

Pharmacy-Based HIV Prevention (PrEP) and Sexual Health Care: Getting Started

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June 3, 2022

Last Updated: 05/24/2022

Logistics

- Webinar is being recorded.
- Type in your questions or comments via Q/A or Chat.
- CE's offered through Washington State Pharmacy Association.
 - Evaluation link will be shared at the end of the webinar via chat and sent to participants via e-mail.
 - Secret Code: PIPAR

Disclaimer

Funding for this presentation was made possible [in part, if applicable] by U10HA29296 from the Human Resources and Services Administration HIV/AIDS Bureau. The views expressed do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government. *Any trade/brand names for products mentioned during this presentation are for training and identification purposes only.*



Data presented in this presentation offer a limited glimpse of health inequities that exist within a larger social context. Racism, not race, creates and perpetuates health disparities.

Disclosures

Annalisa Thomas, PharmD has no disclosures.

Elyse Tung, PharmD received honoraria from CDC, HRSA, Gilead Sciences Inc., and ViiV Healthcare Ltd for advisory boards and speaker's bureau participation.

Objectives

- List options for workflow and setting considerations
- Summarize testing options
- Explain policies necessary to manage reactive or positive test results
- Identify financial considerations for dispensing PrEP medications from a pharmacy
- Describe how long-acting injectable PrEP fits into your practice

Framework for Pharmacist Model

- Collaborative Drug Therapy Agreement
 - State RCW 18.64.011 (23): “Practice of pharmacy includes. . . The initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs.”
- Pharmacist providing PrEP
 - Screening, counseling, prescribing and laboratory monitoring
 - All routine follow up care
- Dispensing of medication
- Paying for services
 - Credentialing and provider status
 - WA State PrEP DAP

Patient Experience and Workflow

1. Patient checks in for their appointment with front end staff
2. Clinical pharmacist conducts appointment
 - Patient interview
 - Makes assessment and plan
 - Orders and collects labs
 - Issues prescription if appropriate
 - Medication and behavioral risk reduction counseling
 - Administers vaccines
 - Documents visit note in EHR, SOAP note style
 - Complete superbill

Patient Experience and Workflow

3. Technician prepares prescription
 - Patient assistance program enrollment
4. Staffing pharmacist checks prescription
5. Front end staff checks patient out and finalizes transaction

Setting Considerations: Administrative Tasks

Pharmacists

- Charting
- Superbill
- Sign labs
- Call on reactive/positive results
- Prior authorizations
- Refill authorizations
- Respond to patient clinical inquiries
- Maintain laboratory competencies
- County STI case reports

Technician

- Patient assistance program management
- Patient scheduling
- Lab processing
- Document scanning
- Prior authorizations
- Laboratory quality control
- Processing prescriptions
- Medical billing management

Setting Considerations

- Where will patient be seen?
- Where will labs be collected?
- What bathroom facilities are available?
- Where will labs be processed?
- How will patients get their medications?
- Where will patients receive deep gluteal intramuscular injections?

Data: March 2015 through Feb 2018

714 patients were evaluated in the clinic

Table 1. Patient characteristics

PrEP, pre-exposure prophylaxis; MSM, men who have sex with men; TDF/FTC, tenofovir disoproxil fumarate/emtricitabine; PDC, proportion of days covered; PCP, primary care provider

Individuals initiating PrEP

Number of individuals (<i>n</i>)	695
Age (mean years, range)	34.7 (18–71)
Male (<i>n</i> , %)	686 (98)
MSM (<i>n</i> , %)	584 (84)
Start same-day medication (<i>n</i> , %)	513 (74)
Person-years (mean per individual, range)	607 (0.83, 0.1–2.8)

Discontinuation

Number of patients that discontinued service (<i>n</i>)	323
Mean days in service (<i>n</i> , range)	241 (22–840)
Transferred care to PCP (<i>n</i> , %)	114 (34)
Lost to follow up (<i>n</i> , %)	135 (41)
Decreased perceived risk (<i>n</i> , %)	40 (12)
Relocation (<i>n</i> , %)	34 (11)

Testing Options

Testing Options

- Lab samples needed: finger stick blood, venipuncture blood, urine, rectal, throat, and vaginal specimens
- Medical Test Site Certificate of Waiver License (CLIA-waiver)
 - Dedicated patient space
 - Dedicated lab processing space
 - Policies for competencies and quality control
- Establish a contract with a medical laboratory facility
- Determine who will complete lab sample collection
 - MA-phlebotomy license is necessary to complete venipunctures
 - Laboratory facility draw sites
 - Provider collection or patient self-collection
 - Rectal, urine, throat, and vaginal specimens

Positive or Reactive Test Results

- HIV:
 - Know what to do with a positive HIV test:
<https://www.hiv.uw.edu/go/screening-diagnosis>
 - Preliminary positives referred out for further evaluation
 - Emphasis on linkage to same day care and same day start for treatment
 - Establish a clear process to connect patients to follow up
- STIs: syphilis, chlamydia, and gonorrhea
 - Refer patient out: PCP, urgent care, or Public Health
 - CDTA to treat STI: stock antibiotics in pharmacy
 - Bicillin LA deep gluteal intramuscular injection
- Renal function decline: follow up parameters, refer to CDTA
- Hepatitis B: reactive HBsAg follow up
- Pregnancy test: refer to your CDTA

Financial Considerations for Dispensing PrEP

Considerations for Dispensing PrEP Medications from a Pharmacy

Medical Benefit

- WA State SSB 5557: provider status for pharmacist
- Clinical visits
- Labs
- Medically administered medications

Pharmacy Benefit

- Medications
- Vaccines

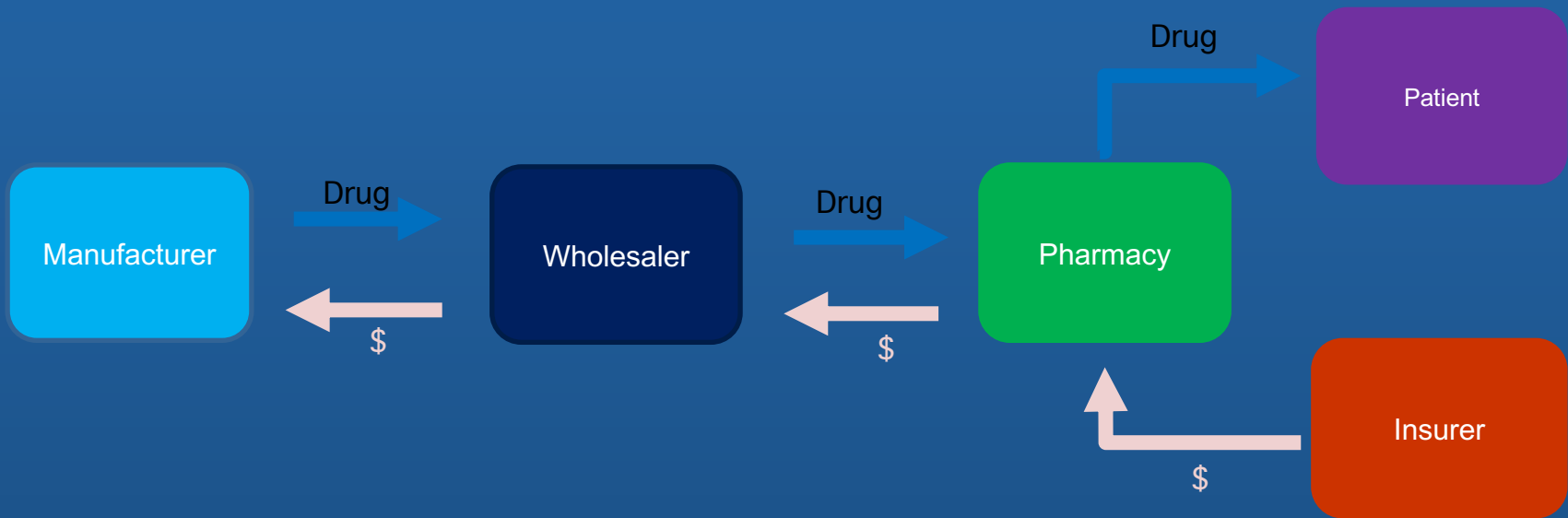
Considerations for Dispensing PrEP Medications from a Pharmacy

- Generic Compliance Ratio
- Taxes
- Carrying costs
- PBM DIR fees

Current commercially available PrEP products:

- Tenofovir disoproxil fumarate/emtricitabine
- Truvada
- Descovy
- Apretude

Traditional Community Pharmacy Reimbursement Model



Insurer payment – Cost of medication = Prescription profit

Considerations for Dispensing PrEP Medications from a Pharmacy

1. Generic Compliance Ratio (GCR)

- Independent and Chain pharmacy contracts with Wholesalers require that a certain percentage of a pharmacy's overall purchases (in dollars) must be spent on generic medications
- Consequence:
 - If a pharmacy spends a significant amount of money purchasing brand name drugs, then the pharmacy would be contractually required to pay more for ALL drugs purchased through the wholesaler

$$\text{GCR} = \frac{\text{Total \$ spent on generics}}{\text{Total \$ spent on all drugs}} \times 100$$

Spending more dollars on brand name drugs causes GCR to decrease

Considerations for Dispensing PrEP Medications from a Pharmacy

2. Taxes: Business and Occupation (B&O)
- Standard tax that applies to any company that sells goods or services
 - Washington = 0.471% of gross sales (not profits)
 - Some cities (including Seattle) add their own B&O tax on top of the state tax



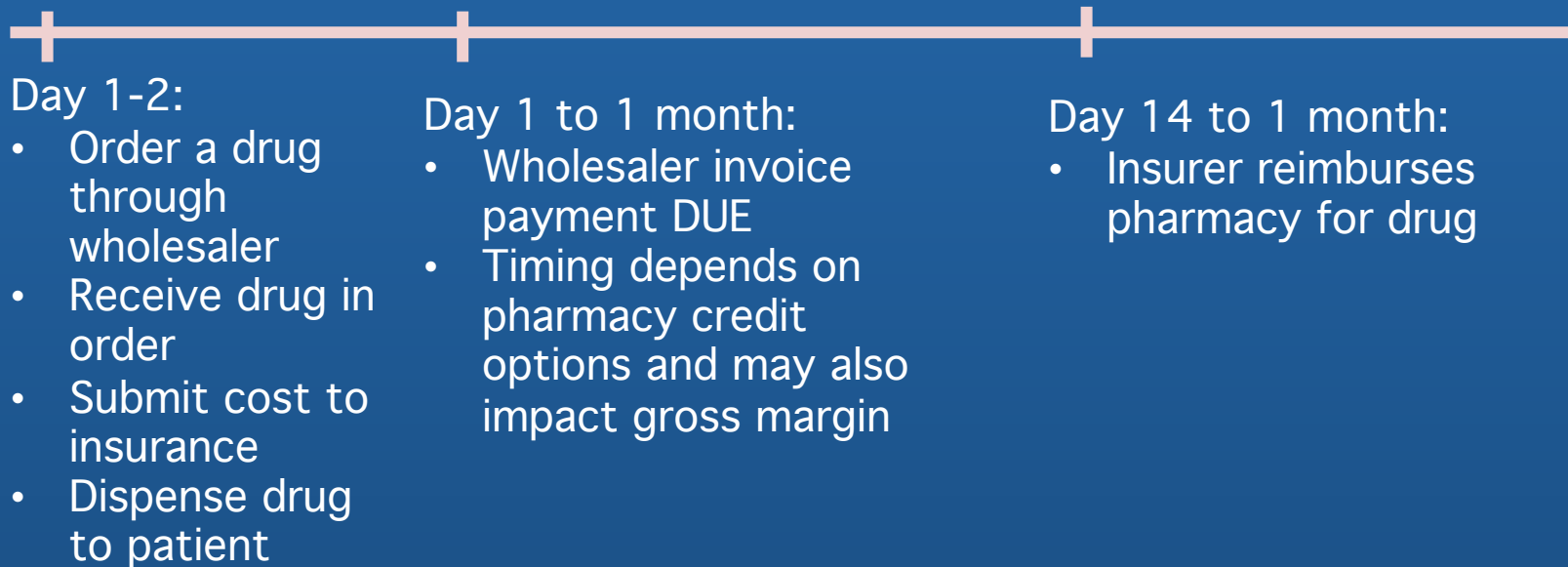
Cost \$2000
Medicaid dispensing fee \$4
Total sales \$2004



Total sales \$2004
B&O Tax: \$9.43
Cost: \$2000
Total Profit: **-\$5.43**

Considerations for Dispensing PrEP Medications from a Pharmacy

3. Carrying Costs: Timeline of Reimbursement



Consequences:

- Pharmacies must use lines of credit to absorb cost of drug between time of payment to wholesaler and reimbursement
- Interest rate on a line of credit = 5.25%

Considerations for Dispensing PrEP Medications from a Pharmacy

4. Pharmacy Benefit Managers (PBM) Direct and Indirect Renumeration (DIR) fees for Med D:

- PBMs regularly take back money already paid to pharmacies after the point of sale
- PBMs often do not explain how they calculate performance-based DIR fees
- How does this affect PrEP:
 - DIR fees become a “catch all” of claw backs.
 - Creates a loss in revenue. A pharmacy can lose money to dispense a medication, but it is not calculated until 6 months after the dispense.
 - The higher the specialty drug, the higher the DIR fee. PBMs use this fee to charge thousands per claim.

Considerations for Dispensing PrEP Medications from a Pharmacy

All these considerations affects a pharmacy's financial ability to dispense brand or generic specialty PrEP medications

- Generic Compliance Ratio
- Taxes
- Carrying costs
- PBM DIR fees

Long Acting Injectable PrEP

Long-Acting Injectable PrEP (Apretude®)

1. Provider screening

- Identify patients who are a good fit
- Adherent to target injection date
- Consider history of depression or suicide
- Drug - drug interactions
- Laboratory testing

2. Provider performs benefit verification

- Medical benefit – specialty wholesale distributor
 - Pre-authorization
 - Pre-determination
- Pharmacy benefit – specialty pharmacy in ViiV network (11)
- ViiV Connect - patient assistant program

Long-Acting Injectable PrEP (Apretude®)

3. Provider obtains medication
 - Specialty wholesale distributor – “buy and bill”
 - Specialty pharmacy – “white bagging”
4. Schedule injection appointment
5. Administer injection
 - Repeat testing if necessary
 - Ventrogluteal injection via z-track

How does long-acting injectable PrEP fit in?

- Identify patients who are a good fit
 - Adherent to target injection dates
 - Consider history of depression or suicide
 - Drug - drug interactions
- How will you be billing these medications?
 - Medical benefit
 - Pharmacy benefit
- Who will be conducting the prior authorizations and benefit management?
- Increased patient visits
- Where will medication be administered?

Assessment Question

- Open Forum:
- What do you foresee as a barrier to implementing a PrEP program at your practice?

Summary

- There are several setting considerations for conducting patient appointments, but they are all feasible in a community pharmacy setting.
- There are multiple testing options for obtaining labs and treating and reporting positive or reactive test results.
- It is important to take into consideration GCR, taxes, carrying costs and PBM DIR fees when dispensing specialty medications.
- There are several steps to incorporate long-acting injectable PrEP into your practice, but it can be done in a community pharmacy.

Thank You!

- Q&A

Patient Case

- MJ is a 26yo Hispanic MSM who comes to your clinic today to start PrEP. Last year he tested positive for rectal gonorrhea and was treated. Today he reports oral and anal receptive and insertive sex with inconsistent condom use. He has had over 20 partners in the last 3 months. He does not use any injection drugs. Patient is covered through managed Medicaid Molina plan.
- You are ready to prescribe tenofovir disoproxil fumarate/emtricitabine.
- Who will pay for the prescription?
 - A. WA State PrEP DAP
 - B. Molina
 - C. Gilead patient assistance

Patient Case

- MJ report discharge and urethritis. What samples would you obtain for STI testing?
- A. urine sample
- B. urine and rectal sample
- C. urine, rectal, and oral sample

Patient Case

- MJ is interested in Apretude. What is your first step for providing this medication?
- A. Determine if patient is a good candidate
- B. Laboratory testing
- C. Benefit inquiry

Acknowledgement

This Mountain West AIDS Education and Training (MWAETC) program is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling \$2,908,478 with 0% financed with non-governmental sources.

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