My first question is, Chris, tell us how the 340B Program was affected by the Supreme Court’s ruling at the end of June?

Chris: I think that’s hard to say at this point. A lot of people ask the question about if the Affordable Care Act would have been repealed if it would have had a major impact on the program. We really don’t know. There is ongoing debate on whether, with the expansion of the Affordable Care Act and everybody having supposedly insurance after 2014, that there may be less need for the 340B Program and maybe time has passed the program by; it’s obsolete – no longer needed. I don’t think that’s the case at all because the Affordable Care Act, there is probably still going to be 40 to 50 million in the country (assuming the Act was unchanged at all with Congress’s vote), there would still be 40-50 million uninsured patients in the country anyway. And then on top of that, even with insured patients and the Affordable Care Act, we all know that many patients (even if they have insurance) they are under insured or they are unable to pay for their copay. So, it’s a choice between whether or not they’re going to eat or whether they’re going to get their medications or get healthcare. And many opt to eat versus getting the healthcare. So the 340B program is needed regardless of what was going to happen with the Affordable Care Act. And after the final vote, the one thing that did change was the requirement for the Medicare Programs to engage. We could see and are already seeing many of the program expansions in doubt now so Medicaid is covering many of the uninsured patients so that puts a lot of these patients in question as to where their healthcare is going to come from. So, 340B and safety net institutions are probably --- again, the role is going to be very vital for to providing healthcare for all patients in the country.

Tell us a little bit about what it is about the 340B Program that is challenging pharmaceutical manufacturer’s right now.

Chris: As far as challenging (the key word there), obviously the manufacturers are concerned about the growth of any federal programs because there are steep discounts associated with federal programs, whether that’s the VA program, the Medicare Program, the Medicaid Program or 340B. So, all of these are federal programs and there are steep discounts involved either through rebates or through direct models that concern the industry. The industry’s
margins are in question. It’s kind of like the last free market is disappearing on them in the country. It’s a global market and the industry is very concerned about that. And probably there is concern there because the Affordable Care Act, number one, expanded the number of 340B entities that are eligible to join the program. You are probably aware that there is a number of 340B hospitals, community health critical access hospitals, or referral centers and sole community hospitals that were eligible to join the program as a result of the passage of the Affordable Care Act. That is some of the growth that we’re seeing.

The other is that the entities are expanding operations. This is out of necessity. A lot of the patients in the country rely on these safety net institutions for care. Declining reimbursement in the marketplace with private physicians has driven more and more patients to the safety net institutions and they are having to expand their operations in order to care for the patients. So, that also contributes to the expansion of 340B. A good example is a number of hospitals expanding their oncology divisions, maybe buying up private physician practices. There are a lot of drivers involved with this. One is the declining reimbursement of private providers that’s causing the shift. That’s causing concern and then the hospitals are obviously having to expand their operations to meet the needs of the patients.

**So, do you see the pharma companies, do you think they view this as an opportunity or do you think they view this as: “Oh, now we have to offer even more of our products at a lower cost?”**

*Chris: I think it could be seen both ways, but I think it depends on who you’re talking about. If you’re talking about big pharma, the branded pharmaceutical manufacturers, I think the first concern is probably more about the growth of the program and expansion of the program and having to extend those discounts to the customers. With generic manufacturers, I don’t think it’s as great of a concern because in the free market it’s highly competitive and the way the drug wholesalers are negotiating contracts and all, there are steep discounts available on generics. Sometimes the free-market pricing can actually be lower than the PHS 340B ceiling price of a product for a period of time until those time lags catch up with it (with all of the formulas that are coming into play with drug pricing). So, the free market with generics is already pretty competitive in driving pricing down. But with branded companies, this is a different scenario and that’s where the greatest concern comes in.

Now, one thing that I’ll add to this as far as growth that is also a concern is the growth of contract pharmacies. That was a change that the Office of Pharmacy Affairs made back in 2010 that will allow multiple contract pharmacies in order to improve access for a lot of these safety net organizations that operate their own pharmacies. And that in itself has contributed to some significant growth of the program because we’ve seen some change like Walgreen’s,
Wal-Mart, CVS get involved in the program now and that has contributed to some growth beyond just growth in the industry.

**So, how does that affect the pharma manufacturers?**

**Chris:** Well, sure it does because let’s just say that the same number of entities may be involved with the program through their own in-house pharmacies and then if they go and they do a contract pharmacy scenario to supplement their own network, that will grow the number of prescriptions that are actually being filled to the 340B program and the number of discounts that those manufacturers have to honor because the manufacturers are having to honor 340B discounts whether it’s being filled in an in-house pharmacy or if a hospital or a clinic networks or partners with retail pharma or independents, as well, in the community. They have to honor those discounts just like it’s the covered entities discount.

**You mentioned that that was something that the OPA changed in 2010. What, if anything, can the industry prepare to expect from OPA in the coming months?**

**Chris:** You may be aware that OPA has initiated random audits effective in January of 2012. They’ve done a little over 50 audits. They are on pace to do about 6-8 audits a month. So, that is an ongoing activity. We are now in July and almost in August and we have no results from these audits at this point. So, what’s happening is these audits have been conducted by the Office of Regional Operations and they are being reviewed by the Office of Pharmacy Affairs to come out with final reports that can be shared with customers and then made available publicly on the HRSA website. There is a section on program integrity on HRSA’s website where all this information is going to be posted. We haven’t gotten any of the results yet, so that tells you that there are some things that are having to be worked on internally at the Office of Pharmacy Affairs. There probably needs to be a little bit more clarity by all stakeholders because we also have manufacturers that are in the process of conducting their own audits if they get the approval of the Office of Pharmacy Affairs. So, we are going to have to have clarification on things – GPO exclusion and definition of patient for all the stakeholders in order for the entities to prepare for audits and put in good systems. And also for HRSA and manufacturers and others to actually participate in audits and to take any action on those things. We are going to have to have clarity on some of these things that are still in the grey area, if you will, and open to interpretation.
So, audits are going to be a big thing in 2013?

Chris: Absolutely. In fact, as you are probably aware there is actually a pending RFP out right now due August 8th or 9th (the responses to this RFP) around auditing activity to support HRSA in their integrity initiatives.

Great. We’ll definitely keep our eye out for that. Now Chris, you have been working with us on the MDRP Summit for a while now. Tell us, what will our audience expect to learn there? Why should they attend?

Chris: Well, obviously it is a good opportunity to network with different stakeholders in the industry who find it very valuable and interfacing with the drug manufacturers. Also, engaging some of the leaders in the Medicaid community because of the opportunities with 340B creating win/win scenarios with states and Medicaid programs. So, those are some of the pluses.

HRSA also attends this Conference. A lot of conferences they can’t attend, but they can attend this one. We will be co-presenting with them, so they will be able to hear the latest updates from HRSA and how integrity initiatives in the audit are a priority for the department. It’s very critical to the program overall.

You are going to hear not only the latest updates from HRSA, but the latest updates from us (Apexus, the Prime Vendor) and some of the different things that we’re doing to support all the 340B stakeholders, solutions for the manufacturers when it comes to manufacturing of refunds and then we are also doing a number of things with the 340B University and Apexus Answer Call Center, which have been opened up to all stakeholders. So, we are becoming a valuable resource for the industry, as well.

Anything else that you think our audience would like to hear? Anything that you would like to add?

Chris: Well, as far as resources and any additions, the Apexus website is certainly a resource for the suppliers. We have FAQs, commonly asked questions that are going on in the 340B market. We also have a Pharmacy Flash Newsletter that anyone can sign up for and they’ll get a copy. It comes out once a month in the beginning of the month and it’s about --- we try to cover all the latest in 340B.

The 340B University is on our website and we’re talking about the sessions we’re having is August (October and December are the next sessions).
Apexus Answer Call Center is open to any stakeholder to call and those questions are vetted by OPA. So, that is a source of truth for getting the right answers to the questions in the marketplace and that’s at 888-340-2787.

Don’t forget HRSA’s website: www.HRSA.gov/OPA That’s for all the fundamentals of the program and you’ll learn about all of HRSA’s integrity initiatives there.

Also, www.healthcarecommunities.org is another website that the government has established to put a lot of resources out there for the entities.

And last but not least, you’re going to hear more about the manufacturer’s workgroup on 340B integrity at the Conference and this is being headed up by David Brown at GSK and Marcus Farbstein at Genentech. They will be talking about a number of the things that they will be working on with OPA to support the integrity initiatives.