

# Financing HIV PrEP



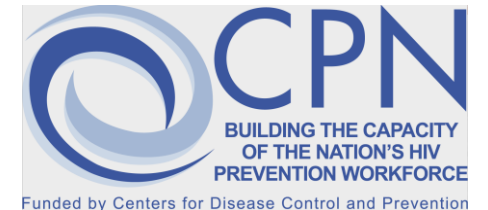
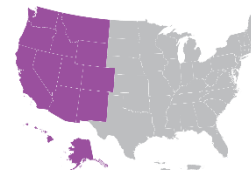
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**POPULATION HEALTH DIVISION**  
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# HIV Capacity Building Assistance (CBA) Program- getSFcba



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Visit: [www.getSFcba.org](http://www.getSFcba.org)  
Email: [get.SFcba@sfdph.org](mailto:get.SFcba@sfdph.org)

# Indigenous Land Acknowledgment

*We acknowledge that we are on the unceded ancestral homeland of the Ramaytush (Rah-my-toosh) Ohlone (O-lon-ee) who are the original inhabitants of the San Francisco Peninsula. As the Indigenous stewards of this land, and in accordance with their traditions, the Ramaytush Ohlone have never ceded, lost, nor forgotten their responsibilities as the caretakers of this place, as well as for all peoples who reside in their traditional territory. As guests, we recognize that we benefit from living and working on their traditional homeland. We wish to pay our respects by acknowledging the Ancestors, Elders, and Relatives of the Ramaytush Ohlone community and by affirming their sovereign rights as First Peoples.*

# Objectives

**By the completion of this webinar, attendees will be able to:**

- Describe changes in coverage by insurance companies.
- Steps to implement 3<sup>rd</sup> party insurance billing.
- Summarize what 340B is and how it fits into the financing landscape.
- List other funding streams and assistance programs which can assist patients to successfully get on PrEP.



# Agenda

- Insurance Billing and Coverage Changes
  - Medi-Caid (Medi-Cal), Medicare, 3<sup>rd</sup> party Insurances
- 340B Opportunities in Providing PrEP
- Blending Funding Streams and Assistance Programs
  - Assisting patients with PrEP navigation and medication adherence.



# Disclosures

No Disclosures

# Polling Question

## **Where do you work?**

- Health Department
- Community Based Organization (CBO)
- Federally Qualified Health Center (FQHC)
- Other

# Contents



**Insured Individuals**



**Uninsured/Underinsured**



**Assistance Programs**



**Navigation/Linkages**



# Providing Access to PrEP in Public Health Settings

- The Centers for Disease Control and Prevention (CDC) recommends [pre-exposure prophylaxis \(PrEP\)](#) as an HIV prevention strategy and is an essential component of PS18-1802 funding.
- Cost of PrEP approximately \$12,000/yr. (Blaylock, 2018, MMWR)
- Cost of ancillary services can be between \$924 to \$2143/yr. (Smith, 2017, JAIDS)
- Financing for medication and medical follow-up can be very complex especially for non-insured or under-insured.

# Patchwork of Funding and Delivery

	Drugs	Clinical Visits and labs	Linkages / Navigation
<b>Insured</b>	Payer coverage; copay assistance through assistance programs	Payer coverage with copays; some State Assistance Programs for copays	Adherence counseling which includes patient education, reminder systems for taking meds and developing plan for adverse effects
<b>Uninsured</b>	Patient Assistance programs (manufacturer, state funded); clinics using 340B savings	State Funded assistance programs; Community Health Centers, Family Planning Clinics, STD clinics using 340B savings or other Federal, State or local funding.	State Funded assistance programs; CDC Prevention grants; Community Health Centers; Family Planning Clinics; STD clinics using 340B savings; or other Federal, State or local funding.

# Insured Individuals



# USPSTF Grade A recommendation for PrEP

- Effective January 2021.
- Most insurance companies and Medicaid expansion programs required to cover Grade A and B services with no cost sharing.
- USPSTF (U.S Preventive Services Task Force) recommendations are not linked to coverage requirements for Medicare Part D.

# USPSTF Grade A recommendation for PrEP

## Some states have passed their own regulations:

### California:

*6/10/20: Notice sent out by Insurance Commissioner Ricardo Lara*

- Must provide PrEP without cost sharing.
- Cover prescriptions.
- Cover services necessary for PrEP initiation and follow up care.
- No prior authorization or step therapy for PrEP drugs.
- Do not apply coverage limits to PrEP drugs and necessary services.

(Ricardo Lara, California Insurance Commissioner; Letter to All Disability Insurers Providing Health Insurance Coverage in California, 6/1/20)

### Colorado:

*New Regulation 4-2-73 released by Department of Regulatory Agencies Effective 1/1/21. Bulletin No. B-4.112 provides guidance for coverage of tests and services.*

- Required to provide coverage for PrEP.
- No copayment or cost-sharing for medication for those clinically indicated for PrEP.
- No prior authorization or step therapy for PrEP drugs.
- Shall not impose additional utilization management procedures that restrict or limit access to PrEP.
- Encourages carriers to cover PrEP initiation and follow up services with copayment or cost sharing.

(Colorado Department of Regulatory Agencies New Regulation 4-2-73 and Bulletin No. B-4.112)

# USPSTF Grade A recommendation for PrEP

- On July 19, 2021 guidance was released through a Frequently Asked Questions (FAQs) prepared by the Departments of Labor, Health and Human Services and the Treasury.
- Clarifies requirements to cover PrEP intervention including ancillary services and testing in line with CDC Guidelines without cost sharing.



(FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 47, July 19, 2021, <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf> )

# USPSTF Grade A recommendation for PrEP

- **Services to be covered include:** HIV testing, Hepatitis B and C testing, Creatinine test, pregnancy testing, sexually transmitted infection testing and adherence counseling per recommended intervals.
- **Medical Management** like prior authorizations, need to be expedited so that accessing PrEP medication can occur on the same day a negative HIV test is received.
- **Plans may cover a generic drug** with no cost sharing and impose cost sharing on equivalent branded version.
  - But plans must accommodate individuals when a particular PrEP medication is medically inappropriate.
- **Providers must be in network** for the insurance to cover with no cost sharing.

# USPSTF Grade A recommendation for PrEP

Noncompliance to providing PrEP without cost sharing can be appealed to the State's Health Insurance Commissioner for discriminatory practices or non-compliance.

Contact information at: <https://content.naic.org/state-insurance-departments>

(NASTAD PrEP Coverage Brief: PrEP Services Covered with No Cost-Sharing, July 2021, <https://nastad.org/resources/nastad-prep-coverage-brief-prep-services-covered-no-cost-sharing> )



# USPSTF Grade A recommendation for PrEP

- **NASTAD's PrEPcost.org** health insurance assessment tool has been retired since the implementation of USPSTF's Grade A recommendation.
- This was a tool PrEP Navigators were able to use to compare health coverage options for clients. Since clients should be able to get services at no share of cost, it is no longer necessary.



# New Considerations

- US Public Health Service PrEP Clinical Guidelines released December 2021.
- Cabotegravir LA FDA-approved as PrEP.
  - Who will be approved to administer?
  - Coverage: cost/no cost sharing?









# Polling Question

## **How many of you bill for services?**

- ☐ Medicaid(Medi-Cal) only
- ☐ Medicaid and Medicare
- ☐ Medicaid, Medicare, Private Insurance
- ☐ Private Insurance Only
- ☐ We currently don't bill for services
- ☐ We currently don't bill for services but would like to in the future

# Insurance Billing Process Overview

-  Pre-planning
  - Update fee schedule
-  Initiate private insurance contracts
-  Provider credentialing
-  Enhance insurance verification
-  Improve coding & medical documentation
-  Develop better clinic flow and staff placement

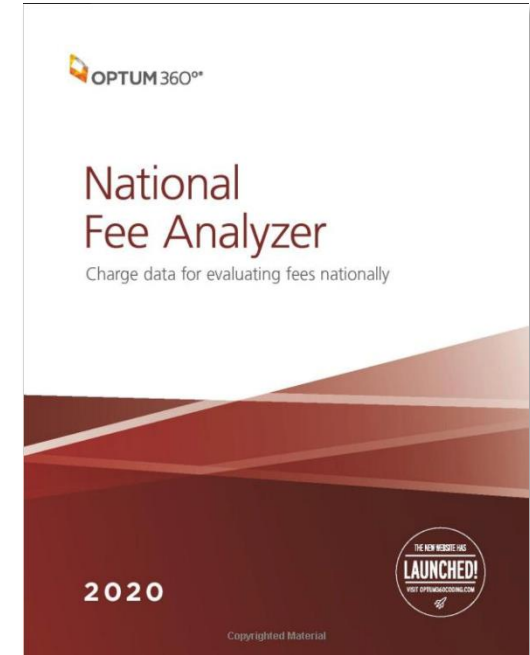
# Pre-Planning

- Review of all services that potentially can be billed.
- Is any insurance billing taking place in the agency already?
- Determine which third party insurance plans are most common in the service area.
  - Survey of current customers
- Review of electronic medical record's capacity to bill.



# Updating Fee Schedules

- Assess costs of service.
- Utilize available tools:
  - Set fees based on Medicare rates (typically 120% to 200%)
  - Fee Analyzer
- Management/Board approval.



# Sliding Fee Scale

1

**Determine  
which services  
need a sliding  
fee schedule**

2

**Determine  
methodology**  
*•For example:  
US Federal Poverty  
Guidelines*

3

**Establish the  
rules for applying  
the sliding fee  
to services**

4

**Establish fee  
waiver protocol**

# Compliance

## State of California Example



- Can't bill Medi-Cal for a service that is provided free to a non-Medi-Cal patient.
- Must ask all patients about insurance.
- Must make an effort to bill other 3<sup>rd</sup> party insurance.

(California Code of Regulations, Title 22 Division 3 Subdivision 1  
Chapter 3 Article 7  
# 51501)



# Initiate Private Insurance Contracts

- Select 3-5 of the top insurance plans that your patients typically have.
- Establish mutual benefits:
  - Numbers of subscribers served (focus on what % of total visits rather than actual numbers);
  - Reasons for visit;
  - Why service is crucial, and therefore reimbursable.



# Initiate Private Insurance Contracts

- Contact customer service representative of the insurance company.
- Determine requirements for contracting (each plan may have different processes).
- Establish a rapport:
  - Document who you talk to and date you phoned;
  - Pay attention to the details;
  - Sell your specialized Public Health services and the value to their subscribers.



# Insurance Company Sample Letter of Intent

## Insurance Company Sample Letter of Intent

[https://calbillables.org/?page\\_id=471](https://calbillables.org/?page_id=471)



CALIFORNIA BILLABLES PROJECT

### Sample Letter of Intent

Print on official County Letterhead [current date]

[Name of Insurance Company]  
Attn: [Name of Contract Representative]  
[Address of Insurance Company]

RE: Letter of Intent for Contractual Agreement between [Specific name of PH Clinic] and [Name of Insurance Company]

[Specific name of PH clinic] requests consideration for becoming a contracted provider with [Name of Insurance Company].

[Name of PH Clinic, followed by acronym] and our multiple outlying district clinics have an array of services that would provide convenient, efficient, and reasonably priced benefits to [name of insurance company] patients. Sensitive services such as family planning and sexually transmitted disease testing and treatments are provided to the public by [clinic abbrev]. Many patients come to [clinic abbrev] as they hesitate to go to their private providers for socially-sensitive services. Local private doctors commonly refer patients to us for vaccine services, as many private providers are not able to keep the amount of vaccine inventory that is available in our clinic. In addition, [county name] has a large number of parents bringing their children to [clinic abbrev] for their back-to-school vaccines.

[Clinic abbrev] currently sees an average of [# of patients seen per month] patients each month, many of whom have private insurance. [Name of insurance company] patients are already coming to [clinic abbrev] because of one or more of the above stated reasons. For many patients, the higher out-of-pocket expense for deductibles and coinsurance prevents them from seeking needed healthcare from non-contracted providers. As a contracted provider, we will provide an increase in customer satisfaction as well as being a convenient local referral for your network doctors.

Services provided (list services that are applicable to your site only):

1. Immunization of adults and children (State full inventory of vaccines)
2. HIV/AIDS testing and counseling
3. STD screening, counseling, and treatment
4. Family Planning education, counseling and treatment
5. Pregnancy testing and counseling
6. Tuberculosis screening and case management
7. Travel Vaccination and information

If you have multiple clinic sites within the PH structure, list them here: [add bulleted list of all locations].

Our multiple district clinics create unique geographic accessibility to patients and are located as follows:

If you have questions, please do not hesitate to call me at [phone #].

Respectfully submitted,

[Printed Name of Official] [Title of official, usually Director of Public Health]

# Private Insurance Contracts

- ▶ Complete steps for contracting as outlined by insurance carrier (application, credentialing, other agreements).
- ▶ Review and negotiate contract terms and rates for services provided.
- ▶ Approval and signature of contract.



# Provider Credentialing

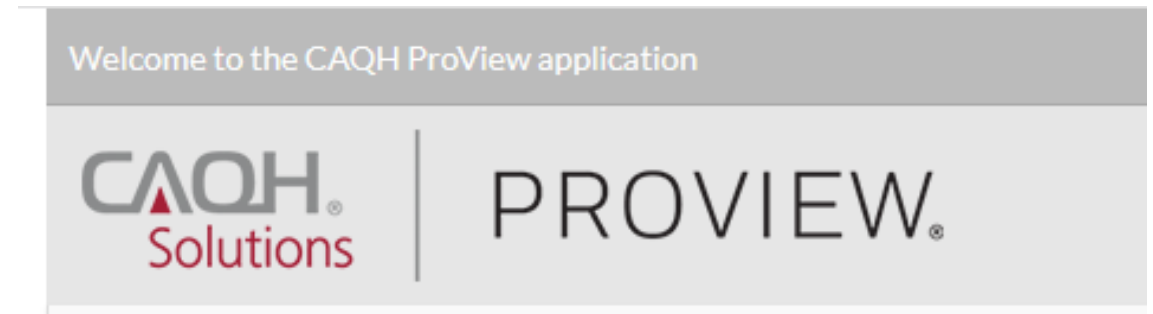
- Obtain NPI (National Provider Identifier) number:
  - The **NPI** is a Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification Standard. The **NPI** is a unique identification number for covered health care providers.
- Will need a Facility NPI and individual NPIs for those staff that will be billing for services.
- NPI number stays with the individual, need to update employer information on new employees.



# Provider Credentialing

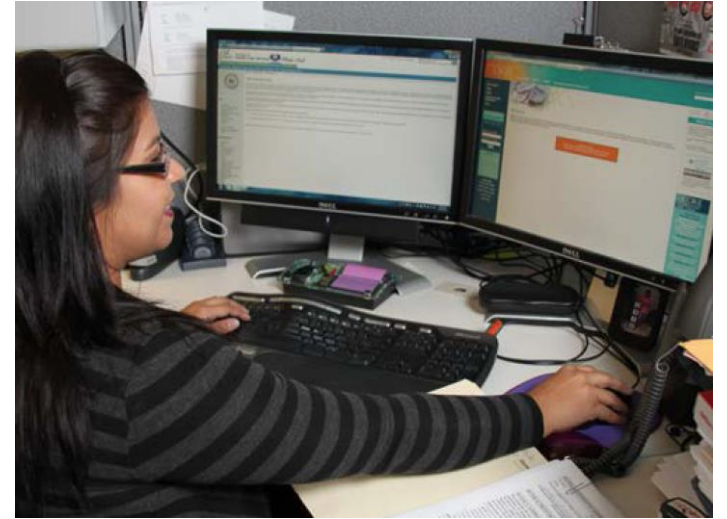
- CAQH (Council for Affordable Quality Healthcare)
  - Nationally recognized: credentialing database that eliminates duplicative paperwork;
  - Government insurance and many private carriers utilize;
  - Utilize for clinicians (ie. MDs, NPs).
- Important to maintain, update regularly.

<https://proview.caqh.org/Login/Index?ReturnUrl=%2f>



# Enhanced Insurance Verification

- ✓ **TRAIN:** Registration staff to ask for insurance cards.
- ✓ **CONTACT:** Contact the carrier prior to services to verify benefits.
- ✓ **RECORD:** Accurately record tracking number and name of representative.
- ✓ **RELAY:** Relay coverage benefits to patient prior to service



# Improving Coding and Documenting

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**If it isn't documented, it didn't happen!**

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Errors occur when documenting is inconsistent, incomplete or illegible.

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Assure providers are familiar with current coding requirements.



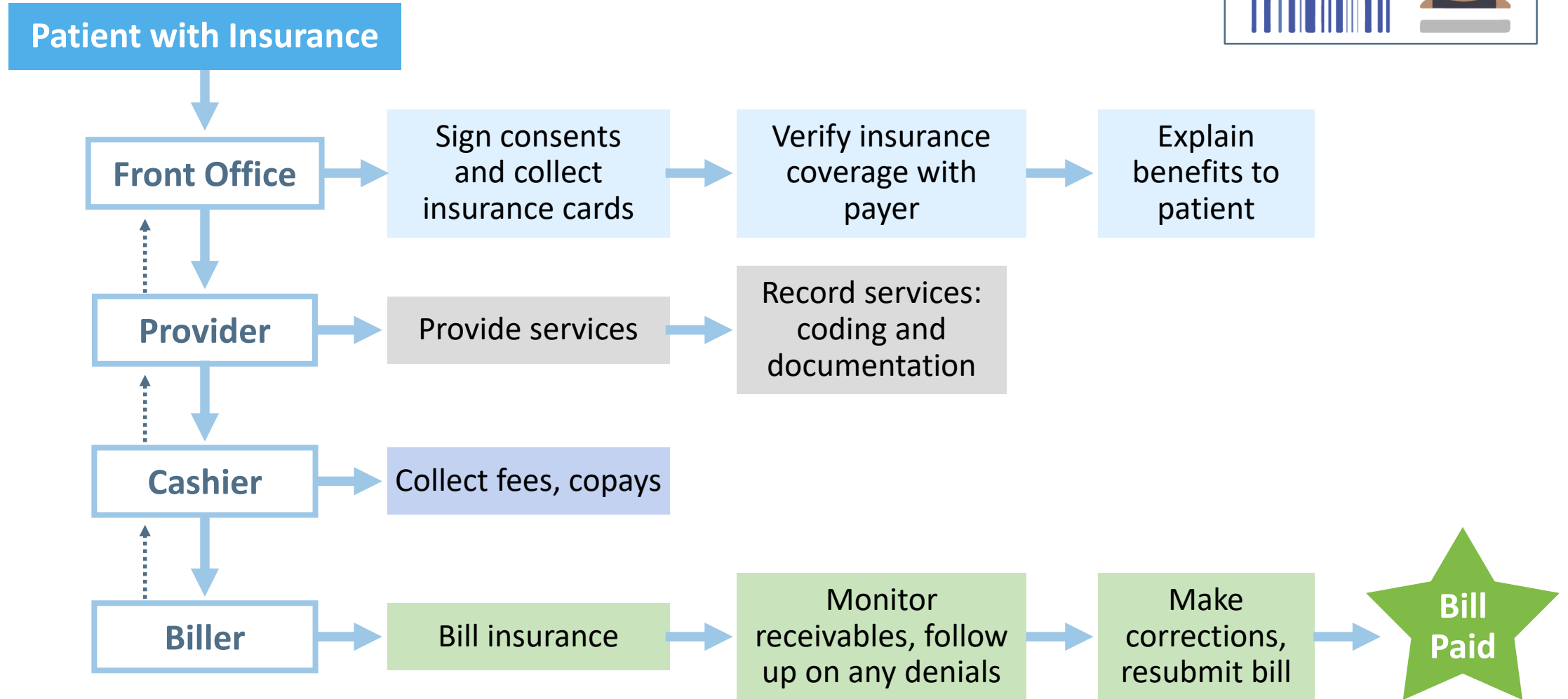


# Coding Services for Billing

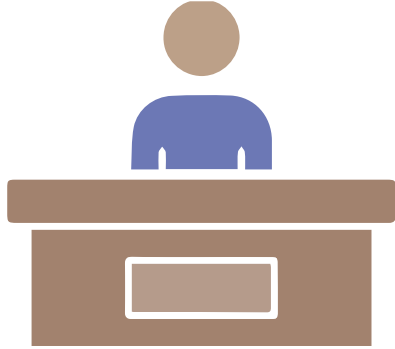
- “Billing Coding Guide for HIV Prevention” developed by NASTAD (2016) is a helpful guide to assist with billing for HIV Prevention Services.
- PrEP services need to be billed separately and may require the CPT modifier 33. This modifier helps commercial health plans to know the service is a covered preventive service.

(Billing Coding Guide for HIV Prevention, Last updated July 17, 2018, [www.nastad.org/resource/billing-coding-guide-hiv-prevention](http://www.nastad.org/resource/billing-coding-guide-hiv-prevention) )

# Sample Clinic Flow



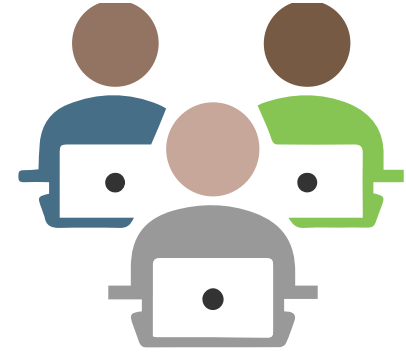
# The Team Approach



**Registration Staff**



**Clinic Staff**



**Billing Staff**



# Potential Barriers

- Contracting with private insurance carriers
- Staff resistance
- Creating/changing fee schedule
- Shared tax ID
- Accounts receivable reporting



# Uninsured/Underinsured



# Leveraging Existing Funding Streams

## **Patient clinical care: Evaluation and labs:**

- Health Department STD and Family Planning Clinics;
- Federally Qualified Health Centers/Community Based Health Clinics;
- 340B.



# Polling Question



*Is your organization currently a 340B Program?*

# What is 340B?



- 340B is a section within the Public Health Service Act-codified at 42 U.S.C. § 256b.
  - Was established by Congress in 1992—requires pharmaceutical manufacturers that enroll in Medicaid to provide discounts on drugs to eligible safety net providers.
- By saving money on the cost of outpatient drugs, qualified safety net providers are able to allocate revenue to expand health services and reach more eligible patients.
- The Federal Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) provides oversight.



# Who is Eligible to Participate?



## **Ryan White HIV/AIDS Program Grantees.**



**Centers:** Federally Qualified Health Centers (FQHC), FQHC Look-Alikes, Native Hawaiian Health Centers, Tribal/Urban Indian Health Centers.



**Specialized Clinics:** Black Lung Clinics, Comprehensive Hemophilia Diagnostics Treatment Center, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, Tuberculosis Clinics.



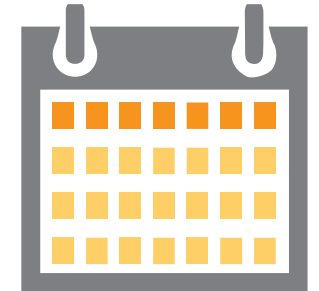
**Qualifying Hospitals:** Children's Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, Free Standing Cancer Hospitals, Rural Referral Centers, Sole Community Hospitals.

(Section 340B of the Public Health Services Act specifies eligible covered entities:

[www.hrsa.gov/opa/eligibility-and-registration/index.html](http://www.hrsa.gov/opa/eligibility-and-registration/index.html) )

# Enrollment Process

- Must register in the HRSA OPA Database.
- New covered entities must register by the following schedule:
  - January 1-January 15 for an effective start date of April 1;
  - April 1-April 15 for an effective start date of July 1;
  - July 1-July 15 for an effective start date of October 1; and
  - October 1-October 15 for an effective start date of January 1.

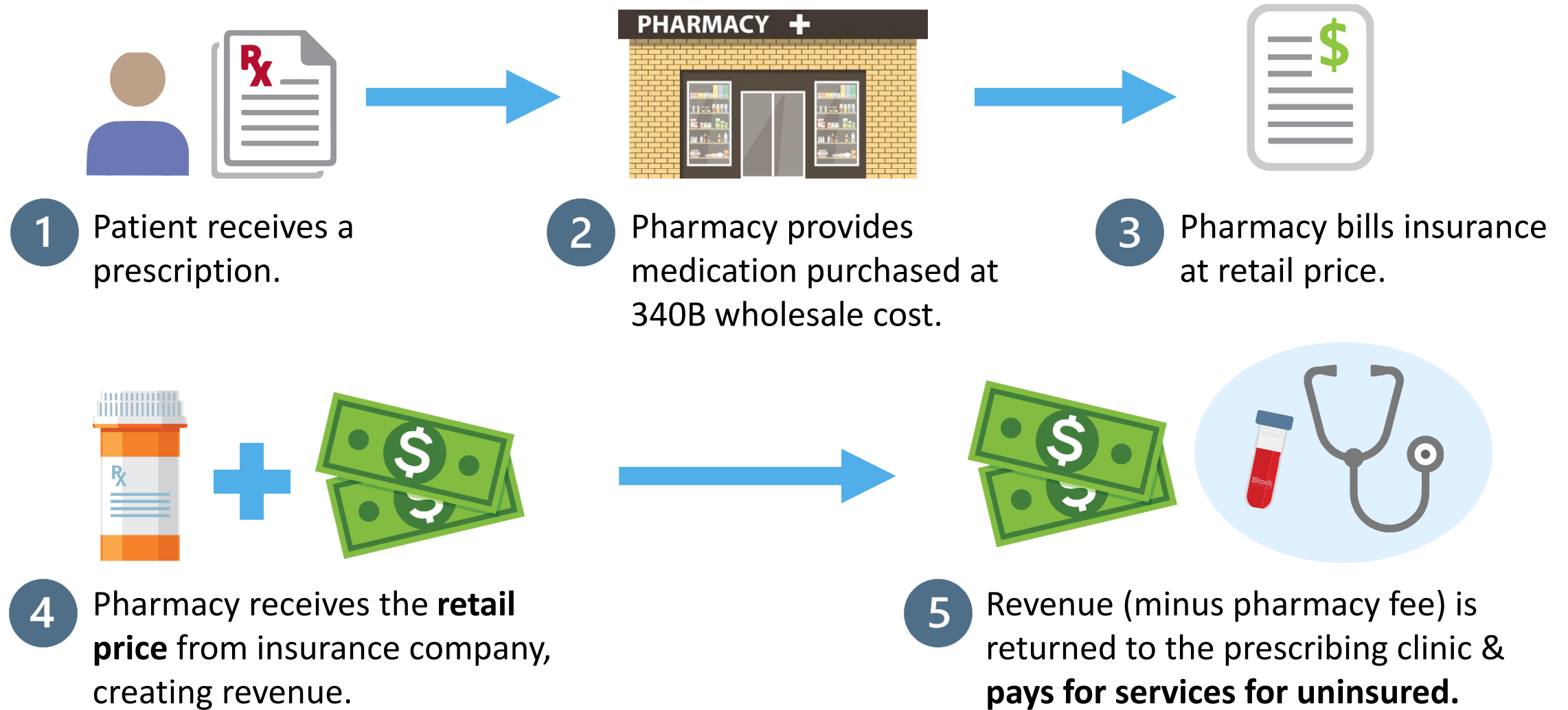


Go to [www.hrsa.gov/opa/registration/index.html](http://www.hrsa.gov/opa/registration/index.html) for more information on registration

# Contract Pharmacies

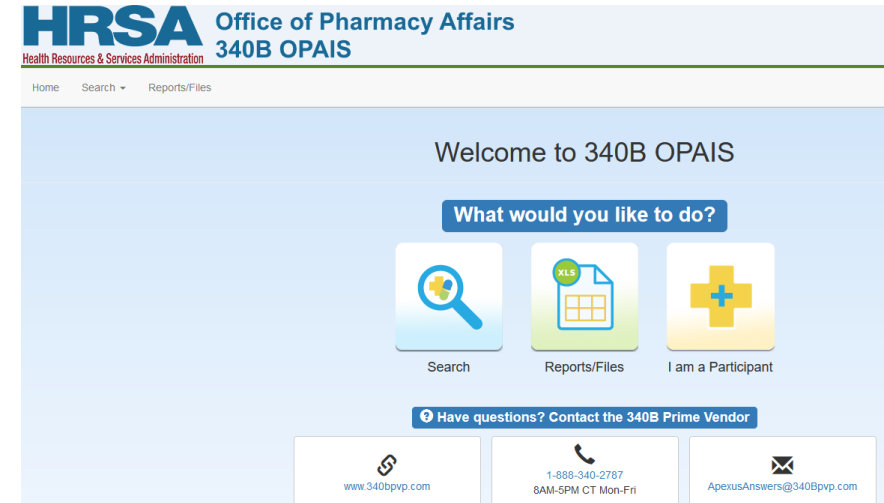
- Starting in 2010, OPA authorized the use of contract pharmacy networks to dispense 340 drugs to eligible patients, under contract with the covered entity.  
(75 Fed. Reg. 10272, March 5, 2010)
- The covered entity maintains the responsibility for purchasing the 340B drugs and they may be shipped directly to the pharmacy.

# How Does it Work?



# Compliance: Site Registration

- Must register with OPA and must list ALL sites within the covered entity on the OPA online database. Failure to list results in the site being disqualified.
- Covered entities must recertify annually.  
(42 U.S.C. § 256b(a)(7)(E))



<https://340bopais.hrsa.gov/>

# Compliance: Duplicate Discounts

- The 1990 Medicaid Rebate Program requires drug manufacturers participating in Medicaid to offer rebates to state Medicaid agencies for out-patients drugs dispensed to fee-for-service enrollees.
- 340 B covered entities must avoid duplicate discounts. (42 U.S.C. § 256b(a)(5)(A)(i))
- Must carve-in or carve-out fee-for-service Medicaid prescriptions from 340 B programs.



# Compliance: Diversion

- 340 B drugs can not be resold or dispensed to individuals who are not patients of the covered entity. (42 U.S.C. § 256b(a)(5)(B))
- Definition of a patient: (61 Fed. Reg. 55156-55158 (Oct. 24, 1996))
  - Has a relationship with the patient and maintains records of the individual's health care. The entity documents in the record the care provided and prescriptions written.
  - The individual receives care by a health care professional that is employed or contracted by the covered entity.
  - The individual receives services that are consistent with the federal funding that qualifies the entity for 340 B pricing.



# Compliance: Contract Pharmacies

- The covered entity is liable for any non-compliance with 340 B requirements.
- Written agreement with pharmacy should duplicate discounts, diversion, and protection of the patient's freedom of choice.
- Agreement should include the ability for the covered entity to review pharmacy records and audit operations.





# Compliance: Written Policies & Procedures

- Must have policies and procedures in place that reflect the entities actual practices.
- Free online template policies are available through 340B Program, Apexus.



# Training

## Apexus Prime Vendor Program: 340 B University

[www.340bpvp.com/education/340b-university](http://www.340bpvp.com/education/340b-university)



# Future Changes with 340B

- Introduction of generic drug reduces the 340B entity savings reinvestment.
- CMS changes in payment methodology could impact revenue stream.\*
- California's Executive Order N-01-19: Transitioning all pharmacy services for Medi-Cal managed care to a fee-for-service January 2021, with a goal to reduce cost.

CMS.gov. CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1736-P)

California's Executive Order N-01-19: Transitioning all pharmacy services for Medi-Cal managed care to a fee-for-service January 2021. (signed January 7, 2019).

# Assistance Programs



# Drug Assistance

## **Gilead Advancing Access Patient Assistance Program:**



- Access to program specialist who can help with insurance related questions and coverage options.
- Provides medication at no charge for eligible patient with no other insurance options.
- Provides co-pay assistance for eligible patients who need assistance paying for out-of-pocket medication costs.
- Patients enrolled in Medicaid or Medicare Part D are not eligible.

[www.gilead.com/purpose/medication-access/us-patient-access](http://www.gilead.com/purpose/medication-access/us-patient-access)

# Co-Pay Relief: copays.org

## Patient Advocate Foundation



- Pays co-pay, co-insurance and deductible.
- Eligibility requirements:
  - 400% or less of Federal Poverty Guidelines (adjusted for Cost of Living index and number in household);
  - All insurance types are eligible.
- Maximum award level \$7,500 per year.

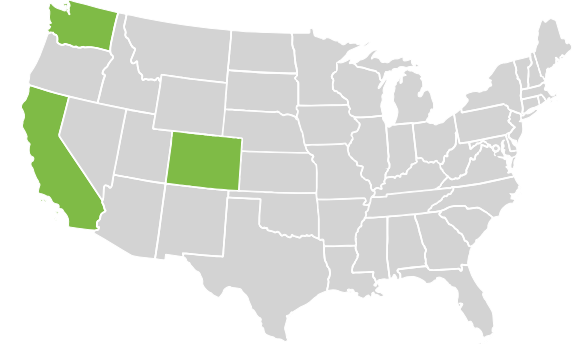
<https://copays.org/funds/hiv-aids-and-prevention/>

# Western States PrEP Assistance Programs

Eligibility Requirements		
California: PrEP Assistance Program (PrEP-AP)	Colorado: Public Health Intervention Program (PHIP)	Washington: Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)
<ul style="list-style-type: none"><li>• Resident of California</li><li>• Negative HIV test</li><li>• At least 18 years of age</li><li>• Income &lt;500%FPL</li><li>• Not fully covered by Medi-Cal or other third party payers</li><li>• Enrolled in a Gilead assistance program (if eligible)</li></ul>	<ul style="list-style-type: none"><li>• Resident of Colorado</li><li>• Income &lt;500% FPL</li><li>• Can't receive if qualify for Medicaid</li></ul>	<ul style="list-style-type: none"><li>• Resident of Washington</li><li>• Test negative for HIV</li><li>• Have a note from your doctor stating your eligibility for a PrEP prescription.</li><li>• No income level identified in requirements</li></ul>

# Western States PrEP Assistance Programs

- Assistance with PrEP-related medical services and medications.
- Will pay for:
  - Approved PrEP related medical out-of-pocket costs;
  - Out-of-pocket cost for medication after all other coverage (insurance, Gilead's Copayment Assistance) have been applied.
- Must receive services through State contracted sites.

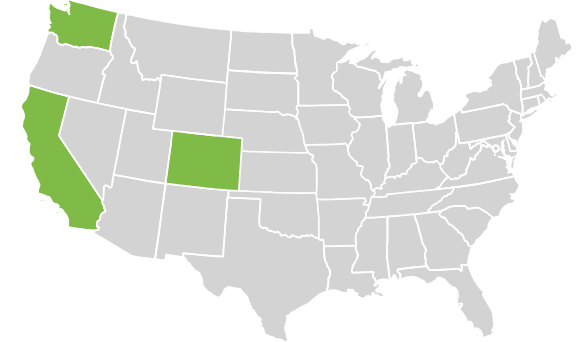




# Western States PrEP Assistance Programs

## More Information:

- **California:** [www.cdph.ca.gov/Programs/CID/DOA/Pages/OA\\_adap\\_benefits\\_prepAP.aspx](http://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_adap_benefits_prepAP.aspx)
- **Colorado:** [www.colorado.gov/pacific/cdphe/public-health-intervention-program](http://www.colorado.gov/pacific/cdphe/public-health-intervention-program)
- **Washington:** [www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIV/Prevention/PrEPDAP](http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIV/Prevention/PrEPDAP)



# Ready, Set, PrEP



- Nationwide program led by United States Department of Health and Human Services launched December 2019.
- **Eligibility requirements:**
  - Lack prescription drug coverage;
  - Be tested for HIV with a negative result;
  - Have a prescription for PrEP.
- Go to [www.getyourprep.com](http://www.getyourprep.com)

[www.hiv.gov/blog/ready-set-prep-expands-access-medication-prevent-hiv](http://www.hiv.gov/blog/ready-set-prep-expands-access-medication-prevent-hiv)

# Ready, Set, PrEP

READY  
SET  
PrEP



<https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-pharmacies>

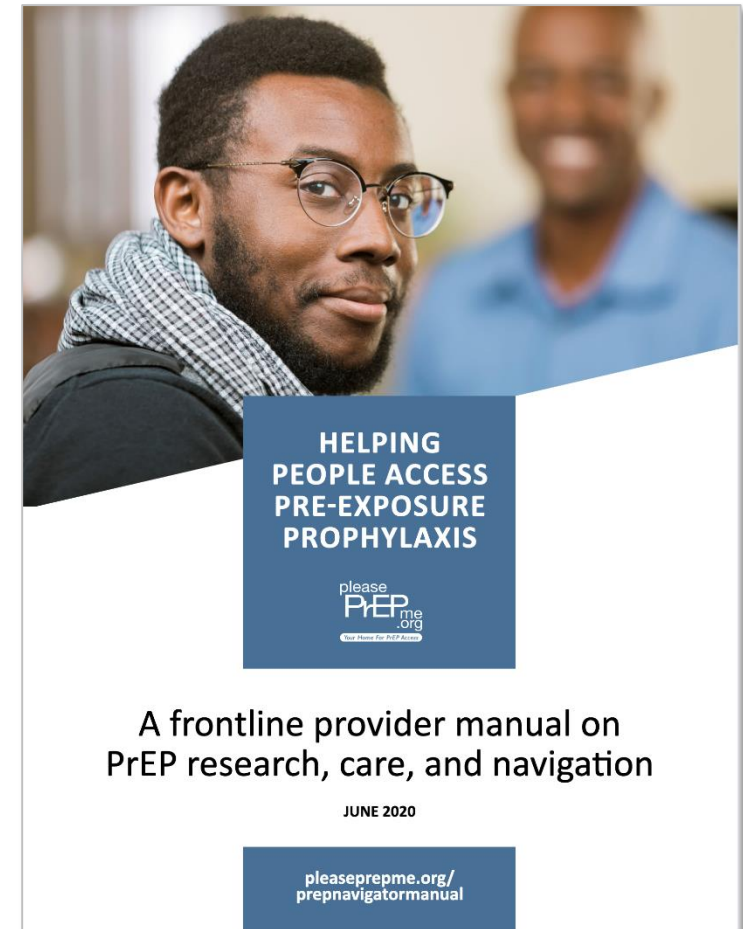
# Navigation/Linkages



# Navigation Services

## PrEP Navigator Tool

[www.pleaseprepme.org/prepnavigatormanual](http://www.pleaseprepme.org/prepnavigatormanual)



# Leveraging Existing Funding Streams

- Public Health Disease Intervention Specialist(DIS) investigating positive Syphilis cases
- Ryan White Clinics – referral of negative partners of HIV positive individuals
- Ryan White Early Intervention Services
- HIV Prevention Funding
- Other case management programs
- Online tools



# Be Prepared

**This is a complex landscape—** anticipate changes, expect changes, keep looking at your landscape so that you can incorporate changes and be able to continue to serve all of your priority populations.



# Patrick Salazar Presentation



# Prep Billing & Coverage

- Ability to serve more people
- Medi-Cal (California Medicaid)
- Family PACT help cover uninsured people
- Close relationship between billing and program staff
- Not everyone qualified
- Integrating PrEP into STD visit
- Navigators learned “do’s & don’ts” of insurance plans

# Gilead Assistance Programs

Process easy & quick for enrollment

Benefitted uninsured

Difficult to use on Kaiser patients

Benefitted those with high deductibles

Partnership with Gilead rep

# Other Assistance Programs

## **CA Office of AIDS – PrEP Assistance Program (PrEP-AP)**

- Fit into existing billing infrastructure
- Covered lab expenses
- Used on uninsured
- Navigators report clients not interested
- Disconnect with same-day PrEP process

## **Other Drug Manufacturer Programs**

- Additional assistance
- Limited frequency
- Navigators' research



Questions?

# References

- Blaylock JM, Hakre S, Okulicz JF, et al. (2018). HIV preexposure prophylaxis in the U.S. military services—2014-2016. *MMWR Morb Mortal Wkly Rep.* (2018; 67(20):569-574). <https://www.cdc.gov/mmwr/volumes/67/wr/mm6720a1.htm>
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