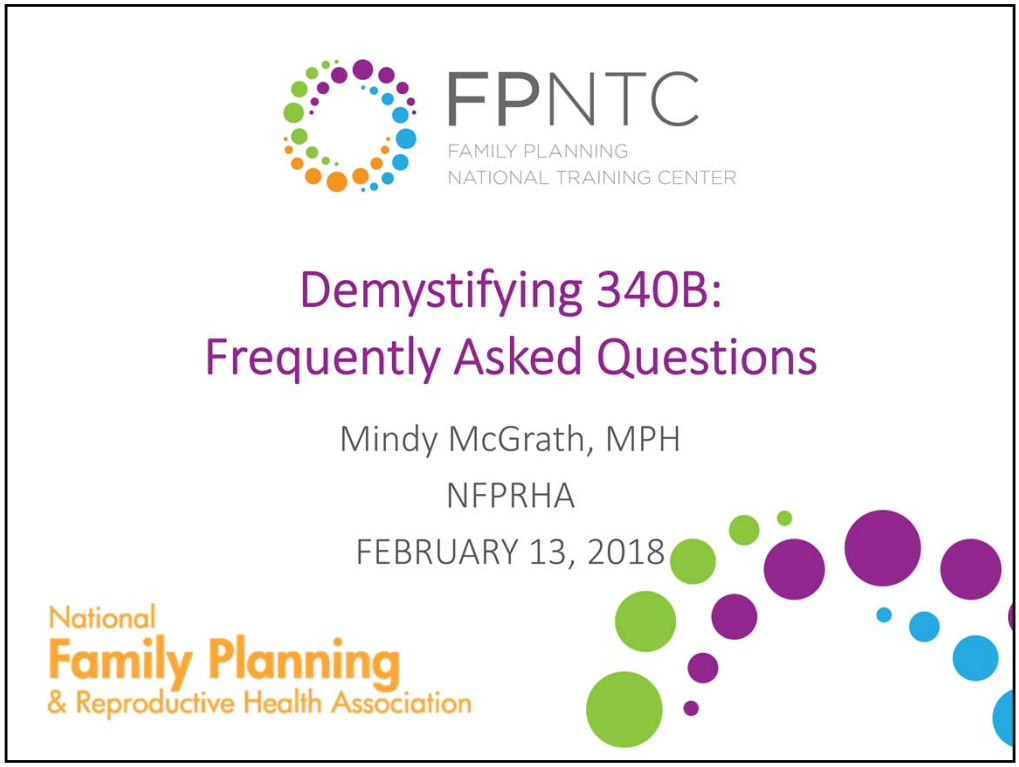


Katie Saul:

Hello everyone. We're happy to have you all with us today. This is Katie Saul from the Title X Family Planning National Training Center. I'm pleased to welcome you all to today's webinar, which is Demystifying 340B: Frequently Asked Questions. A few things before we begin today. Everyone on the webinar today is muted given the large number of participants we have. Please use the chat at the bottom left of your screen to ask questions at any time during the presentation. We'll address all of the questions at the end of the presentation today. We're recording today's webinar and it should be available on FPNTC.org by the end of the week. Along with a transcript and the PowerPoint slides with talking points. So you can use these slides to train your staff and network.

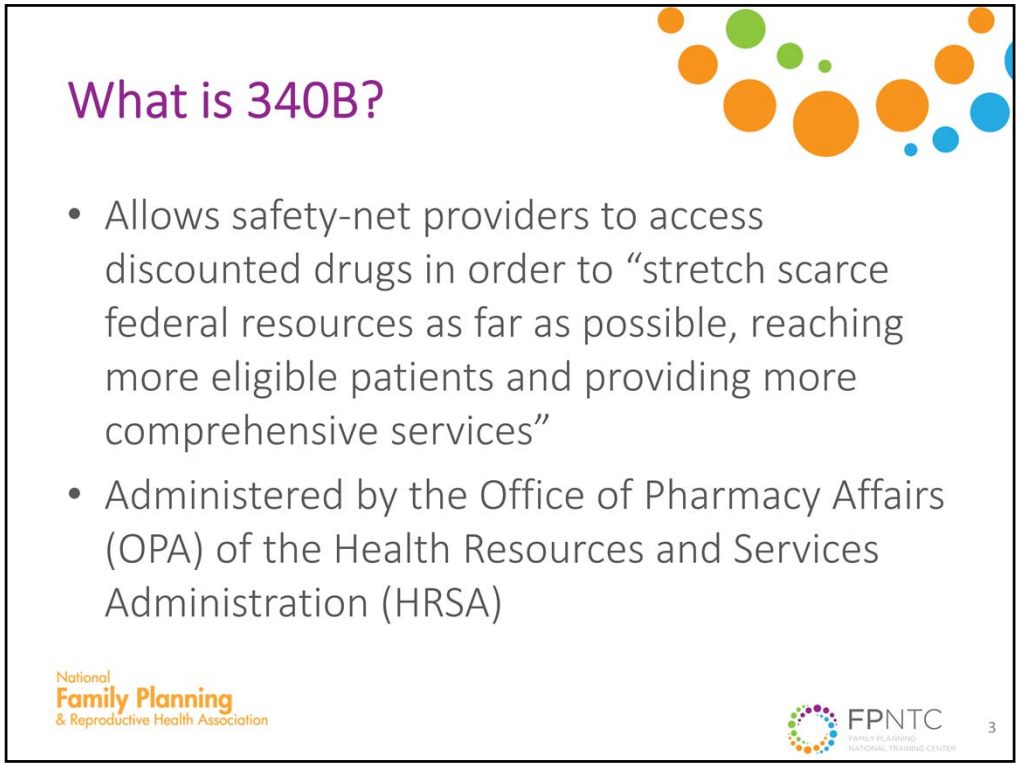
Okay. Let's get started. I'd like to introduce you to our speaker today, who is Mindy McGrath. I think many of you probably know Mindy quite well. Mindy is director of advocacy and communications at the National Family Planning and Reproductive Health Association or NFPRHA. She has over 10 year of policy experience in Washington, DC. Mindy's worked on a variety of issues including The Affordable Care Act and Health Reform, 340B Drug Pricing Program. As well as Health Workforce and Access to Care. Mindy is intimately familiar with 340B in the Title X context so we're excited to have her here today to answer some of the common questions that we hear from you all, and to clear up some of the common misperceptions about this program.

With that, Mindy, I'm going to turn it over to you.

Mindy McGrath:

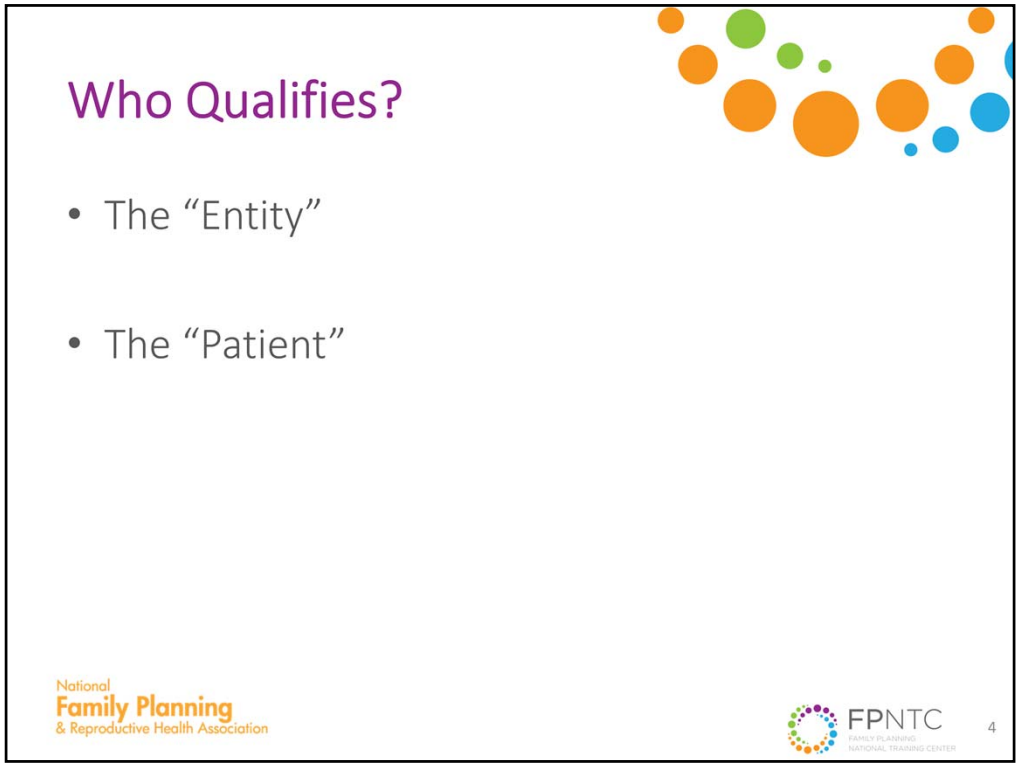
Thanks Katie. Good afternoon to everyone or good morning for those of you who are on the west coast. Thanks to the training center for having me. I find that there is really no end to the questions and concerns around 340B. I'm really pleased to be able to be helpful to as many of you out in the field as possible. So we can make sure you are all prepared and ready in the event of a 340B audit. Today we're going to be going through information about the 340B program based on a lot of the frequently asked questions that I get from NFPRHA members all the time.

That's me, if you haven't met me yet. That's a great picture from our hill day a couple of years ago.

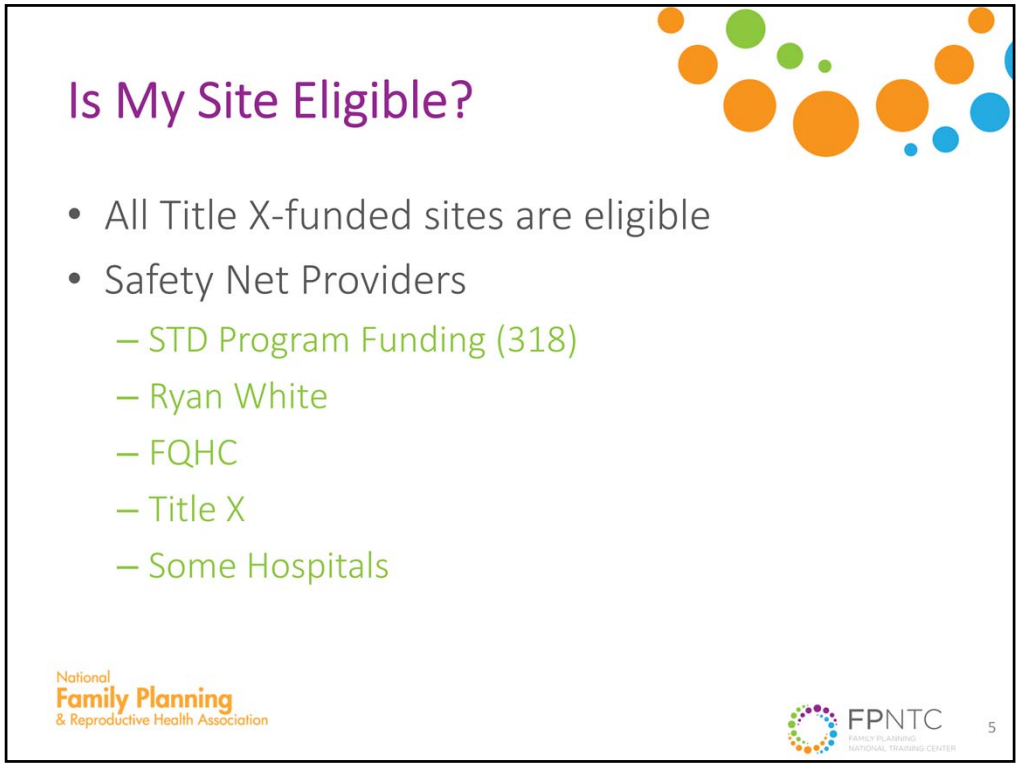


We're going to start with the really basic question of what is 340B? 340B Drug Pricing Program is it's official name. Named that because it is section 340B of the Public Health Service Act. The program allows safety-net providers to access discounted outpatient drugs in order to ... and this is quote you will see everywhere and we believe this is the intent of the program by Congress. It was included in report language by Congress. To "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 340B program is administered by the Office of Pharmacy Affairs at the Health Resources and Services Administration of HHS, the Helping Human Services Agency. This is often in the 340B community referred to as OPA. That is not to be confused with the Title X OPA, Office of Population Affairs.

340B entities, once they go through the registration process that we will talk about in just a second, are not allowed by law to be charged more than the 340B ceiling price. Which is actually in law a formula for determining what the ceiling price is. It's actually the average manufacturer price minus the rebate amount. You can certainly pay less than that and many 340B entities do. But by law you can't be charged more than that if you are a 340B covered entity.

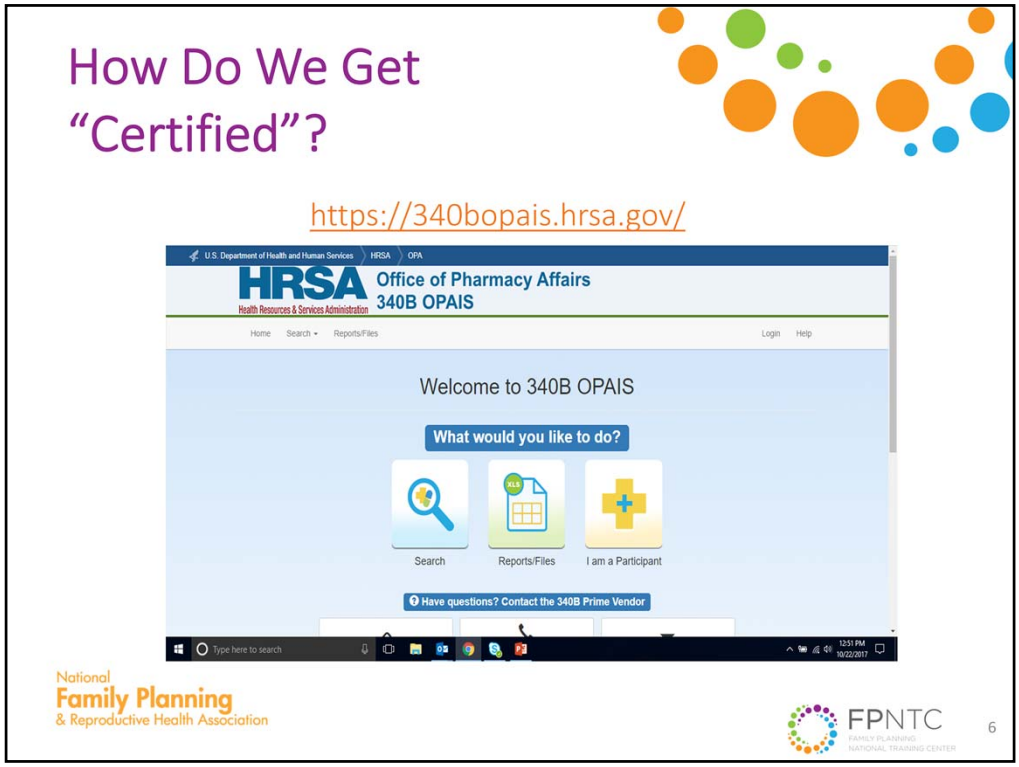


Who qualifies for the program? This is a two step answer. We're going to walk through each one. The first answer to qualifies is around the entity and whether or not the entity qualifies to participate in the program. Then there's a second layer of whether or not a patient qualifies to have access to 340B priced drugs.

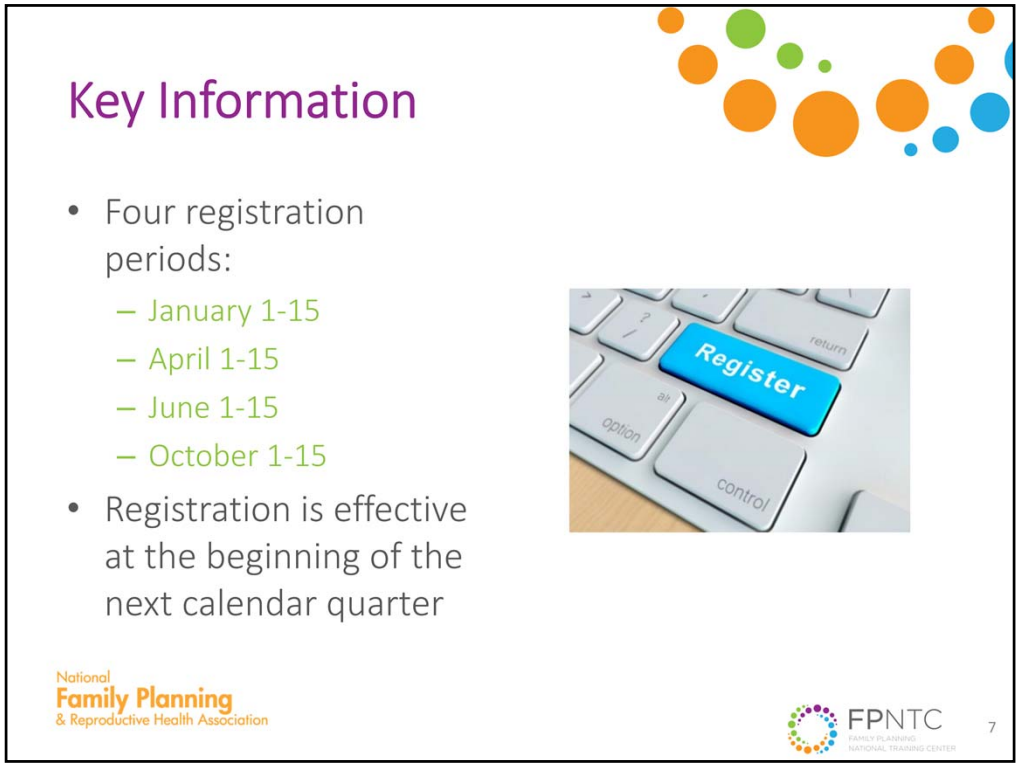


Is your site eligible? When the 340B program was established in 1992 they included a list of safety net providers that they wanted to be eligible for this program. There are DSH hospitals and a handful of other hospital types. Some of those were added in the Affordable Care Act. Then there are a list of HHS grantees. Recipients of certain HHS grant funds. That includes Title X funds. It also includes the CDC STD Section 318 Program; Ryan White; FQHC grants; FQHC lookalikes also qualify for 340B; and a handful of other smaller programs like hemophilia treatment centers.

On the STD 318 front it's important to note that that program allows for both funding, as well as in kind donations to qualify you for 340B. In many states the 318 program, the grantees, are almost always the state. In many states that grantee makes a choice to give drugs to their "sub recipients" directly rather than giving them actual funds. Those drugs then do qualify you as a 318 recipient. Therefore, qualifies you to be eligible for the 340B program.



If you are one of those eligible entities and you want to participate in the 340B program. Your first step is to get certified. That makes you officially a 340B covered entity once your certification process is complete. This is a screen shot of the online database where you can register and make changes to your records once you are registered. It's recently updated. It is a new system, the Office of Pharmacy Affairs Information System. When you register you will need to designate both an authorizing official and a primary contact. In this new system those have to be two individual people and you cannot share a log in information. The authorizing official has to be able to legally sign for the organization and attest to compliance. The primary contact is a backup contact essentially.

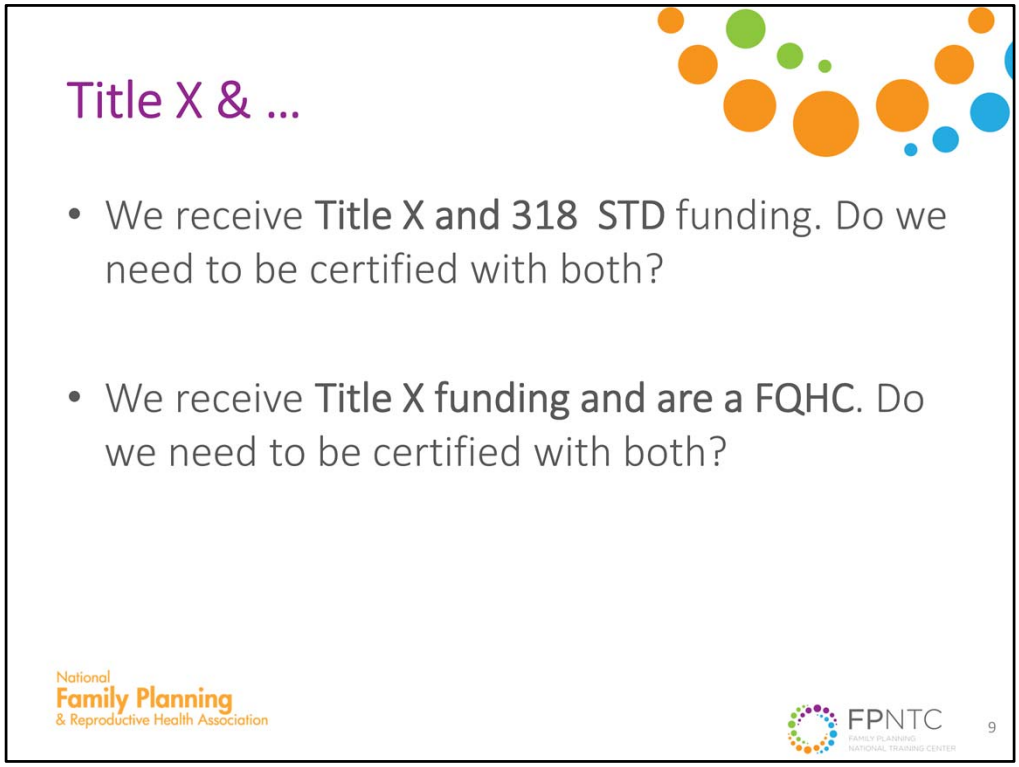


How do you register? There are four registration periods in a year. They are the first 15 days of each calendar quarter. You can register within that 15 day window. Then your registration will become effective at the beginning of the next calendar quarter. There is about a three month lag in between when you initiate your registration and when you would be eligible to purchase 340B drugs and start participating in the program. As you can see on your screen, those four registration periods are the first through the 15th of January, April, June and October. Sometimes they will make allowances based on weekends and holidays. They will make public if those dates change slightly. Sometimes it will go to the 16th or the 17th to make allowances for those changes, but for the most part these are the registration periods.

These are also the periods when you can add contract pharmacies. Outside of that you can't register a new site or register a contract pharmacy, out side of those registration period.

In addition, once you've registered, your primary requirement on an annual basis is that you are required to re-certify every year that you are compliant with the program, that you are still eligible for the program, and that you intend to continue to participate. Each grant program has their own designated re-certification period every year. The Title X re-certification is usually in the May to June time period. Last year the Title X 340B covered entities and the FTD 318 entities were both re-certified during the same period. That was the first time, at least in my time working on this program, that those two grantees had shared a re-certification period. I think it actually ended up working out pretty well because there is a fair amount of overlap there.

Failure to re-certify during that designated re-certification period will result in termination from the program. I get a lot of questions during re-certification period of, "I don't see the place on the 340B database for me to re-certify." That's because your direct link for re-certification is sent by email to your authorizing official and your primary contact. This is one of the reasons why it's really important to make sure that your information is up to date and that your authorizing official and primary contact both still work at your agency. That their contact information is correct, etc. because that is the only way that you get your link to re-certify.

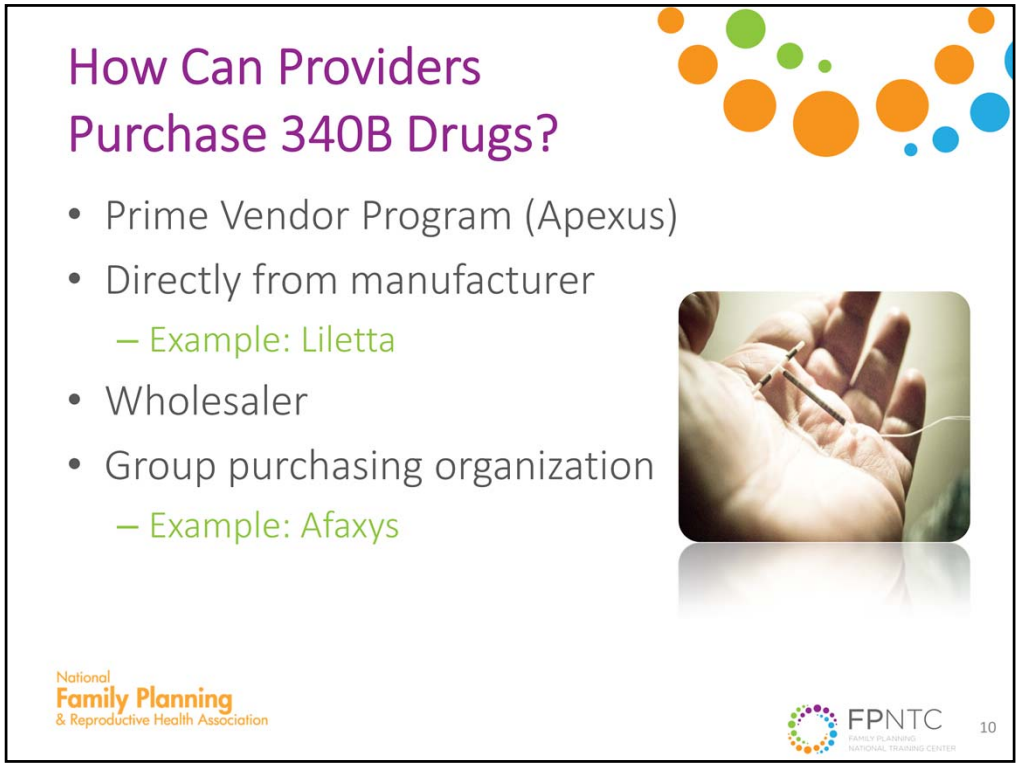


You will also get emails from me during the re-certification period if you are Title X funded. I tend to ping people pretty regularly during that period. The past several years we've had a 98% to 99% rate of re-certification in Title X. Some questions about registration and re-certification that we often get from Title X funded entities are around how you handle it if you have more than one qualifying funding stream. One question we often get is, "We receive both Title X and CDC 318 STD funding. Do we need to be certified for both?" You are not required to registered under every single funding stream you receive. You can make a choice about which funding streams you'd like to maintain 340B registrations for. But it is important to remember that for every 340B registration your site or health center maintains, you have re-certify under that funding streams re-certification period.

If, in this example, you have Title X and 318 and you decide that you want to maintain two separate registrations for those two programs. You will need to re-certify twice a year. Many, especially with the overlap between Title X and 318 because Title X often includes most STD services, will make the decision to register for just Title X. However, in the current political environment we therefore have a lot of members who've chosen to have registrations in both programs. In the event that they potentially lose one funding stream. That way they will at least continue to be able to participate in the program in the event of that happening.

Another question we get a lot is from health centers that are federally

qualified health centers that also received Title X funds and whether or not they have to certify both. In this instance more and more as years go by we see that the FQHC that are Title X funded health centers often only maintain they're FQHC registration. Since the services included in FQHC grants are so broad that family planning and everything that would be covered by a Title X registration is also covered by an FQHC registration. Obviously maintaining only one in this situation where you can be sure that the most amount of your patients can be eligible for drugs is a lower compliance burden, because you only have to re-certify once per year.

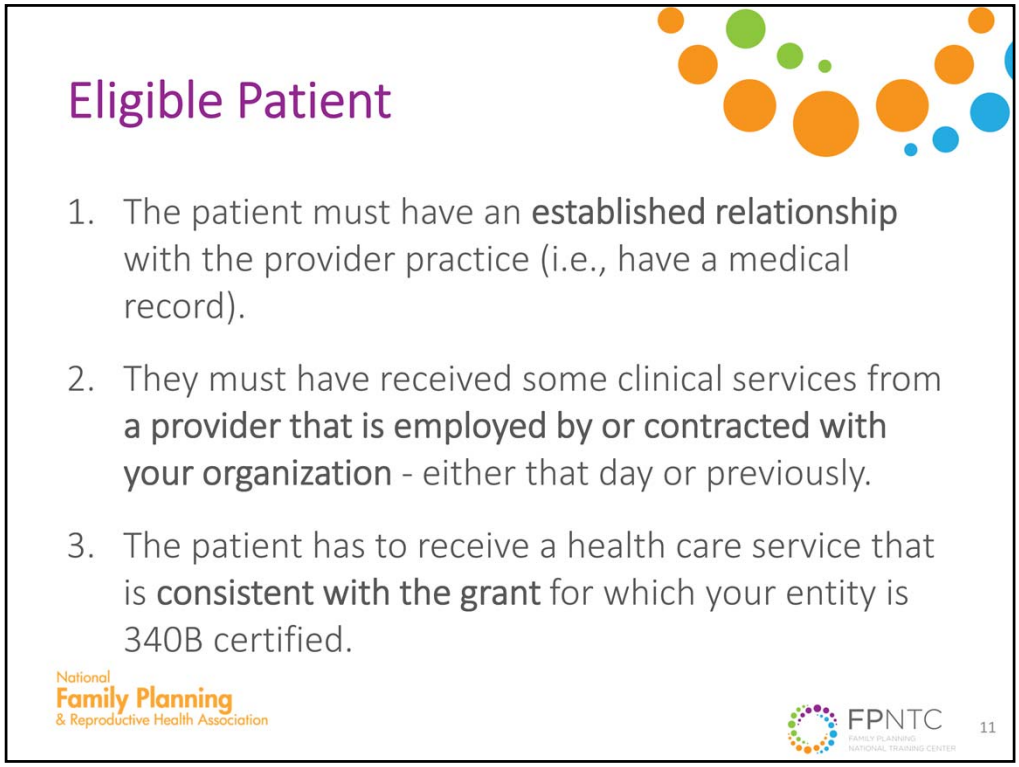


You register. You're official. You can start purchasing 340B drugs. How do you purchase those drugs? There's a variety of pathways towards purchasing 340B priced drugs. The primary one is the Prime Vendor Program. It is operated by a company called Apexus through a cooperative agreement with [HRSA 00:12:53] and the Office of Pharmacy Affairs. They are a government contract. They basically function like a group purchasing organization. That they offer what are referred to as sub ceiling prices on most products. Their prices are often below the statutory required 340B ceiling.

They also offer a suite of products that are not 340B eligible, but are considered value added products. In the Title X setting you can buy through the Prime vendor program things like condoms, test kids, etc. Those are not 340B because they don't meet the definition of an outpatient drug, but Prime Vendor program has setup contracts so that you have access to lower prices for those products.

Your other options are to purchase directly from the manufacturer, or that manufacturers designated specialty distributor. In the case of most, if not all, of the LARCs the manufacturer of those IUD's and of the implant have a designated or two designated specialty distributors that you have to purchase their products from. Those distributors are required to give you a 340B price if you are a registered 340B covered entity. You can also go through a standard wholesaler, or another group purchasing organization. An example ... excuse me of a GPO that caters to the

Title X and family planning market is Afaxys. They carry a lot of contraceptives. They originally were affiliated with Planned Parenting, but now make their products available to all family planning providers.



I mentioned at the beginning of this section that there are two steps to the question of who qualifies for 340B. This is the second part of that answer. Once you determine if your entity is eligible and participating in 340B. Then you have a second step you have to take, which is to determine whether or not a patient is eligible to receive 340B priced drugs. What you have on your screen is referred to as the 340B patient definition. Patients have to meet all three of these prongs of the definition in order to qualify to receive 340B priced drugs. They have to meet these three prongs at any specific visit in order for them to get 340B drugs at that visit.

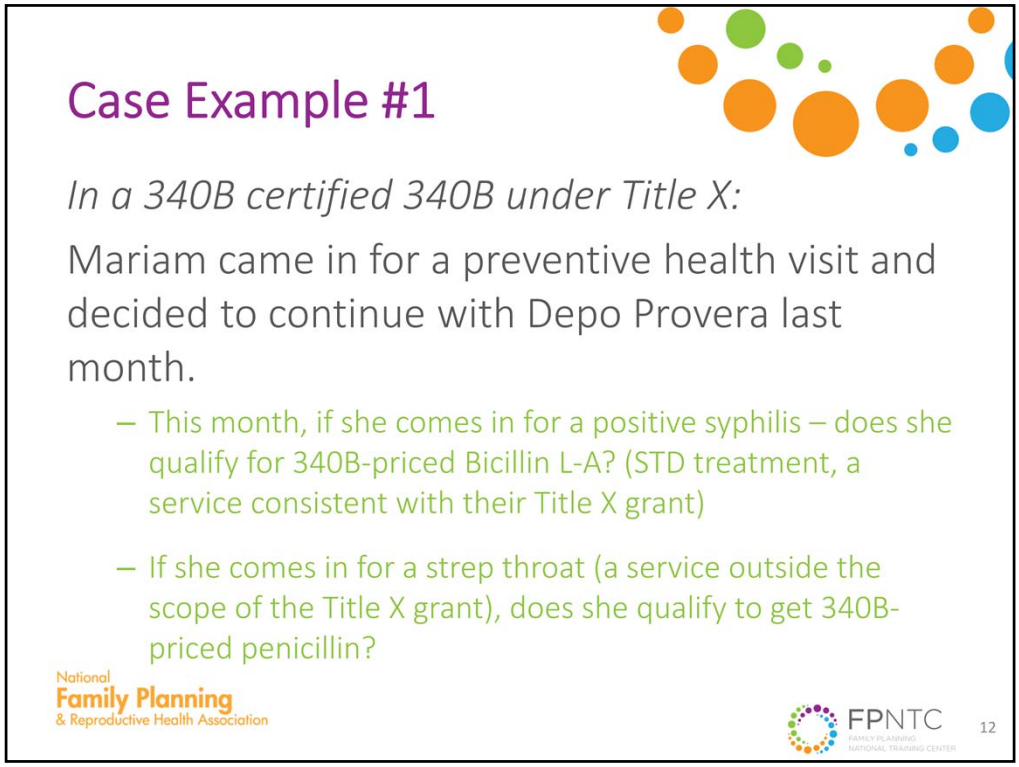
The first prong of the definition, the patient must have an established relationship with the provider. That established relationship is usually documented in a medical record of some sort. This prong I find is often confusing to people because they use the term "established." Many in the community interpret that to mean they have to be an established patient, rather than a new patient using the terminology from coding and billing. That is not true. New patients can be eligible for 340B. You just have to have a medical record or some other record of them being your patient.

The second prong is that they have to receive some clinical services from a provider that is either employed by you, the covered entity, or under some sort of formal contract with the covered entity when they provide that service. then

the third prong, and this prong actually only applies to the HHS grantees that participate in 340B. It does not apply to hospitals. That the patient has to receive a healthcare service or services that is consistent with the grant for which your entity is 340B certified. What does that mean in the Title X setting? A patient has to receive a service that is consistent with the Title X grant. How you interpret that is relatively up to you.

You can obviously refer to what is actually written in your grant. But we will talk about policies and procedures a little later in the presentation. We'll talk about how you can define what you believe to be services consistent with your grant. As long as those are enumerated in your policies and procedures, and reasonable to be considered consistent with in Title X grant. That you should be covered to be using all of those services to qualify a patient. In a Title X setting there are very few instances in which a patient is not going to meet this definition.

The one example that I have consistently been able to come up with is that if you sell emergency contraception from your front desk to anyone who walks in. That would not be 340B because that person ... unless you have some sort of system in place where you provide that person with counseling by someone who works for you. They are not actually meeting the patient definition because they're not receiving a healthcare service. They may or may not be one of your patients.

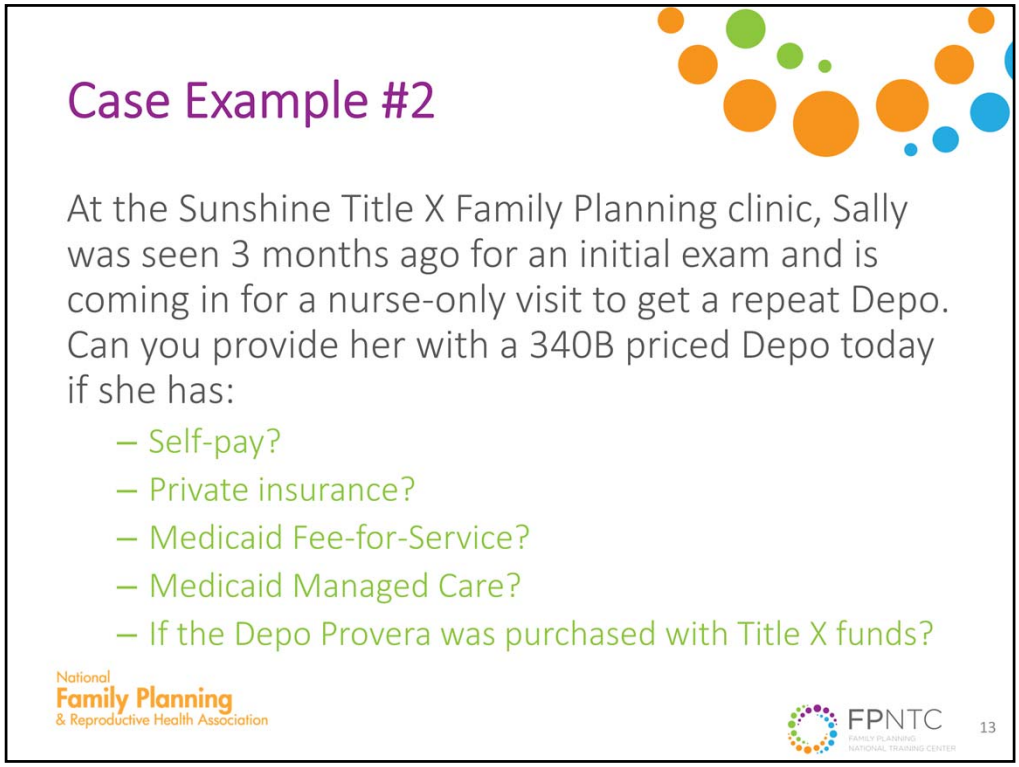


Let's do some case examples. This first one, you're in a Title X funded health center. Your 340B covered entity. Your patient Mariam came in for preventative health visit and decided to continue with Depo last month. She returns this month. She comes in and has a positive Syphilis test. The question is, does she qualify for 340B priced Bicillin to treat her Syphilis? In this instance, I believe you can interpret that STD testing and treatment are consistent with a Title X grant. As they are related to the health of the overall reproductive system. That visit in and of itself, coming in for a Syphilis test, testing positive, and then requiring treatment would count under the patient definition as a eligible patient. That is not related to her previous visit for preventative health and Depo.

The second example is she comes in for strep throat. Does she qualify for 340B priced Penicillin? In that instance, if you are purely a 340B entity because of your Title X funding. The answer would be no. A strep throat test and treatment is not consistent with a Title X grant. You couldn't say that that patient would be eligible.

But it is important to note that if Mariam came in on that first visit for preventative health visit and to initiate or continue a contraceptive method, and happened to also present with strep or have that positive Syphilis test at the same visit. Any prescription that you give to a patient at a visit where they would meet the patient definition can be 340B. The drugs themselves do not have to be

necessarily consistent with the grant. It's just that the patient has to receive services that are consistent with the grant at a visit.



Case example two. We are again at a Title X health center. Sunshine Title X Family Planning Clinic. Sally, a patient, was seen three months ago for an initial exam and is coming in today for a nurse only visit to get a repeat Depo. So she initiated Depo at her first visit three months ago. She's coming in for a repeat Depo. Can you provide her with a 340B priced Depo today? We broke it out in this question by payer source. It's important to note that you will see in the patient definition there is no mention of coverage source. There is no requirement that a patient be either uninsured or under insured or any type of coverage in order to qualify for 340B drugs. They just have to meet that three pronged patient definition.

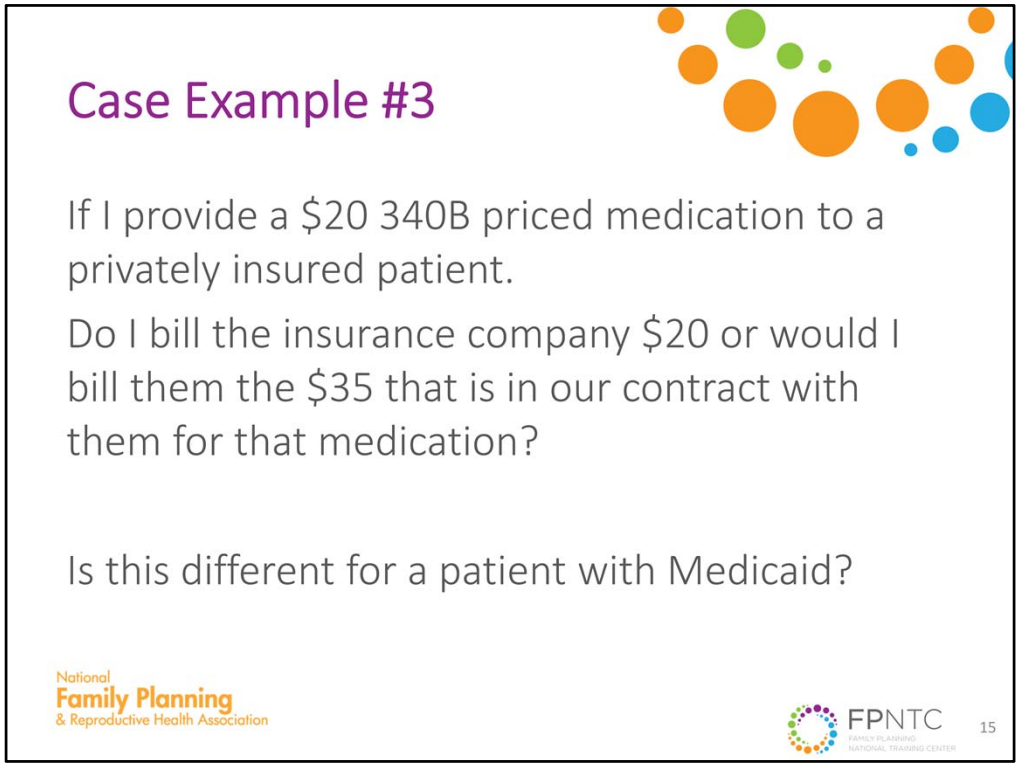
If Sally is a self paid patient, she would qualify for 340B priced Depo. Refills on a prescription that originated on a visit that would qualify for 340B, which this one would have. She came in for an exam and initiated Depo at her first visit three months ago. This visit is considered a refill of that original prescription and can be a 340B priced Depo shot. For self pay, yes you can. For private insurance also, absolutely. That can be a 340B priced drug. We're going to talk a little bit more about how you bill for these things on the next slide. Medicaid Fee-For-Service and Medicaid Managed Care are slightly more complicated. We will dig more into that a little bit later on in the presentation. Regardless of whether or not you purchased the Depo with your Title X funds. If this patient met the patient definition at her initial visit, and this is a refill Depo, then that could be a 340B priced Depo.

Billing for 340B

Insurance	Can I use 340B?	How do I bill for drugs?
Self-Pay	Yes, if patient meets eligibility criteria	Use sliding fee scale and charge according to Title X requirements.
Private	Yes, if patient meets eligibility criteria	Bill co-pay and insurance contracted rate.
Medicaid FFS	If "carve in." Yes, if patient meets eligibility criteria	Bill the state Medicaid agency as specified in state policy.
Medicaid Managed Care	If "carve in." Yes, if patient meets eligibility criteria	Bill the Medicaid MCO according to your state Medicaid agency's policy

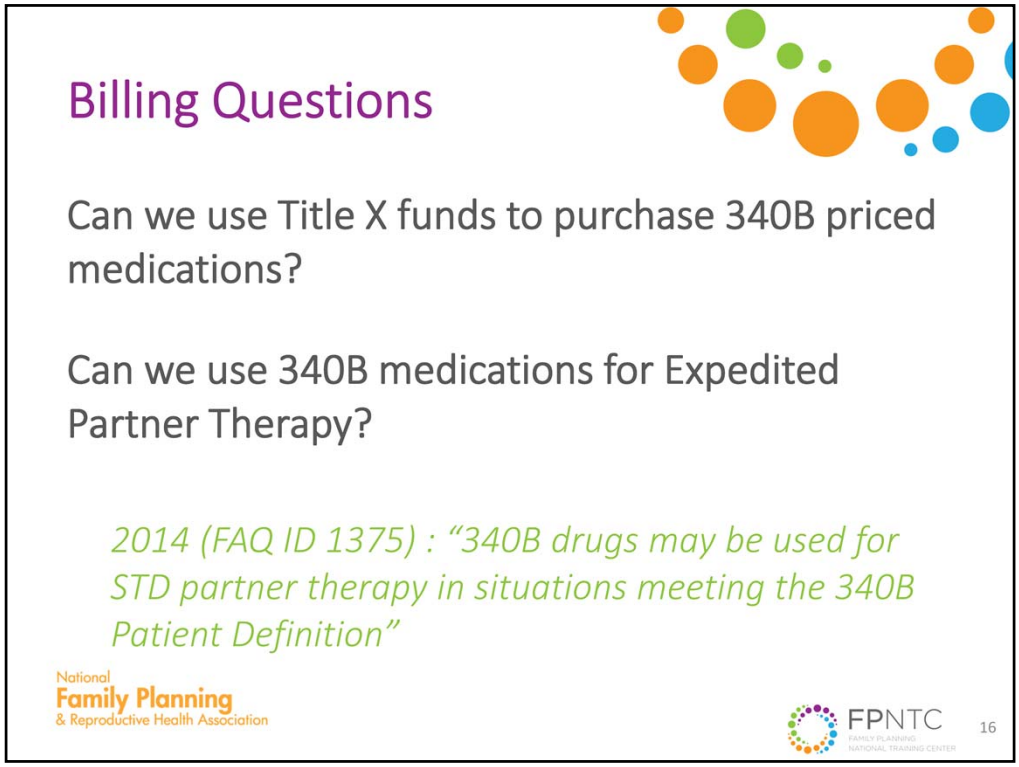
So billing. If you have a self paid patient. Then you treat that patient like you always would in a Title X setting where you use the sliding fee scale and charge according to Title X requirements. If you have a patient who meets the 340B patient definition. You give them a prescription. If they are under 100% of the federal poverty level they would pay nothing. If they're between 100% and 250% obviously you would put them on the sliding fee scale.

For private insurers, patient that have private coverage. As long as the patient meets the 340B patient definition you would bill the patient their copay. You would slide it if necessary if they met the Title X requirements. You would bill insurance your regular contracted rate. Medicaid Fee-For-Service and Medicaid Managed Care. We're going to talk about more. I'm not going to dig into this here. But then you will have this table for your notes later on.



Case example three. I provide a $20 340B priced medication to a privately insured patient. Do I bill that insurance company $20? Which was my cost. Or do I bill them the $35 that is in the contract with them for that medication? For a privately insured patient, you should be billing whatever your contracted rate is. In this instance, if your contracted rate is $35, you should be billing $35. The whole point of the 340B program is for you to be able to pull in more than what you're sending. So that you have additional resources available to see more patients and provide more comprehensive services. This is actually very inline with the intent of the 340B program for you to make this $15 margin on this drug.

Then the second question is, is this different for a patient with Medicaid? Yes. It is different and we're going to dig into that more in just a little bit.



Can we use Title X funds to purchase 340B priced medications? I get this question a lot. Absolutely, you can. You certainly don't have to use your Title X funds to buy those drugs in order to have access to 340B priced drugs. It depends on how you use your Title X grant and how your health center is structured. But you absolutely can use Title X dollars to purchase those drugs.

Another question we get a lot is around expedited partner therapy and whether or not you can use 340B drugs in an EPT context. You'll see here the FAQ answer that we got from [HRSA 00:25:47] a few years ago that, "340B drugs may be sued for STD partner therapy in situations meeting the 340B patient definition." The argument that has been made is that expedited partner therapy is actually treatment for your patient that you are seeing because it is preventing reinfection. We are aware of health centers that use 340B drugs for EPT. Have had 340B audits and have not had any findings around that policy. It's important to have that really spelled out in your policies and procedures. We're going to talk about that more in a little bit. But we have received pretty solid indications that it is an allowable use of 340B drugs. To use them for expedited partner therapy provided that your state allows expedited partner therapy.

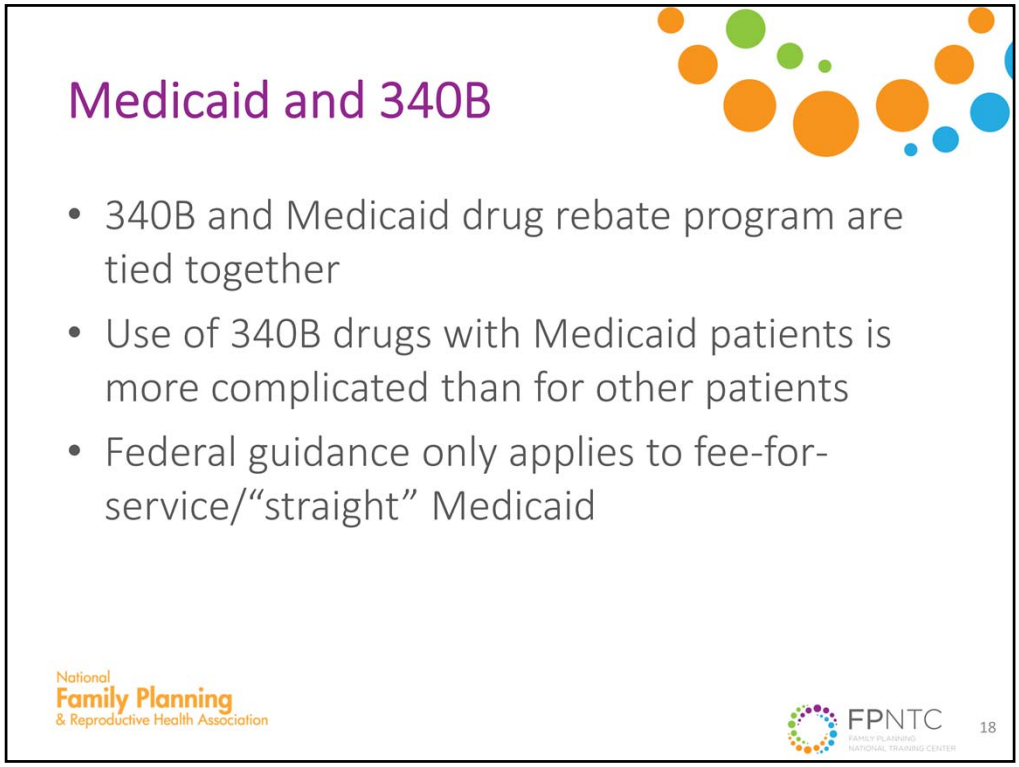
We talked a lot about who is eligible for 340B drugs. Now we're going to dig into who is not eligible for those drugs. These are kind of the big areas that we hear about a lot. Or that I hear about a lot from NFPRHA members. The big one ... I get this question so many times I cannot even tell you how many is that patient that are in an in patient setting, including immediate post partum insertion of LARC, are not eligible for 340B drugs. 340B is strictly an outpatient program. The patient has to be designated an outpatient when they are given the drug. There are ways to workin your hospital setting to discharge another and do say a nexplanon insertion in a way that is close to immediate post partum but still follows the 340B rules. But an immediate insertion of an IUD immediately post delivery would not be eligible fro 340B priced IUD.

In addition, individuals receiving no service other than the administration or dispensing of a drug, are not eligible for 340B drugs. In the Title X context that is basically that example of selling emergency contraceptive over the counter on a walk in basis. That person isn't receiving any other health care service. They're just walking in giving you their money and then walking out with an EC does. That would not qualify as 340B. We have members who just keep a small separate inventory that is not 340B of EC at the front desk to handle that problem.

This obviously, as we already talked about, does not apply to return visits for repeat administrations or resells. If it is a refill or a Depo shot that

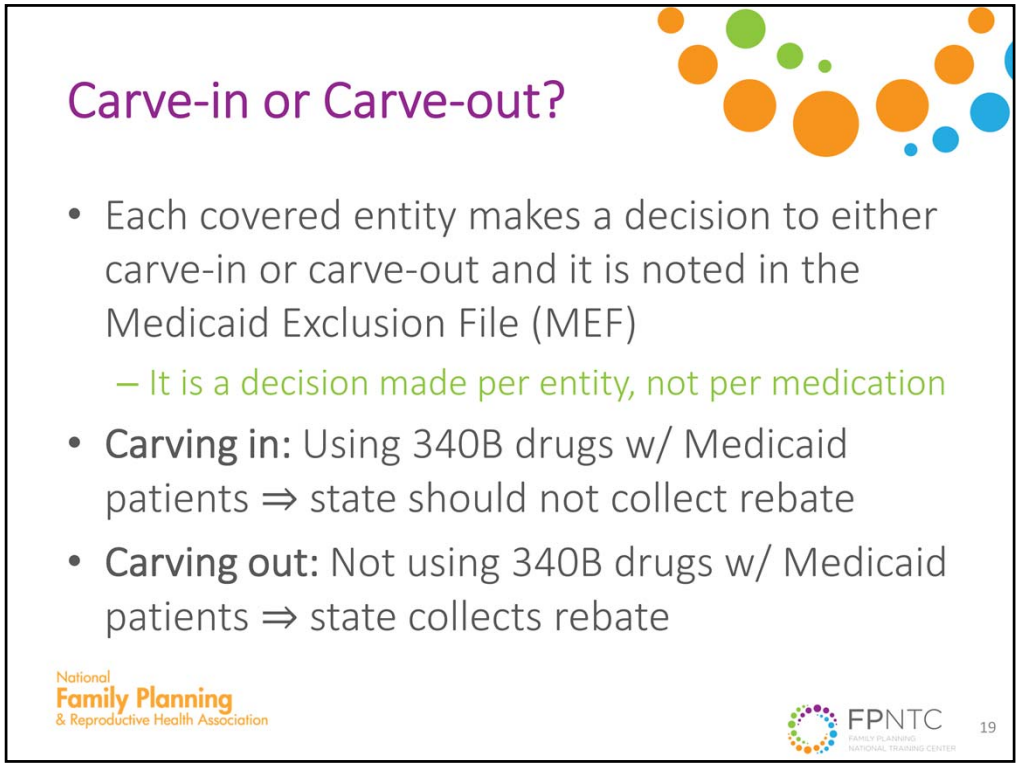
originated with a visit that made the patient eligible, then that is allowable.

Finally, employees of your organization, unless they independently are meeting the three pronged patient definition are not eligible for 340B drugs. If you have a staff member who has a headache and would like a 340B Motrin. Unless they are actually coming in and being seen as a patient, they're not eligible for the drugs.



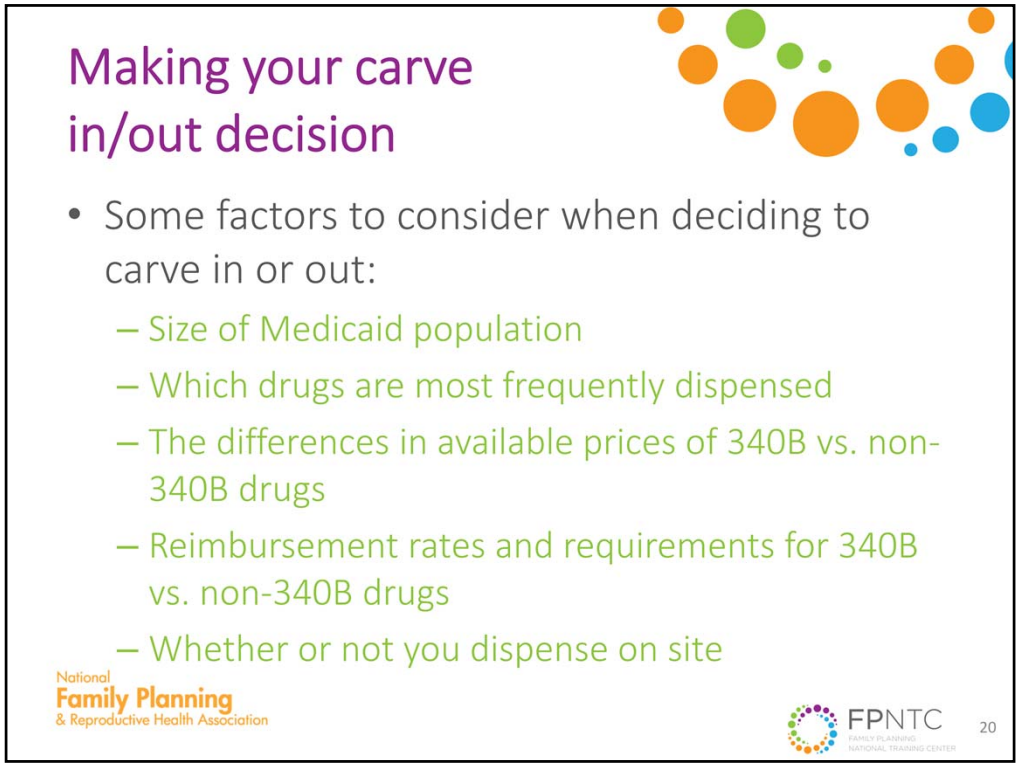
Now we're going to dig into Medicaid and 340B. These two programs are linked in the law. 340B is tied to what is referred to as the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Program allows for Medicaid agencies when they reimburse for an outpatient drug to receive a rebate from the drug manufacturer. So that Medicaid is paying a discounted price for all of the drugs that are going to it's covered patient. When they establish the 340B program they put protections in place to make sure that manufacturers were not in a position of having to pay a rebate on a drug that was already sold at that 340B discounted price. Because of this there are some added rules and complexities around using 340B drugs with Medicaid patients.

Unfortunately, it's even more complex because federal guidance around how to handle 340B drugs with Medicaid patients only is required to apply to fee-for-service or straight Medicaid. We're going to talk a little bit more about Medicaid managed are in just a moment.



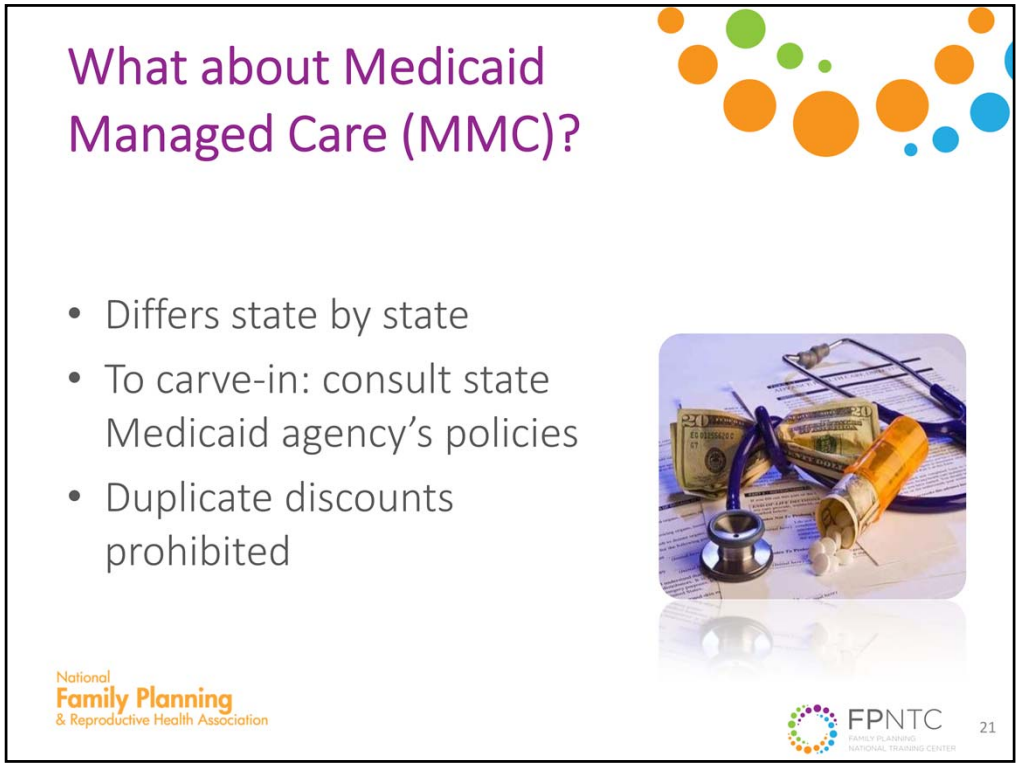
If you have spent any time digging into 340B related issues you have probably heard the terms carve in and carve out, and have been perplexed by them. They're not self explanatory obviously. What these terms mean is whether or not you are giving 340B drugs to your Medicaid fee-for-service patients. Carving in means that you've decided that you are going to use 340B drugs with your Medicaid patients. Carving out is the opposite. You are not using 340B drugs for you Medicaid patients.

This is a decision that is all or nothing decision. Your health center is either always using 340B drugs with their Medicaid fee-for-service patients or never using 340B drugs with those Medicaid patients. It's not a per medication decision. It is an entity level decision. If you decide that you as a health center want to carve in and use 340B drugs with your Medicaid patients. You will be listed in what is known as the Medicaid Exclusion File. It's a federally managed database. Then the state Medicaid agency will know that they can't collect a rebate on any drugs that you are dispensing to Medicaid patients. They use that Medicaid Exclusion File, as do the pharmaceutical manufacturers, to identify where rebates should be paid and where they should not be paid.



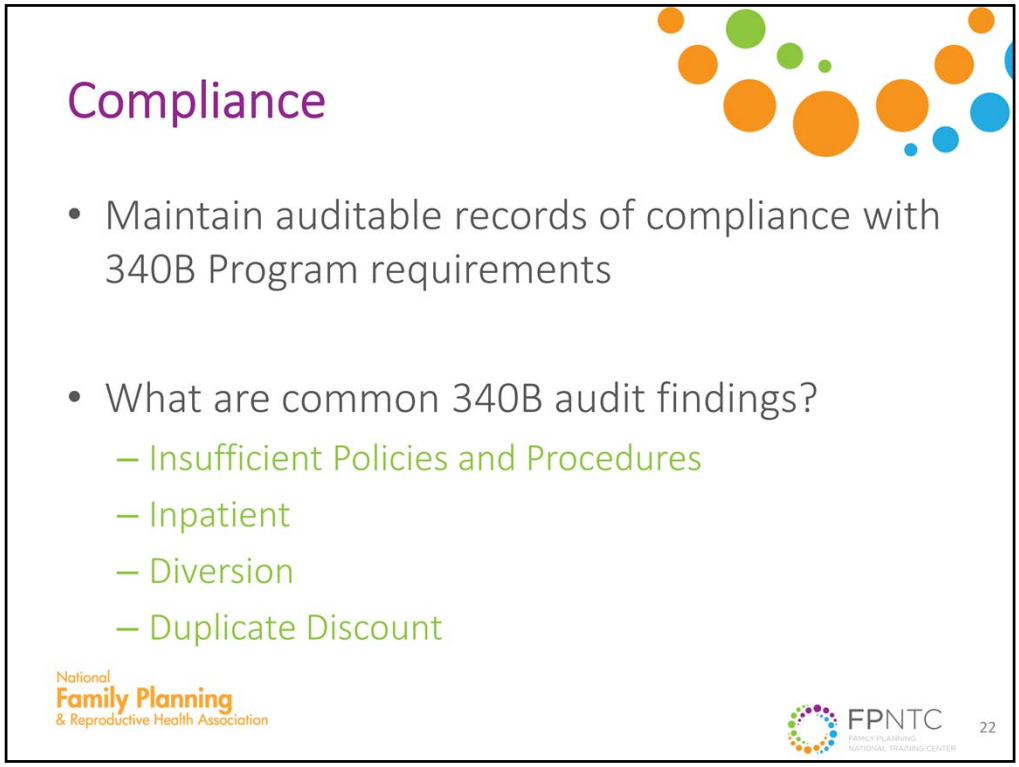
How do you make your carve in, carve out decision? This is a decision that you have to make when you register for the program. It's important to note that you can always change your mind, change your decision. But the Medicaid exclusion file is only updated once a quarter at the beginning of the calendar quarter. You can make a change at any time during the year but it won't become effective until the beginning of the next calendar quarter. You should be sure not to change your practices to match that change until the beginning of the next calendar quarter.

Factors to consider when you're deciding whether or not to carve in or carve out. Is the seize of your Medicaid population; the drugs you're most frequently dispensing and the prices of those both inside and outside of 340B; the reimbursement rates and requirements both inside and outside of 340B; and whether or not you dispense on site. This is a very individual decision. I am happy in my role doing technical assistance on 340B to try to help you walk through it. But ultimately it will have to be a very local decision based on your particular circumstances.



Medicaid Managed Care. I mentioned this is sort of the most complicated area of 340B because there really isn't any federal guidance on how to avoid that duplicate discount. Avoid a rebate being paid on a drug that was already sold at a 340B price in managed care. The federal government has only gone so far as to say that if you want to carve in and use 340B drugs with your Medicaid Managed Care patient, you have to consult your state Medicaid agencies policies on how to accurately bill for those drugs. But also on what their policies are for identifying those as 340B drugs so that no duplicate discount happens.

Unfortunately, there is a pretty broad diversity across states of how well this is being implemented. Some states have very clear policies. They use modifiers attached to any 340B drug claim so that they can very easily identify it as a 340B drug. Then there are other states that just have not quite gotten there yet. It's very difficult to determine what your obligations are and what your options are in Medicaid Managed Care. It is just an unfortunate reality of where we are in the 340B program. Managed Care was not added to the 340B program until the Affordable Care Act in 2010. Even though that is almost ... next month will be a full eight years ago. The states and the federal government really haven't come up with a good approach or plan to how to handle Managed Care Patients and 340B.

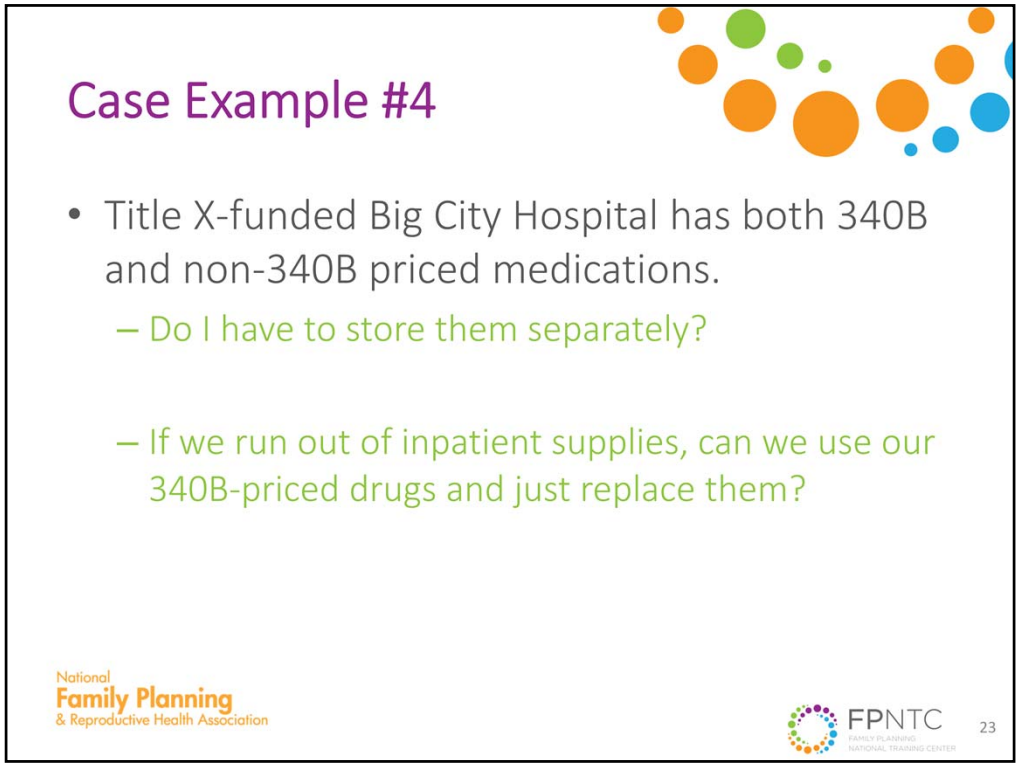


We're going to switch into talking about compliance and what are some common audit findings in 340B audits. Also what you can do to try to avoid those findings. It is responsibility of a 340B covered entity to maintain auditable records so that in the event of a 340B audit those records are available to an auditor. You can go onto HRSA, the Office of Pharmacy Affairs website. You can see what they're data request looks like and when they do audits. You can also read all of the audit results of all of the audits they have completed. The Office of Pharmacy Affairs has really stepped up over the past five years. They're emphasis on auditing and program integrity. I like to tell people that it is not if you will get a 340B audit, but when. At some point you will be selected. Most of the audits are selected randomly for 340B audit. It's important that you get ready and are prepared now so that when that happens it's not too much of a disruption.

Some common audit findings for 340B. Insufficient policies and procedures. From my experience out in the Title X field I think this is very common. Apexus offers a sample policy and procedure manual for Title X funded health centers. It would not be considered sufficient by a 340B auditor if you printed out that sample and put called it your 340B policies and procedures. It is meant to be a sample and it is meant to be adapted to your individual health center circumstances. We will talk more about the types of things that it's important to have policies and procedures on in just a moment.

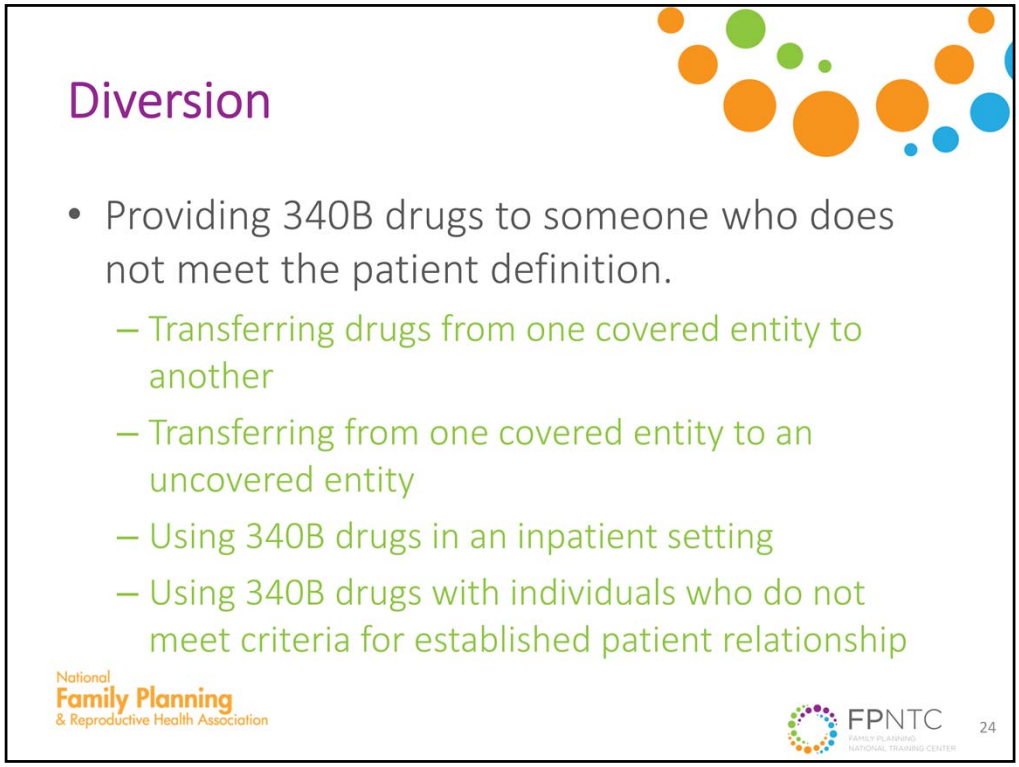
Another common audit finding is 340B drugs being given to

inpatients. Not so much in the Title X setting because most Title X health centers are not dealing with inpatients, but it is a common audit finding. The two big buckets of compliance areas in 30B are diversion and duplicate discount. Diversion is HRSA's word for giving a 340B drug to someone who is not eligible to receive that drug. A duplicate discount is, as I've mentioned already, if a state Medicaid agency collects a rebate from a drug manufacturer on a drug that was already sold at a discounted 340B price.



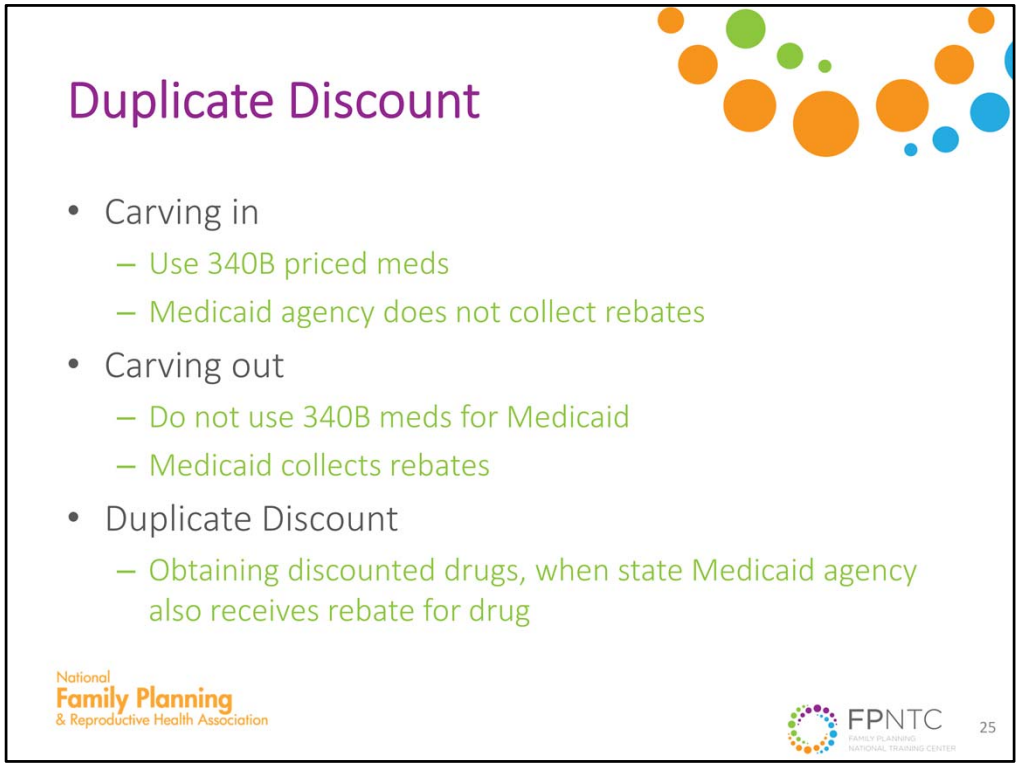
Another case example. A Title X funded health center in a big city hospital has both 340B and non 340B priced medications on site. Do you have to store them separately? If you run out of inpatients supplies can you use your 340B priced drugs to replace them? The first question about storing them separately. Yes, you absolutely have to store them separately if you make the decision to have two separate physical inventories. One that is 340B priced and one that is not 340B priced. They have to be maintained separately at your site. We have many health centers that do this. It just requires that you have the space to be able to maintain them separately.

It is also an option, particularly for hospital based settings that are what is referred to as mixed use ... so they're both inpatients and outpatients being treated in a particular site. That you can have what is known as a virtual inventory. Where you buy your initial inventory at a non-340B price and you have software that manages whether or not a patient is inpatient or outpatient. Refill stock based on whether or not somebody is 340B eligible or not. In a Title X funded setting that is just a Title X funded setting, I don't think the expense of that software and managing it is necessary. Because you likely don't have any inpatients but you will need to keep different inventory separate. That also goes for if you have an inventory that you purchase under your Title X 340B ID and another inventory that you purchase under say your CDC 318 340B ID. Those inventories also have to be kept separate and maintained separately.



As I mentioned, diversion, is the term for a 340B price drug going to someone that does not meet the patient definition. But it is actually a bit broader than that. HRSA interprets diversion to also include transferring 340B drugs from one covered entity to another. This also in most instances applies to health centers that may be owned and operated by the same organization, but have their own unique 340B registrations and ID's. Organization Y has seven health centers across three counties, but each of those health centers maintains their own individual 340B ID and registration. It would be considered diversion if you transfer inventory from one of those health centers to another.

It is also diversion if you transfer 340B priced drugs from a covered entity to a not covered entity. If you use 340B drugs in a inpatient setting or obviously if you use them with individuals who don't meet the patient definition.

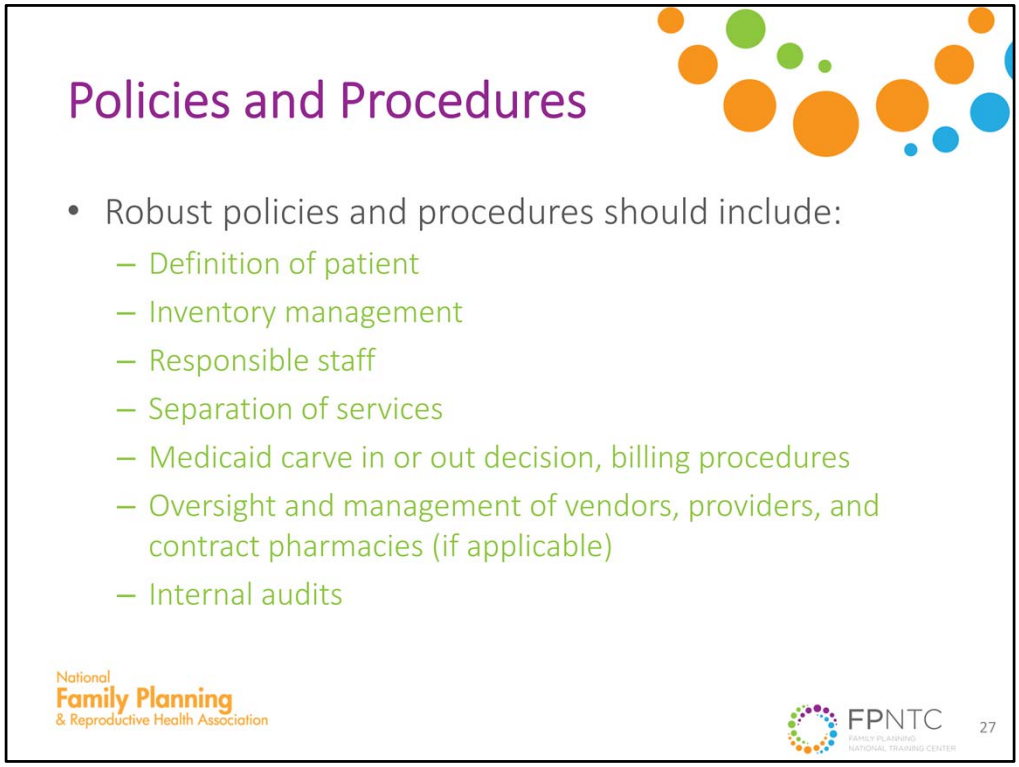


Illegally obtaining discounted drugs, when state Medicaid agency also receives rebate for drug, is referred to as “Duplicate Discount.”

Duplicate discount. It's your responsibility according to HRSA to ensure that duplicate discount doesn't happen as a covered entity. If you have carved in you have to make sure that your practice matches that decision and that you're only giving 340B priced drugs to your Medicaid patient. That you are adequately listed in the Medicaid Exclusion File. The opposite being true if you've chosen to carve out. That you never give 340B drugs to your Medicaid patients.

Best practices. The first one probably seems like a minor thing and not very important. But there are a variety of reasons why it is actually quite important, and it would be a finding on a 340B audit, if your 340B database entry is not up to date and correct. That include that your authorizing official and primary contact are both still your authorizing official and primary contact. They're still employees of your organization. If you have a mailing address change or phone number change or any of those things. That has to be kept up to date in the 340B database. It's a best practice to check and update if necessary your 340B database entry on a quarterly basis.

It is also a best practice for you to be conducting your own internal audits on a regular basis. We can talk a little bit more about that will look like. You're also expected to regularly train your staff. All staff that are in anyway engaged in the management, purchasing, or dispensing of 340B priced drugs. That includes training on 340B in all of your new staff onboarding for any staff that would be engaged in the management of 340B drugs. Of course, having robust written policies and procedures.



What are the types of things that is important to include in your 304B policies and procedures? The first one, and one that I often don't find in people's policies and procedures, and will really help you a great deal in the event of an audit, is for you to as a health center identify, list out how you define a patient at your health center. Included in that would be all the services that you believe to be consistent with your grant. As well as how are you making sure that a patient has an adequate medical record. All of those things. I would say overall with policies and procedures you want to be sure that they are explicit and clear as possible. So that when an auditor comes in and does the chart review, and starts to look at your policies and procedures. They can very clearly see how you are maintaining compliance and how you are making sure that 340B drugs are only going to eligible patients.

You should also include information about your inventory management practices. Including what staff are involved in purchasing, in doing physical inventory on site, in managing the physical inventory on site, who is involved in dispensing, where you keep the drugs and make sure that they are kept properly stored in a locked room or cabinet and separate from other non 340B inventory. Separation of services would really only apply in a Title X setting if you also offer other health care services that are not consistent with Title X. If you for instance offer some primary care services in addition to your Title X funded services. Then you need to have a very clear policy and procedure about how you

identify when a patient is eligible and when they aren't based on those services.

Your Medicaid carve in and out decision, your billing procedures, how frequently you review those things. Your oversight and management of vendors, providers and contract pharmacies if you have them. HRSA has an expectation that in addition to doing regular internal audits that you also are doing regular audits of any outside vendors that you work with on 340B related practices. Your internal audit schedule. So who conducts those audits, how frequently are they done, how many charts you look at on any particular basis, etc.

What's actually not listed here is also that you should have a policy on how you define material breach. A material breach is when a lapse in compliance reaches the point where it needs to be reported to HRSA. It is up to the individual entity to define what that threshold is. Some sites will use a percentage of charts in a chart review. Or a flat number of charts in a chart review. It really is dependent upon your patient volume, how frequently you're doing audits, etc. What your material breach threshold should be. But you should include that in your policies and procedures as well.

That's it. I know I went really quickly. But I wanted to make sure that we had as much time as possible for questions. I think Katie now is going to help me take those questions.

Katie Saul:

Thank you, Mindy. We do have quite a few questions. We'll see how many we can get through today. Just for those of you who have asked questions, and if for some reason we can't get to them all. We will include any unanswered questions on the webinar today in the transcript so that we make sure that everyone's questions are addressed.

Mindy. The first question goes back to the patient definition. This question is from Debbie. She said that the slides said that the patient must receive clinical services from a "provider." She said the wording from the Apexus website says, "healthcare services from a healthcare professional." She said that she's interpreted that to mean that the person doesn't have to be a provider. Gave an example if a patient comes in for emergency contraception and nurse dispenses the EC based on a standing order and doesn't seen a provider, but does receive contraceptive counseling and other Title X family planning services. Does that qualify?

Mindy McGrath:

Yeah. That's a good question and good a point of clarification. Yes, the wording that HRSA uses is healthcare professional. We interpret that to include lay contraceptive counselors or nurses operating under standing orders. This is another place where I think it would be really important for you to make all of those practices clear in your policies and procedures. But yes, they don't actually have to be a provider, a clinician. They just have to be offering some kind of healthcare service. Contraceptive counseling or STD prevention counseling would constitute a service under Title X.

Katie Saul:

Great. Okay. A related question from Laura about the patient definition. "We provide expedited partner therapy at our clinic. Typically they are not established patients. Does that mean we can't use 340B meds?"

Mindy McGrath:

If the partner who comes in and see you counts as an established patient. Not in terms of new versus established, but they come in, you have a medical record for them. You see them. Probably provide them with an STD test and then are treating them for a positive result. Then it is our belief and interpretation that because that patient, the index patient who you're seeing, does qualify under the patient definition. That doing expedited partner therapy for that index patient's partner is actually treatment for your patient. Therefore, you can use 340B priced drugs for your expedited partner therapy there.

This is a place where I would strongly recommend very clearly having policies and procedures that you do this, what your rational is for doing it, etc. But it is our understanding ... it's not clearly answered by HRSA. Quite frankly we're not going to ask them to make it more clear right now. But from what we know, based on audit findings and based on our conversations with HRSA and Apexus and folks in the field. It is allowable and has not been a flag for auditors.

Katie Saul:

Okay. Thank you. This question is from Rebecca. "If a patient comes in for family planning services and also has an opioid use issue. Does she qualify for 340B Vivitrol or Naltrexone?"

Mindy McGrath:

As long as the patient does meet the patient definition at a visit. As long as in a Title X funded health center. As long as they come in. They're receiving a health care service or services. That health care service or services is consistent with your Title X grant. Any prescription, any outpatient drug you give that patient at that visit can be 340B priced. The drugs themselves don't have to be consistent with the grant. It's just that the patient has to receive a service consistent with the grant.

Yes. If you have a patient who comes in for some sort of family planning or family planning related visit. That is in your policies and procedures as a service consistent with your grant. Then any drugs you give them that day including Vivitrol or anything else related to that patient's opioids dependency could be 340B priced.

Katie Saul:

Okay. Just to clarify as a followup. If they require alcohol or other drug referrals. Can we use 340B pricing for Vivitrol or Naltrexone monthly? Can we use the 340B each month?

Mindy McGrath:

I will admit that I am not super familiar with how Vivitrol and other opioid dependency drugs work. But if it would be perceived to be a refill on a prescription that originated in an eligible visit. If when your patient comes in for family planning or family planning related visit. You put in a prescription and dispense whatever that drug might be. Included in that prescription are a certain period of time of refills then those refills can continue to be 340B priced.

But if it's something where it's like done at each visit that the patient comes in for. It's independent of that original qualifying visit. It would have to be a service consistent with your grant at each visit the patient comes in for in order for that patient to be eligible fro 340B price drugs at each of those visits. It is a visit by visit determination. Unless you're talking about refills.

Katie Saul:

Okay. Great. Back to emergency contraception. This is from Renee. A related question. "If an established patient calls to come pick up EC without a visit. Is that eligible for 340B? Even if it's not a refill?"

Mindy McGrath:

No. Not unless they're receiving some kind of healthcare service or services when they come in to pick it up. You could have a process in place where that patient when they come to pick up the EC has a counseling visit with a nurse or whomever. If you have included in your policies and producers that counseling about EC is a service consistent with your grant. Then that could get you to a place where that patient would qualify. But if they are just coming in to pick up EC and walk out the door. They're not receiving any other services. Regardless of whether or not they are an existing patient of yours. That would not qualify for 340B. They have to get a qualifying service the day they get the drugs at the same visit.

Katie Saul:

Okay. All right. We're going to transition a little bit into some more billing and administrative questions. "When billing private insurance for 340B drugs.

Can we determine the margin over cost that we bill or is there a standard?"

Mindy McGrath:

This is going out of my area of expertise. Bu ti don't believe there is a standard. I also see that Amanda [Keper 00:55:06] is stilt online and she would know the answer better than I would. She's my colleague here at NFPRHA. That's our billing and coding expert. I don't believe there is a standard. I believe that it's dependent upon whatever your contracted rate with the payer is.

Katie Saul:

Okay.

Mindy McGrath:

But if I'm wrong Amanda. You should IM me and tell me.

Katie Saul:

Okay. We'll stay tuned. Let us know if you have an update.

Mindy McGrath:

Okay.

Katie Saul:

This question is from Angela. "What options exist for expired 340B medication including LARC methods? For example return, donate, exchange with another agency."

Mindy McGrath:

There are obviously always going to be state level requirements about what your options for expired medications. But under 340B a medication will have to be either returned or destroyed if it's expired based on whatever your state requirements are. But there are ... they're known as reverse distributors. That will give you some sort of margin of what you paid if you return expired drugs. But you cannot give them to another provider. That is diversion.

Katie Saul:

Okay. This question is from Debra. "If you elect to carve in for Medicaid patient. Can you charge Medicaid a fee that is more than the actual 340B price?"

Mindy McGrath:

That is an excellent question. If you're talking about fee-for-service Medicaid patients. Then there is actually a federal regulation that was finalized in 2016 that requires that Medicaid reimburse at actual acquisition cost for any covered outpatient drugs whether they are 340B or not. Each state in that regulation was required to submit a state plan amendment of how they were going to determine

what actual acquisition costs was. They were also required to include in that state plan amendment how they were going to handle reimbursement with 340B covered entities specifically.

Most of the state [inaudible 00:57:28] that I have looked at related to this for 340B covered entities. They're going to reimburse at your invoice price. Plus in some instances what's referred to as a professional dispensing fee. Usually those dispensing fees are an flat amount. They're usually between $5 and $15 or $20. But there are some states that for physician or clinician administered drugs. So if you're dispensing onsite not with a pharmacy. Then some states have opted that they are not going to offer a dispensing fee in those scenarios. But you have to check your state Medicaid agencies policies on that particular piece of it.

But in fee-for-service, they're mandated by the federal government to only reimburse at actual acquisition cost. In managed care that's a whole different story. This is another instance in which it really is sort of the wild wild west. In terms of there are no requirements on what Medicaid agencies and Medicaid Managed Care can reimburse for 340B drugs or really for any drugs. In some states we're still seeing folks getting reimbursed at a contracted rate that's higher than their cost by Medicaid Managed Care organization. In other states we're seeing the state moving towards applying that actual acquisition cost reimbursement to both fee-for-service and managed care Medicaid.

Again, you would have to consult your state Medicaid agencies policies to find out how they're handling it in particular. If you're having a hard time finding it please feel free to reach out to me. I'm happy to try to help. But I will just say that with a caveat of there are states that I have tried to find more information about and have not been successful. Because there are some states that have not done a great job of putting those policies in place and making them publicly available.

Katie Saul:

Great. Thank you, Mindy. Unfortunately everyone we are at the end of our time together. I know that there are quite a few unanswered questions remaining. As I said earlier, we plan to incorporate that Q&A into the transcript which we'll post to FPNTC.org within a week or so. We'll also have a recording of today's session available. As well as these actual Power Point slides with the talking points so that you can use these slides for training purposes with your staff and network.

I also want to add that we've developed two additional resources that are posted on FPNTC.org. We have a written FAQ as well as compliance tips for Title X funded agencies. You can find those on FPNTC.org in the Third Party Billing Training Package or you can just search for them. If you have any other questions at any other time, please feel free to email us at FPNTC@jsi.com. We do ask that you all take one quick minute to complete the evaluation today. It's going to pop up when you exit

this session. We'd really love your feedback. We do use it to form our future webinars. Thank you all again for joining us today. That concludes the webinar.

Mindy McGrath:

Thank you, Katie.

Katie Saul:

Thanks, Mindy.

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