

**NWX-OS-OGC-RKVL**

**Moderator: Sue Moskosky  
September 16, 2011  
12:00 pm CT**

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. At the end of the presentation we will conduct a question answer session. To ask a question, please press star 1. Today's conference is being recorded. If you have any objections you may disconnect at this time. Now I will turn the meeting over to Ms. Susan Moskosky, ma'am, you may begin.

Sue Moskosky: Thank you very much. I'd like to welcome all of the folks who are on the phone to the webinar for Title X grantees, the 340B, and the Prime Vendor programs. This afternoon we are happy to have with us the experts in the field and first we'll be hearing from Krista Pedley who is the - Commander Krista Pedley who's actually the director of the HRSA Office of Pharmacy Affairs.

And then after Commander Pedley finishes speaking, Lisa Scholz from the Pharmacy Services Support Center, and then finally Mary Ellen England from the Prime Vendor Program, which is Apexus. At the conclusion of the presentation there'll be plenty of time for you all to have questions and answers.

And we want to, again, thank our friends from the Office of Pharmacy Affairs and from the Prime Vendor Program. So with that, I'll turn it over to Commander Pedley.

Krista Pedley: Thank you so much and thanks for having us today. We're excited to be presenting to the Title X grantees. And hopefully today we're able just to provide you some information from a 30,000-foot level on what the program is, and then any changes that have been occurring, and then of course the opportunity to you all to ask questions.

So if we could go to the next slide. I just wanted to go over the mission of the Office of Pharmacy Affairs and we're actually in the Health Resources and Services Administration, which is in the Department of Health and Human Services. And our mission is to promote access to clinically and cost-effective pharmacy services.

Pretty simple, but we do that through two platforms, obviously the one that you are all very familiar with, which is the 340B Program, which assists with the cost-effective portion of pharmacy services and access to medications for underserved populations.

But on the clinical side we also run a Patient-Safety Pharmacy Collaborative, which I'll just touch on briefly at the end of my talk, to really discuss how we're moving and our approach from, not just access to the drugs, but also to ensure that the drugs that are used are done so in a safe and effective manner.

So on the next slide, so really how we operate and you'll get to see that on the call today based on the three presenters. We really couldn't do this alone as the federal government. We have a small federal team in the Office of Pharmacy

Affairs, between 15 and 20 individuals that work here in the office, and then we have two contractors that we work with.

The first is the Pharmacy Services Support Center, which is a contract through the American Pharmacists Association to provide technical assistance to our covered entities and other value-added services like webinars such as this, they go out to meetings, they have tools and resources that the entities can utilize.

And then our 340B Prime Vendor Program, which is managed by Apexus, who can negotiate even subceiling prices on behalf of the covered entities in order to receive even steeper discounts and other value-added products, and you'll get to hear from both of them today.

So on the next slide, it's very important to understand why 340B and what is its purpose? Really this program was intended to permit the covered entities, so all of you as the grantees, to help you stretch scarce federal resources as far as possible so that you can reach more patients and provide more services.

So being able to acquire these medications at a lower cost will help you to treat more of the patients that come through your clinics.

Next slide, again, just 30,000-foot level overview of the program. This program is providing outpatient drugs, and again it's only outpatient drugs, to certain safety-net covered entities, and those entities are defined in statutes. Again, the intent is to allow the entities themselves to benefit and to increase the services and the savings.

There is an estimated \$6 billion in purchases in the 340B Program last year. And believe it or not, 340B is fairly small in the big picture. We're about 2%

of the drug sales in the country. And then also you may wonder why do manufacturers participate in this program if they have to sell at a discounted rate? And the answer to that question is because they have to by statute.

And manufacturers that participate in Medicaid have to also participate in 340B. They sign an agreement with the Secretary in which they agree to selling the drugs to the covered entities at a price that is set in statute or some price below that ceiling price.

So on the next, what are the benefits? Just to name a few, the average savings on medications is about 25% to 50% on the outpatient drug purchases, so a very significant savings on these drugs.

And these savings may be used in a variety of ways, but I will say that the 340B statute does not define how entities use savings, but the different grantee programs, for example like the Title X Grantee Program, does have certain stipulations on how you use those savings and being able to put them back into the program.

The next slide shows some of the eligible entities. Since the Affordable Care Act, there were five new entities that were added to the program, I believe we're up to 22 entity types that can now participate, and of course that includes the Title X family planning clinics.

But those that were added by Healthcare Reform were the children's hospitals, the critical access hospitals, rural referral centers, the sole community hospitals, and the free-standing cancer hospitals. So a good bit of expansion with Healthcare Reform and the sites that now have access to these drugs as well.

So the next slide talks a little bit about the enrollment process. If you're not already enrolled in the program, this is how it would occur. You first have to determine if you're eligible, and that's all set in statute. You have to receive a grant as a Title X family planning clinic for one.

You now complete the appropriate forms, which I do want to tell everyone that that process is now all online, and you can go to our Web site at [hrsa.gov/opa](http://hrsa.gov/opa) to acquire those forms, and then of course await the decision from OPA. And that occurs, as I'll mention here in a couple of slides, on a quarterly basis.

So on the next slide, then once you're enrolled in the program and that you then show up on our public database so that manufacturers can make sure that you're now eligible to purchase, you have to setup your accounts. You have to determine if you're going to use a contract pharmacy, so are you going to contract out in your communities to a pharmacy that will provide the drugs to your patients?

Contact PSSC for any additional assistance that you may need in setting up your program to ensure compliance, and also to contact the Prime Vendor to discuss participation in their program to receive even steeper discounts on these medications.

So the next slide just shows the deadline dates. And as I mentioned, we do this process on a quarterly basis and the deadline for the submission of all of your paperwork is one month prior to the start of the next quarter. So it's really important that all that paperwork is received by then so that we have adequate time to enroll the entities and to verify eligibility.

And each site does go through a very robust process to ensure that they meet that criteria before we enroll them into the program.

So on the next slide, a couple of words about our OPA database. Obviously as I mentioned, an entity cannot - if you go to the next slide, an entity cannot participate unless they are listed on that public database, and wholesalers will not ship these drugs unless it is an exact match.

So it is the responsibility of the covered entity to provide any necessary updates that may have changed through the process to make sure that we have the most update information so that you can actually receive the drugs, and you would do that through a Change Request form, which is also on our Web site. And then that information is actually updated daily if you have any changes.

You also have to alert OPA at the time of enrollment, and on an ongoing basis if there are changes, of how you plan to bill Medicaid for your drugs, whether you will use 340B drugs for your Medicaid patients or whether you will carve-out those patients. And you have to provide that information to us upfront, and again as that information changes, to ensure against any duplicate discounts that may occur.

So the next two slides talk about the two big prohibitions in the 340B program. And the first is diversion of drugs. And what this means is diverting drugs, or providing drugs, to patients that are not eligible for the program or providing 340B drugs to non-patients.

And how you know whether that is occurring, we currently have a guidance in place from 1996 on patient definition that lays out the requirements on who is

and is not a patient for the purposes of 340B. It's very important that these guidelines are followed and that drugs are not being diverted to non-patients.

And then the next slide talks about the second prohibition, which is on duplicate discounts. As I mentioned, it's important that you determine upfront whether you will be billing Medicaid for your 340B patients or not. If you are using 340B for Medicaid, the state then cannot also go get a rebate from the manufacturer. This would be counted as a duplicate discount and is a prohibition in the program.

It's also very important that you work closely with your state Medicaid agency then, to also ensure that appropriate billing is in place. HRSA's guidance is that, in terms of reimbursement, that you do follow your state policy on what that might be. And we encourage you to work with your state on creating win-win partnerships to ensure that, again, everyone wins in the process when it comes to reimbursement for Medicaid.

The next slide lays out some of our program integrity initiatives that are ongoing currently and that we're really refocusing our efforts around. Obviously as I mentioned, each site has to go through a robust determination of eligibility when they apply to the program, and then we maintain that database to ensure it's accurate and up-to-date.

We also do recertification, which I'll talk about a little further on the next slide. We do quarterly calculations of the 340B prices. We post the Medicaid Exclusion file, which is the file that lists all of those sites that are using 340B for their Medicaid patients.

We do investigations and resolutions of any alleged drug diversions to make sure that there is no patient definition violations or duplicate discount

violation, in addition to ensuring that the manufacturers are charging the appropriate prices as set in statute.

We also are having a re-emphasis on audits that we will be conducting, and have the authority to do, of the covered entities to ensure that all of the guidelines are in place within each covered entity as they use the program.

And we also do very extensive technical assistance, webinars like this one, we post FAQs on our Web site, and we have multiple guidances that are all available to the public to ensure that you are able to follow the guidelines of the program.

So a little bit more about recertification on the next slide, we are currently doing recertification for certain entities. We do look at the federally qualified health center on a quarterly basis. We review disproportionate share adjustment percentages for the hospitals on a quarterly basis and those that fall below are removed from the program.

We're checking ownership status. We're also, just this fall, have begun a phase implementation of annual recertification. This is a new requirement of Healthcare Reform and we will be doing this process in a phased approach.

And I did want to alert the family planning clinics that we'll be working with the Office of Population Affairs late this year on getting ready for all the family planning clinics to do recertification, probably sometime in January, where you will have to ensure that all of your information is updated on our database.

So that will likely occur for the family planning clinics sometime in January, so stay tuned for that.



The next two slides, just a little bit more on contract pharmacies and the decision that's made by covered entities on whether they will have an in-house pharmacy or contract out, as of April of last year, the 340B Program now allows entities to contract with multiple pharmacies. It used to just be 1:1, but they're now able to contract with multiple pharmacies, and we do have a guidance in place that lays this all out, and it's on our Web site.

The covered entity purchases the drug, they're always responsible for the drug, but then they can ship it to this contract pharmacy where it can be then used and picked up by the patients. And again, the covered entity always retains the legal title to all drugs purchased under 340B and it's also up to the covered entity to ensure compliance of the contract pharmacies.

The next slide, again, just shows that in addition to the covered entities being subject to audit, so are the contract pharmacies to ensure against diversion and duplicate discounts. And a single-covered entity, or what we would call parent organization, is permitted to enter into contracts with one or more pharmacies as I had mentioned, which is really great in providing more access points for those patients.

So on the next slide, now that we move from really this access piece to 340B to ensuring drugs are being used in a safe and effective way. The Office of Pharmacy Affairs has led what's called a Patient-Safety and Clinical Pharmacy Collaborative for over three years now and we're getting ready to enroll new teams to our fourth year.

We're currently enrolling new teams and you can find that information on our Web site. And what that project is all about is creating community-based

teams across the country that are focusing on high-risk patients whose health and safety are out of control.

And what this collaborative does, it's an action-learning collaborative modeled after the Institute for Healthcare Improvement, to create rapid results in population health status, medication safety, and the community capability to build patient-centered integrated delivery systems.

We use a model where we have evidence-based best practices that these sites use. There's a national faculty experienced in this work to help guide the teams through this process. It's an amazing effort. Again, we're going into our fourth year. We'll be partnering with CMS this year where all of the state quality improvement organizations will be participating as part of their tense scope of work.

They'll be recruiting teams in every state and we're excited to see this grow and spread to more populations across the country. So to learn more about that effort you can go to the Web site that's listed there, [hrsa.gov/patientsafety](http://hrsa.gov/patientsafety).

And the last slide just has contact information for both the Office of Pharmacy Affairs, and also for the Pharmacy Services Support Center, and the Prime Vendor Program, which you're going to hear from next.

I also want to introduce you to Lieutenant Commander Josh Hardin who will actually be taking over the enrollment process and any assistance you might need for Title X family planning clinics here in the Office of Pharmacy Affairs.

Feel free to contact him if you need anything, I'm sure you'll be hearing from him through, definitely the recertification process if you're already in the

program, if you're not in the program and plan to enroll, that's who you will be working with.

So with that, I'd like to turn it over to Lisa and we'll take your questions at the end. Thanks.

Lisa Scholz: Okay. Well thanks, Krista, and thank you, everyone, for joining us on our call today. And as Krista mentioned in her presentation all about what the 340B is, and how to participate, and all the different various activities, I'm going to drill down a little bit more with you today and talk specifically about how the Pharmacy Services Support Center can be a resource to you as you make your way through the 340B program.

So again, I'll tell you a little bit about our background and describe what our purpose is, our function, some of the valuable services that you can utilize, and then follow it up with some of our foundational principles for which we operate under. And hopefully by the end of our discussion today, you'll have some resources readily available to you to help you with your 340B program.

So as Krista mentioned, HRSA's Pharmacy Services Support Center is a government contract with the American Pharmacists Association and the Office of Pharmacy Affairs. We were established in 2002 to be the primary access information resource regarding the 340B Program, specifically to help eligible healthcare sites with the goal of optimizing the 340B Program.

So what is our vision and what is our mission? And Krista framed it with the vision and mission of OPA and we match and mirror that in every respect. And that is our vision is to have a patient population that has access to affordable, clinically, and cost-effective pharmacy services with the additional

value statements of providing the information, the education, and the policy analysis to help you as a covered entity optimize this program.

But at the same time, taking in those elements that Krista was talking about with the Patient-Safety and Clinical Services Collaborative, and ultimately improving medication use, and advancing patient care. So again, not just about the 340B drugs, but also about using those drugs in the most effective manner.

So to pull all those pieces together, we created a framework which we call The Four Cornerstones of Providing Clinically and Cost-effective Pharmacy Services, and they're based on these four principles. And that is, having access to medications, and we are hoping that you are accessing the 340B Program and other valuable programs that are out there, such as utilizing the Prime Vendor Program as a value add, and patient assistance programs.

Following around that circle, you also need to have efficient operations, so having a pharmacy that is run appropriately, staffed appropriately, and with appropriate standard operating procedures.

And then the other two pieces of that pie are quality, having quality assurance programs built in to your medication management system, and then last but not least, having outcomes, or what we call data collection. So having a full comprehensive pharmacy program, not just centered on the drug, but centered on the patient and having these four components.

So what is our value proposition? And that is, as the primary information access arena, we are there to help covered entities understand the program, implement it, so folks who are brand new to the program just getting started, and for those who've been in the program for some time, helping them to

optimize it, and looking at new ways of doing business and doing it according to the policy and the guidance that's out there.

And again, our intent is that we are timely with the information we provide to you, it reflects current policy coming from HRSA's Office of Pharmacy Affairs, and we meet high-quality standards in making sure that the information you are provided is up-to-date.

So what are our services? We bundle them into three packaged areas and that is, there's the information analysis and management piece, which we'll talk about later, is our call center. Then there's the relationship and networking component of what PSSC does, which is being on calls like today, and bringing information out to the various stakeholders who participate in the program.

And then lastly, putting all of those piece together to create what we call program development, and that is, creating those tools and resources that will help you as a covered entity, ensure that there is program integrity in your program. So we will develop, and you'll see later in some of our slides, tools that help you with developing standard operating procedures around the 340B Program, how to do a financial analysis.

So our call center is available Monday through Friday. Basic operating hours are 9:00 am Eastern Time until 4:30 pm Eastern Time. We are also accessible through our Web site, and I'll show you that slide next, but we also have email. And I always tell everyone, this is for those that, when you have a dying, burning question at 9:00 pm or 9:00 am, you can shoot it off to this email account and we will turnaround a response to you within 24 hours.

So through the call center, that's where we initiate your basic questions that you may have regarding the 340B Program. For those eligible sites that have the opportunity to have more of what we call enhanced technical assistance, we have a pharm TA program, which is pharmacy technical assistance, which is managed by a consultant pool of pharmacy experts to help covered entities with their 340B Program.

And again, it is accessible through the call center and we make determinations at the call center as to who is approved for this level of technical assistance.

This is an example of one of the interactive tools that we have available for covered entities that really want to have a better understanding of areas like contract pharmacy. As Krista mentioned earlier, that's one of the latest developments in the 340B Program with the ability to have multiple pharmacies helping a covered entity get access to 340B.

And this tool will help you do that financial assessment to make sure that you're building a program that will be financially viable in the long run.

When I work into the policy analysis portion of what PSSC does, as Krista mentioned in her slide deck, the Affordable Care Act has made several changes to the 340B Program from having more covered entities eligible for it, as well as requiring some of the other things, such as recertification as Krista mentioned.

So what we are doing constantly through the PSSC is watching and monitoring the various policy activities, such as the Affordable Care Act, as well as diving deeper into the states and what the states are doing with regard to the 340B Program.

This is our Web site. And this is what I call, for the independent user, when you maneuver through our Web site you will find all of our tools and resources that are available for free for covered entities as well as other stakeholders.

We have policy updates that you will find here, some basic FAQs that are posted, and information about new programs that are out, latest announcements, it's a great way for you to stay up-to-date with what's happening in the 340B space.

So more on our relationships and networking, just a quick run through is that, we do offer live presentations and we love being out in the field doing webinars such as this, to get information out to our stakeholders. We're also available - we have a monthly article that we do in the pharmacy today specifically on 340B covered entities and the successes that they have had with their programs.

Our purpose is to get to as many stakeholders as we can. So we're looking forward to working with our stakeholder group, such as the Office of Population Affairs and many of the other organizations that participate in this program, to get the latest information to you.

One of the things I wanted to talk about today and focus on with this call is we mentioned that we have a call center, we mentioned that there's technical assistance, and March 1 of this year we made some changes to how technical assistance is offered to the 340B entities because the program has grown tremendously.

So we developed a program called a peer-to-peer network and that was our way of being able to get information to stakeholders in this program, not in a

one-on-one format, but a one-to-many. And that is, we were looking to identify peers in this program, in the 340B Program, that were operating successful programs built upon the four cornerstones of providing clinically and cost-effective pharmacy services in the 340B space.

So again, our purpose of this program was so we could reach people, we could connect stakeholders so that they could share the real boots-on-the-ground operational issues that people face day-to-day with implementing the 340B Program.

And we also at the same, and you'll learn more about what the peer-to-peer program offers, is we wanted to strengthen pre and post-graduate training of our next generation of pharmacists in the 340B Program, and at the same time promote expansion of clinical pharmacy services in the underserved communities.

So to learn more about our peer-to-peer program, we have resources that are available online, and you'll see noted on your slide deck is that we ask that you go to [www.healthcarecommunities.org](http://www.healthcarecommunities.org) and we have what's called a 340B peer-to-peer community.

And that initially gets you connected to a group of other 340B stakeholders that you can share information with in a listserv format as well as we have what are called national webinars that are now held twice a month starting this October.

And we've, as you'll see on your slide, we've already had a couple of introductory national webinars and they're focused on issues that we are hearing in our call center that we believe would be useful and beneficial for



our peer-to-peers who've been selected as leading sites to tell the 340B community how they've operationalized different components.

So you'll see we have how to make purchasing optimized. Our September webinar, which is going to be held in two weeks, is on Medicaid billing practices, which is a really hot topic around the 340B Program, and we'll also be offering contract pharmacy implementation, and other ways that you can help in preventing diversion by verifying patient eligibility.

So some really exciting topics and we encourage you to go to our Web site and enroll. And this will then get you access to the 1-800 number to join in on this call as well as the live webinar slides that'll be available. We offer these slide presentations and the recorded webinar for everyone to listen in on later.

So if you can't make those specific dates, they are recorded and the slides are made available. So again, we encourage you to enroll in this. It's just another way for you to stay engaged. And more importantly, be engaged with people who are just like your covered entities, so we're really making an effort.

In this coming year, we're looking for hopefully adding some more Title X covered entities who are able to show best practices in how they're implementing their 340B Program. So we encourage you to go to our Web site and learn more about us.

So our applications for 2011 were available when we were going to talk with you in August, but as a result of our call being extended into September, we have actually closed out our application period for 2011, but we do have a space on our PSSC Web site where you can go to join a distribution list so that you can get more information when the 2012 application process is opened.

So the benefits of being an actual peer-to-peer are listed here. And that is that each organization that is recognized through this program receives a plaque and you're also acknowledged in publications as well as on our Web site.

And there's complimentary membership to the American Pharmacists Association for three of your leadership team members in your organization as well as a stipend of up to \$25,000 for those programs that have an ambulatory care or community pharmacy residency program or a student program in pharmacy.

So again, those are some of the benefits of participating in this and then additionally, we utilize the peers that are selected through this program to attend conferences and speak and represent the 340B stakeholders. So the Web site below is how to learn more about the peer-to-peer network, specifically if you're interested in becoming a peer in the future, we encourage you to look at our site.

Again, this is more along program development is that we have several educational programs that are available and these are just some of the examples of partners that we have in developing 340B education.

As I mentioned earlier on our Web site, all of the resources and educational tools are available for free and they're easy to download. If you have questions with the tools, you're more than welcome to call our call center and they will point you in the right direction if you have any issues or questions with how a tool works.

And then I wanted to leave you with an educational partnership that we have, which is called Project Chance.

And this is an area, if you have a college of pharmacy located near your organization, we're encouraging you to reach out to your college of pharmacy, your school of medicine, and develop a program around 340B and how those students can help your organization take care of the safety-net community and have an interdisciplinary team which goes very well in line with what we're doing with the Patient-Safety and Clinical Pharmacy Services Collaborative is building teams to have successful patient care.

So the application for this particular project is due by February of 2012. And we are hoping that if you are interested in this you give us a call and we'll tell you more about that program, but again, another opportunity to stay engaged with the 340B community.

So my last slide here is just our contact information, and I want to thank you all again for attending, and hopefully you've taken a piece of information back so that if you do have questions regarding the 340B Program, and we're not able to answer them today in this format, that you have an avenue now moving forward. Thank you.

I'm going to turn it over now to Mary Ellen England with the Prime Vendor Program.

Mary Ellen England: Thank you, Lisa. Good afternoon, everyone. I think I have an exciting part of the 340B Program to share with you. It will help you to understand where there are areas that you can still continue to stretch your budget.

Next slide please. The Prime Vendor is the value arm of the 340B Program, as mentioned earlier, with HRSA's Office of Pharmacy Affairs bringing you the integrity of the program, the policies of the program, with PSSC helping you

with the knowledge and the access of the program, how to utilize it, the Prime Vendor Program brings you the value.

Where we go in and help you with the cost of some of the medications, we work with the manufacturers to bring you subceiling prices, or sub-340B prices, on the cost of drugs.

Next slide please. Apexus is the company that was awarded the status of Prime Vendor in 2009 for a five-year period of time. We have a mission to leverage the unique purchasing power of all of the 340B stakeholders and to deliver value to you for all of the eligible facilities and public health service organizations that are in 340B to help you get unmatched savings and optimize the performance within 340B.

Next slide please. As many of you have found out who have enrolled in the Prime Vendor, we have a catalog of products and services that we've negotiated with manufacturers, and with other organizations, to bring you a significant discount.

So for medications, we approach manufacturers and asked for an additional discount below 340B, since in this 340B statute, a ceiling price is established. That's where the Prime Vendor begins. We start at the ceiling price and ask for additional savings and pass it on to all of the eligible facilities.

For those of you who are having issues with distribution solutions or wholesalers that will tell you that the amount of purchases is not large enough for them, we help you find wholesale distributors and specialty distributors that really and truly work in the space that you're in.

You may not have large volumes, \$50,000 a week purchases, but maybe you have that special niche, which is the Title X family planning, that needs somebody who specializes in your medications and making sure that they have them available for you whenever you need them.

So we work to help you matchup with a distributor that meets your needs. We also work with drug manufacturers that are not in the 340B space. One of the big areas that we work in is vaccines. The vaccines that are available are not traditionally now covered under the 340B Program.

So based on the input that we have received from many of the participants in the Prime Vendor Program, we have approached all of the vaccine manufacturers, GlaxoSmithKline, Sanofi Pasteur, Merck, and Novartis, and asked for discounts that we can pass along. So we do have Cervarix and we do have Gardasil at discounted prices through the Prime Vendor.

Next slide please. So our strategic initiative is to make sure we increase the value that the Prime Vendor brings to all of its participants. We want to make sure that you're satisfied with the list of products and services that we provide for you and that we keep improving critical elements of our program.

Currently we're working on our Web site to make it much more user-friendly, we're trying to make our catalog easier to search, and provide you with additional opportunities to learn more about the program.

We also work to meet the evolving needs of HRSA. So as new things and new projects come up, if the Prime Vendor is able to help HRSA in meeting some of their goals, that becomes a strategic initiative for ourselves as well.

Next slide please. So many people will ask, what is the benefit that we get? There is absolutely no cost to any facility that's a 340B eligible facility to participate in the Prime Vendor Program. You do not have to change your distributor that you have right now if you choose not to, you can keep the one you have. My slide just went dead.

We pass on to you all the savings that we provide. For some reason my slides are no longer on my computer. I've had to log back in so you'll have to forgive me here. We work to help you in any way we can.

If someone were to call the Prime Vendor Program and ask for input or a longer term contract with the cost of products and services that you use, we would then go back to the manufacturer and try to negotiate either a different contract, one that gives us firm pricing.

Many of the contracts that we have are based on the 340B ceiling price with a percentage off. And some of the prices that we have will give us a definitive price and that is locked in for anywhere from one year to three years. Many of our contracts are three-year contracts that have extensions of one additional year times two years.

So if a manufacturer will say well I'll commit to this price for three years and I will give you the option to extend that price for up to two additional years, but they give it to use at one-year increments. So we try, as best we can, to lock in that price for as long as we can.

The last thing that we do is we provide pricing transparency. On the secured side of the Prime Vendor Web site, we will list what the 340B price is based on the pricing that we get from the wholesalers and then we'll give you what the Prime Vendor price is so that you can see on a spreadsheet, specifically to

Title X facilities, all of the available therapeutic classes of drugs as well as which ones have Prime Vendor subceiling pricing and what is the price that's available from your wholesaler for the others.

Next slide please. So when asked what particular price discounts can we expect on our drugs? The Prime Vendor is now up to about 3800 NDCs with additional discounts. So that is based off of over 22,000 NDC numbers for drugs that's already available in the 340B space.

So we do not have a discount on every single product that's there, but our goal is to have at least one or two products from every therapeutic class of drug that's on the market. So if you were to go to the Prime Vendor Web site in the 14 different categories that's available for Title X, we have at least one product in every single one of those categories.

The key thing to remember about the Prime Vendor pricing is that it is not a rebate. It is an upfront discount so that you will see what the price that you will actually be paying. I mentioned that we have advisory panels. We do have an advisory council for Title X and it's made up of 15 individuals from across the country that represent each of the different regions (unintelligible) the Title X facilities across the country and they represent your interests.

So if you have an individual that you know that is on our advisory council, please feel free to let them know some of your (unintelligible), some of your (unintelligible) for either price relieve or additional products with discounts. They will then bring that back to us when we have our meetings and we work with all the manufacturers of those particular items to see about getting a discount.

I think the key thing to remember is that while the 340B price is (unintelligible) price, making it the Prime Vendor is a voluntary aspect of the program because of the fact that manufacturers already give a discounted price under the 340B umbrella. Then the Prime Vendor goes and asks for additional discounts, we really negotiate hard for you to get those discounts, and not every manufacturer is willing to give additional discounts.

I traditionally am asked about some manufacturers of contraceptives and why do we not have a discount on that? And many times it's because the company itself feels that they've discounted enough. We do go back periodically and revisit every company that does not work with us. Many times they will start with one product, and when they see the benefits of working with the Prime Vendor, they do offer additional products in pursuing years.

Next slide please. So what is covered? We mentioned that it's outpatient prescription drugs only, but it also includes over-the-counter drugs accompanied by a prescription, and then any medications that are administered in your clinic.

For those facilities that have inpatients, inpatient drugs are not included, nor are vaccines. But as I mentioned previously, the Prime Vendor has gone out and gotten contracts for discounts on vaccines, including Gardasil and Cervarix.

Next slide please, so other services that we provide, patient assistance software, auditing and overcharge recovery services.

One of the newest reports that the Prime Vendor has on their Web site is whenever there is a pricing debate that has transpired due to the fact that a manufacturer may have miscalculated, or a wholesaler has maybe transposed



a price on their Web site, and you may have been overcharged, the Prime Vendor goes back and checks every quarter to make sure that all the prices are correct.

We then go back to the manufacturer and the wholesaler to have them correct the pricing so that you are never overcharged. We do have contracts for prescription vials, for labels, for printers for medication, diabetes meters and strips. We have contracts with several companies that will give you the lowest price on strips for diabetes meters that are out there.

For those facilities that need help with automation, we have several contracts with that. And then what we call reverse distribution, which is the return of pharmaceuticals to the wholesaler, the manufacturer, if they are out of date. We do have contracts for those as well.

Next slide please. I'm showing you the current Web site for the Prime Vendor. So if there's anyone out there that is not enrolled and would like to take advantage of the Prime Vendor part of the program, this is what our current Web site looks like.

On December 2, it's going to look entirely different. So currently if you need to apply to register with the Prime Vendor, which allows us the ability to go to your wholesaler and have them download the Prime Vendor prices, you would just click on the Apply Here to Participate button in the upper right-hand side of the screen.

If you are already enrolled, on the lower left-hand side of the screen where it says Participant Login, directly under that if you do not have a username and password, the red sign that says Sign Up, that's where you would go to sign up

for a username and password that gives you access to the secured side of the Web site and allows you to see the entire product catalog.

Next slide please. We have several tools and reports that are on our Web site right now. We have what's called a Best Buy Report that is when you open it, it's an Excel spreadsheet. And if you highlight the column with the price and then utilize the function bar that puts it in descending order, it will bring up all of those items from the lowest price to the highest price so that you could review what particular items have significantly dropped in price.

We also have a section that's just for Title X. And under the Women's Health Section in Title X, what we have done is taken all of the medications that are for Title X clinics and put them on one particular spreadsheet so you don't have to surf the catalog to find the pricing for all of the items that you would be looking for.

Next slide please. On the horizon, I mentioned that our Web site is being updated. We do have a date that we hope to be able to launch it, and that is December the 2nd. We have also started using the social network. The Apexus/340B Prime Vendor is our Facebook page where we post information.

We also have a LinkedIn under Apexus 340B Prime Vendor. And whenever we're having information that we feel is important to send out, we put it on our social networking sites. When we go to major meetings, such as the (NEFRA) meeting earlier, we tweeted, you know, the fact that we were there. Please come and stop at our booth and have questions answered.

We also have taken a new look at our newsletter. We do send out on a monthly basis, the Pharmacy Flash. In the Pharmacy Flash, it's information about the program, information coming down from HRSA, we have

information on government regulations for healthcare, as well as information about our industry partners.

We've started a second newsletter called The Contract News Briefs, and that goes out on a weekly basis on every Friday before 5:30 Central Time, that contains information about new contracts or updates to contracts. If a manufacturer should drop the price lower, we send that out so that you know it in real time, what has happened this week.

The last thing that we have, not only on the horizon, but in real time, is we have started a program in collaboration with Pharmacy Services Support Center and HRSA called 340B University. We are currently updating the University, since we had our first pilot earlier this month.

We are proposing that if you need to have extensive knowledge about the program, to look for on our Web site, the dates for grantees to come to 340B University.

Currently, this year, we've set aside two dates for hospitals, since the hospital eligible group has expanded due to the Affordable Care Act, and next year we will have one in the first quarter for all of the grantees, taking you through and having an opportunity to have more of a hands-on approach to learning about 340B.

Next slide please. Contact information, this is my contact information, my phone number and my email address, as well as Beverly Daniel's, who handles membership, and our customer service hotline. The key thing is, if you cannot remember our phone number when you're out, is it's 340BPVP, 340-2787, and the prefix to that is 888.

At this point in time, we'd like to open it up for you to ask questions. I was given a few questions beforehand and I will throw this out. The first question that came my way was grantees do not know who to call at the Office of Pharmacy Affairs if they need to make changes to their eligibility sites. Who should we contact?

Krista, would you like to take that question?

Krista Pedley: Sure, if you have a change to your site, you need to fill out a Change Request Form, which is available on our Web site. You fill out that form and then we process it as you submit it. If you have any questions though, you can contact Lieutenant Commander Josh Hardin and he can help you through that process.

Mary Ellen England: Okay. The second question I have is, the Nevada state grantee would like to forward along the following question. Are 340B providers required under federal law or regulation to bill at actual acquisition cost or 340B cost of drugs? Lisa, do you want to answer that? That's the only thing that I've gotten on the question, so it's the state of Nevada.

Lisa Scholz: Okay.

Mary Ellen England: And are we required to bill at acquisition cost for 340B priced drugs?

Lisa Scholz: Okay. So, Mary Ellen, this is Lisa, can you guys hear me?

Krista Pedley: Yes.

Mary Ellen England: Yes.

Lisa Scholz: Okay, good. I'm sorry, I'm traveling in route to the airport, but regarding that question with Nevada, and I'm going to make the assumption that the caller was asking about Nevada State's Medicaid and whether or not their Medicaid program requires them to bill at acquisition or at 340B.

And currently, as a report went out this past August regarding state Medicaid programs and 340B is that, it is up to the covered entity to work with their state to determine what their state's policy is on their billing procedures, so each state takes on that responsibility.

And OPA encourages covered entities and states to work together to create those billing processes and that they're communicated so that the covered entities know what the state's preference is. And, Krista, you may want to elaborate on that a little bit more, but I think right now we're really pushing for the covered entities to work within each of their respective states.

Krista Pedley: No I think, Lisa, that's spot on. We recommend that you follow the state policy. The OIG report that Lisa's referencing is on our Web site and they came to found that not all states have policies in place, but they will be in the future, encouraged to do so.

And we encourage covered entities to work with the state to find a win-win partnership so that the reimbursement rates are appropriate for both the covered entity and for the state, so I recommend you read that OIG report. It's very helpful and it identifies which states have policies in place.

Mary Ellen England: Thank you. I'll answer the next question. Could we ask the explanation on where we are with negotiating discounts for Ortho products and Durex condoms?

We actually, at the Prime Vendor, have contacted ortho several times. They have not come to an agreement yet with working on us with their Ortho-McNeil. And Durex condoms, we do not have a contract with them, but if you go to our Web site, we do have two other condom manufacturers that we have on contract.

Okay. Next question, what are the restrictions, if any, on requesting patient contributions on items purchased through 340B and/or the Prime Vendor Program? Krista, would you like to handle that one?

Krista Pedley: Could you repeat that Mary Ellen?

Mary Ellen England: Sure. What are the restrictions, if any, on requesting patient contributions on items purchased through 340B? Sounds like a co-pay or...

Krista Pedley: Yes, I'd have to get back to you on that one. I'm guessing that that's what they mean, but I'm not sure.

Mary Ellen England: Okay.

Krista Pedley: It would be up to the entity to determine those co-pays or what type of insurance they have, so I'm not clear on the question.

Susan Moskosky: Okay. Moderator, if you would like to open up the call to additional questions.

Coordinator: All right, thank you. We will now begin the question and answer session. If you would like to ask a question, please press star 1, please unmute your phone, and record your first and your last name. Your name is required to introduce your question. To withdraw your question, you may press star 2.

Once again, if you would like to ask a question, please press star 1. One moment please for our first question. Our first question is from (Laurie Patterson). Your line is now open.

(Laurie Patterson): Yes, my question is whether or not we can purchase private stock for insured people using 340B purchasing rates?

Mary Ellen England: As far as the vaccines are concerned, as long as you are a Prime Vendor participating facility, you are allowed to purchase under the Prime Vendor vaccines contract. And as long as you are following the agreement that we have with the manufacturers, you can use the purchased products for all of your patients.

With vaccines, because it is not a 340B covered item, the contract that we have stipulates that you can use vaccines for your employees. And should you decide to do, such as a flu vaccination program at your facility, you can also open it up to the community, but that strictly goes with only vaccines. As long as you are purchasing for patients of your facility, then you can utilize 340B drugs for them.

(Laurie Patterson): Okay, thank you.

Mary Ellen England: Okay.

Coordinator: We have no further questions at this time.

Krista Pedley: Well this is Krista Pedley, again, I just want to thank everyone for tuning in today and really encourage you all that if you have questions, to contact Office of Pharmacy Affairs, PSSC, or Prime Vendor if you have any follow-up questions.

We are really here to help, not only get you into the program, but to make sure you're optimizing the program to the fullest extent and to ensure also that you're able to stay in compliance with the program. We're also always open to suggestions. If you feel it would be helpful for us to have certain FAQs on our Web site or to clarify any points that may be confusing, we'd be happy to address those with you directly.

And then also with everyone else so that we can expose everyone to those clarifying points, Sue, did you have any closing thoughts or comments?

Sue Moskosky: No, I didn't. I just want to thank you and the other presenters and also thank all of the grantees and staff who participated. Hopefully this is a much better experience for you than last time.

And again, hopefully, I know that with us both having OPA as acronyms, Office of Population Affairs and Office of Pharmacy Affairs, that you were clear on them that when Commander Pedley and the other folks were talking about, when they said OPA they were talking about Office of Pharmacy Affairs.

So I just want to make sure that if anybody has questions, again, you know, please feel free to contact the Office of Pharmacy Affairs directly or if we can help in any way.

If you have additional questions, because I recognize that a couple of the questions that were asked are probably more on program functions that actually are policy calls that reside here in the Office of Population Affairs, so be sure to let us know if you have questions of us as well.



And again, thank you to everybody, and in particular to our friends from the Office of Pharmacy Affairs, and Apexus, and Pharmacy Support Center, so thanks so much.

Mary Ellen England: Thank you very much, everyone.

Coordinator: This now concludes today's conference. You may disconnect at this time.

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