

**NEW YORK STATE  
DEPARTMENT OF HEALTH**

**AIDS INSTITUTE**

# **Uninsured Care Programs**

**Pre- Exposure Prophylaxis Assistance Program  
(PrEP-AP)**

**SPECIALTY PROVIDER AGREEMENT**

**518-459-1641**

**EMPIRE STATION  
P.O. BOX 2052  
ALBANY, NEW YORK  
12220-0052**

**NEW YORK STATE DEPARTMENT OF HEALTH/AIDS INSTITUTE  
HIV UNINSURED CARE PROGRAMS**

**Specialty Agreement to support the use of HIV Pre-exposure Prophylaxis, or PrEP through approved New York State Article 28 Providers**

This Agreement signed today, sets forth the terms and conditions governing participation in the New York State Department of Health, AIDS Institute Pre-Exposure Prophylaxis Assistance Program, (the “Program”) administered by Health Research, Inc. (hereinafter referred to as HRI) in cooperation with the New York State Department of Health, AIDS Institute (hereinafter referred to as the “AIDS Institute”) as a “specialty provider”.

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**BACKGROUND**

Pre-Exposure Prophylaxis (PrEP) is an HIV prevention method in which people who do not have HIV take a daily pill to reduce their risk of becoming infected. Based on studies showing significant reduction in HIV acquisition among HIV-negative persons who use PrEP and receive a package of prevention, care and support services, the U.S. FDA approved combination anti-retroviral therapy (ART) for use as PrEP among sexually active adults at risk for HIV infection. A detailed description of the guidelines for the use of Pre-Exposure Prophylaxis (PrEP) to prevent HIV transmission can be found at: <http://www.hivguidelines.org>

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**REIMBURSABLE SERVICES UNDER PrEP-AP**

The services reimbursable under PrEP-AP include the following medical services, provided on an out-patient ambulatory basis. PrEP-AP uses established fee for service Medicaid rate schedules and coding for payment of covered services. No co-payment can be charged to participants. As a PrEP-AP participating provider, you agree to provide your patients with the following services:

1. **Initial Pre-Prescription Education and Evaluation** – Must include the following elements; evaluation and education for the patient regarding the risks, benefits, and options of PrEP. This education includes:
  - How PrEP works as part of a comprehensive prevention plan;
  - The limitations of PrEP;
  - PrEP use, including dosing and adherence;
  - Information regarding prevention of the transmission of HCV infection;
  - Common side effects;
  - The long-term safety of PrEP;
  - Baseline tests and the schedule for monitoring;
  - The criteria for discontinuing PrEP;
  - The possible symptoms of seroconversion;
  - For women, the potential benefits/risks if pregnancy occurs during use of PrEP;
  - Perform laboratory tests (reporting of the test results to the patient):
    - Baseline HIV Test
      - Third-generation and fourth-generation HIV test
      - Nucleic acid amplification test (NAAT, viral load) for HIV for:
        - Patient with symptoms of acute infection
        - Patients whose antibody test is negative but who have reported unprotected sex with an HIV-infected partner in the last month
    - Basic Metabolic Panel
    - Urinalysis
    - Serology for Viral Hepatitis A, B, C

- Screening for Sexually Transmitted Infections (NAAT for gonococcal and chlamydia infection-3 site screening (genital, rectal, pharyngeal)
- Pregnancy Test

## 2. Prescribing and Monitoring PrEP

- Lab report and Prescription visit:
  - Write a 30 day prescription of Truvada (TDF/FTC), one tablet daily to begin when patient has a confirmed negative HIV test result
- 30-day visit:
  - Assess side effects
  - Serum creatinine and calculated creatinine clearance for patients with borderline renal function or at increased risk for kidney disease (>65 years of age, black race, hypertension, or diabetes)
  - Discuss risk reduction and provide condoms
  - Provide a 90 day prescription
- 3-month visit:
  - HIV test
  - Ask about STI symptoms
  - Discuss risk reduction and provide condoms
  - Serum creatinine and calculated creatinine clearance
  - Pregnancy test
- 6-month visit:
  - HIV test
  - Obtain STI screening tests
  - Pregnancy test
  - Discuss risk reduction and provide condoms
- 9-month visit:
  - HIV test
  - Ask about STI symptoms
  - Discuss risk reduction and provide condoms
  - Serum creatinine and calculated creatinine clearance
  - Pregnancy test
- 12-month visit:
  - HIV test
  - Obtain STI screening tests
  - HCV serology for MSM, IDUs and those with multiple sexual partners
  - Pregnancy test
  - Urinalysis
  - Discuss risk reduction and provide condoms

## 3. Discontinuation of PrEP Regimen

PrEP should be discontinued and the participant terminated from PrEP-AP if the patient:

- Receives a positive HIV test result
- Develops renal disease
- Is non-adherent to medication or appointments after attempts to improve adherence
- Is using medication for purposes other than intended
- Reduced risk behaviors to the extent that PrEP is no longer needed
- Requests discontinuation with referral to risk reduction support services and documentation of referral

Note: For women who become pregnant while using PrEP, continuation of PrEP during pregnancy is an individualized decision based on whether there are ongoing risks for HIV during pregnancy.

The approved Provider agrees to be legally bound to the following:

1. Provider's RESPONSIBILITIES:

- A. The Provider agrees to participate in the Program and to comply with all Federal and New York State laws generally and specifically governing participation in the Medicaid Programs. The Provider agrees to be knowledgeable of and to comply with applicable rules, regulations rates and fee schedules promulgated under such laws and any amendment; thereto. The Provider further certifies that it has all licenses, certifications and regulatory clearances required under State and Federal law and/or regulation to perform the services to be reimbursed hereunder, and that it is legally qualified in all aspects to perform such services.
- B. The submission by or on behalf of the Provider of any claim for payment under the Program shall constitute certification by the Provider that:
  - 1. the services or items for which payment is claimed was actually provided by the Provider to the PrEP-AP member(s); and
- C. The Provider will accept payment from HRI as payment in full and will not seek additional reimbursement from PrEP-AP members.
- D. The Provider agrees to prepare and maintain contemporaneous records demonstrating its right to receive payment under the Program and to keep for a period of six years from the date of service all information regarding claims for payment submitted by or on behalf of, the Provider and to furnish such records and information, upon request, to the New York State Department of Health (NYSDOH), HRI and its agents and/or designees.
- E. The Provider will not discriminate in its provision of services reimbursed under this Agreement based on any non-merit factor, including race, national origin, color, religion, sex, sexual orientation, gender identity, disability (physical or mental), age, status as a parent, or genetic information. The Provider has an affirmative duty to take prompt, effective, investigative and remedial action where it has actual or constructive notice of discrimination in the terms, conditions or privileges of provision of services to a member or potential member hereunder based on the factors listed above.
- F. The Provider will permit audits of claims made under this Program. Such audits may be performed by the Federal Government, NYSDOH, HRI and/or their representative.
- G. The Provider will submit claims for payment on officially authorized claim forms or other acceptable methods approved by the Program. All such payments shall be subject to correction and adjustment upon audit under Paragraph (F) above.
- H. The Provider certifies payment made by HRI under this Agreement shall not duplicate reimbursement of costs or services provided pursuant to this agreement that are received from other sources including, but not limited to client fees, private insurance, public donations, grant, or legislative funding from other units of government of any other source.
- I. Provider represents that the information submitted in or with the application for enrollment to participate in the Program and from which this Agreement ensued is true, accurate and complete. The Provider agrees further that such representation shall be a continuing one and that the Provider shall notify HRI (in writing within fifteen (15)) days of its occurrence, if any fact arises or is discovered subsequent to the date of the application which affects the truth accuracy or completeness of such representation.

- J. Provider agrees that it shall not claim or assert any proprietary interest in any of the data or materials produced or delivered by the Provider in the performance of the covered services reimbursed hereunder. The Provider shall not infringe upon any copyright, trademark, patent, statutory or other proprietary rights of others and will hold harmless HRI, the New York State Department of Health and the State of New York from any costs, expenses, and damages resulting from any breach of this warranty.
- K. Provider agrees to indemnify and hold harmless HRI, the New York State Department of Health and State of New York from and against any and all claims of any third parties for damage and expenses of whatsoever nature arising from growing out of, or related to the Provider's negligence or sole failure to perform any and all services reimbursed under the Agreement.
- L. The Provider, its officers, agents and employees and subcontractors shall treat all client/patient information, which is obtained by it through its performance under this Agreement, as confidential information to the extent required by the laws and regulations of the United States and laws and regulations of the State of New York.
- M. The Provider is a corporation authorized to expend funds for any loss, claim, action or judgment. The Provider will defend, settle, and without limitation satisfy any judgment against it in connection with claims and/or litigation filed against it.

2. ADDITIONAL TERMS

- A. The effective date of the agreement is \_\_\_\_\_ and shall remain in effect until terminated in accordance with this Agreement. Termination of the agreement shall not relieve the restitution of overpayment for services or items made prior to termination in accordance with paragraphs 1. (C) and 1. (G).
- B. It is understood that either the Provider or HRI by giving 30 days written notice, may terminate this Agreement. It is understood and agreed, however, that in the event that the Provider is in default upon any of its obligations here under at the time of such termination such right of termination on the part of HRI shall expressly be in addition to any other rights or remedies which HRI may have against the Provider by reason of such default.
- C. HRI may terminate this Agreement at any time. HRI may honor claims for services properly submitted within 90 days of such approved services, which in its judgment arose from services rendered by Provider prior to the date of termination by HRI.
- D. This Agreement shall not be construed to contain any authority, either, express or implied, enabling the Provider to incur any expense or perform any act on behalf of HRI and/or Program.

Provider Commitment:

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Title



Make additional copies of this form to include all Locator Codes for this Facility:

**ADDITIONAL LOCATIONS FOR THIS FACILITY:**

MMIS Locator Code:  Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State:  Zip Code:

Main Phone: (  )  -  Ext:

Patient Phone: (  )  -  Ext:

MMIS Locator Code:  Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State:  Zip Code:

Main Phone: (  )  -  Ext:

Patient Phone: (  )  -  Ext:

MMIS Locator Code:  Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State:  Zip Code:

Main Phone: (  )  -  Ext:

Patient Phone: (  )  -  Ext:

MMIS Locator Code:  Facility Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State:  Zip Code:

Main Phone: (  )  -  Ext:

Patient Phone: (  )  -  Ext: