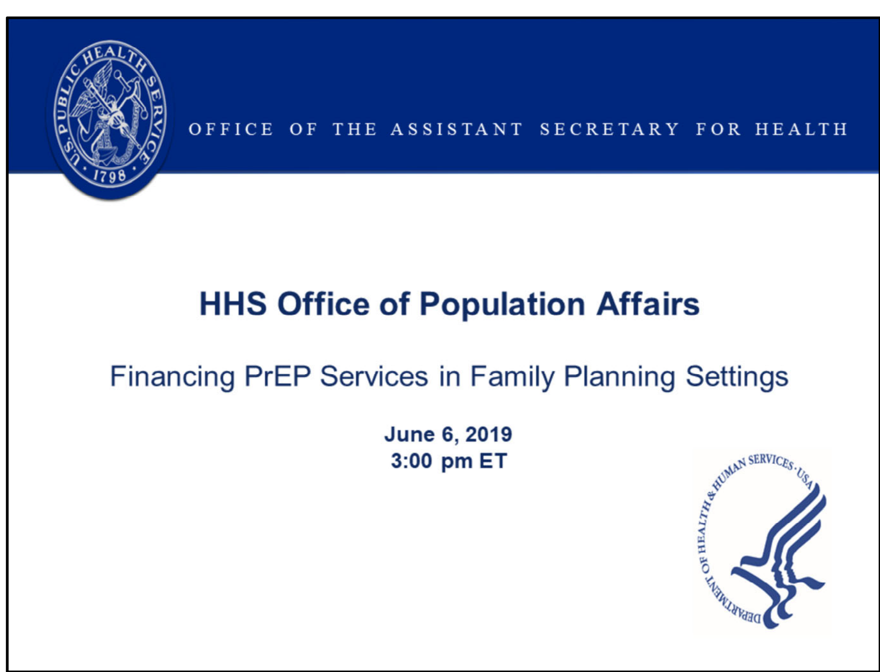
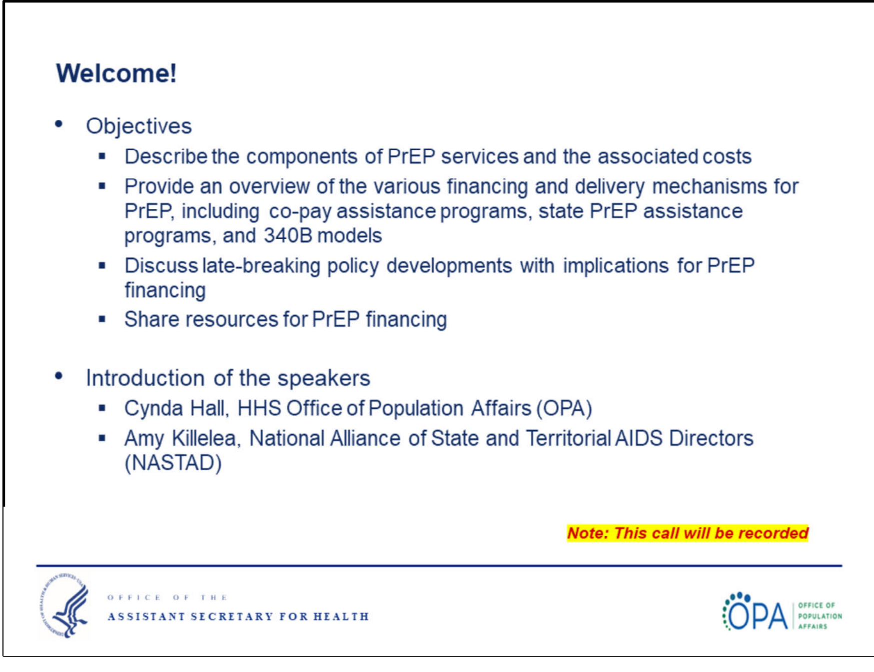


Slide 1 HHS Office of Population Affairs, Financing PrEP Services in Family Planning Settings

Katie Quimby

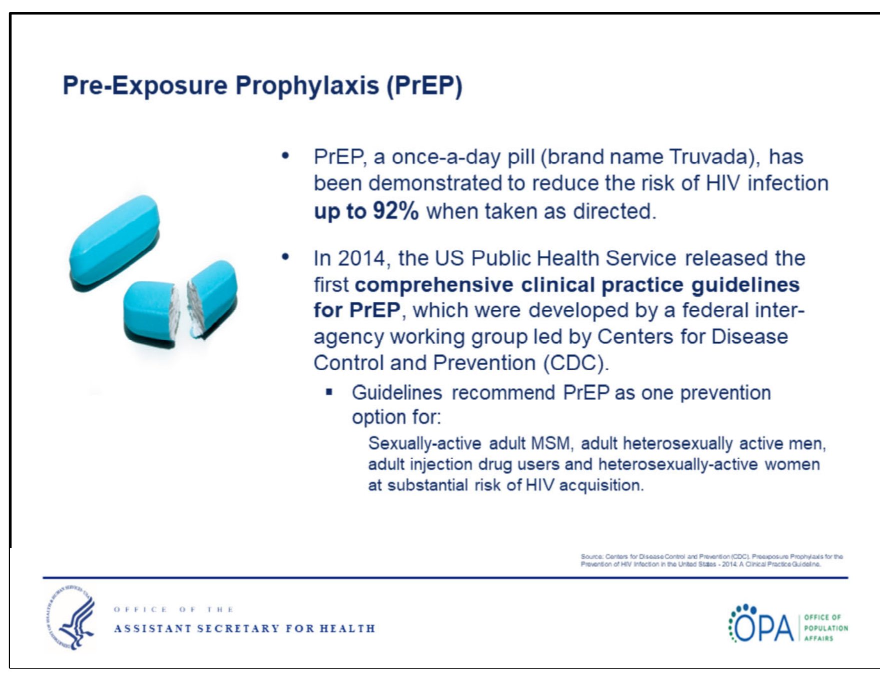
Hello everyone, and welcome to today's webinar, Financing PrEP Services in Family Planning Settings. This is Katie Quimby, from the Title X Family Planning National Training Center, and I am very pleased that you are here joining us today. A few things before we begin. Everyone on the webinar today is muted, given the large number of participants. We ask that you please use the chat at the bottom left of your screen to ask questions at any time, and we will have time at the end of the presentation to address all questions. Any resources that we'll be talking about today are available on fpntc.org. Following today's webinar, we will also be posting a recording of the webinar, along with a slide deck and a transcript.



Slide 2 Welcome!

The objectives of today's webinar are to describe the components of PrEP services and the associated costs, to provide an overview of the various financing and delivery mechanisms for PrEP, including copay assistance programs, state PrEP assistance programs, and 340B models, to discuss late-breaking policy developments with implications for PrEP financing, and lastly, to share resources for PrEP financing.

I'm thrilled to introduce our speakers for today's webinar. Cynda Hall, from the Office of Population Affairs, will lead off with some expectations from OPA around offering PrEP services, and then we'll hear from Amy Killelea, the director of health systems integration team at the National Association of State and Territorial AIDS Directors. Amy leads the alliance's health reform, public and private insurance, and health care financing efforts, including providing resources and technical assistance for state HIV programs, and developing recommendations to inform state and federal policy. Previously, Amy worked as a senior fellow in Harvard Law School Center for Health Law and Policy Innovation, conducting legal and regulatory analysis of federal health care reform, Medicaid, and private insurance. With that, I will turn it over to Cynda to get started.



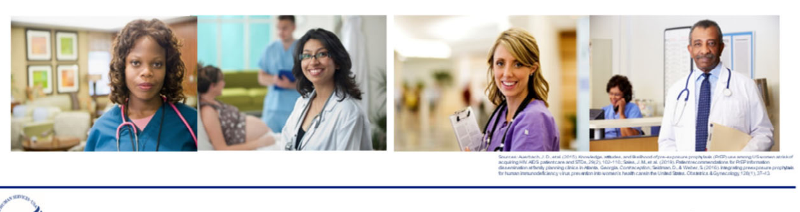
Slide 3 Pre-Exposure Prophylaxis (PrEP)

Cynda Hall

Thanks, Katie. For quick background as we get started, pre-exposure prophylaxis, or PrEP, is a once-a-day pill that has been demonstrated to reduce the risk of HIV infection up to 92% when taken as directed. In 2014, the U.S. Public Health Service released the first comprehensive clinical practice guidelines for PrEP, which recommend PrEP as one prevention option for sexually active adult MSM, adult heterosexually active men, adult injection drug users, and heterosexually active women at substantial risk of HIV acquisition.

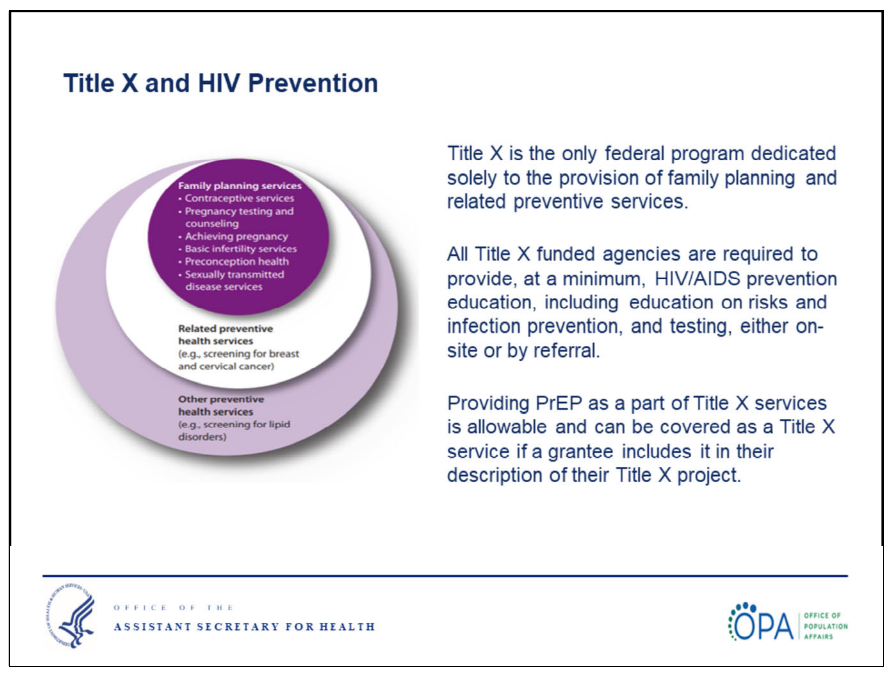
Family Planning Services and PrEP

- Title X family planning sites are a primary source of care for many women, serving approximately **3.5 million women** annually
- **Family planning providers are exceptionally qualified** to provide HIV prevention services to women while incorporating clients' health goals into individual health care decisions
  - Women also consider **family planning clinics a preferred source** for information about PrEP and access to PrEP services



Slide 4 Family Planning Services and PrEP

In our context, we are discussing integrating PrEP services in family planning settings as a way to reduce the barriers to PrEP awareness, access, and uptake that we know cisgender women face specifically. Title X family planning sites are a primary source of care for many women, and serve approximately 3.5 million women annually, and research shows that women want to learn about PrEP and access PrEP through their family planning providers. Title X sites have a key opportunity to address gaps in PrEP awareness, and access among women, by integrating PrEP services into existing HIV prevention services, which often include HIV and STD prevention education, testing and referral, risk reduction counseling, and behavioral intervention such as condom use promotion and post-exposure prophylaxis.



Slide 5 Title X and HIV Prevention

Today's webinar will cover PrEP financing, and Amy will discuss the various financing and delivery mechanisms for PrEP more broadly, but I do want to start by speaking to the Title X context, specifically. In 2014, OPA and CDC released the MMWR, Providing Quality Family Planning Services, or QFP. In the QFP, STD and HIV services are considered family planning services, because they improve the health of both men and women, and can influence a person's ability to conceive or to have a healthy birth outcome. And all Title X-funded agencies are required to provide, at a minimum, HIV AIDS prevention education, including education on risk and infection prevention and testing, either on site or by referral. Family planning clients who are at risk for an STD should be screened for HIV and other STDs in accordance with CDC's STD treatment guidelines.

PrEP also offers an option for those clients who are at risk for HIV infection, and the family planning visit provides a key opportunity to educate the client about HIV prevention, and about PrEP, and many family planning service sites are already offering PrEP counseling, referral, or on site services. Providing PrEP as a part of Title X services is allowable, and can be covered as a Title X service, if a grantee includes it in their description of the Title X project.

OPA PrEP Training Webinar Series

Webinar Topic	Date
National Kick-Off Webinar: PrEP for HIV Prevention in Family Planning Settings*	April 4, 2019 3 pm EST
#1: Prescribing PrEP in Family Planning Sites*	May 20, 2019 12 pm EST
#2: Financing PrEP Services in Family Planning Sites	June 6, 2019 3 pm EST
#3: Innovative Models for PrEP Programs in Family Planning Sites	July 2019 (TBD)
#4: Community Partnerships for PrEP in Family Planning Sites	August 2019 (TBD)

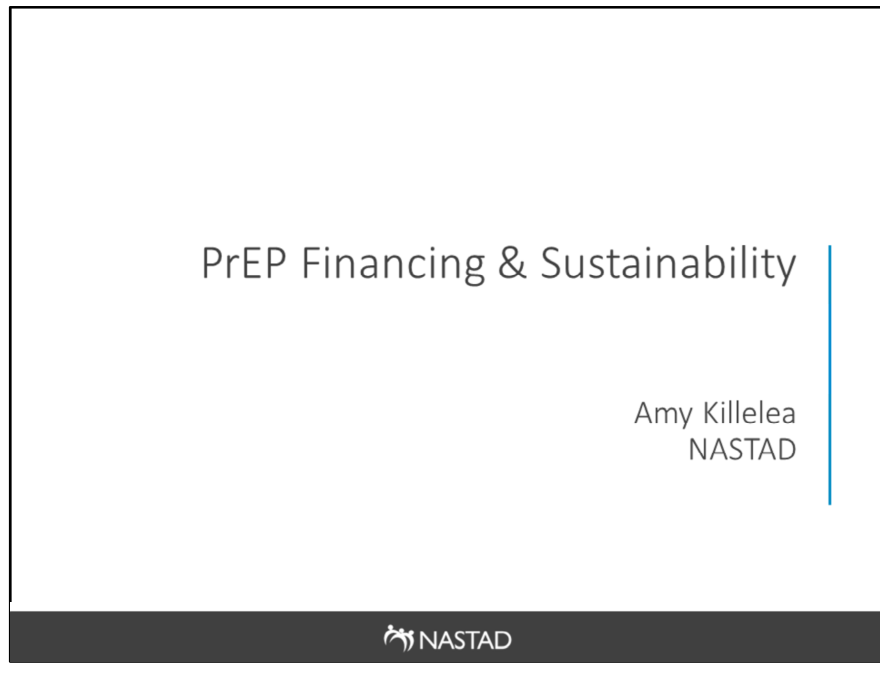
*Recordings and slides for past webinars are available on www.fpntc.org

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

OPA OFFICE OF POPULATION AFFAIRS

Slide 6 OPA PrEP Training Webinar Series

Lastly, I'd like to note that this webinar is a part of a PrEP training webinar series our office began in April. Our future webinars this summer will cover innovative models for PrEP programs and family planning sites, and leveraging community partnerships for PrEP and family planning sites. If you did not have an opportunity to participate in these past webinars, the recordings and slides are available on the Family Planning National Training Center's website, at fpntc.org. With that, I will turn it over to Amy to discuss the PrEP financing and considerations for sustainability.



Slide 7 PrEP Financing & Sustainability, Amy Killelea, NASTAD

Presentation Road Map

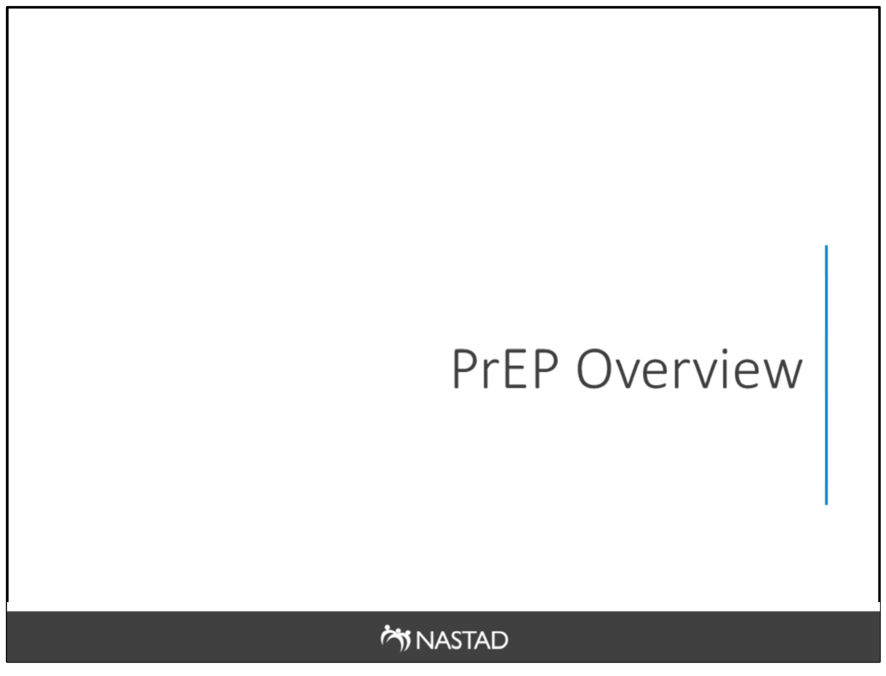
- PrEP Overview
- PrEP Pipeline Overview
- Coverage and Cost Landscape
- Coverage Policies Impacting PrEP Access and Affordability
- Considerations for Sustainable PrEP Payment and Delivery Models

NASTAD

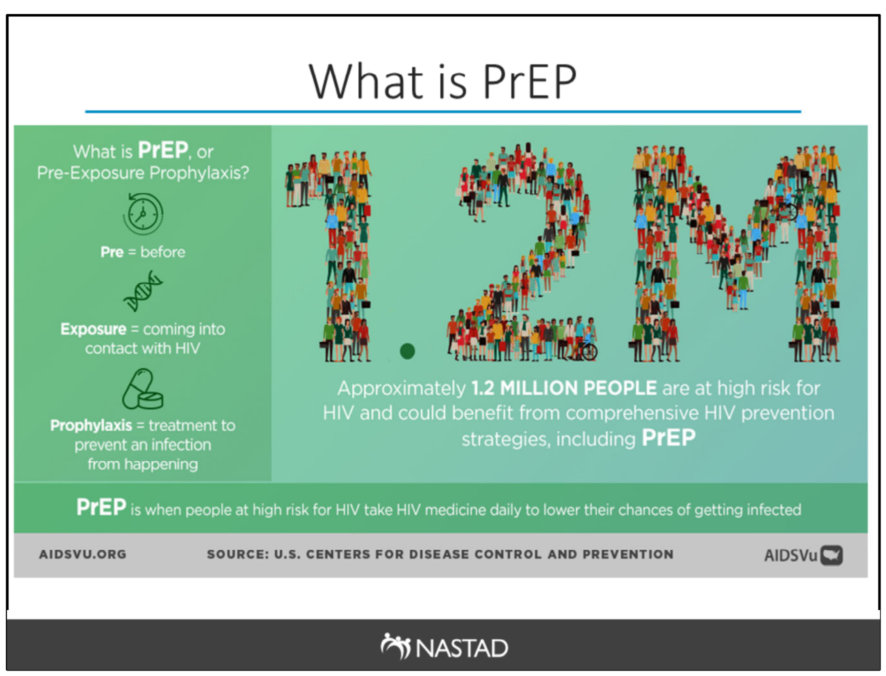
Slide 8 Presentation Road Map

Amy Killelea

Terrific. Hi everyone. Good afternoon. This is Amy Killelea with NASTAD, and thank you for the opportunity to talk about this dynamic and complex topic. To give you just a sort of road map of what I want to cover in fairly short order, is to do a quick rundown of the importance of PrEP, what it offers as a prevention intervention for HIV, and some of the unique financing challenges that we're confronting with PrEP. I do want to spend some time talking about the PrEP pipeline. We've got a lot happening in terms of the PrEP medication landscape, and particularly a lot is going to change over the next months and couple of years that will impact how we finance and deliver PrEP. And then I really want to focus the rest of the presentation on our current coverage and cost landscape, the coverage policies that will impact PrEP access and affordability, and then considerations for how we can really leverage family planning clinics and other delivery settings to support sustainable PrEP payment and delivery models. And I will leave some time at the very end for questions and comment, and definitely want to hear from all of you.



Slide 9 PrEP Overview

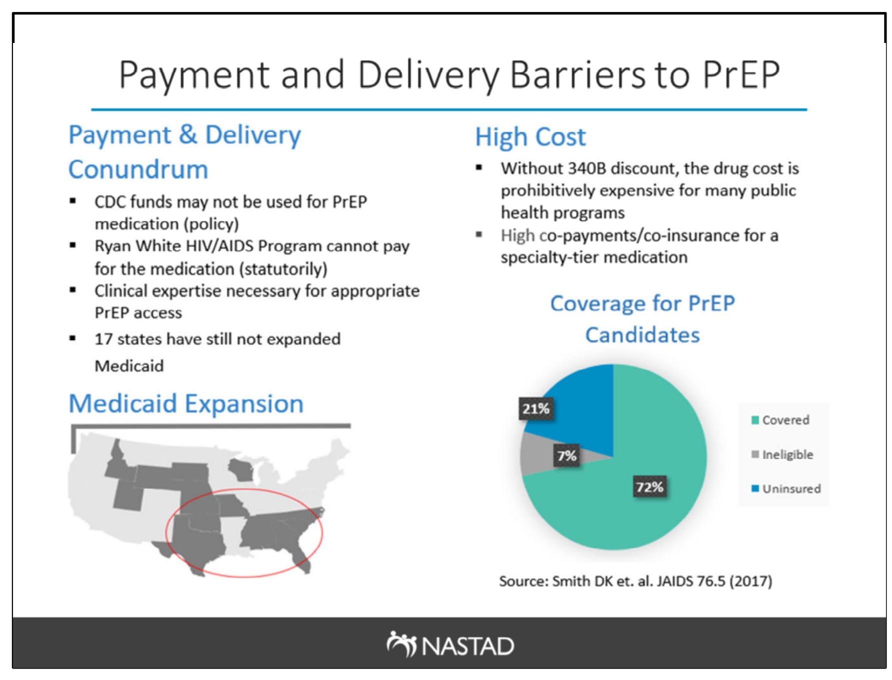


Slide 10 What is PrEP

To get started at the beginning, in terms of PrEP as a real opportunity, and I won't repeat the great background and context for the clinical guidelines for PrEP. I think those are an amazing resource. It really is sort of one stop shop for both the populations who are at highest risk for HIV and are indicated for PrEP, and so what I want to underscore here is that we've got an intervention that is both highly effective, and so I really just want to reiterate the efficacy that was just presented of nearly 99% effective when used regularly at preventing HIV acquisition. I do want to note in terms of PrEP, just something that I think is important, that yes it's an antiretroviral medication, but unlike ARVs which are used for treatment, individuals typically aren't on PrEP for a lifetime. They may use PrEP for a period of time where they might be at higher risk of HIV, and then stop if those circumstances change, and that makes sense.

In the most recent studies presented at CROI earlier this year indicated that that average timeframe that someone's on PrEP is about 14 months, and I just add that at the outset as I think an important distinction, and an important data piece when we think about financial forecasting, when we think about sustainability models for PrEP access. And then just to end with a number in bold print in front of you there, and

that's taken the CDC recommendations and the populations that were just described, in terms of who is indicated for PrEP, that ends up being 1.2 million people who are actually indicated for PrEP in the U.S., so a significant potential as an HIV prevention tool, and we'll discuss throughout why we have not quite managed to scale up access in a way that really meets the potential of PrEP.



Slide 11 Payment and Delivery Barriers to PrEP

And so one of the things to think about at the outset, and many of you may be more familiar or somewhat familiar with the HIV treatment and care landscape, where we've got a fairly sophisticated system mostly built on the foundation of the Ryan White HIV/AIDS Program, that offers an incredibly comprehensive... There are still gaps, to be sure, but a comprehensive safety net for people living with HIV, and so at the outset of this question of PrEP payment, and delivery and access, is a question of why is PrEP different? Why does PrEP pose these financing and cost barriers that are unique in the HIV space? And I think there are actually a couple of reasons.

I think first and foremost, we have this financing conundrum when it comes to federal grants. We have two main programs at the federal level when it comes to HIV. One is the Ryan White HIV/Aids Program, which I just mentioned, out of the HRSA HIV/AIDS Bureau, which funds care and treatment for people living with HIV, and it's a statutory requirement. You have to be living with HIV to get services under that program. That program houses the AIDS Drug Assistance Program, which is the program for medication access and delivery for uninsured individuals. It is a 340B entity. That is the infrastructure for medication access, but we cannot use that funding for people who are not living with HIV.

We can use the infrastructure, and we'll learn about how jurisdictions are doing that, but that really is one funding stream that is cut off because of the statutory prohibition. Then the other side, you have the CDC, which is a major funder for HIV prevention services, however, they have a fairly long standing, and up till now immovable, though we'll see what happens, policy to not allow CDC grants to be used to actually pay for the medication itself. So that, unlike the Ryan White HIV/AIDS Program situation, that is a policy decision by CDC that is not a statutory bar, so more likely to change than the Ryan White situation, but still... That creates sort of a no man's land of the two major federal programs dedicated to HIV are not able to actually fund payment for the medication.

And so what that has really caused is this sort of outsized reliance and leveraging of public and private insurance, so Medicaid, Medicare, and then commercial insurance, individual plans and employer sponsored plans, to really ensure there's a payer source for PrEP, and I think there are a couple of problems with that. On the Medicaid side, in the states that have not yet expanded Medicaid, there's a big gap there, because if you think about the populations who are indicated for PrEP, they are not the populations who are meeting the really strict eligibility standards in those states who have not yet expanded Medicaid, so that cuts off a chief payer source for low income folks in those states. That's one big barrier.

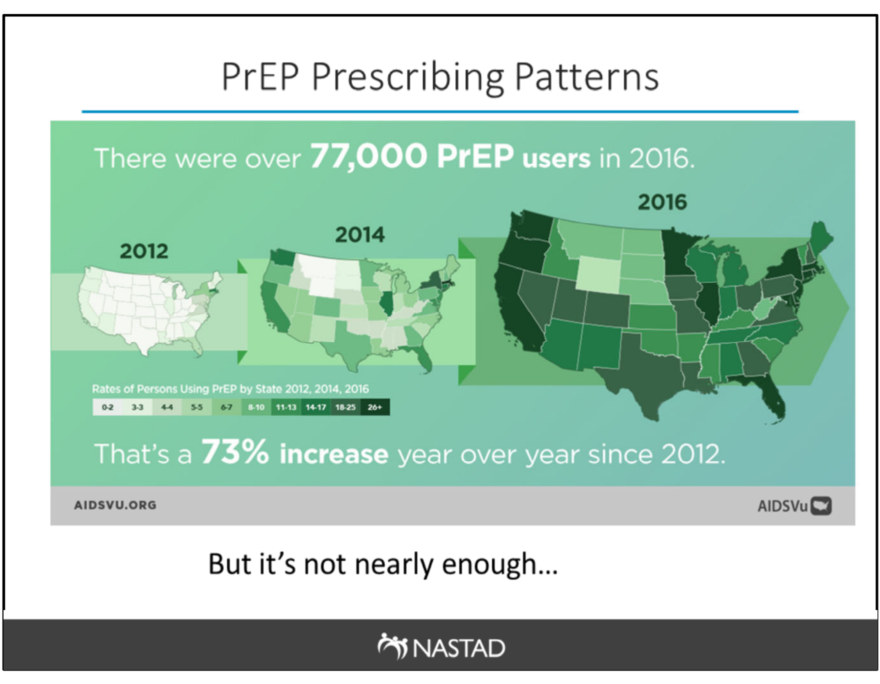
And really if you kind of visually overlay this Medicaid expansion map in front of you, with thinking about PrEP utilization disparities, there's a real big overlay there, or connection there, that the states who have not yet expanded Medicaid also tend to be the jurisdictions where PrEP uptake is pretty low.

So, that's kind of one, and then on the private insurance side, I think we've actually done a pretty good job of really advertising private insurance as a way to pay for PrEP, of creating pathways to get people enrolled in insurance when they're eligible, but it's also a little bit problematic that private insurance is not always the best public health intervention mechanism, especially when the intervention, like Truvada, is expensive, so we've seen problems in terms of high tiering for Truvada, and subsequently high cost sharing, and other issuer behavior that makes it hard to actually be able to afford the medication, even when you do have insurance.

And I'll just note, and this is... The pass for this is at the bottom of the slide, and I'd urge you to take a look if you haven't, but CDC came out with a paper about two years ago, that really looked at the financial barriers in particular to PrEP. And they found some interesting things, and one of the things they found was that the majority of folks had some form of insurance. They had some form of access to public or private

insurance, but where the barriers were was on cost, and that was a really big barrier for folks who... Their Truvada was on a specialty, really high cost tier, and so the prescription copays were very, very high, so that was a noted barrier.

I will say the other thing, and we'll talk about this, because I think it's important to the story of PrEP financing in this country, is that paper, and it doesn't lead with this. You kind of have to read the whole thing and then say it back, and say, "What is this saying?" But what the paper really did find was that we have an outsized reliance, a really significant reliance on the Gilead Patient Assistance Program, and the copay assistance program, when it comes to filling those gaps, and in some ways it sort of masks the health systems gaps, because people are still in that patchwork able, in some cases, to get access to the drug, or access to copay assistance programs through the manufacturer programs, but it's not really a substitute for an integrated and well-functioning health care and public health system, and I think that's an important point, and was an important finding of that paper.



Slide 12 PrEP Prescribing Patterns

I do want to give a shout out to the folks at Emory University, who put together aidsvu.org, and you see them referenced in a couple of these slides, and if you haven't taken a look, I really would urge you to do that. It is a great resource, and for PrEP, their PrEP data is fairly new, but you can really look at by state, to look at what does utilization for PrEP look like in your jurisdiction, to see kind of where you stack up, and sort of what utilization looks like compared to rates of HIV infection, for instance, so it's a great resource.

But I think this is... One piece of the story is that since 2012, when the FDA first approved Truvada for PrEP, PrEP use has certainly gone up. That is a story told by the data. There's been a 73% increase, year over year, since 2012, but I want to caution that while national PrEP uptake is going up, it is not going up for everyone, and in fact I think we've got increasing disparities when it comes to PrEP uptake.

PrEP Disparities

- PrEP prescriptions varied significantly based on gender, geography, and race/ethnicity:
  - Only ~7% of the 1.2 million people eligible for PrEP are actually using it as a prevention tool
  - Among Black and Latino gay and other men who have sex with men, only 1% and 3% are using PrEP respectively
  - Women had far lower rates of PrEP prescriptions (93% of all PrEP users in 2016 were men)
  - The U.S. South, which accounted for half of all new HIV diagnoses in 2016, had lower rates of PrEP prescriptions

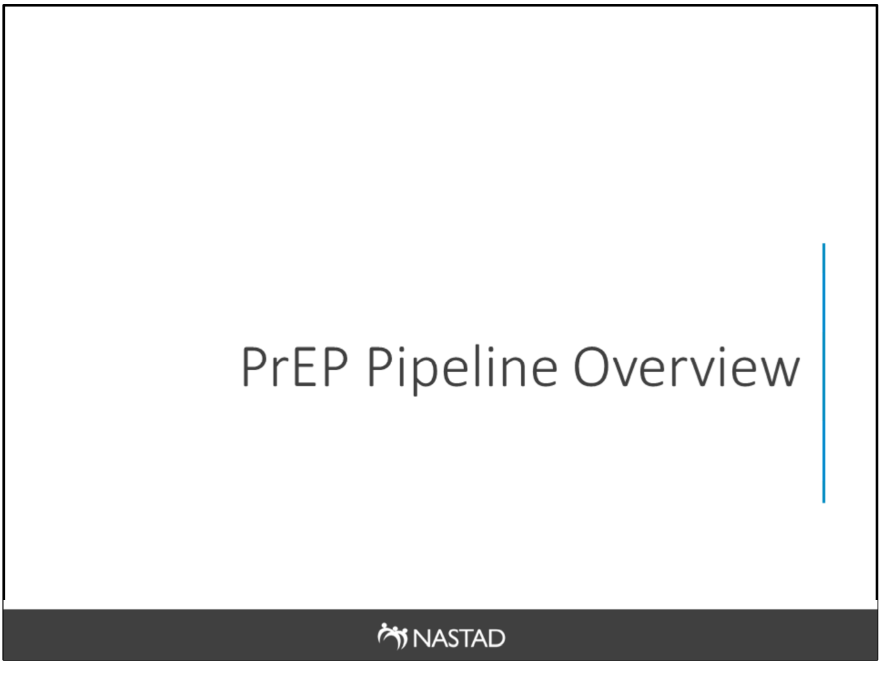
NASTAD

Slide 13 PrEP Disparities

In drilling down in the disparities, and this is based of AIDSVu data, and CDC data, but in drilling down into what the disparities look like, you disparities based on gender, based on geography, and race and ethnicity, and even before we get into the disparities, just kind of taking a step back and looking at of those 1.2 million people that we talked about are actually indicated for PrEP in this country, we only have uptake of about 7% of that number, so 7% of the 1.2 million people who are eligible for PrEP are actually using it, so that is very, very low.

And then when we even go into that, okay, who are those 7%? Those 7% are not the folks who actually have the highest rates of new HIV infections, so among black and Latino gay men, and other men who have sex with men, for instance, only 1% and 3% are using PrEP, respectively. Women, which I know is a focus area for family planning clinics, have far lower rates of PrEP prescriptions. 93% of all PrEP users in 2016, according to the AIDSVu data, were men. And then we also see geographic disparities, which I mentioned. The U.S. South, again, home of a lot of non-Medicaid expansion states and some other sort of health systems inequities, the U.S. South accounts for half of all new HIV diagnoses in 2016, but also had lower rates of PrEP prescriptions than the national average.

So, some real disparities there, and I want to say at the outset, there are many, many reasons for these disparities. I think we can probably spend the remaining time just kind of naming them. Stigma. Provider willingness to prescribe PrEP. Consumer knowledge about PrEP, and willingness to access and use PrEP. All of those, and I don't want to minimize any of those other driving forces behind these disparities, because I think that you could do, and should do a presentation on each one of them. I'm going to drill down into one challenge in particular today, and that's really the financing coverage and cost challenges with accessing PrEP, because I think that they are unique, and they do, I think, need some individualized attention, to get at what's going on and how can we best address them.



Slide 14 PrEP Pipeline Overview

PrEP Pipeline: At-a-Glance

Product	Route of Administration	Status
TDF/FTC	Oral	Single generic competitor in Sept 2020; multiple competitors beginning March 2012
TAF/FTC	Oral	Phase III (Phase I-II in African women)
RAL/3TC	Oral	Phase IV
Cabotegravir	Long-acting	Phase III
Dapivirine	Ring	Phase III/FDA review (ring); 3-month ring and rectal gel in development
Tenofovir	Ring	Phase I
Dapivirine or tenofovir + levonorgestrel	Ring	Phase I
Tenofovir, TAF/EVG, IQP-0528, Griffithsin, PC-1005, DS-003	Vaginal or rectal inserts, enemas, and tablets	Pre-clinical – Phase I

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Slide 15 PrEP Pipeline: At-a-Glance

And I debated this. I will say, of kind of where to put this PrEP pipeline update, and so one thing I debated doing was just putting this at the end and leaving you all with this, going through an entire presentation of PrEP financing and sustainability, and then ending with, "But wait a minute, this is all going to change," and so I decided not to do that. I wanted to start with... We've got existing financing models right now that are based on the current landscape, which is a one drug landscape. It is Truvada, a brand name product, the only FDA approved drug for PrEP right now, but that landscape is changing, and is going to change fairly rapidly, and so I think it's important just to start with that, and a quick overview of the dynamic PrEP medication landscape.

Very soon, we're going to see competition in this PrEP space for the first time, and I think there are both benefits to that competition, mostly competition drives down prices. That is a huge benefit. But there are also challenges, as the space becomes more complicated, so for this slide, I'm only going to focus on the medications in the slide that are moving the quickest, and so for the other ones, so particularly the ring updates, I wanted you all to have them, but for time's sake, I am not going to focus on those. Those approval timelines are far longer down the road.

But the first one I want to talk about, the first major change to the PrEP landscape, is likely actually going to be very quick, before the end of the year and as early as October, when Descovy, which is another Gilead brand name product, gets an FDA indication for PrEP. So, Descovy is a slightly different formulation than Truvada. Truvada is TDF/FTC, and Descovy swaps out TDF for TAF. There is some indication, and Gilead has shown some indication that there is slightly lower toxicity for a TAF-based regimen. I think there is some clinical evidence that questions exactly what that benefit is, and how to quantify it, so I'll just leave that there, as there's some back and forth on that.

But Gilead has secured a fast track review process for FDA approval of the PrEP indication, so this is happening rapidly. This is before the end of the year, we're going to have more than one product for PrEP. We also have a generic form of Truvada, so again, that's the TDF/FTC, so generic form of Truvada on the horizon. There will be a single generic competitor, offered by Teva Pharmaceuticals, which will happen in September of 2020, with multi-generic competition beginning of March, 2021, after the six-month exclusivity period has ended. So, I will say in terms of impact to the system, probably that last one, the multi-generic competition has the most potential for impact to the system, and we'll talk about that throughout.

So, I wanted to start here, just because I'm going to be referencing some of these changes throughout, and how they could potentially impact our financing approaches to PrEP.

Slide 16 PrEP Coverage and Cost Landscape

PrEP Components and Costs

PrEP Components	Cash Price*
Medication (Truvada is only FDA-approved medication for PrEP currently)	~$1,700/month (Wholesale Acquisition Cost, no discount); ~$440/month (340B Price)
Lab costs** (at PrEP initiation and every three months) • Baseline HIV test • HBV tests (at initiation only) • Metabolic panel/creatine test • Gonorrhea and Chlamydia screening • Syphilis screening	~$291 to $3,955
Physician visit (at initiation and every three months)	~$60 to $177 per visit

* Above costs are estimates, the cash price of services varies significantly depending on geography and provider. Many providers provide lab and clinical services to uninsured patients at a reduced rate.

** Providers should refer to the CDC PrEP Clinical Guidelines for specific lab recommendations based on patient risk and other factors.

Source: Whitman, et al, Costs of Providing PrEP for HIV Prevention: Estimates from a Community Health Center, (Abstract PS3-44, 39th SMDH, 2017).

NASTAD

Slide 17 PrEP Components and Costs

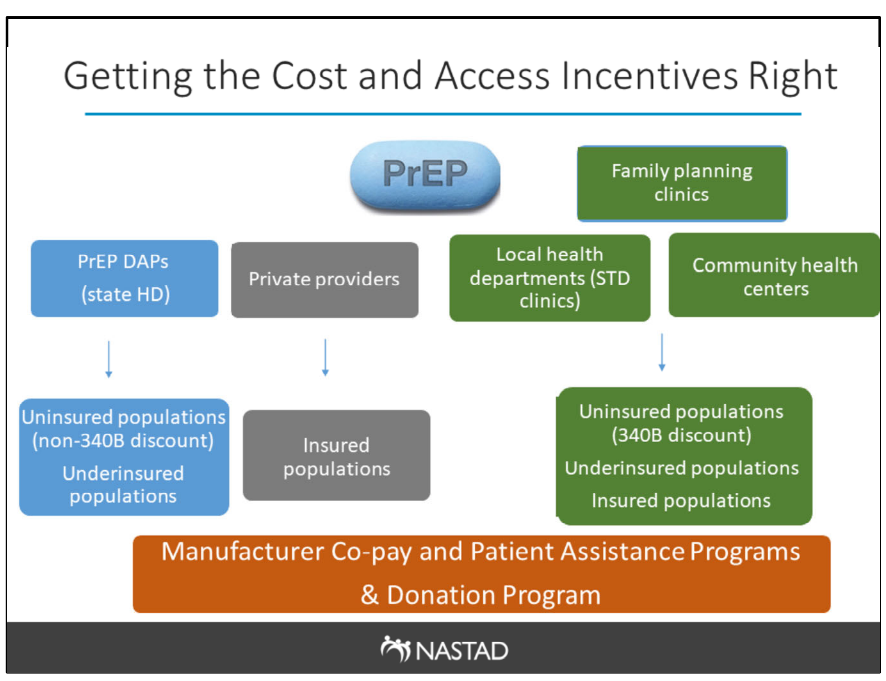
Now I'm going to move into a deeper discussion of the PrEP coverage and cost landscape, and what's going on there, what's changing, what's working, what's not working, and where the gaps are, and so I want to start very briefly, because throughout, and I think I've probably done it already, I reference the high cost of PrEP, and so I don't want you to take my word for it. I want to have some numbers and data to sort of back that up, and so this includes the cash price for three components of PrEP, and I will say these are probably not all of the components that we could say should be included in our definition of PrEP. We all know it is not just the medication, and some things that are probably missing from here are counseling and linkage services, so I want to note that for simplicity purposes I wanted to focus on the big three that are the focus of the CDC clinical recommendations, as well, and that breaks down into medication, the lab cost, and then physician visit costs.

The medication, as we've said, Truvada is the drug right now that's approved for PrEP, and right now it has a... and this is actually a little bit outdated. It's a little bit closer to $1,800 a month now, wholesale acquisition cost, or list price, so that's without a discount. And then, and I will say just for completion purposes, Descovy has the exact

same list price as Truvada, so if folks were thinking of that, that's actually not going to be... That piece of competition will likely not drive down price immediately.

And then you've got lab costs, and so I went back and forth of do I just kind of take an average between those two numbers and leave it at that, but I think having the range there is really important. This is all over the board. We use a national claims database to sort of get our averages, but we also do validation testing with focus groups of providers, and what we get are just answers that are all over the place in terms of the actual cost of the labs, and this really does vary, and varies also by discounts that providers are able to negotiate with labs, so I want to note that. This is a variable element, but this is the range, and it can be a fairly significant cost. You've got lab costs that need to happen at initiation, and then every three months in accordance with the CDC PrEP clinical guidelines.

And then you have physician visit, and again, this varies as well, but also varies by type of provider, and so a primary care provider, if you're able to bill a provider, that's going to be different than if you're a specialty provider within an infectious disease clinic, so these are also variable. But this gives you a sense of the general cost breakdown, and I think that's an important starting point.



Slide 18 Getting the Cost and Access Incentives Right

Before getting into some of the components of how we are financing PrEP right now, I do think it's... And I like to do this at the outset of just taking a step back and thinking about how the financing mechanisms really do put a thumb on the scale for a certain delivery mechanism, and so I think in thinking about PrEP in particular, and you could probably apply this to a great many interventions and services in the public health space, but thinking about PrEP in particular, if we step back, and if we decided to design a system where the primary goal was to A, get PrEP into as many hands as possible, and B, get PrEP into hands that were disproportionately impacted by HIV, and not getting access to PrEP currently, so the folks that I mentioned when we were talking about PrEP access disparities. So, if that were my goal, I might design a system that is very different than the system that we have right now. I might really put my thumb on the scale of innovative, and varied, and community-based providers that were really able to meet people where they were.

I would really think about who are the populations, and how do I pick and cultivate providers that are able to best reach them, and I say this because this is not the system that we have. We really have, and very much driven by the high cost of Truvada in this

case, we have a system that's kind of the opposite. We start with the financing, and we use that to really guide what exactly our delivery systems look like, so it's a little backwards than if you really wanted to think in a public health lens, and access lens, how would you do it? We're a little bit hamstrung by the high cost of PrEP, frankly, and so I think that means in the 340B context, and we're talking about... We're talking to 340B entities here. In the 340B context, that means there is a thumb on the scale of 340B entities being primary providers of PrEP because of the unique sustainability models that are available in those settings, so family planning clinics, local health department STD clinics, community health centers, and then that does leave out some of the other non-340B entities, mainly PrEP drug assistance programs, from that equation.

They are not 340B entities. They're only 340B entities for people living with HIV, so you are leaving out sort of a swath of public health providers there, so that's one thing, and the other thing I'll say, just to reiterate the point that I made with the CDC paper, is that we do, then, kind of rest our system heavily on the manufacturer copay and patient assistance programs, and as we talk about those programs, I do want to just kind of note the ways in which that ends up with a fairly fragmented system for PrEP access. And some of you may be out there who have models where you are sending people to the patient assistance program for their medication access, or the copay assistance program, and you know that anytime you add different access points, where you say you get your medication here, but you get your lab services here, and this is how we'll pay for this thing, and this is how we'll pay for that thing, you add complexity to a system, and you run the risk of creating a complex system for a consumer who's not going to want to deal with that.

So, I want to just note that this patchwork does have an impact I think on access, and I think the biggest thing that turns this patchwork, and turns these incentives on their head, is the multi-generic competition that I talked about. That's the even playing ground that allows us to provide access across a larger swath of providers.

Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms…

	Drug Access	PrEP Clinical Visits & Lab Costs	Counseling and Linkage
Uninsured	Manufacturer Patient Assistance Program PrEP Drug Assistance Programs or "PrEP DAPs" (state funded) Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings	PrEP DAPs (state funded) CDC prevention funds to pay for HIV/STD testing Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings	PrEP DAPs (state funded) CDC prevention grants and 340B savings Community Health Centers; Family Planning Clinics; STD Clinics using 340B savings
Insured	Covered by payers; co-pay assistance through manufacturer assistance program	Largely covered, but with patient co-pays PrEP DAPs pay for lab/clinical visit co-pays (state funded)	Not well covered by public or private insurance

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Slide 19 Financing Models for PrEP: A Patchwork of Funding and Delivery Mechanisms…

I'm going to spend the next several slides really picking apart this patchwork that I talked about, and really getting at how each of these patchwork systems and programs work, and how they interact with one another, and I'm hoping that we can also use this as a way to figure out where some of the gaps emerge. And so the slide in front of you tries to provide a visual of both the components of PrEP programs, and so again, a slight oversimplification, or probably more than slight, but sort of dividing it up into three buckets that make up a PrEP access program. You've got drug access, that is probably one of the most important buckets, but not the only bucket. You then have the PrEP clinical visits and lab cost, and then you have counseling and linkage services. So, those are the three buckets.

And then you also have another dividing line, in terms of uninsured folks and insured folks, and the way in which individuals access each of these buckets of services does vary quite a bit, both depending on the service, and depending on whether they have insurance. So, just to sort of start out with the uninsured population, for drug access, we have several different mechanisms. These are probably the most common. First

and foremost, the manufacturer patient assistance program, that is a huge source of access to the medication itself for uninsured folks. We'll talk about that in a minute. You have PrEP drug assistance programs, or PrEP DAPs, these are often using the AIDS drug assistance program infrastructure at the state level, but are state or local funded. You cannot use federal funds for that, and are not 340B eligible, so PrEP drug assistance programs that are purchasing drugs, are purchasing at the full drug price. There is no discount there.

And then you have community health centers, family planning clinics, STD clinics, and really the... I think the sustainability story there is the ability of those clinics to generate 340B program income and savings via their models with insured clients, to then be able to provide the medication to folks who are uninsured. And you see that play out for, and I'll just kind of go through the rest of it, from left to right, that is the same way that PrEP clinical visits and lab costs are paid for uninsured folks for those 340B entities, and that counseling and linkage services are paid for by those 340B entities.

The clinical visits and lab costs provide more of a conundrum, in terms of making sure that those services are covered for uninsured folks. Again, it's a patchwork. Some PrEP drug assistance programs are able to step in and fund those services. CDC prevention funds are able to pay for some, but not all, of those services. And then we talked about the 340B entity savings reinvestment, and then the same thing holds true for how counseling and linkage services are paid for for uninsured folks.

For insured folks, the drug access piece is a little bit more straightforward. It is covered by payers. NASTAD does analysis of commercial plan coverage, and we've got access to a national database of plan coverage, and really the vast majority of plans have Truvada on formulary, and we don't see a lot of examples of prior authorization that denies Truvada when it's used for PrEP, so we've got pretty saturated coverage on public and private formularies, and then we do see access challenges and affordability challenges with high copays, or even coinsurance, where folks are paying a percentage of the list price of the drug, and we talked about what the list price of the drug was, so that can get very, very expensive, when you're paying 30, 40% of that list price at every fill.

And so, for insured folks, those costs, those out of pocket costs for copays and coinsurance associated with your medication, those can go through the manufacturer, the copay assistance programs, through the manufacturer. And many, many people have used that. In terms of insured folks for PrEP clinical visits and lab costs, largely covered. Patient copays do exist. They're obviously not going to be as high as for a medication, but there still can be a barrier, and there are some ways that both clinics have been able to help with that, and that state PrEP drug assistance programs have

been able to help with those copays, as well. And then the counseling and linkage services is actually one thing that is not super well covered by public or private insurance. Counseling a little bit more, but linkage is not a very well defined, sort of CPT code and service for public and private insurance.

Patient and Co-pay Assistance Programs

Patient Assistance Programs			
Program	Clinical Visits & Labs	Health Insurance	Income Eligibility
Gilead Patient Assistance Program	Not covered	Uninsured	500% FPL

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Slide 20 Patient and Co-pay Assistance Programs

So, that's kind of the landscape. What I want to do, because I've mentioned several times now the role that the patient assistance programs play, I do want to just spend a second walking through what these look like, because they often are, even when a clinic, or a public health program has a sophisticated PrEP program, often the sort of first referral out is to the Gilead Patient Assistance Program. Not always, but that's a part of how a lot of these programs run. That might be a part of how your program runs, and so I just want to spend a second walking through this.

And so, the first, for uninsured folks, and really the program for uninsured folks who are looking to access PrEP is the Gilead Patient Assistance Program, and this is for uninsured people. There is an income eligibility limit on this, and just to sort of underscore the point, this is just for the medication. This is not for clinical visits and labs, so it does leave patients who are accessing the drug through this program on their own, or with the help of assisters, to really figure out how to get those other costs and services covered. And I will just note, as we talked about, when Descovy is approved, the patient assistance program is likely to be very similar if not identical to the one for Truvada. I think that will become important when we have new drugs, to

make sure that we don't have confusing systems with different rules, and it looks like that's going to be fairly similar.

Co-pay Assistance Programs

Co-pay Assistance Programs				
Program	Medication Copay Max	Clinical Visits & Labs	Health Insurance	Income Eligibility
Gilead Advancing Access Copay	$7,200/yr	Not covered	Private health plans	Any income
Patient Advocate Foundation	$7,500/yr	Not covered	Plans covering Truvada	400% FPL
Patient Access Network Foundation	$8,000/yr	Covered (limited)	Medicare	500% FPL

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Slide 21 Co-pay Assistance Programs

So then, for underinsured individuals, so folks who have insurance, but they have really high copays or coinsurance, we've got a number of different copay assistance programs, although I will say the first one up there, the Gilead Advancing Access copay program is the most widely used. It is fairly generous. There is no income limit for that, and in fact, the medication copay maximum last year was raised up to $7,200 a year, and that was a fairly significant increase from what it was before. So again, clinical visits and lab copays are not covered, and this covers copays associated with private health plans, so not Medicare and not Medicaid.

And then you've got charitable programs, as well, so these are not operated by manufacturers. These are charities, and so they have to have income eligibility thresholds, and so the two programs listed there do. The first one, the Patient Advocate Foundation, it tends to ebb and flow in terms of when they're open and when they have to close, because they do not have funding, and so it's been typically used as a backstop to the Gilead Advancing Access copay program. That's usually the first stop, and then the Patient Access Network Foundation is even less used. It is only for Medicare, and we have not seen much uptake
there. But that's kind of the landscape for copay assistance.

State PrEP Assistance Programs

STATE	DRUG ASSISTANCE COPAY ASSISTANCE	DRUG ASSISTANCE MEDICATION ASSISTANCE	CLINICAL VISITS AND LAB TEST ASSISTANCE	PATIENT INCOME LIMIT
California	Yes	Yes	Any participating provider	Up to 500%
Colorado	Yes	Yes	Any participating provider	Below 500%
District of Columbia	Yes	No	Local health department clinics	Up to 500%
Florida	No	Yes*	Local health department clinics	No threshold
Illinois	Yes	No	Select grantees	No threshold
Massachusetts	Yes	No	Select grantees	Up to 500%
New York State	No	No	Any participating provider	Up to 435%
Ohio	Yes	Yes	Any participating provider	Below 300%
Virginia	No	Yes*	Local health departments and contracted providers	No Threshold
Washington State	Yes	Yes	Any participating provider	No Threshold

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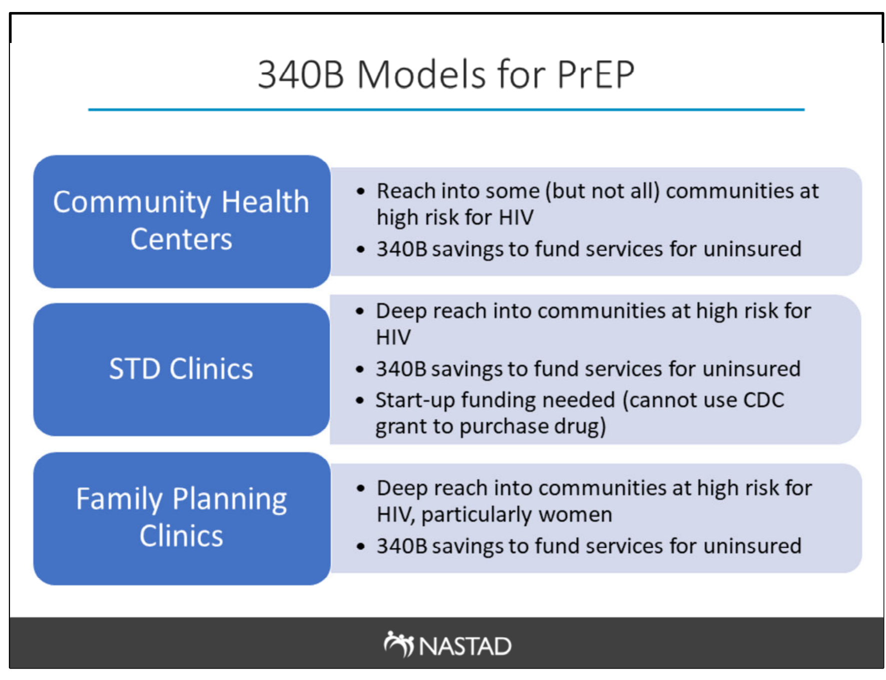
Slide 22 State PrEP Assistance Programs

And then I've mentioned a couple of times now the state prep assistance programs, or PrEP DAPs, and really this list has grown, and perhaps is continuing to grow. There may be jurisdictions on there that we need to add. This is updated as of about, I think four months ago, and this is constantly evolving, but these are programs that have used some combination of state and local funds to create, and these are all at the state level or District of Columbia level, a PrEP program that covers some degree of medication assistance, copay assistance, clinical visit, and lab. You see it's kind of... It differs by jurisdiction, but these are state run programs that are really attempting to mirror the Ryan White HIV/AIDS Program models, and provide financing and distribution models.

So, if you're in one of the states, they all have websites, and those website links are actually up on NASTAD's website. I'll show you the link at the end of the presentation, but it's good to check out what your state is doing, and what's available to folks.



Slide 23 340B Models for PrEP

In terms of 340B, and this was another area where I want to have a few caveats at the outset. This, as you've probably heard by now, or gathered by now, this is a very coverage and policy heavy presentation. I am not going to get into the 340B compliance and regulatory weeds. That is a topic for another day, and probably many, many hours, and folks with more 340B legal compliance background certainly than I do. I approach this from a coverage and systems financing piece, and so that is the mindset with which I present this, and I think what I want to really underscore here is that the 340B models for PrEP have really been a sustainable, and sort of innovative financing mechanism for PrEP, but it looks a little bit different depending on what type of 340B entity you are, and I think there are pluses and minuses and unique challenges for each one.

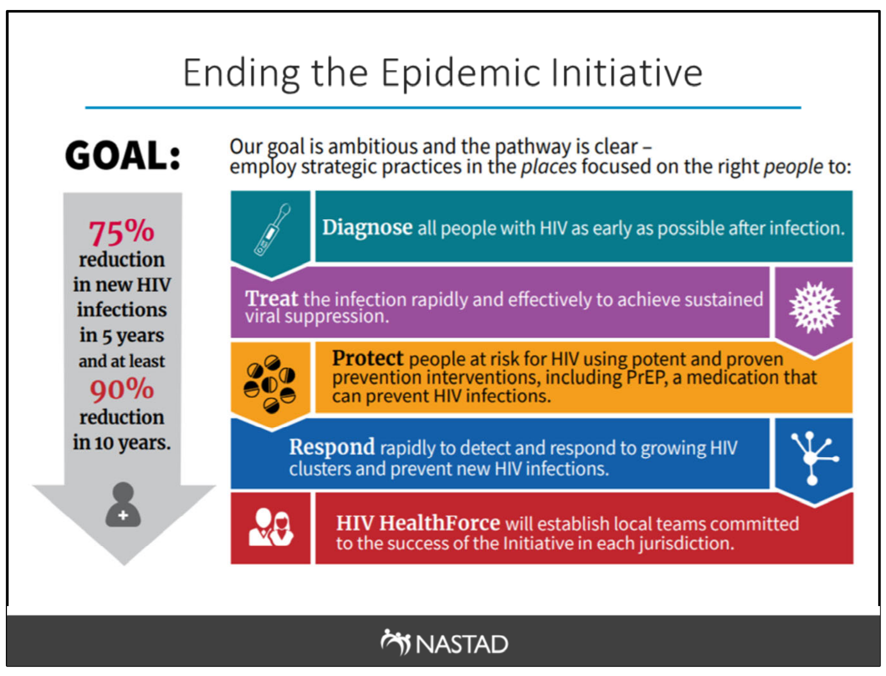
And as I said at the outset, the sustainability part of this, and it's a little bit of a perverse relationship, but here it is. The sustainability part of this is that you have a drug, Truvada, that has a fairly high, if not very high list price, and you also have a drug, Truvada, which has had price increases year on year for the past several years, and that combination of facts means that the drop down to the 340B discount, from that list

price, is significant. And that means that the drop down from the commercial usual and customary rate, down to the 340B discount, is significant. And so that means if you've got a population of commercially insured folks, that you are really able to use that spread, which is significant, to cover a whole bunch of services for uninsured people. And I say reinvest the savings. These are program income, this is not sort of a profit, but really it has allowed programs to be able to cover medication and other services for their uninsured population.

So, that is probably sort of old hat to most of you, but I think that's important just to kind of name the exact reason why the 340B models work. And so they're used, we see them pop up in community health centers and STD clinics, and then in family planning clinics, and I think for the community health centers, that is the biggest model. They have probably the most funding, in terms of the different settings we're talking about. They have reach into some, but not all communities at high risk for HIV. By their mission, they have to serve folks who are in need, and have special population focuses, and so that is one area.

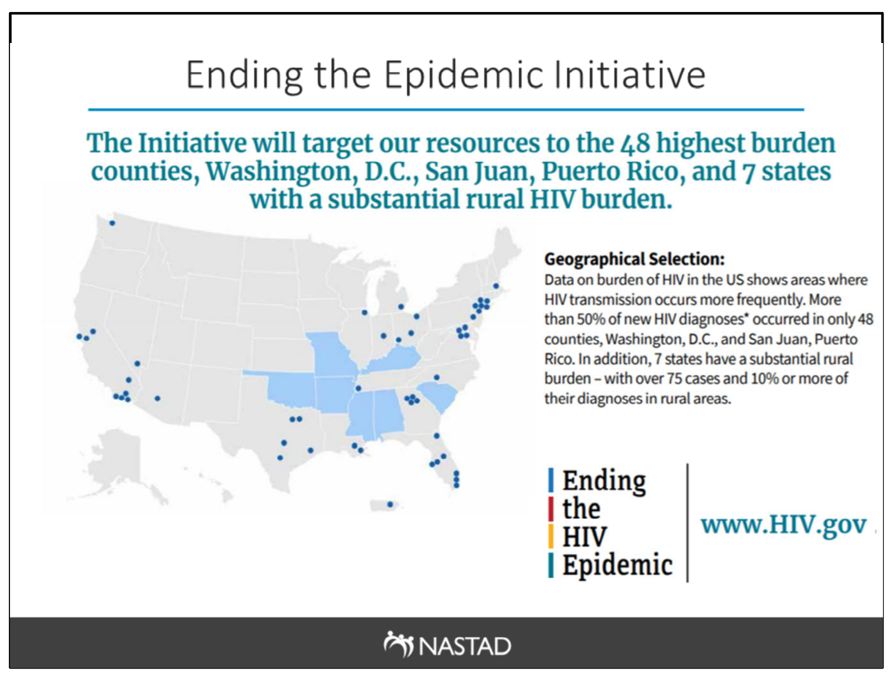
STD clinics, another really good entry point into communities at high risk for HIV. Probably in some ways reaching different populations than those who are going to community health centers, including gay and other men who have sex with men, and women, and so a little bit of a more diverse community reach. Again, the 340B savings can be generated. The trick with the STD clinics has been that startup funding identified, state or local funding, has been needed, because going back to the financing conundrum that I talked about the beginning, CDC grant funds cannot be used to purchase the drug for STD clinics. So, we've seen more STD clinics go down the route of using their 340B status to stand up PrEP programs. We've actually seen an expansion of the 318 designation for STD clinics to get 340B status, and perhaps we will see some loosening of the grant restrictions on PrEP medication payment, as well.

And then family planning clinics. I think in many ways, similar to the SDT clinics, and probably the two have and can learn a lot from one another in terms of how these models are set up, and I think that the real draw in family planning clinics is in a deep reach into communities at high risk for HIV, particularly women, who perhaps are not as well served in the other settings that are scaling up access to PrEP, so there's a real opportunity there.



Slide 24 Ending the Epidemic Initiative

Very briefly, and this is another one where I sort of scratched my head and said, "Where do I say this? I don't think anyone can give a presentation on PrEP or anything having to do with HIV, without finding some way to reference the administration's Ending the Epidemic Initiative," and so I will do that. I think it is important, and I think it is in many ways focusing us, and putting a spotlight on PrEP access, both in some of the gaps for PrEP access, and I think in identifying areas for new funding. And so, in terms of PrEP, it is actually in the front and center there, one of the pillars of the administration's plan to end HIV, and so is going to be a piece of new funding for PrEP, and I think more attention to innovative models for PrEP, and expending PrEP access particularly to populations who are not really using PrEP in ways that would be indicated by our HIV incidence rate.



Slide 25 Ending the Epidemic Initiative

And then in terms of where is the Ending the Epidemic Initiative focusing, it is a geographic focus, at least in the first iteration, so it's focused on the 48 counties and seven jurisdictions with the highest rates of HIV infections. So, that is the map that you see in front of you, so I'd urge you, if you are in one of those jurisdictions that are in blue, or, and it's a little bit harder to see, you may have to go to the website to kind of figure out that list of counties, this might be a real opportunity in terms of new funding, new community planning, and just new attention to how that jurisdiction is going to meet the PrEP indicators in this Ending the Epidemic Initiative. I actually think that we could see some real movement, in terms of support of new models, and certainly some new funding.

Gilead PrEP Donation

- On May 9, 2019, Gilead Sciences announced they will donate PrEP medication (Truvada and then Descovy) for up to 200,000 individuals per year for up to 11 years to assist in the ETE 2030 initiative
- Details are forthcoming, but Gilead intends to make PrEP available to uninsured individuals, largely through community health centers

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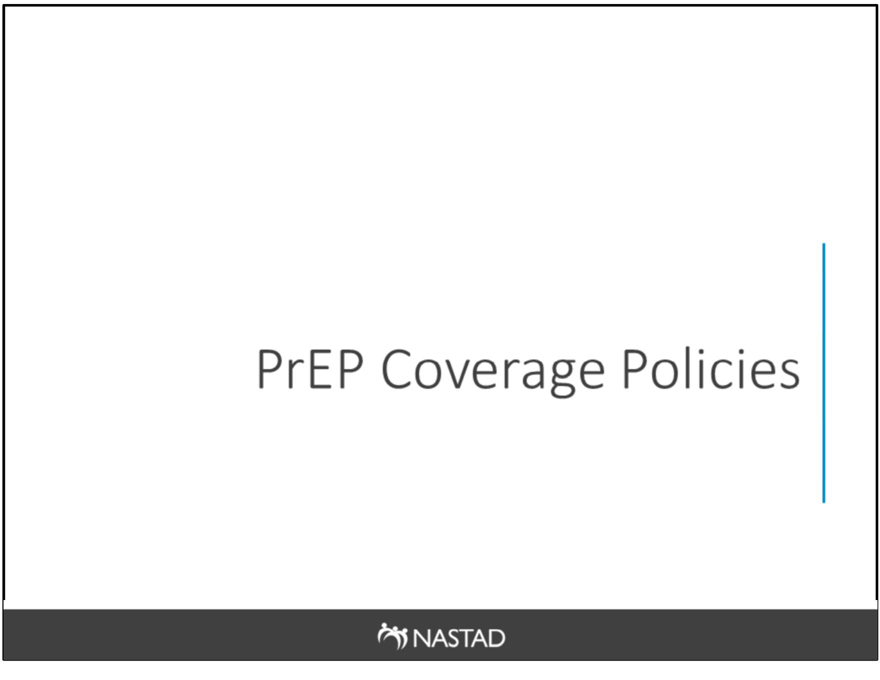
Slide 26 Gilead PrEP Donation

And speaking of new funding, one thing that has been connected with the Ending the Epidemic Initiative has been the Gilead PrEP Donation program, and I'm not sure if folks are familiar with this. On May 9th, so not so long ago, Gilead announced that they will donate PrEP medication, so Truvada, and then once Descovy is approved, Descovy, for up to 200,000 individuals per year, for up to 11 years, to assist, and this is part of meeting the Ending the Epidemic Initiative. I will say details are forthcoming, that is... I'd just bold and underline that. The dust has not settled, and I do not think there's a concrete plan as of yet to operationalize this. It has been committed, so I think that the Gilead has sort of stepped up and committed to doing this, but I think the details of how that happens, to be determined. But this could be an opportunity, I think something that... One way this could happen is to sort of put the thumb on the scale of community health centers, and that's certainly been talked about as a key piece. I think NASTAD and others have really pointed out that in order to really expand access to PrEP to populations who are not accessing it, you really need to think innovatively about settings, including public health settings that would include health departments and family planning clinics.

But more to come on that, but that's something to watch. That has not yet been rolled out, and details are forthcoming.



Slide 27 PrEP Coverage Policies

USPSTF Draft Grade A Recommendation

Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition	A

- ACA mandates that private insurance plans and Medicaid expansion programs cover preventive services with a USPSTF A or B rating **at no cost**
- Plans must adopt in the plan year that begins at least one year following the final USPSTF recommendation

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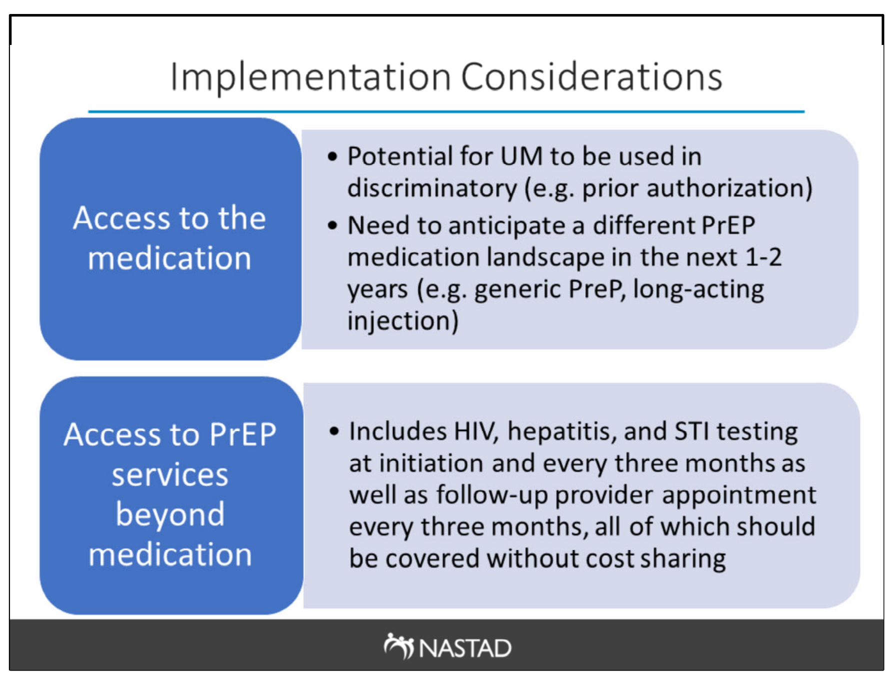
Slide 28 USPSTF Draft Grade A Recommendation

So, the last sort of substantive thing that I want to cover before opening it up for questions is the U.S. Preventative Services Task Force. So, the USPSTF is an independent body, and it reviews clinical evidence, and issues recommendations for preventative services. So, this was sort of a wonky, lesser known body before the ACA, and when ACA came around, there's a really exciting provision in the ACA that requires the majority of private insurance plans to cover any preventative services with an A or B rating, without cost sharing. That's huge, and that really makes these grades that USPSTF issues very, very important.

So, for PrEP, in November of 2018, the USPSTF issued a draft recommendation after a multiyear review process, and I will just underscore, this was a laborious process. There were many comment periods, and they really are heavily clinically based. So, after this process, PrEP was given a grade A. That is the highest grade, that indicates there is a high certainty of substantial net benefit, so that's very, very exciting for PrEP access. The recommendation has not yet been finalized. We're anticipating that the final draft could come out as early as this month. I think we're anticipating at least some time before the end of the year, and in terms of the mandate to cover PrEP

without cost sharing, of when that would go into effect, that would be January, 2021. There's about at least a year lag between the final recommendation and when plans actually have to start covering.



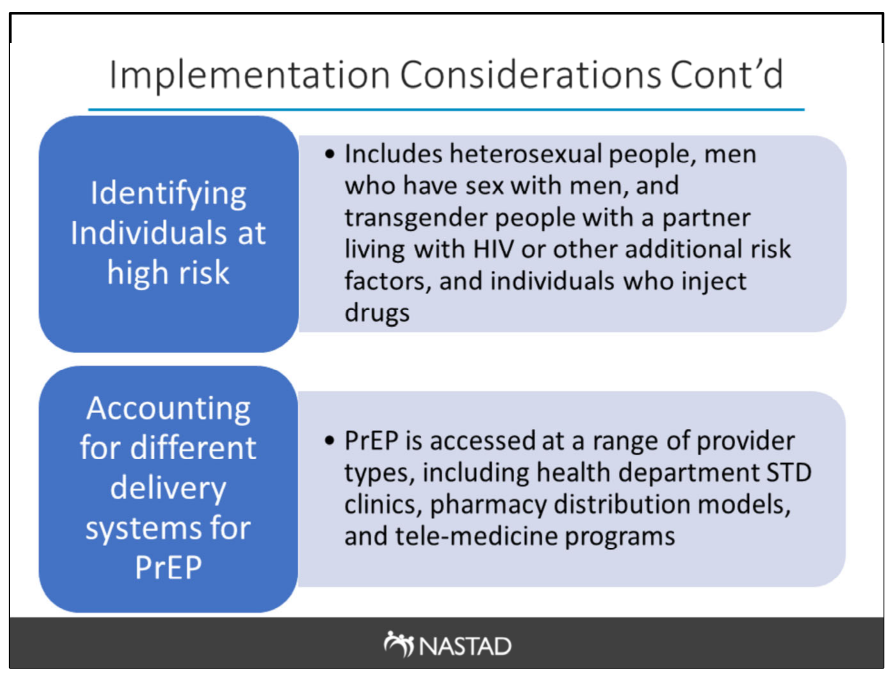
Slide 29 Implementation Considerations

I want to talk through four major considerations when it comes to the USPSTF recommendation, and I'd say it is exciting. We heavily commented, like, "Yay, you did the right thing," but I think there are going to be some implementation questions and challenges that we need to be aware of. Number one is access to the medication, and really I think the big thing there is that you've got this interesting circumstance, where the final recommendation is going to be released in a point in time where there's only one FDA approved product for PrEP, but then let's jump to January of 2021, when the recommendation will be implemented by plans, and that will be a time where we could potentially have, and likely will have three products for PrEP. Two brand name and one exclusive generic. So, that's very different, and so part of the question that was not well defined in the draft recommendation is what will plans be required to cover? Will they be required to cover everything? Will they be able to say, "We're only going to over one thing?" Will they be able to say, "We're going to start you on a generic, and if you fail on the generic, then we'll move you to Truvada or Descovy?“

Will they be able... You could sort of generate endless questions on what they will be able to do, and so that is a real question, that sort of will impact how expansive the

USPSTF recommendation is, both for coverage, and then coverage without cost sharing for folks in the insurance market, and the Medicaid expansion programs. The USPSTF recommendations also cover Medicaid expansion programs.

The second consideration is access to PrEP services beyond the medication, so we talked about PrEP is not just the medication. I think the recommendation actually did a fairly good job of walking through and citing heavily to CDC guidelines about all of the ancillary services that make up PrEP, but not a lot of specific guidance for payers of, "You have to cover this entire suite of services, and you have to cover them without cost sharing." And so I think we will look to see either clarification in the final recommendation and or subregulatory guidance clarifying that.



Slide 30 Implementation Considerations Continued

Identifying individuals who are at high risk. Our, I think, main concern here is that identifying folks for whom PrEP is appropriate really should be at the provider level, and should not be in the hands of an insurance company, so using prior authorization, for instance, to identify who is eligible for PrEP, really has potential stigmatizing and discriminatory implications, and so I think we would certainly argue that that is not an appropriate use of prior authorization, and that that sort of decision is a clinical one, and it should be with the provider.

And then finally, there are different delivery systems for PrEP than I think the USPSTF body typically writes for. Their primary audience is primary care clinicians, and we know that PrEP is provided in many, many settings, including public health, family planning settings, and really ensuring that the recommendations are disseminated and applied across varied settings, because they're applicable across varied settings.

Next Steps for USPSTF Implementation

- Anticipated CMS/CCIIO and CMS/CMCS guidance to private insurance plans and state Medicaid agencies about appropriate implementation
- Anticipated state insurance regulator bulletins and guidance to plans (e.g., NY Department of Insurance Bulletin on non-discriminatory practices for PrEP coverage)
- Provider and consumer education is critical to ensure that USPSTF and CDC guidelines are being followed and to ensure consumers know about new cost-sharing protections

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Slide 31 Next Steps for USPSTF Implementation

So, in terms of next steps, I think we can anticipate federal subregulatory guidance. We are certainly working to inform what that looks like, to make sure that... And federal and state subregulatory guidance, to make sure that the recommendation is interpreted as widely and broadly as possible. And then provider and consumer education, I actually think the USPSTF recommendation will be a really, in addition to the Ending the Epidemic Initiative, those two one two punch together, are really a great way to build provider education and awareness around PrEP, and I think will be a good rallying cry, just to build awareness of PrEP.

Considerations for Sustainable PrEP Payment and Delivery Models

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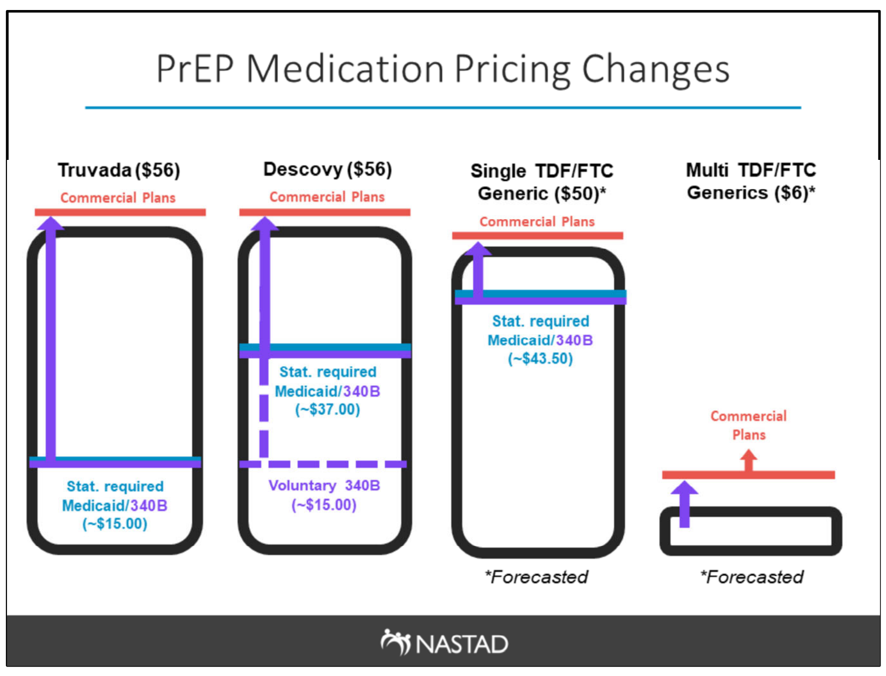
Slide 32 Considerations for Sustainable PrEP Payment and Delivery Models



Slide 33 PrEP Medication Pricing Changes

So, the thing that I want to end with, and again, this is a little dicey to end with, but I'm hopeful that this sort of brings it together in terms of what's on the horizon, and what we're kind of looking at in terms of changes to the medication landscape, and how that impacts sustainability, and so... And I will give all the credit in the world to my brilliant colleague, Tim Horn, who put together this slide, but I think it does a great color coded way of really walking through what are some, particularly 340B, implications for how our landscape is changing, and so Truvada and Descovy, as I said, those are priced identically. The rebate for Truvada is a little bit more, because again, as I said, they've had more year on year increases, but the manufacturer's offering supplemental rebates for Descovy, so that really makes those two products identical, and you could see why the manufacturer would want to do that.

Amy Killelea: We're probably going to see more pushes from them to get people onto Descovy, particularly as the TDF/FTC-based regimen goes off patent. And then the thing I really want to draw your attention to is on the right hand side of the screen, September, 2020, we have the first, the single TDF/FTC generic. No competition there. Without competition, that price is not going to come down that much, and so because

it's a generic, though, you really don't get the spread that you get on a high list price brand name drug, so really the long story short there is that the large impact in terms of sustainability is a couple years out to 2021, where we have multiple TDF/FTC generics, and so this is all a little bit in flux, and I think we'll have to observe systems and payer behavior, and particularly when it comes to Descovy, when it comes to the single generic, but this kind of the lay of the land.

Considerations Moving Forward

- Do we need to rethink our current PrEP models in light of changes to the PrEP medication landscape?
- How do we make sure that PrEP is getting to the right places and people, while also designing a cost-effective delivery model? Are those two priorities in tension?
- How should we prepare to engage community health centers given their central role in PrEP expansion as part of the ETE 2030 initiative?
- How should the community respond to formulary designs that preference certain forms of PrEP over others based on cost?

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Slide 34 Considerations Moving Forward

And you know, in the interest of time, because I want to open it up for questions, I'm just going to end with this, the last question that I put on there. And I think this is really important for the entire HIV community to really grapple with, and that's how do we respond to formulary designs, in particular, but you could say it's program designs, that preference certain forms of PrEP over others based on cost? And I think this is a real ethical question we need to grapple with of who gets what, and we're sort of there, and I think we'll see that when Descovy is approved, of who gets a TAF-based regimen, and for whom is that indicated, and we'll see that when payers start making decisions about preferencing generic or lower cost options over brand name and higher cost options, and I think we as a community will have to be prepared to deal with that, and to sort of message that to consumers, as well.

Resources

- Amy Killelea, NASTAD, email: akillelea@nastad.org
- NASTAD PrEP Resources
- AIDVu PrEP Mapping
- CDC PrEP Guidelines

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Slide 35

Resources:

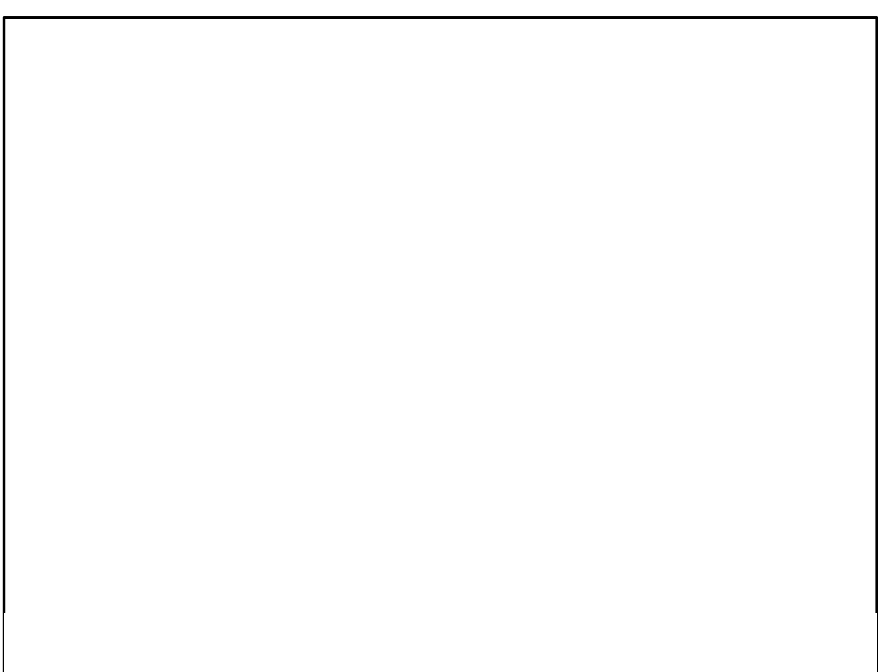
Amy Killelea, NASTAD email
akillelea@nastad.org

NASTAD PrEP Resources
https://www.nastad.org/prepcost-resources/additional-resources

AIDVu PrEP Mapping
https://aidsvu.org/prep/

CDC PrEP Guidelines
https://www.cdc.gov/hiv/risk/prep/index.html

So, that's the point that I will end on, and I will leave up the slide with my contact information, and then some of the resources that I mentioned throughout, so I will pause there, and I will hand it to our moderator.



Questions and Answers

Katie Quimby: Thank you so much, Amy. We do have a few minutes for questions here, and we've started to receive some already, and please if you have any questions, chat them in the bottom left corner of your screen. We'll get to as many as we can in the time we have left.

Katie Quimby: The first question is have you seen an increase in copay accumulators with private insurances when the copay card payments do not count towards deductibles or out-of-pocket maximums? And do you have any suggestions for help with funding for drug costs when someone has an accumulator program, especially if they do not qualify for other foundation funding?

Amy Killelea: Yeah, so that is a really good question, so as you said, the copay accumulators happen when... And the short answer is there has been an uptick, particularly in employer plans, of plans saying, "We'll accept the manufacturer copay card, but we will not allow it to count towards someone's deductible and out of pocket maximum," and so you create the situation where someone is forever in their deductible, and you create a situation where they blow through the annual cap on the

manufacturer copay assistance, so we talked about the cap is raised, actually for this reason. It's $7,200 for the Gilead program, but if you never get out of your deductible, and your medication is on a really high tier, you might blow through that annual $7,200 before midyear, and then get hit with a $1,700 pharmacy bill.

Amy Killelea: And so that's all to say it is a problem. I will say we were successful in getting the federal regulation that will go into effect for plans beginning in January, 2020, to prohibit use of copay accumulators for instances when there is not a generic equivalent, and so right now, we do not have a generic equivalent for PrEP. Now, let me just say by September, 2020, we will no longer be in that boat, so this is a time limited protection, but starting in January, 2020, those copay accumulator programs will be prohibited in the vast majority of insurance products. As an advocacy mechanism now, it may make sense to cite that to your insurance regulator and to issuers. It has not gone into effect yet, and in terms of what you do if somebody's in that situation right now, we've heard fixes all over the place.

Amy Killelea: Sometimes folks are able to go to the charitable program as kind of the stopgap. We've heard that raising the Gilead cap has actually helped quite a bit, so we're not seeing examples as much, but in this interim, before it's prohibited, it certainly is a challenge.

Katie Quimby: Great. Another question for you, Amy, and maybe you can clarify this, going back to Medicaid reimbursement, can you speak at all to the Medicaid reimbursement rate for PrEP?

Amy Killelea: Yeah. This is, and I will say the drug pricing is a little bit outside of my wheelhouse, so this is going to be a little bit sort of back the envelope, and high level, but where I got that number in that, or sort of rough estimate, is you start with the list price, and this is why it's back of the envelope. It's not exactly the list price, but you start with that, and then there's a mandatory rebate in Medicaid of like 23.1%, I believe it is, and then you add on the percentage, the penalty for the price increase, and that's another percentage, and I can't remember the percentages for Truvada versus Descovy, but as I said, Truvada has had several price increases, so that's why that rebate down to Medicaid is actually quite a bit, and to end up with... Even though the list price for Truvada is very, very high, the Medicaid price is a lot lower than that.

Katie Quimby: Great. And our last question, we've had a few questions about how Title X funds can be used to pay for PrEP related costs, and we heard at the beginning that as long as it is written into the grant, that those costs can be covered by Title X, but I'd like to invite Cynda to potentially say a little bit more about that, or if there's anything else to say?

David Johnson: Great, hi, this is actually David Johnson of the Office of Population Affairs. Cynda is with me, as well. I'm the operations and management officer here, so the questions around this, and I think it was related... I believe it was slide five that the first question is about, was is it covered. So yes, PrEP services are covered as a part of your Title X grant, so if within your grant application as the grantee, or if you're a sub-recipient to that grantee, if it's in there, you can use your Title X grant funds to cover the cost of PrEP, and so it would be the same equivalent service, and those services related to PrEP, so the labs, et cetera, as well as the drug, that would be coming from the grant award.

David Johnson: Again, it would be any... It would be a similar service as providing methods, contraceptive methods, et cetera. I think from... And there was another question about reimbursement, so Title X, just for clarity, is not a reimbursement program. It's a grant program.

David Johnson: I think when we think now about what it looks like in reality, one of the biggest challenges is that dollars. We know that Title X dollars are about, on average, about a fifth of what the entire revenue of the entire program, and that obviously is different for each grant. What I mean to say from that is the expense of PrEP services is the expense. We know that it is not an inexpensive set of services, and that the Title X grant most likely is not going to be able... The hard part is the amount of Title X dollars that you're granted, what is the proportion that you're going to be able to direct that to covering your PrEP services? It's kind of a math problem.

David Johnson: But yes, in the end, the issue is you can use Title X grant dollars to cover PrEP services. Again, the drugs as well as the labs, in accordance with your project, including your sliding schedule of discounts. So, incorporating PrEP services into your sliding schedule discounts.

Katie Quimby: Great. Thank you so much, David. That concludes the questions we've received, and that we are at the top of the hour, so thank you all again for joining us today. As a reminder, in addition to this webinar, OPA is hosting a training webinar series on several PrEP training topics. The next webinar will be on innovative models for PrEP programs in family planning sites, which will be held in July. Registration about that webinar will be available on fpntc.org shortly.

Katie Quimby: And as I mentioned, we hope to have a recording of today's session available within the next few days. It will also be posted on fpntc.org. If you have any other questions for us, FPNTC, our presenter, please don't hesitate to email us at fpntc@jsi.com. And finally, we kindly ask that you please complete the evaluation today. It will pop up automatically when you exit this session. We'd really love your feedback, and we rely on your input to improve future webinars. An important note is

that in order to receive a certificate of completion, you do need to first login to fpntc.org, before completing the evaluation, after you login, you'll need to copy and paste the URL into a new tab if it doesn't launch automatically. In order for the system to track your completion, you must be logged in.

Katie Quimby: With that, thank you so much for joining today. That concludes today's webinar.