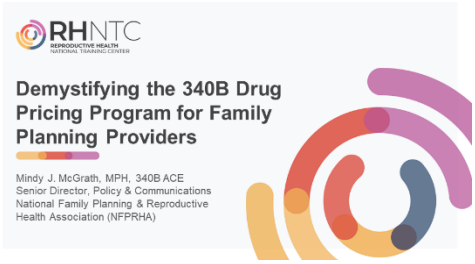
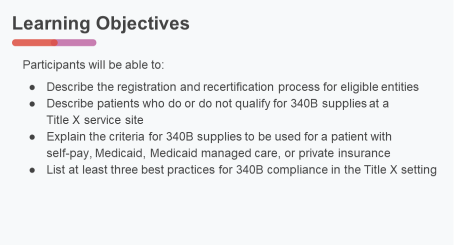
Demystifying the 340B Drug Pricing Program for Family Planning Providers
August 29, 2023
Transcript

Slide 1



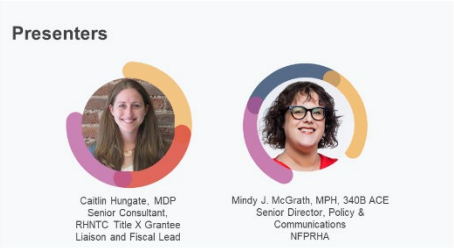
[Caitlin Hungate] Good afternoon everyone. This is Caitlin Hungate, Title X Fiscal Lead. I'm a training and technical assistance provider and grantee liaison with the Reproductive Health National Training Center, and I'm really honored and delighted to be with you all this afternoon for today's webinar about demystifying the 340B drug pricing program for family planning providers. I have a few announcements before we begin. Everyone is muted given the large number of participants and we are so excited and grateful you're here. We do plan to have questions at the end of the webinar and please feel free to use the chat function at any time during the webinar. We will be tracking these questions and try to get it to as many as we can this afternoon. We will have some questions for you and polls throughout the webinar and we encourage you to participate as you're able in these Zoom polls. A recording of today's webinar with the slide deck and transcript will be available on rhntc.org within the next few days. Closed captioning is available and it has been enabled for this webinar. So to view, you can click on the closed caption or cc icon at the bottom of your screen, and your feedback is really important today and it has enabled the RHNTC to make quality improvements on our work based on your comments. Please take a moment to open up the evaluation. Taylor, thank you so much, has just chatted it out, and in real time you can follow along and complete an evaluation of the webinar. In order to obtain a certificate of completion for attending the webinar if you need a certificate, you must be logged in to rhntc.org when you complete the evaluation. And lastly, this presentation was supported by the Office of Population Affairs, OPA. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of OPA.

Slide 2



On the next slide, you'll see our learning objectives for today. We'd like to see as a group where we're starting from in terms of how confident you all are with what we can do with the stated objectives. We're going to launch a brief poll where we'll ask you to rate your confidence on a scale of one to five, where one is not at all confident and five is extremely confident. So please take a few seconds to answer these four poll questions. The first one is how confident are you that you can describe the registration and recertification process for eligible entities? Secondly, how confident are you that you can describe patients who do or do not qualify for 340B supplies at a Title X service site? And I'm going to just stay quiet. I won't read out the rest as you are all completing the polls, so thank you so very much. We'll give it another 10 seconds or so. Keep on responding as you're able and thank you to everyone who's already responded to these four questions. We'll show the results as soon as it's closed. Okay, shall we close it out? Okay, so thank you so much for joining. You can see the results on your screen that 40% of you are not at all confident around the registration process and recertification, so hopefully Mindy will be diving into that soon. And there's a good spread around understanding and having the confidence to be able to describe what patients do or do not qualify for 340B supplies at a Title X service site. So again, we'll dig into that. The third question around the criteria for 340 B supplies that can be used for self-pay, Medicaid or managed care or private insurance. Again, there is a spread, so not a lot of confidence that hopefully we'll address in our time together. And lastly, again, a similar kind of spread. So 50% of you or so not confident about listing best practices for 340B compliance. So this is really helpful to know and in just a minute we'll be turning it over to Mindy to dig into all of this and hopefully we'll see some change in confidence at the end of the hour.

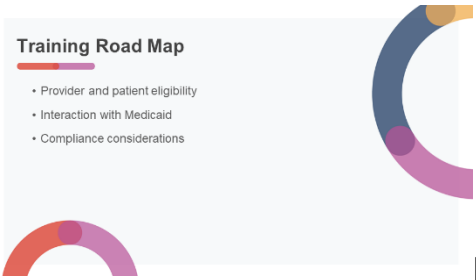
Slide 3



Okay, as I said, my name is Caitlin Hungate. I'm a training and TA provider, fiscal lead and grantee liaison, and I'm really excited to introduce today's speaker. Mindy McGrath is a Senior Director in Policy and Policy Communications at the National Family Planning and Reproductive Health Association or NFPRHA. She has nearly 20 years of policy experience in Washington, DC and elsewhere. Mindy's portfolio of issues at NFPHRA include the Affordable Care Act and health reform, Medicaid and the 340B drug pricing program. Mindy joined NFPHRA in April, 2014 and prior to coming to NFPRHA, Mindy was the Director of Government Relations at the Association of Academic Health Centers. She received her

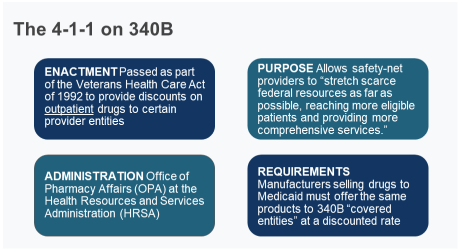
BA in history at Bryn Mawr College and her MPH in maternal and child health from the University of North Carolina Chapel Hill School of Public Health. Her previous experience includes work at Planned Parenthood, Southeastern Pennsylvania Ipas and the National Breast Cancer Coalition. With that, I'm going to turn it over to Mindy to get us started.

Slide 4



[Mindy McGrath] Thanks so much Caitlin, and hopefully we will be able to get everyone feeling a bit more confident about all of the questions we started with. I'm going to do my best to make as much time at the end for questions as possible. This is a lot of content and does get a little complicated at points, but please, as Caitlin said, feel free to chat in questions. We'll get to as many of them as we can and we can always try to tackle more of them during the office hours webinar next month. So these are the rough categories of topics we're going to talk about today, and I am going to dive right in because we've got a lot to do.

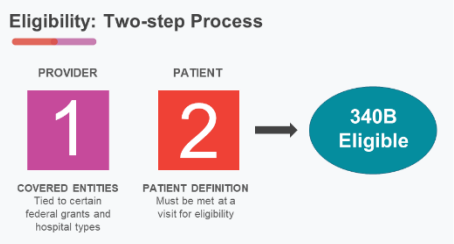
Slide 5



So the basics of the 340B program, this is a program that was enacted in a larger Veterans Healthcare bill in 1992, designed to provide discounts on outpatient drugs to certain provider entities. The program is administered by the Office of Pharmacy Affairs at the Health Resources and Services Administration or HRSA. You will notice that's a pretty familiar acronym for the Title X folks. So I generally will refer to them just as HRSA to not confuse the Title X folks who are used to OPA being Office of Population Affairs, but in the larger 340B world, they refer to the administering office as OPA. This program is designed to allow safety net providers to stretch scarce federal resources as far as possible, reaching more patients and providing more comprehensive services. And the way it is structured is it requires pharmaceutical manufacturers that want their products to be available to Medicaid beneficiaries that they must enter into an agreement with the federal government and they must offer all of those products at a discounted rate to 340B covered entities. We will dive into who those entities are, but in general I will say there is a formula in the law or in the statute that determines what the 340B ceiling price is. So that is the highest amount that a 340B covered entity can be charged for each product, but it is based on proprietary information. And so the pricing, 340B ceiling price for each product is only

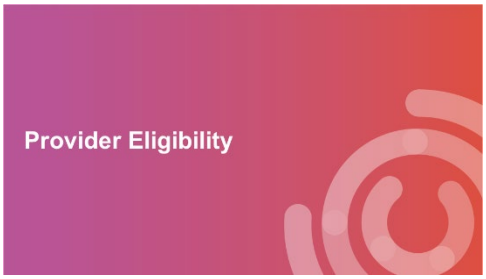
available to covered entities, the manufacturers and Medicaid agencies. It is not publicly available information.

Slide 6



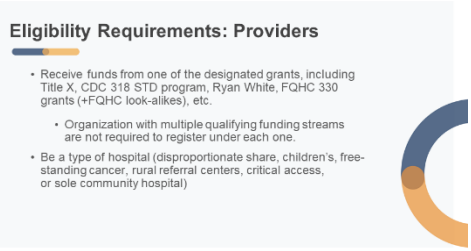
So when we're thinking about eligibility, I like to frame it as a two-step process. The first step being that the provider, the health center or service site has to be eligible and registered as a 340B covered entity. Once that hurdle has been crossed, it's not the word I'm looking but that's fine. Then we have a second step to determine if each patient is eligible to receive 340B price drugs at a visit.

Slide 7



So let's start with provider eligibility. I also realized that in interest of time I cut out some of the stuff about registration, but I will try to weave it in here. So eligibility requirements.

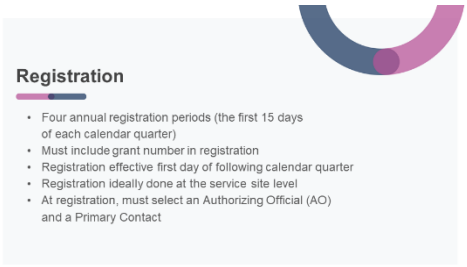
Slide 8



In order to be a 340B covered entity, you have to receive funds from one of the designated grants in the law. Those grants include Title X, the CDC 318 STD program, Ryan White, Federally Qualified Health Centers, or FQHC lookalikes and a handful of other smaller programs. It's important to note here that if you have more than one of these qualifying funding streams, say you have Title X and STD funds, that's fairly common. You are not required to register under each one. It is your choice how you want to handle your registration. The other grouping of eligible providers are certain types of hospitals. We are not going to talk very much about hospitals in this webinar because we are focusing on family planning

providers who tend to be in a Title X setting and the STD setting and not so much under hospital designations, but the types of hospitals are listed on this slide.

Slide 9



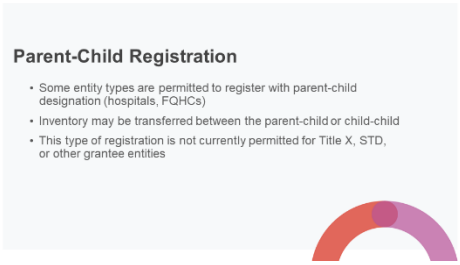
So registration, once you have one of these qualifying funding streams or you are one of the hospital types, the next step is to register for the program. That can only be done in one of four designated annual registration periods in the year, that those are the first 15 days of each calendar quarter, so the first 15 days of January, April, July, and October. Some important notes when you are doing registration, and this is if you have a new service site that's included under your grant or you have just received a new grant and want to register under that funding stream, you would go through this process. You have to include your grant number in the registration and that if you are not a grantee, you have to make sure to obtain the correct grant number from your grantee. Once you complete registration, there is a lag time of three months, so your registration will be effective the first day of the following calendar quarter. So if we're thinking about the upcoming October registration period, if you complete your registration, it's confirmed that you are eligible, you'll be able to start purchasing and dispensing 340B price drugs January 1st, 2024. Ideally that registration is done at the service site level or as close to the service site as possible. We want to make sure that the individuals that are designated at registration are actually able to attest to that service site's compliance with the 340B program's requirements and so therefore it is best for that person to be as close to what is happening at the service site as possible. It used to be pretty standard practice that grantees would register and handle all of the 340B work for all of their sub-recipients, but because in many, many instances the grantee doesn't own and operate those sub-recipients and is a few steps removed from the actual practices of what's happening in that health center, it is now the recommended and approved gold standard that that registration happen at the service site level. The other thing you will do when you register is select an authorizing official and a primary contact. Those have to be two different people and the authorizing official has to have the legal authority to sign for the organization and attest to that organization's compliance.

Slide 10

The other key moment in time in a year for covered entities is that every covered entity must recertify annually. Each grant program that confers 340B eligibility is given a designated recertification period

each year. It is usually about five weeks long and for several years now, the Title X and STD program have shared a recertification period. Also with the TB program, if you are holding more than one qualifying funding stream and have registered under more than one qualifying funding stream, you have to complete recertification for each one of your 340 IDs. So if you are entitled to an entity but you are also registered for 340B as an STD entity, you'll need to do recertification two times during that recertification period to make sure that both of your IDs have been re-certified and that process is handled usually through email. The authorizing official will receive an email from HRSA notifying them of when recertification is starting and then sending them a link to complete recertification. Failure to recertify during the designated five week period will result in termination from the program. You will be able to come back into the program. It's not a permanent bar, but that will mean there will be a lag of several months depending on when your recertification period is before you can get back into the program and you won't be able to purchase or dispense any of your existing 340B inventory during that lag. So recertification, while a pretty standard administrative action is critically important to make sure you can remain in the program.

Slide 11



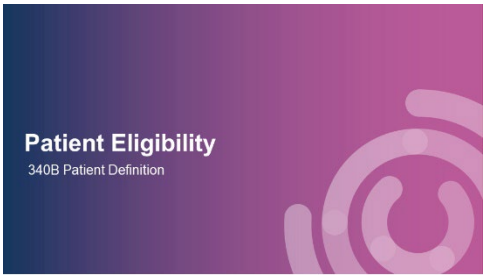
One side note about registration is that some entity types are permitted to register as what is referred to as parent child registration or sometimes parent and associated sites. This allows for inventory to move more freely across that unit, so between parent and child and back and forth and between multiple child sites. Unfortunately, the parent child registration option is not currently permitted for Title X, STD or other grantee entities. It is only available to FQHCs and hospitals. So it is important for folks to understand, especially grantees that have FQHCs in their network that this is a type of registration that you might see. But if you are just registering under Title X, you won't have this option. What it will look like if an entity is registered in this way is that the primary administrative office of the entity will have a 340B IDS standard 340B ID, and then all of its service sites will have that same number with sequential letters after the number so A, B, C, D, E and so on.

Slide 12

Contract pharmacies have been a part of the program for quite some time, are largely not terribly common in the Title X space mostly because it is much more common in Title X for entities to dispense

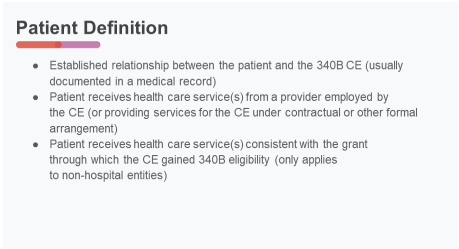
all of their drugs onsite directly to patients rather than sending them with prescriptions to retail pharmacies. But it is an option for 340B covered entities to engage in arrangements with retail pharmacies to dispense 340B drugs to that covered entity's patients. It brings with it a lot of added compliance burden and need for monitoring and evaluation, and because of the growth in contract pharmacies, has become a target of manufacturers and there have been several manufacturers that have put restrictions on 340B drugs in contract pharmacies. I will not talk a ton about contract pharmacies today, but we can certainly dig into it more if folks have questions.

Slide 13



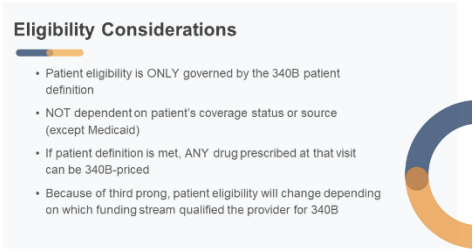
Okay, so you have completed the registration process. You are officially a 340B covered entity. So you are now at the beginning of the next calendar quarter, you are listed in the publicly available 340B database that's referred to as POAIS HRSA, Office of Pharmacy Affairs Information System. Now you have to make decisions on a day-to-day basis of whether or not each patient that is seen at your site is eligible to receive 340B price drugs.

Slide 14



That is governed by this three-pronged patient definition. It is not ... Exceptions in Medicaid that we're going to talk about in the next session, is not governed by the patient's coverage status. All of the patients that you see in a 340B covered entity service site if they meet these three prongs are eligible to receive 340B price drugs. So you'll often hear people say this is a program for the uninsured or for people who are low income. That is incorrect.

Slide 15

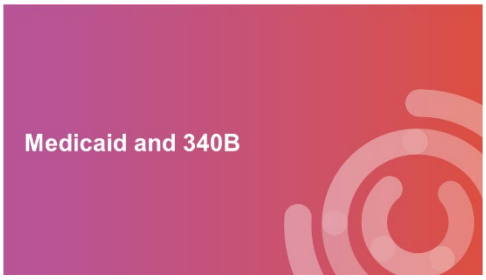


This is a program that was created to bolster providers who largely see patients who are uninsured or underinsured and living with low incomes, but there are not restrictions on only providing 340B drugs to those patients. So your privately insured patients, if they meet this three-pronged patient definition should still be receiving 340B price drugs. There are exceptions for Medicaid. We're going to talk about that in a bit. But this three-pronged patient definition should be something that we all can recite by heart if we are dispensing 340B drugs because this is the holy grail of how we're making these determinations. So when you have a patient come in to determine if they are eligible for 340B priced drugs, they should have an established relationship with the covered entity that's usually as documented in a medical record. It's important to note that the use of the word established in this context is not the same as the use of the word established in a medical coding context where it is the opposite of a new patient. New patients are eligible for 340B price drugs provided that they meet this definition. At the visit, they also have to receive a healthcare service or services from a provider employed by the covered entity or providing services for the covered entity. And they have to receive a healthcare service or services that's consistent with the grant through which the covered entity has gained 340B eligibility. So in the Title X context, this means yeah, the patient has to come in, receive a healthcare service or services that are consistent with Title X, so family planning or family planning related service. That can be counseling, only if that is what is clinically appropriate for the patient, but they do have to receive some form of service other than the administration of a drug. Some considerations for patient eligibility. Like I said, it's only governed by that patient definition we just looked at and not dependent on coverage status except for the Medicaid exception. If the patient definition is met at a visit. So you have a patient come in, they receive a service from one of your providers that's consistent with Title X, any drug prescribed at that visit can be 340B priced. So it is important to remember that eligibility for 340B is not tied to the drug. It is tied to the services provided at the visit. And because of that third prong of needing the services to be consistent with the grant, patient eligibility will look different in each different provider type. So if you are maintaining more than one 340B ID, like Title, X and STD, patients will qualify for medications purchased under one and not the other sometimes. So if a patient comes in and they only want a family planning method, they are not sexually active or not interested in any STI services, they qualify under Title X, but they wouldn't necessarily qualify under the patient definition under ST.

Slide 16

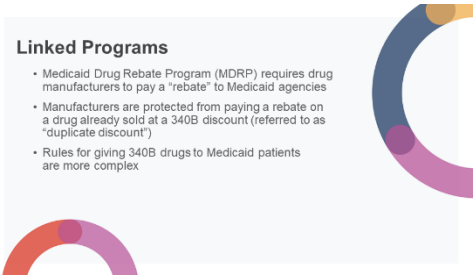
So important other considerations of when not to use 340B drugs. One is you may have noticed that I said this is a program that is only for outpatient drugs. Largely in the Title X context, that's not an issue. But for those hospital-based Title X clinics, it is important to ensure that patients are only receiving 340B price drugs when they're classified as outpatients. And as I said, the patient has to receive a service other than the administration or dispensing of that drug in order to be eligible. So the most common example of something that would happen in a Title X setting where the drug would not qualify to be 340B priced is for those folks that are selling emergency contraception, over the counter emergency contraception directly from the front desk on a walk-in basis to anyone who walks in and the people purchasing that EC are not receiving any other healthcare service. So there are lots of ways to operationalize this if you want to be able to sell EC from the front desk in this way. One is to maintain a small inventory of non-340B priced EC. The other is to have patients meet with a counselor and have a counseling session and have that documented in a medical record and then they can be 340B priced.

Slide 17



Okay, so I mentioned that things get more complicated when we were talking about Medicaid patients, so we're going to dig into what those complications are and why they're there. This does tend to be the point in every 340B training when people start to get confused. So bear with me and take note of your questions and we will do our best to dispel the confusion when we get to that point.

Slide 18

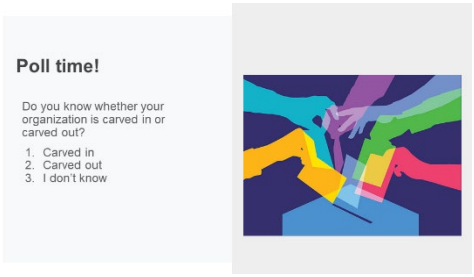


The reason why there are additional rules for Medicaid patients in the 340B program is that the program is tied in the law to what is known as the Medicaid Drug Rebate Program. This is a program that requires drug manufacturers to pay a rebate when Medicaid agencies reimburse for a pharmaceutical product effectively to ensure that Medicaid agencies are receiving the best price on the market. So because Medicaid agencies can receive this discount in the form of a rebate from manufacturers when they establish the 340B program that would sell these same drugs out of discount directly to providers, provision was put into place to make sure that manufacturers were not put in the position of having to pay a rebate or an additional discount on a drug that was already sold at a discount to a 340B provider. When this happens, where a rebate is paid on a drug that was purchased at A 340B price, it is referred to as duplicate discount. We're going to talk about that more when we get into compliance, but it's an important term to know and understand. So because of these provisions and protections for manufacturers, there are additional rules about how and when 340B price drugs can be dispensed to Medicaid patients.

Slide 19

Before we launch this poll, I'm going to talk about what carved in and carved out means because this tends to be one of the things that confuses people pretty significantly. So when you are registering as a 340B covered entity, you make a decision and it is an all or nothing decision for your Medicaid fee for service patients only under federal rules. Either you are going to only give 340B priced drugs to your Medicaid fee for service patients or you are never going to give 340B drugs to those Medicaid fee for service patients. If you are choosing the always giving 340B drugs to those patients, that is referred to as carving in. And if you choose the never option of never giving 340B drugs to Medicaid fee for service patients, that's referred to as carving out. We will talk more about managed care in a moment, but let's launch the poll and see if you all feel confident and know whether or not you are carved in or carved out.

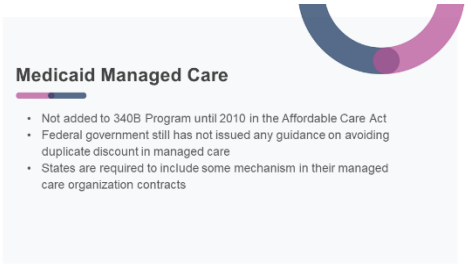
Slide 20



So it looks like just over half of you are carved in and then a little over 40% are unsure. So let's dive in a little bit more to how these rules work, but I expect that many of those don't knows are actually carved in because it is more common in Title X for folks to be carved in than carved out. Like I said, the federal

rules for carving in and carving out only apply to fee for service Medicaid patients. So many of you may be in states where you see very few fee for service Medicaid patients as many states have moved most if not all Medicaid beneficiaries into managed care. So things are more complicated for managed care patients, but for fee for service patients, like I said, this is an all or nothing decision. You can change your decision at any point, but you can't actually change your practice until the beginning of the next calendar quarter after you make the change in your database entry because it's only updated at that point. So if you choose to be carved in, so you are always dispensing 340B drugs to your fee-for-service Medicaid patients, then your NPI, your national provider identification number is listed in a federally maintained publicly available database known as the Medicaid exclusion file. That way when claims are coming through and being processed by the Medicaid agency, they can look at the claim, at the NPI number on the claim and compare it to the exclusion file and determine, okay, these were 340B drugs, so we cannot collect a rebate on these drugs from the manufacturer. And the converse is true too. So if you are not listed on the Medicaid exclusion file because you've chosen to carve out, then when Medicaid receives claims from you from your NPI, they will know that they can collect rebates on those drugs because those drugs were not sold at a 340B price.

Slide 21



So let's talk about managed care. So Medicaid managed care was not added to the 340B program or the drug rebate program until 2010 when the Affordable Care Act passed, which in my mind is still very recently but is actually going on 14 years ago now. So in that time, in the ensuing 13 plus years since the ACA was passed, the federal government has made a decision not to issue any guidance or regulations on how to avoid duplicate discount in the Medicaid managed care space. What they have said is that states are required to develop some mechanisms for how to avoid duplicate discount, but it's up to the state to determine how they want to do that, and those mechanisms are supposed to be reflected in their contracts with managed care organizations. So it is important if you are choosing to provide 340B drugs to your Medicaid patients, that you do some research into what your state's policies are in terms of billing for Medicaid managed care. Many states require an added modifier to identify those as claims with 340B drugs on them. I will say that despite the fact that the federal government has said states have to have policies on how they handle these, there are some states that if they have those policies, they are very difficult if not impossible to find. So this is what I often refer to a little bit as the Wild Wild West in terms of how manage managed care, which can be very confusing and stressful for folks that are trying to be compliant. One important thing to note for all of you is that HRSA has said that when they do audits and they're looking for duplicate discount, they're only going to look at fee for service Medicaid patients because those are the only patients where there are federal rules governing how things are handled. That doesn't mean that you should completely ignore how to handle Medicaid patients. You should make sure that you are being compliant with whatever policies your state has put into place that you can find. If you need help, you can feel free to reach out to me if you can't find it after the fact and I can try to help figure out what your particular state's policies are.

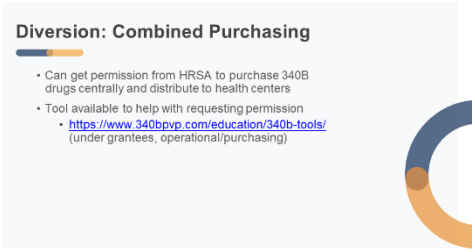
Slide 22

So okay, we're about halfway and we're going to dive into compliance and this obviously is where the rubber meets the road. So I mentioned just a moment ago around HRSA audits. So HRSA has the authority and does in fact do 340B audits. Mostly those entities are selected randomly for audits, although they do have the authority to audit for cause. A manufacturer can raise a concern with HRSA that could trigger an audit. They audit on two primary compliance areas.

Slide 23

The first one is what is referred to as diversion. Diversion is a government-ese term for a 340B drug ending up in the hands of someone who shouldn't have it. So that looks, that means a variety of things. A big one is dispensing a 340B drug to someone that does not meet the 340B patient definition, but diversion is also transferring 340B drugs from one 340B ID to another, unless you're in one of these exception categories. Or I've gotten the question many times before of like, "I have this 340B inventory, it's going to expire. I would like to donate it to someone who can use it." That is diversion and is not permitted in the program as much as it is a very laudable desire to want to make a donation and make sure a product isn't wasted, it is not permissible to move 340B inventory outside of the 340B service site that purchased it. Another action that would be classified as diversion is dispensing a 340 B drug in an inpatient setting.

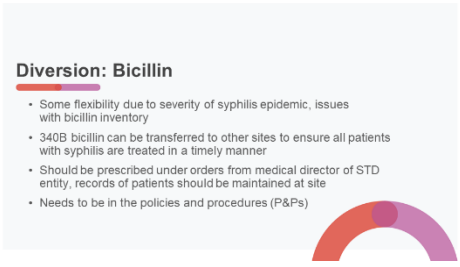
Slide 24



So there are some exceptions here. So I'm going to talk through like I just did, the two compliance areas, but afterwards we'll talk through some exceptions and other sort of considerations and things to think about. So it is permissible to get permission from HRSA to have a combined purchasing plan. This is pretty common with state governments where they operate a state pharmacy and purchase all of the drugs for all of the local health departments or sub-recipients through that state pharmacy. It is important that if that is happening in your state that you make sure that you have an approved combined purchasing plan. If you don't, Apexus, which is the company that through a cooperative agreement with the federal government operates all of the technical assistance education, et cetera around 340B can help walk you through the process of applying for that permission. And there have been many instances of entities that had been doing it for a long time, didn't realize that they shouldn't or wasn't permissible and then applied for a combined purchasing plan and were approved. So don't think that you shouldn't own up to it because you're already doing it. It's important to move towards compliance. There is a tool available this website, this 340bpvp.com, this is Apexus's website. They run the prime vendor program, which some of you may be familiar with, where you can purchase 340B drugs at usually sub-ceiling prices through them, but they also do 340B University. They do a variety of education and technical assistance. They also operate the hotline so they have a tool available to walk you through the process for applying for combined purchasing. I'm going to walk you through a couple of things that are exceptions that if you are in a position to do it and are making sure that you are adequately documenting how you're doing it in your policy and procedure manual, that can be exceptions to diversion. I would encourage you if you are not already doing these things and you want to, to reach out to me and we can think through whether or not that's something that's feasible for your particular situation.

Resource: Tool available to help with requesting permission (under grantees, operational/purchasing)

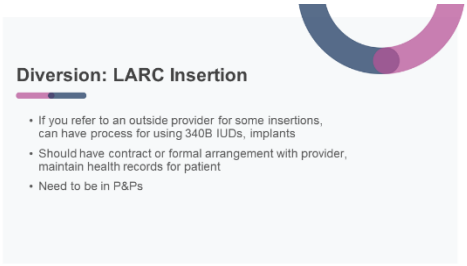
Slide 25



So the first one I'm not going to talk a ton about, but if you have questions, we can talk through them. With the understanding that the syphilis epidemic continues to worsen and that particularly congenital syphilis continues to worsen and that Bicillin and is the only treatment, there is the possibility of

arranging for Bicillin to be transferred to other non-340B sites when there is a patient that has tested positive for syphilis in order to make sure that that patient is treated in a timely manner. Because a lot of private providers don't keep Bicillin. It's expensive, it is significantly more expensive outside of the 340B program. It's actually quite affordable as a 340B price drug and we want to make sure that we are not telling patients that they have a positive syphilis test and not sending them away with treatment right away to combat the syphilis epidemic. But again, this is something that you should not do lightly and you want to go through a very particular process. If it's something you're interested in, please feel free to reach out to me.

Slide 26



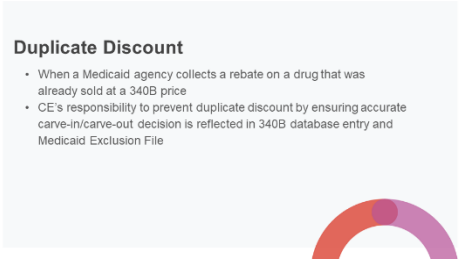
Another similar situation is if you have ... This is something I hear about particularly in more rural environments where you may not necessarily have providers on site who are trained to do insertions for IUDs or implants or you have an arrangement with another provider for difficult insertions. If you have a patient come in, they want an IUD, but your provider for a variety of reasons is unable to place that IUD and you want to refer them out to someone you have an existing arrangement with to have that difficult insertion handled, you can set up a situation where you have a formal arrangement with that non-340B provider where a 340B priced IUD can move with that patient to that provider because you are maintaining responsibility for that patient's care. Again, not something to enter into lightly and should always be documented in your policies and procedures of how you do it and how you remain compliant while you do it. But it is something that we can talk through if you are interested in it.

Slide 27

Expedited partner therapy is another one of these exceptions, but this is the one exception that I can tell you definitively we know of entities that are using 340B price drugs for expedited partner therapy, have had 340B audits that have pulled charts that included EPT and that there were no findings on those audits. So this is a pretty commonly accepted practice that if you have a patient in front of you, that patient tests positive for an STD, and that patient meets the 340B patient definition, you may use 340B drugs for expedited partner therapies. So giving that patient additional courses of treatment for their partner or partners. The rationale for how this is allowable under 340B is that EPT is actually a treatment for your patient because you are preventing reinfection after that patient goes through their course of

treatment. Again, this should be reflected extensively in your 340B policies and procedures, but it is a permissible use.

Slide 28



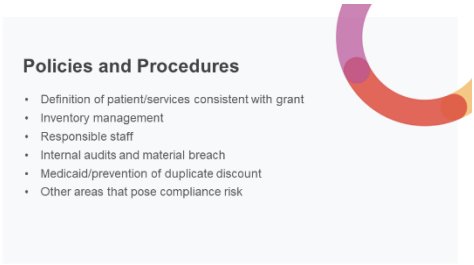
Something I should have started out with and usually do but forgot. The important thing to remind oneself when we're talking about 340B is that there are very few hard and fast regulations that govern this program, which means a lot of how you implement 340B lives in a gray space. And what will go a long way in terms of audits and showing that compliance is a priority for you is making sure that things are documented in your policies and procedure manuals, your 340B policies and procedure manuals. And that you are always thinking about how to ensure that you are following the requirements of the program when you are making decisions about how you provide care. Okay, the other compliance area that HRSA has the authority to audit on is that duplicate discount we talked about earlier when we were talking about Medicaid. So it is HRSA's estimation that it is the responsibility of the 340B covered entity to prevent duplicate discount. So the way you do that is to make sure that your carve in or carve out decision is reflected accurately in the 340B database, and that whatever your database entry says actually matches your practice. So it is a good idea to check in and see what it says in your database entry. Anyone can look up any 340B covered entity in that OPAIS database. I encourage you to look at your own entries and see what is reflected there. There will be a tab along the bottom that says Medicaid billing. If you click on that, that will have your answer for whether or not you're carved in or carved out. If the yes radio button is clicked, that is carved in, and if the no button is clicked, that is carved out.

Slide 29

Key elements of 340B compliance. Like I said moments ago, the most important one, and if you walk away from this webinar with nothing else, I hope that you walk away understanding that you need to have robust policies and procedures that how you handle everything related to the 340B priced drugs in your health center should be documented thoroughly in your policy and procedures manual. There are sample manuals available on the Apexus website, that 340bpvp.com. They are an excellent place to start, but they should be seen as just a template and a starting place. They need to be filled in and should adequately and thoroughly reflect how you are providing care uniquely in your own setting. And

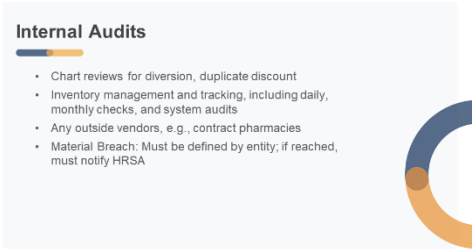
we will talk more about each of these. Also internal audits. It is HRSA's expectation that you will engage in regular internal audits and that you will establish your own material breach threshold so that if during an internal audit you reach that threshold that you will self-report to HRSA of a compliance breach, you do regular staff training. It is extremely common in the work that I do, in educating family planning providers and different members specifically about 340B that I meet people who tell me, "I just started this job and I'm responsible for 340B, but I don't really know anything about it." Happens all the time. Please make sure that you are making sure that all of the staff that are in any way engaging with 340B price drugs in your health center are receiving regular training about the program and how it works. And finally, just general maintenance of your entry in the database system in the OPAIS database. It seems like a small administrative thing, but if during an audit they determine that there is incorrect information in your database entry, that can be a finding on an audit.

Slide 30



So let's dig in a little bit more to those four areas of compliance. So policies and procedures, these are some areas that I think everyone should consider whether or not they want to include these practices in their policy and procedure manual. The first one of definition of a patient and services consistent with the grant. As we talked about when we talked about the patient definition, that third prong of the patient definition is the patient has to receive a service consistent with the grant. So one thing that will get you very far in a chart review of a 340B audit from HRSA is if you have included in your policies and procedures a list of all of the CPT codes of all of the services you deem to be consistent with your grant. That way they can just hold up that page of the policy and procedure manual up against each chart they review and they can make sure that every patient who received a 340B drug received one of those services. That is a pretty easy way to make it easier for auditors to determine that you are in compliance with the patient definition. And as I said earlier, counseling is a healthcare service in Title X, it is a critical part of providing high quality family planning care. So you can list counseling as one of those services. And if a patient is not clinically needing any other services, that is sufficient to be eligible for 340B price drugs at a visit. Other areas to have documented in your policies and procedures. Your inventory management. So how are you tracking drugs from the moment they're purchased to the moment they walk out the door with a patient? Are you able to follow all the way through and identify what drugs have gone to which patients so that you can confirm in charts that no 340B price drugs went to someone they shouldn't go to? Listing out who all of the responsible staff are for various 340 B functions at your health center, how often you engage in internal audits and then what your material breach threshold is, your policies around how you handle Medicaid, whether you're carved in or carved out, and how you are making sure that you are doing everything in your power to prevent duplicate discount. And then any of those exception areas that we just talked through under diversion, things like that. If you want to do anything like that, that is in a gray area, that should be thoroughly documented in your policies and procedures.

Slide 31



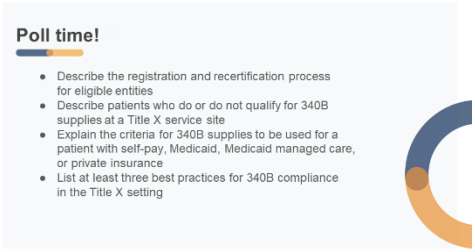
Internal audits. So the HRSA audit and you can find a sample of the data request you would get from HRSA if you were selected for a 340B audit on the Apexus website is largely once they're on site chart review process. So you want to make sure that you are doing regular internal audits and doing chart reviews of your own. You are also expected that if you are working with any outside vendors for 340B, so that's often contract pharmacy arrangements, but if you are using software to manage your 340B inventory, any outside vendors, you should be doing regular internal audits as well. And for all of these audits, it is the responsibility of the covered entity to define what a material breach is for that entity. So for folks who are not familiar with that term, that basically means the threshold at which you are going to self-report that there has been a breach in compliance. So I think one of the more common material breach thresholds that folks use is a hard number or a percentage of charts during a chart review reflecting a compliance problem.

Slide 32

Your material breach threshold should be documented in your policies and procedures. And then if in the course of any internal audits you reach that threshold, that needs to be reported to HRSA. As I said, the pre-audit data request is available or a sample of it is available on the Apexus website. But some of the information they're going to ask for is listed here. They will ask to see your full 340B policies and procedures manual, the list of authorized providers, contract pharmacies, all of these things. And then once you've completed that data request about a month later they will do an onsite audit including chart review. I think we have one last poll, and I know that felt like a lot in a really short period of time and we are already in the last 10 minutes. This is a lot of content to cover in an hour. Thankfully we are doing the office hours webinar next month, so there will be another opportunity to talk through more questions. I think we will have some time to take questions today too, but I think we can move forward with the poll. And I see Caitlin is back.

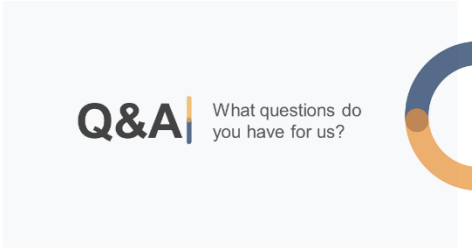
Resource: Sample pre-audit data request

Slide 33



[Caitlin Hungate] Yep. Thank you Mindy, thanks for this great presentation. We are going to launch the poll. This is a lot of information. So as Kaylee said, thank you for explaining such a complex program. So again, these are the same questions that we asked you at the top of the hour, at the beginning of the hour. If you can answer how confident you are from a scale of one, not at all confident, to five, very confident, for those four questions, we'll give you all of a minute or so to weigh in. And then we are going to take as many questions as we can. A lot have come in through the chat. Please do keep typing them and sending them in because we are going to save every question and we'll be updating some frequently asked questions documents and other resources later this year in the fall. So keep those questions coming. Awesome. So it looks like from ... Thank you, we're going to show the results of the poll. So it looks like there is definitely some movement in confidence, which is great, and that's what we want to hear and see. And we know this is a complex program, so again, the RHNTC, Mindy, and NFPHRA, we are here to support you. But before we dive in, Mindy with questions and we'll get to as many as we can, I want to make sure we share out another opportunity to dig into the 340B program with Mindy. So the RHNTC is hosting a 340B office hours on Thursday, September 21st, and our colleague Tayhlor is going to chat out the registration momentarily. And this is only available to Title X staff and we are limiting the capacity at 60 participants. So there will be a short presentation and then the majority of the time will be interactive questions. So although we won't get to many today, that office hours we will get to a lot more. So please consider registering for the office hours on Thursday, September 21st at 3:00 PM.

Slide 34



So with that Mindy, I'm going to just try to get through as many as we can back and forth in our remaining time. And I'm just going to go in the order that they were received. So this is a question around eligible grant funding sources. Does funding sources, does this also include WISEWOMAN which is a CDC program? I don't know if you've heard of it. I can ...

[Mindy McGrath] I have and no, that is not one of the eligible sources of funding. So a lot of times states will take a bunch of different funding streams and bundle them together and include it in, it will be a 340B eligible funding stream. And so sometimes folks receive sort of a bucket of funds as passed

through the state and the state labels it as something. And it's a little confusing when it comes to 340B. But no, the grant programs are the ones I list[ed on the slide. And then there's also TB, hemophilia treatment centers, black lung clinics, there's a handful of other small programs, but WISEWOMAN is not one of the qualifying.

[Caitlin Hungate] Thank you. Is the authorizing official and the contact person the same person?

[Mindy McGrath] No, they actually are not permitted to be the same person. They need to be two different people. So the authorizing official must be someone who can legally sign for the organization. So usually a CEO or a COO or someone like that. And then the primary contact is usually the person who has primary responsibility for managing 340B at the health center. And I think they receive most of the same communications that the authorizing official does, but it is the authorizing official who ultimately has to complete recertification and attest to compliance.

[Caitlin Hungate] Thank you. So let's say a person on our webinar today has two programs like Title, X and Ryan White and you only register under one. Do you only need to recertify under the same one?

[Mindy McGrath] Yes. So you only need to recertify those that you have registered for 340B under. In that case, if you have Title X and Ryan White, those are such different patient populations that that's a situation where I would recommend that you do register under both of them because Ryan White is only for HIV positive patients. Title X obviously has a much broader patient rule, but if you are only registered, if you are say Title X or if you're an FQHC, that also gets Title X, that's pretty common in those instances that the FQHC will only maintain their FQHC ID. Because the services consistent with the FQHC grant are comprehensive primary care. Everything you're doing under Title X is also encompassed under your FQHC grant. So then they just maintain the one then you would only be doing one recertification per year. The number of recertifications is the same as the number of 340B IDs you have.

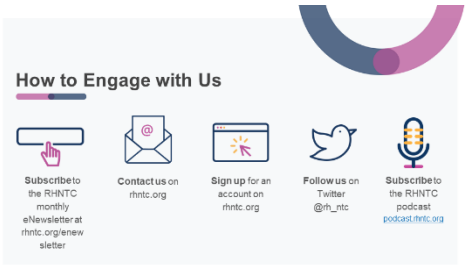
[Caitlin Hungate] Got it. Okay. I feel like we have maybe one last question potentially, and then we'll have to close that. I'm sorry folks. So if a family planning agency has multiple clinics, do they use only one 340 ID and this, you kind of touched on this a little bit [inaudible 00:55:18], and feel free to just jump in the chat if we don't answer your question, but it stems from Mindy, your explanation of the parent child relationship for FQHCs in hospitals.

[Mindy McGrath] Yeah, so if you are registered under Title X, then there are ways, particularly if you get an approved combined purchasing plan through HRSA, that you can just have one registration and manage everything for all of your health centers under that one. But if you don't have that, the standard is that you would register each individual service site as its own 340B ID. What HRSA says is if you are providing care at a site on a regular basis, that site should be registered as a 340B covered entity. So then each one would have its own ID, inventory would be purchased for that site under its ID and remain at that site. That's why parent child has advantages. Unfortunately, Title, X entities can't register that way.

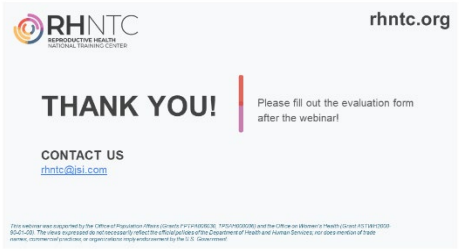
[Caitlin Hungate] I'm sorry if you talked about this Mindy, but just how to engage with the RHNTC. We are grateful for everyone's questions. I'm so sorry we have run out of time. But please before you leave, please take two minutes to fill out the webinar evaluation. We do rely on your feedback to continuously improve and better meet your needs. And to stay in touch with the RHNTC, please subscribe to our monthly e-news by visiting our website and signing up through that link. You can sign up for an account, you can contact us, send us an email. And again, I know that so many questions for Mindy about 340B. So please do register if you're able to or have someone from your team register for the office hours. Or if you want to dig in further, consider submitting a technical assistance request and we can dig into it

more in depth with you and your Title X grantee. This is a critically important area of the program and we want to make sure we're here to support you.

Slide 35



Slide 36



To stay in touch with the RHNTC, subscribe to our monthly eNewsletter by visiting rhntc.org backslash newsletter; contact us through our website (rhntc.org); sign up for an account on our website; follow us on Twitter (find us @rh underscore ntc); and, finally, subscribe to our podcast at podcast.rhntc.org or in your favorite podcast app. Thank you all for joining us today. Thank you for bearing with us as our internet crashed at the very end. I hope you'll join us in thanking Mindy. Mindy, as always, it's an honor and privilege to work with you and rely on your expertise. And we'll have the materials from today's session available on RHNTC. So again, a recording, the slides, and the transcripts within a few days. And if you have additional questions on this topic, feel free to again, sign up for the office hours or email us at rhntc@jsi.com and we'll get those emails and questions filtered to Mindy and we'll be working on some updated FAQ documents later this year. So this concludes today's webinar. Again, Mindy, thank you. It's an honor and privilege. Have a wonderful rest of your day everyone. Thank you.