webinar**

**June 14, 2017**

# Post Exposure Prophylaxis (PEP) is HIV Prevention

An HIV un-  
infected  
person



Single high  
risk event



Takes 28  
days of  
medication



to prevent  
becoming  
infected  
with HIV



# National Guidelines

## Post Exposure Prophylaxis

- Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Post-Exposure Prophylaxis
  - Infect Control and Hosp Epidemiology 2013: 34(9): 875-892
- Updated Guidelines for Antiretroviral Post-Exposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016
  - <https://stacks.cdc.gov/view/cdc/38856>



# New York State Guidelines

## Post Exposure Prophylaxis

- HIV Prophylaxis Following Occupational Exposures
  - October, 2014
- HIV Prophylaxis Following Non-Occupational Exposures
  - October, 2014
- HIV Prophylaxis for Victims of Sexual Assault
  - October, 2014

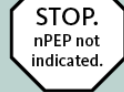
# FIGURE 1. Steps for Evaluating and Managing a Non-Occupational Exposure

## STEP 1: Evaluation of exposure: *Is nPEP indicated?*

### LOWER-RISK EXPOSURES:

- Oral-vaginal contact (receptive and insertive)
- Oral-anal contact (receptive and insertive)
- Receptive penile-oral contact with or without ejaculation
- Insertive penile-oral contact with or without ejaculation

*See text for factors that may increase risk. If PEP is indicated, go to Step 2.*



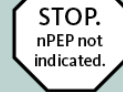
### HIGHER-RISK EXPOSURES:

- Receptive and insertive vaginal or anal intercourse with HIV+ or unknown source
- Needle sharing with HIV+ or unknown source
- Injuries with exposure to blood or other potentially infected fluids from HIV+ or unknown source (including needlesticks with a hollow-bore needle, human bites, accidents)

### EXPOSURES THAT DO NOT WARRANT nPEP:

- Oral-to-oral contact without mucosal damage (kissing or mouth-to-mouth resuscitation)
- Human bites not involving blood
- Exposure to solid-bore needles or sharps not in recent contact with blood
- Mutual masturbation without skin breakdown or blood exposure

*Provide risk-reduction counseling and offer HIV test.*



## STEP 2: Is patient presenting within 36 hours?

YES<sup>a</sup>



## STEP 3: Initiate first dose of nPEP regimen

**STEP 2:** Is patient presenting within 36 hours?

YES<sup>a</sup>



**STEP 3:** Initiate first dose of nPEP regimen


**28-DAY REGIMEN — Recommended PEP Regimen:<sup>b,c</sup>**

Tenofovir 300 mg PO qd + Emtricitabine<sup>d</sup> 200 mg PO qd

**PLUS**

Raltegravir<sup>e</sup> 400 mg PO bid or Dolutegravir<sup>e</sup> 50 mg PO qd

*See text for alternative regimens*



**STEP 4:** Baseline testing

## STEP 4: Baseline testing

### BASELINE TESTING OF EXPOSED PERSON:

- HIV test\*
- Pregnancy test for women
- GC/CT NAAT (based on site of exposure)
- RPR for syphilis

\* nPEP should not be continued in those who decline baseline HIV testing

See Section IX for hepatitis B and C post-exposure management.



### SOURCE TESTING, *if source is available*:

- Obtain consent for HIV testing
- Obtain HIV test with turnaround time <1 hour
- If the test results are not immediately available, continue exposed person's nPEP while awaiting results
- If the source person's HIV screening test result is negative but there may have been exposure to HIV in the previous 6 weeks, obtain plasma HIV RNA assay
- Continue exposed person's nPEP until results of the plasma HIV RNA assay are available

## STEP 5: Provide risk-reduction counseling

- Provide risk-reduction and primary prevention counseling
- Refer for mental health and/or substance use programs when indicated; consider need for intensive risk-reduction counseling services
- Discuss future use of PrEP with persons with ongoing risk behavior (see Appendix C for AI-funded referral sources)

<sup>a</sup> Decisions to initiate nPEP beyond 36 hours post-exposure should be individualized, with the realization of diminished efficacy when timing of initiation is prolonged; assess for hepatitis B and C; recommend serial HIV testing at 0, 4, and 12 weeks; provide risk-reduction counseling.

<sup>b</sup> If the source is known to be HIV-infected, information about his/her viral load, ART medication history, and history of antiretroviral drug resistance should be obtained when possible to assist in selection of a PEP regimen. **Initiation of the first dose of PEP should not be delayed while awaiting this information and/or results of resistance testing.** When this information becomes available, the PEP regimen may be changed if needed in consultation with an experienced provider.

<sup>c</sup> See Appendix A for dosing recommendations in patients with renal impairment.

<sup>d</sup> Lamivudine 300 mg PO qd may be substituted for emtricitabine. A fixed-dose combination is available when tenofovir is used with emtricitabine (Truvada 1 PO qd).

<sup>e</sup> See Appendix A for drug-drug interactions, dosing adjustments, and contraindications associated with raltegravir and dolutegravir.

# Timing of PEP Initiation

- When a potential exposure to HIV occurs, every effort should be made to initiate PEP as soon as possible, ideally within 2 hours. ([AII](#))
- Decisions regarding initiation of PEP beyond 36 hours post exposure should be made on a case-by-case basis with the realization of diminished efficacy when timing of initiation is prolonged. ([AII](#))

*NYS Guidelines*





# Initiate PEP

- **HIV**
- STI
- Hepatitis B and C
- Pregnancy

# Adherence

- You may experience side effects, and if you do, these are the things you can do.....
- If these do not help, let us know and we can help manage the side effects or change your medications.
- Do not stop medication without speaking with your provider first.
  - Provide a number to call

# PEP Follow-Up Schedule

Table 6: Monitoring Recommendations After Initiation of PEP Regimens Following Occupational Exposure<sup>a</sup>

	<b>Baseline</b>	<b>Week 1</b>	<b>Week 2</b>	<b>Week 3</b>	<b>Week 4</b>	<b>Week 12</b>
<b>Clinic Visit</b>	√	√ Or by telephone	√ Or by telephone	√ Or by telephone	√	
<b>Pregnancy Test</b>	√					
<b>Serum liver enzymes, BUN, creatinine, CBC<sup>b</sup></b>	√		√		√	
<b>HIV test <sup>c</sup></b>	√				√	√

<sup>a</sup> For post-exposure management for hepatitis B and C, see [Section XI: Occupational Exposures to Hepatitis B and C](#)

<sup>b</sup> CBC should be obtained for all exposed workers at baseline. Follow-up CBC is indicated only for those receiving a zidovudine-containing regimen.

<sup>c</sup> Recommended even if PEP is declined.



## Priorities 2015-2016

Increase awareness of and access to nPEP through consumer materials, clinical provider education, nPEP guidelines and CEI line access for clinical provider questions.

# Increase Consumer Awareness

- A list of PrEP/PEP prescribers who have volunteered to be included in the directory. Please see the PrEP-AP Participating Providers list in PrEP-AP.
- [PrEP-AP Participating Providers](#) (PDF)
  - A list of PrEP providers that meet the criteria of the PrEP-AP program.
- [PrEP and PEP Consumer Education Materials On-Line Order Form](#)

## Exposure to HIV is a Medical Emergency

There is emergency protection after a possible exposure to HIV, but you must act quickly. Exposure to HIV is a medical emergency.

You may be able to stop the infection by taking medications.

- [I Might Have Been Exposed to HIV... What Should I do?](#) (PDF)
  - [Podría Haber Estado Expuesto Al VIH...¿Qué Debo Hacer?](#) (PDF)
    - To order copies, [please use the on-line order form.](#)

Go to a hospital emergency room right away or talk to your medical provider right away.

Print this fact sheet and take it to the emergency room with you

- [Fact Sheet](#) (PDF)



### HIV/AIDS

- General Information
  - 1-800-541-AIDS
  - 1-800-233-7432 Spanish
- AIDS Drug Assistance Program (ADAP)
  - 1-800-542-2437
- HIV Confidentiality Hotline
  - 1-800-962-5065

### CEI Program & Services for clinicians

- (315) 477-8479 or visit [www.ceitraining.org](http://www.ceitraining.org)
  - Post-Exposure Prophylaxis Hotline (PEP Line)
    - 1-866-637-2342
- HIV/Hepatitis C
  - 1-866-637-2342
- STDs
  - 1-866-637-2342

## What Is PEP?

If you are HIV-negative and you believe you have just been exposed to HIV, PEP (Post-Exposure Prophylaxis) is medication you can take that may prevent HIV infection. PEP works best if taken within 36 hours of exposure.


**If you think you were exposed to HIV, go to a hospital emergency room (ER) right away and bring this information with you. Or, if you can talk with your primary care provider right away, call as soon as possible if you:**

- Didn't use a condom -- or the condom broke or slipped off -- during anal or vaginal sex with someone who is HIV positive or who may be HIV positive.
- Had unprotected oral sex with someone who you know is HIV positive or someone whose HIV status you don't know. (You are less likely to get HIV from oral sex.)
- Shared needles or other drug injection equipment.
- Were raped or sexually assaulted.


**What can you expect when you go to get PEP?**

- Questions about your exposure --- answering honestly will help you and the provider figure out your risk.
- An HIV test.
- Tests for sexually transmitted diseases.
- Offers of a pregnancy test and birth control, if appropriate.
- A prescription for PEP, if needed.
- Information about the next steps you should take.

**Resources for your health care provider**  
 PEPLine: 1-866-637-2342 (providers only)  
[www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis](http://www.hivguidelines.org/clinical-guidelines/post-exposure-prophylaxis)




Save this information to your mobile device in case of emergency.




# Increase Consumer Awareness


## PEP




**Had Sex Without A Condom?**



**Don't Know Partner's HIV Status?**




**Condom Broke?**



**Shared A Needle?**

Go To Emergency Room Within 36 Hours For Medicine (Post Exposure Prophylaxis or PEP) That Can Prevent HIV Infection.

[health.ny.gov/pep](http://health.ny.gov/pep)



### Payment Options for Post-Exposure Prophylaxis Following Non-Occupational Exposures Including Sexual Assault (nPEP)

**Sexual Assault**  
Chapter 39 of the Laws of 2012 amending Section 2805-1 of Public Health Law requires hospitals to provide the first seven days of medication to victims of sexual assault. Prescriptions must be given for the remaining 21 days.

<b>Medicaid</b>	PEP is covered.
<b>Private Insurance</b>	PEP coverage is based on plan. Large co-pay may be a consideration. NYS Office of Victim Services (OVS) may reimburse co-pays of a victim who submits an eligible application with the agency. Co-payment cards are available from the manufacturers. Gilead - 1-877-505-6986 Merck - 1-855-834-3467 or <a href="http://www.isentress.com">www.isentress.com</a> ViiV Healthcare - 1-866-747-1170 or <a href="http://www.mysupportcard.com/">http://www.mysupportcard.com/</a>
<b>Insured, but does not use insurance</b>	A victim may decline to provide insurance information if he/she believes provision of that information would substantially interfere with his or her personal privacy or safety. A victim may ask the provider to directly bill the OVS for the Forensic Rape Exam (FRE), including the first seven days of medication.
<b>No Insurance</b>	OVS may be directly billed as above and the victim may apply to OVS for expenses beyond the FRE, including a prescription for the remaining 21 days.
<b>NYS Office of Victim Services (formerly the Crime Victims Board)</b>	OVS has an Emergency Award Procedure designed to pay the pharmacy in 1-4 days. It is important that the forms be filled out correctly and submitted with the supporting information requested. Emergency awards are available for up to \$2,500. It is best to work with Victim Advocates in your community to pursue this process; they know the community connections and the procedure to expedite this process. Call 1-800-247-8035 or go to <a href="http://www.ovs.ny.gov">www.ovs.ny.gov</a> for more information.

For All Other Non-Occupational Exposures in any Health Care Setting

<b>Medicaid</b>	PEP is covered.
<b>Private Insurance</b>	PEP coverage is based on plan. Co-payment cards are available from the manufacturers. Gilead - 1-877-505-6986 Merck - 1-855-834-3467 or <a href="http://www.isentress.com">www.isentress.com</a> ViiV Healthcare - 1-866-747-1170 or <a href="http://www.mysupportcard.com/">http://www.mysupportcard.com/</a>
<b>Uninsured</b>	<ul style="list-style-type: none"> <li>• Treating institution provides immediate access to drugs.</li> <li>• Begin application process for Medicaid, if appropriate. (Coverage is not guaranteed).</li> <li>• Explore the Patient Assistance Programs from pharmaceutical companies.</li> <li>• Contact your human service/social work department for special funds.</li> </ul>
<b>Patient Assistance Programs</b>	Common Patient Assistance Program Application (HIV) <a href="http://dhah.hrsa.gov/files/programassistform.pdf">http://dhah.hrsa.gov/files/programassistform.pdf</a> HIV meds are listed by company with instructions on how to submit the application. You may need to apply to more than one company depending on regimen chosen. Please see specific application processes on the next 2 pages for Gilead, Merck, and ViiV Healthcare.




I MIGHT HAVE BEEN EXPOSED TO HIV... WHAT SHOULD I DO?

WHAT IS PEP?

PEP (post-exposure prophylaxis) is medicine that you can take if you are HIV-negative and you believe you have just been exposed to HIV. If you take PEP as directed, it can stop the HIV virus from infecting your body.

Do not delay. You need to take PEP as soon as possible after the exposure.

Exposure to HIV is a Medical Emergency. You may be able to stop the infection by taking PEP.



Scan this information to your mobile device in case of emergency.

[www.hivguidelines.org/what-is-peg](http://www.hivguidelines.org/what-is-peg)

NEW YORK STATE DEPARTMENT OF HEALTH AND THE NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

# Increase Clinical Provider Knowledge



## HIV CLINICAL RESOURCE

OFFICE OF THE MEDICAL DIRECTOR, NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE  
IN COLLABORATION WITH JOHNS HOPKINS UNIVERSITY DIVISION OF INFECTIOUS DISEASES



[www.hivguidelines.org](http://www.hivguidelines.org)

### *What's New – October 2014 Update*

- The Medical Care Criteria Committee now recommends **tenofovir + emtricitabine\* plus either raltegravir or dolutegravir** as the **preferred initial nPEP regimen** because of its excellent tolerability, proven potency in established HIV infection, and ease of administration. **Zidovudine is no longer recommended** in the preferred PEP regimen because it is believed to have no clear advantage in efficacy over tenofovir while having significantly higher rates of treatment-limiting side effects.
- **Plasma HIV RNA testing of the source person** is recommended in addition to HIV serologic screening in the following settings; nPEP should be initiated and continued in these situations until results of the plasma HIV RNA assay are available:
  - If the source person's HIV screening result is negative but there has been a risk for HIV exposure in the previous 6 weeks
  - If the source person's HIV screening result is positive but the confirmatory antibody-differentiation assay is nonreactive or indeterminate
- [Figure 1](#) lists steps for evaluating and managing non-occupational exposures.

# Increase Clinical Provider Knowledge



### RECOMMENDED REGIMEN for Exposed Patients ≥ 13 years old

**28-DAY REGIMEN**

Tenofovir 300 mg PO qd + Emtricitabine 200 mg PO qd  
**PLUS**  
Raltegravir 400 mg PO bld or Dolutegravir 50 mg PO qd


**PREFERRED ALTERNATIVE REGIMENS**

Tenofovir 300 mg PO qd + Emtricitabine 200 mg PO qd  
**PLUS**  
Darunavir 800 mg PO qd or Atazanavir 300 mg PO qd  
or Fosamprenavir 1400 mg PO qd  
**AND**  
Ritonavir 100 mg PO qd

Speak with a clinician experienced in managing PEP if exposed patient is <13 years, pregnant, breastfeeding or requires an alternative regimen

For more information regarding occupational PEP or non-occupational PEP guidelines go to [www.hivguidelines.org](http://www.hivguidelines.org)


To speak with a clinician experienced in managing PEP call the CEI Line 24/7 at **866-637-2342**



### PEP TRIAGE PROTOCOL

**STEP 1: EVALUATE EXPOSURE: IS nPEP INDICATED?**

Did a puncture, mucous membrane, or sexual exposure to potentially HIV-infected fluid occur?

**NO** 

**YES**

Is patient presenting within 36 hours?

**NO** Decision to initiate should be individualized. Assess for Hep B and C, offer serial HIV testing (0, 4 and 12 weeks) and provide risk-reduction counseling

**YES**

**STEP 2: INITIATE FIRST DOSE OF nPEP REGIMEN**  
Refer to recommended and preferred alternative regimens on alternate side of card

**STEP 3: PERFORM BASELINE TESTING**

<p><b>EXPOSED PERSON:</b></p> <ul style="list-style-type: none"> <li>• HIV test</li> <li>• Pregnancy test for women</li> <li>• GC/CT NAAT (based on site of exposure)</li> <li>• RPR for syphilis</li> <li>• Assess for Hep B and C</li> </ul>	<p><b>SOURCE PERSON:</b></p> <ul style="list-style-type: none"> <li>• Obtain HIV test with turnaround time &lt; 1 hour</li> <li>• If results are not immediately available, continue nPEP while awaiting results</li> <li>• If result is negative but there may have been exposure to HIV in the previous 6 weeks, obtain plasma HIV RNA assay</li> <li>• Continue nPEP until results of the plasma HIV RNA assay are available</li> </ul>
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**STEP 4: PROVIDE COUNSELING AND REFERRAL**

- Provide risk-reduction counseling; consider need for intensive risk-reduction counseling services
- Refer for mental health and/or substance use programs when indicated
- Discuss future use of PrEP with persons with ongoing risk behavior

Rev. 1/2014

CLINICAL INQUIRY FOR: HIV • HCV • STD • PEP • PrEP



cei line

1-866-637-2342

ASK AN EXPERT

Call for a clinical inquiry for your patient with an STD, HIV, HCV, or those in need of PEP or PrEP

[www.ceitraining.org](http://www.ceitraining.org)  
866-637-2342



# Increase Access to Healthcare

DECEMBER 1, 2016 | Albany, NY

## Governor Cuomo Announces Series of Groundbreaking New Initiatives to End the AIDS Epidemic in New York State

AIDS

HEALTH

Increase access to post exposure prophylaxis by allowing pharmacists to dispense up to a seven day “starter kit.”

# PEP in Pharmacies

- Laws of 2016, Chapter 502
- Effective March 14, 2017, the New York State Board of Regents has amended the scope of practice of licensed pharmacists in NYS to allow for pharmacists to dispense up to seven days of the HIV post-exposure prophylaxis (PEP) medication regimen to individuals who indicate a recent exposure to HIV. Licensed pharmacists who dispense the initial seven days of medication would be responsible for referring the individual to a health care provider for full evaluation of the exposure, HIV testing and to receive a prescription for balance of the twenty-eight-day medication regimen.
- Link to regulations:  
<http://www.regents.nysed.gov/common/regents/files/317ppca2revised.pdf>

# PEP in Pharmacies

## Next Steps:

- Statewide Implementation Pilot
- Create protocol, FAQ and consumer education sheet
- “Dear Colleague” letter to distribute to clinical providers
- CEI to develop pharmacist education
- Develop a web site
- Develop a media campaign
- Create a decal for pharmacies to post on window
- Continue to pursue issue of ‘breaking bottles’

# Minor Consent

Public Health Law, Section 23.1 and 23.2 of Title 10

- Section 23.1
  - Addition of HIV to Group B, making HIV an STD
- Section 23.2
  - Addition of the reference to ‘prevention services’ (PEP, PrEP)
  - Remove reference to ‘are suspected’ and add ‘at risk’

State register Notice of Adoption

<https://docs.dos.ny.gov/info/register/2017/april12/pdf/Rule%20Making%20Activities.pdf>

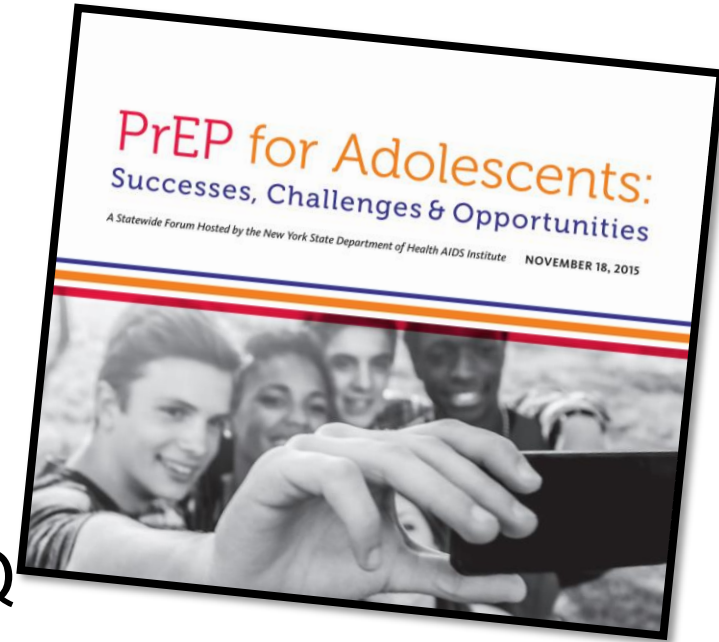


Department  
of Health

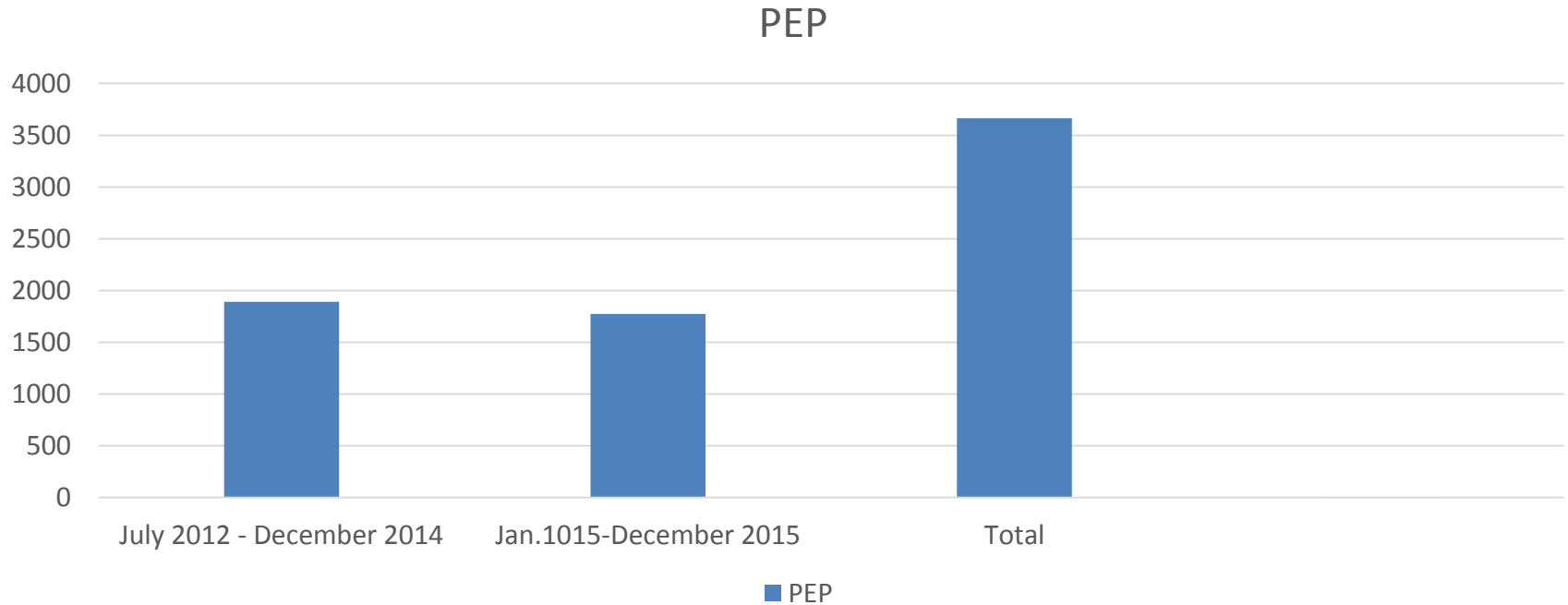
# Minor Consent

## Next Steps

- “Dear Colleague” letter and FAQ
- Consumer brochure
- Continue work on Explanation of Benefits issues



# Use of PEP by Medicaid Recipients



**GET TESTED.  
TREAT EARLY.  
STAY SAFE.**

**End AIDS.**



[health.ny.gov/ete](http://health.ny.gov/ete)

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