David Glendinning (00:12):

340B Insight, from 340B Health.

Hello from Washington DC and welcome to the very first episode of 340B Insight, the podcast about the 340B Drug Pricing Program. I'm David Glendinning with 340B Health. This isn't quite how we envisioned 340B Insight starting. After all, I'm speaking to you from my home office. But despite the challenges we're all dealing with, we remain committed to providing you with the best information you need to run your 340B Programs and take care of your patients. And we hope that is valuable to you not only during this COVID-19 pandemic, but also once we are past it.

I'm very excited that our first guest on 340B Insight is Rear Admiral Krista Pedley. But before we go to that interview, let's take a minute to talk about the latest news on 340B.

Despite protests from hospitals across the country, the centers for Medicare and Medicaid Services is going ahead with its controversial survey of 340B hospitals on their drug acquisition costs. This is a CMS strategy to justify deep cuts in Medicare Part B drug payments to many 340B hospitals. You might recall that those cuts are the subject of a pending federal appeals trial, but in the meantime, the CMS survey is going ahead and could lead to future cuts. You can find several 340B health resources about this issue in the show notes. Meanwhile, on Capitol Hill, lawmakers continue to discuss 340B policy issues as they talk about the next steps and the response to COVID-19. Representatives, Doris Matsui, a Democrat from California and Chris Stewart, a Republican from Utah, are the lead authors of a bipartisan letter to House Leadership on 340B. It asks leaders to include provisions in the next coronavirus legislation that would prevent certain 340B hospitals from losing access to the program because of the shifts in patient care during the pandemic. And in the Senate, Republican Ben Sasse from Nebraska is pursuing legislative language that would provide flexibility in this area as well. Again, you can find out more on our show notes for this episode. And federal pandemic assistance and stimulus money continues to flow to hospitals and other healthcare providers, including some of those participating in 340B. The government is using various metrics to determine who receives the money and how much, and not all the $175 billion in health provider funding has gone out the door yet.

Today's feature interview is with Rear Admiral Krista Pedley. She is Director of the Health Resources and Services Administration’s Office of Pharmacy Affairs or OPA for short. Our president and CEO here at 340B Health, Maureen Testoni, recently spoke with Admiral Pedley on a range of subjects. Here's what she had to say.

Maureen Testoni (03:01):

I'm Maureen Testoni, the president and CEO of 340B Health. I am thrilled to introduce our very first guest. Admiral Krista Pedley is the Director of the Office of Pharmacy Affairs in the Health Resources and services Administration. Her office administers the 340B Drug Pricing Program, which requires drug manufacturers to provide outpatient drugs to eligible safety net providers at reduced prices. Admiral Pedley began her career as a pharmacist in the United States Public Health Service in 2000, and recently she received a distinguished and well-deserved promotion to Rear Admiral in the US Public Health Service. Admiral Pedley, welcome to 340B Insight. We're excited to have you as our first guest. Admiral Pedley, can you please tell the audience a bit about the Office of Pharmacy Affairs?

Admiral Pedley (03:58):

Hi, Maureen, and thanks for having me on today. I really appreciate it. I'm so excited to be your first guest. The Office of Pharmacy Affairs, or OPA, oversees the 340B program by ensuring that covered
entities are able to utilize the program to stretch their scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Our office is headquartered in Rockville, Maryland, and we have 25 staff who work on a variety of issues in the program from registration and operations, to information technology and systems, to audits and policy. We’re also a mix of both Public Health Service Commissioned Corps officers and civil service employees.

Maureen Testoni (04:44):
Terrific. The COVID-19 pandemic has created unprecedented challenges for everyone, especially healthcare providers. OPA has provided flexibility for 340B hospitals so they can focus on patient care. Can you tell us a little bit more about the flexibilities that you've provided?

Admiral Pedley (05:02):
First, I want to thank all the providers on the front lines and those supporting them. You're all doing amazing work and it's so much appreciated. HRSA understands that many of the 340B stakeholders are concerned about the evolving impact of the COVID-19 pandemic and the impact on program implementation and compliance. We also understand the critical role that the entities are playing at this time more than ever, which is why we’re providing targeted technical assistance that supports the unique situations of each covered entity that contacts us.

So, in each of these situations, we're evaluating the circumstances to ensure that entities are able to maximize all possible opportunities to participate in the program during this challenging time, while also maintaining program compliance which is very important. We've also proactively provided certain flexibilities for entities to ensure that they can remain focused on patient care. For example, we've moved towards conducting 340B audits remotely for the next several months as we monitor and assess the impact on those entities. So if a covered entity has specific concerns regarding their audit when contacted, they should reach out to the Bizzell Group, which is the 340B audit contractor. The Bizzell Group will coordinate with HRSA to provide necessary flexibilities, including potential postponement or cancellation of that audit.

Maureen Testoni (06:27):
Thank you. We have heard from some hospitals who asked to have their audits postponed, and they have been able to do that. And also others that went through with it but under some of the remote options that the Bizzell Group is offering as well. So they certainly appreciate that flexibility. And your webpage does have a lot of information on it which is very helpful. You've recently announced that HRSA was limited in its ability to enforce 340B rules through audits. Can you tell us more about how you believe HRSA is limited in its enforcement ability?

Admiral Pedley (07:01):
We’ve recently completed an evaluation of our audit process, and our other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in a program that's primarily administered by guidance. HRSA's enforcement ability is limited, as you stated, and guidance does not provide HRSA the appropriate enforcement capability. We place the highest priority on the integrity of the program. And we continue to enforce the statute to the greatest extent possible. The agency's audit process consist of reviews of the statutorily required program integrity elements that include eligibility, diversion, and duplicate discount prohibitions. HRSA believes its program policies are sound. We are unable to enforce guidance unless there’s a clear violation and tie to the statute. Therefore, we have to
evaluate each audit and any noncompliance on a case by case basis to determine potential findings and violations of the statute.

Our limited enforcement capability is also why we’ve requested regulatory authority in the president’s budget each year since fiscal year ‘17. Binding and enforceable regulations for all aspects of the program would provide HRSA the ability to more clearly define and enforce policy, and would significantly strengthen HRSA’s oversight of the program. So it’s really important to be familiar with that budget request because we have outlined it for quite some time, what our limitations are.

Maureen Testoni (08:30):
Okay, that’s helpful. Switching gears, I want to ask you about something that was a really important issue that you really saw to fruition, and that’s the 340B ceiling price website that you launched a year ago. I can tell you it’s been a really useful tool for hospitals. It helps them to know whether or not they're being charged the correct amounts for drugs. And I'm wondering, what have you learned in the first year of the website's operation?

Admiral Pedley (08:57):
We have now completed four full quarters of pricing adjudication. We continue to learn more and more about the manufacturer reporting practices and CMS reporting requirements. Over the past year, we've captured important trends and learn important lessons with the pricing system. I'll say the communication between HRSA and our external stakeholders in relation to price reporting and price comparison practices, has improved significantly. Manufacturers have expressed their appreciation to submit and verify a published ceiling price that's accessible to the authorized covered entities. Since the implementation of 340B OPAIS, the pricing component itself, we've had a significant reduction in notifications of potential incorrect prices in the market. The increased transparency in 340B pricing is significant for both covered entities and manufacturers. We also continue to use the system internally to monitor manufacturer compliance by performing regular spot checks of prices and any necessary follow-up on pricing errors or discrepancies that we're seeing within that system.

The number of labelers that did not submit data, either because they did not create accounts or did not provide the data within the requested timeframe, has also significantly decreased. In the first quarter of 2020, 95 labelers did not submit data compared to the first quarter of the release, there were 106 labelers, which represented about 6,300 NDCs, did not submit data. So for those labelers who did not submit data, HRSA published a ceiling price solely from the information received from our third party, First DataBank and CMS. So while all labelers are still not submitting, HRSA is still publishing a ceiling price based on the data we have internally. As we enter our second year of the pricing component, we welcome your feedback on system improvements. We know that there are a lot of suggestions out there for how to do that, whether that's how you interface with the system, what you're seeing within that system, we do want to hear from you. And then we'll work to prioritize that based on the features that we're looking at internally as well.

Maureen Testoni (11:17):
That's really interesting. It sounds like from when it started to now, people, manufacturers and others have had to get used to it and that that has really made a difference in terms of allowing everybody to understand what the rules are. I also wanted to thank you. We do recognize that, although it’s been a couple of years, it's still in the process of everybody figuring out what works best, and we appreciate your openness to hearing covered entity comments on that. I'm wondering, do you have any advice for
340B covered entities? Things that they could be doing to make the program successful and your job easier?

Admiral Pedley (11:51):
That's a great question. While we continue to provide oversight of the program, HRSA's goal is to also provide the utmost flexibility to the fullest extent possible to all stakeholders that participate, especially during the pandemic. We value and appreciate again, the work that's done by the frontlines. And we're asking entities to reach out to us if they have any questions or concerns, as we also want to hear from you about what's working, what can be done better to support the stakeholders during this challenging time. The biggest point I want to make is to document as much as possible. Outline your unique situations and how you follow HRSA guidance and your policies and procedures. It's absolutely critical that you do that. Keep auditable records of what makes you eligible to participate, so that you can produce that documentation at any point.

It's important that you all, as covered entities, are in the program, but you have to keep the documentation to support that. It's critical. It's also critical that you have a system in place to track every purchase of a 340B drug to an eligible patient. You need to have that full scope of process in place, that from the time of purchase to the time of dispense, the records support the eligibility of that patient and the purchase of that drug. Those are some key basics to ensure compliance, which is important to ensure that you continue to be able to benefit from what the program has to offer.

Maureen Testoni (13:18):
We certainly see a lot of information up on your website, which we try to make sure we get out to our members as well. So they have multiple ways of seeing it. The COVID pandemic is having an impact on all of us. How are you and your staff at OPA coping with all of the different requirements and new issues that it's raising?

Admiral Pedley (13:36):
So the OPA staff, they're really doing a tremendous job in this new environment of balancing the need to run a successful program while at the same time taking on even more personal responsibility in their homes, including homeschooling their children, caring for a loved one, or in general just dealing with the uncertainty surrounding the pandemic. We, like so many others across the country, are juggling those priorities and are faced with the same realities. So we need to make sure that you all understand that we are also people that are working through this pandemic. We're moms, we're dads, we're kids of elderly parents that are just trying to make our way through it, in addition to keeping the program alive. I'm so proud to be supported by such a strong team and a talented group of individuals to really make what has happened work so well.

I know that I can rely on each of them and we have a lot of trust with each other to be able to work in a professional manner, while knowing that so much personally is going on in all of our lives. OPA also has a special cadre of public health service commissioned officers, including myself, which means that many of us are called to deploy to this public health emergency. And many who have already deployed or are standing by to do so, whether that's supporting the frontline providers, screening at the border and in airports, or supporting headquarters in response to the pandemic. So not only are they making important sacrifices for their country, the OPA staff that are not deployed, have to take on their additional work while they're out of the office and supporting this critical work. So, we also have that dynamic at play as well.
So I'm going to give a special shout out to my team for all that they do to support the mission of this program, especially during this time. We're all motivated by the stakeholders and the work they are doing on the frontlines. We know this program is helping them to ensure we can flatten the curve with this pandemic. And we thank each of you for those tireless efforts. So, thank you for that.

Maureen Testoni (15:52):
That's really interesting to know that your staff, some of your staff have actually been deployed to address the pandemic. That's really interesting. And I believe you have an important anniversary coming up as well, and I wanted to say congratulations. I understand that very soon you will have completed 20 years of service in the public health service Corps, so congratulations. That's a really impressive milestone. I'm wondering, is it possible that you could be deployed and if so are you preparing for that?

Admiral Pedley (16:22):
So, yes, I could be deployed at any point as any officer could be. We are all in essence on standby and have been asked to have our go-bags ready and position our families to assist in response to the pandemic. Whether that's actually going out again on the frontlines, have had staff in a nursing home, or supporting headquarters down in DC at the operation center to help navigate others going out into the field. So there's been a diverse range of deployments and I, as well as every officer, needs to be ready at any point in time. That's why I wear the other hat that I do. And if that duty calls, then we will work to figure that out, but I have a strong team and know what to do to make it happen.

Maureen Testoni (17:15):
That's really impressive. Thank you for that. You have been working with the Office of Pharmacy Affairs for over a decade now in 340B and I'm wondering, during your tenure, if you've seen many changes in the program? How does it compare now to how it was say back in 2010 or earlier for example?

Admiral Pedley (17:34):
I will say that I've seen tremendous change. I believe all for the good in what is occurring through the program, but the intent and the premise has always been what drives those decisions and the program forward. Compliance, as you're aware, has been a focus and critical to ensuring that those that do benefit are doing the right thing with the program. I also think transparency has also been a big focus, I think first with the covered entities and now with the manufacturers and providing that ceiling price system, and how important it is that both sides are seeing the dynamic of what they have to go through and what their challenges are with implementing the program.

Maureen Testoni (18:20):
Yeah, those are two really good points. Definitely compliance and transparency have been big focuses over the past decade. I'm also wondering, you have to work with all stakeholders in 340B including both covered entities and manufacturers, and often covered entities and manufacturers have very different views on key 340B policies. I'm wondering how do you approach those situations?

Admiral Pedley (18:42):
So, what's important from my standpoint is to listen and to listen to all sides of a situation, and the pros and cons and benefits and pitfalls to all the different stakeholders regarding different practices or policies before we consider a way to move forward. Because there are such diverse views on how things
should be implemented in the program. And I'm truly convinced that while it often seems that there may be differing sides to a situation, that there is common ground in a lot of what we put forward. HRSA always ensures we're grounded in the statute as we make these decisions. But again, important that we just listen to those stakeholders to hear them out, understand their concerns and find a path forward.

Maureen Testoni (19:33):
Great. And 340B, as you mentioned, has been really under a spotlight for the past several years, and you've been called to Capitol Hill for many briefings and to testify at hearings. Yet, you've really remained committed to 340B for a long time. And I'm wondering, with all the stress and all the oversight and everything involved with 340B, may I ask you why you stay in your position?

Admiral Pedley (19:56):
So what grounds me every time to that question in which I am often asked, is the intent of the program and how important it is for the stakeholders, for the community, for the safety net, to ensure these safety net hospitals and clinics around the country are receiving discounted drugs and providing them to their patients. And that's what brings me back every time. There has been a lot of stress. There has been a lot of points throughout the past 10 plus years where it been quite challenging, but seeing that through and having the context necessary, it's important that the program is where it is, and what continues again to bring me back, is how important the program is. And that's why I stay.

Maureen Testoni (20:43):
Great. Well, we're certainly glad that you do. I consider your term at OPA to be really impressive. It's not just that you started doing audits at both covered entities and manufacturers, you've also started recertification. You launched a ceiling price website. You've done a number of policy releases to make guidance more clear for both covered entities and manufacturers. So we appreciate all the work that you and your staff do to help maintain the 340B program. So, thank you very much, Krista Pedley.

Admiral Pedley (21:10):
Thank you. Thanks for your time.

David Glendinning (21:12):
Thanks again go to Admiral Pedley for taking the time to speak with us. We hope you enjoyed our first episode of 340B Insight. We want to hear your feedback and any questions you might have about 340B. If you send us a question, we just might answer it on an episode of our podcast. Please email podcast@340bhealth.org, that's podcast@340bhealth.org. We will be releasing episode two in just a few days. After that, we plan to settle into our schedule of releasing a new episode about once every two weeks. So be sure to subscribe on your favorite podcast player so you get all the episodes right when they come out. Thanks for listening and be well.

Speaker 4 (21:55):
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