David Glendinning (00:14):
Hello from Washington, DC. And welcome back to 340B Insight, the podcast about the 340B Drug Pricing Program. I'm David Glendinning with 340B Health.

David Glendinning (00:24):
On today's episode our feature interview is with one of the nation's leading experts on 340B. Maureen Testoni is the president and CEO of 340B Health, which represents more than 1400 hospitals that participate in 340B, in urban areas and rural areas and everywhere in between. She's also my boss. Our own Myles Goldman talked with Maureen about several topics, including how COVID-19 is affecting 340B hospitals, the current state of the program, and even what inspired her to become involved in 340B. Let's hear what Maureen had to say.

Myles Goldman (00:58):
Hello, I'm Myles Goldman from 340B Health, and I'm joined by the president and CEO of our organization, Maureen Testoni. Maureen has been leading 340B Health since April, 2018, and prior to that was the senior vice president and general counsel at the organization.

Myles Goldman (01:16):
Maureen is nationally recognized for her expertise on the 340B Program and was named by Modern Healthcare in 2018 as one of the 100 most influential people in health care. Maureen, I'm looking forward to discussing with you the state of 340B during these challenging times. Welcome to 340B Insight.

Maureen Testoni (01:36):
Thank you for having me, Myles.

Myles Goldman (01:38):
As I mentioned in your bio, you've been involved with 340B for nearly a decade. How did you become interested in 340B and what makes you passionate about advocating for the program?

Maureen Testoni (01:51):
So the most important thing to me about the program is the fact that it is intended to help those hospitals that help low income people to get healthcare. And that is really what makes me passionate about the program, making sure that people really do have access to the healthcare that they need.

Myles Goldman (02:10):
I've been involved in healthcare my entire professional career. Every job out of college has been focused on healthcare, from working on the Hill in the early nineties and working on these kinds of issues. To becoming a healthcare attorney where I represented a number of different providers, a lot of both large and small providers, from hospitals down to small community health centers in terms of also their ability to provide healthcare. So issues around Medicare, Medicaid and that type of thing. And it allowed me to really see some of the challenges that those kind of entities have with providing care.

Myles Goldman (02:47):
These are obviously very challenging times. The COVID-19 public health emergency is an unprecedented challenge to the entire country, and especially to safety-net hospitals that are caring for patients on the front lines of the pandemic. You interviewed Admiral Krista Pedley, Director of HRSA’s Office of Pharmacy Affairs in our first episode on this topic. What is your analysis of the actions HRSA has taken so far to provide flexibility to 340B providers?

Maureen Testoni (03:16):
Well, I commend HRSA for the actions that they’ve taken. When this really started to take over the country, we reached out to HRSA and expressed some of the concerns that we had for our members about some various issues in the 340B rules and regulations that made it difficult to do what hospitals needed to do to treat their patients. And HRSA was definitely responsive to that, and they made a number of changes in order to help hospitals.

Maureen Testoni (03:46):
So for example, there are various drug shortages going on, which is very difficult for 340B hospitals, because for most of the hospitals, by being in the 340B program, they are limited as to where they can purchase drugs from. And one thing that HRSA did, we’d asked them to do, is they reduced the documentation to allow 340B hospitals to purchase drugs from their group purchasing organizations when they are in shortage situations.

Maureen Testoni (04:17):
There are also issues, hospitals have had to really change the way that they deliver care. They’ve had to do things like move their clinics, or their outpatient clinics, to a different site. And so, one thing that HRSA has allowed hospitals to do is to register those locations more quickly. They have also made it clear that telehealth is something that 340B hospitals can absolutely do and use 340B for drugs that are prescribed as a result of those visits. That has been very helpful.

Maureen Testoni (04:51):
So we’re pleased that they took some of the actions that we had asked to make it a little bit easier for hospitals to manage the 340B compliance, and also changing things in the way that they need to, to help their patients with COVID-19.

Myles Goldman (05:07):
And one of those areas of flexibility is around telemedicine, right?

Maureen Testoni (05:13):
Yeah. So telemedicine is something that has been permitted under the 340B Program, but hospitals just have not been using it anywhere near to the scale that they are using it now. So some of the hospitals are much newer to telemedicine and there have been a lot of questions about, well, if the physician is not in the same room with the patient, does that really count then for 340B purposes? Does that meet the definition of patient for 340B purposes?

Maureen Testoni (05:42):
And the answer is yes, that absolutely can. And what hospitals should do is document in their policies and procedures what their standards are for telemedicine, and why those patients still count as their patients.

Myles Goldman (05:54):
Are there further actions you'd like to see HRSA take?

Maureen Testoni (05:58):
There are actions I would like to see taken, and I think there's maybe a difference of opinion between 340B Health and HRSA on things such as the interpretation of the GPO prohibition. For example, the GPO prohibition is in the statute that it says, for many of the hospitals in the 340B Program, if they want to participate in 340B, they cannot use their group purchasing organization for outpatient drugs.

Maureen Testoni (06:25):
Our legal interpretation of that is that it can't be a regular thing that you do all the time. We would like them to see them take a more open position, at least through this pandemic. They have waived a lot of documentation, but that still puts hospitals in a position of having to buy drugs that they can't get at 340B at a much more expensive price than they would otherwise be able to purchase through their GPO, which offers them a discount.

Maureen Testoni (06:55):
Another thing I would like to see is for new clinics that are being opened, if it's a brand new clinic that has not yet been on the hospital's cost report, there are limits under current rules for how hospitals, whether hospitals can actually use 340B in those locations. Now I do believe that HRSA is offering more flexibility on that if it's set out in your policy procedures, but we would love to see more explicit recognition of that situation. So that hospitals aren't wondering exactly what HRSA's take would be if they were audited.

Myles Goldman (07:34):
We've been hearing a little bit about an issue around maybe eligibility for DSH hospitals specifically. Can you speak a little bit to that?

Maureen Testoni (07:43):
Sure. So the issue with DSH hospitals, in order to be part of the program, you have to be seeing a lot of Medicaid or low-income Medicare patients. What hospitals are having to do with all of their care is postpone anything that is not an emergency. And what that does is it can have an impact on the percentage of Medicaid or low-income Medicare patients that they are seeing. And it's affected their payer mix in a way that makes them very concerned about whether they will continue to qualify for 340B.

Maureen Testoni (08:22):
And that's a big risk because if you don't qualify and you are aren't in the program, you have to wait a whole year before you are able to try to apply to get into the program again. So that would mean a whole year of not getting 340B discounts for these hospitals, which for many of them, they are already
in the red. Or just barely in the black and are providing a lot of charity care. That's something that could be really devastating for them.

Myles Goldman (08:53):
Can you talk about how we've been working to support our members during the pandemic?

Maureen Testoni (08:58):
We contacted HRSA, we worked with HRSA to achieve some of the flexibilities for hospitals that I discussed earlier. We've also reached out to the Secretary of HHS and also asked for various flexibilities. We are also working with Congress to address some key issues like this DSH percentage issue and other eligibility concerns, in order to see if we can get legislation that would waive that eligibility requirement. Basically put a pause on it for the period during which the hospital is operating during the pandemic.

Maureen Testoni (09:34):
And we also have a number of resources that we have developed for our members on this. So we have a resource center on the 340B Health website that is dedicated to COVID-19 issues. Many of them are 340B specific. Some of them are hospital specific, but maybe not even necessarily 340B specific. The government and HHS has done a number of things to waive different regulations and other requirements for hospitals. And we are including that information up on our website as well.

Myles Goldman (10:05):
And as important as COVID-19 is, and that is where we know our members are spending a lot of their focus right now, there are some other issues taking place in 340B as well. What are the top issues that we should be keeping an eye on?

Maureen Testoni (10:23):
One thing that happened very recently, and that was disappointing, was that CMS released a survey for most 340B hospitals, that does not apply to critical access hospitals, but all other hospitals were asked to complete a survey on what their cost is of acquiring 340B drugs. And this is a survey that really relates to something that CMS has been working on for the past couple of years, which is they would really like Medicare to pay less to 340B hospitals. And they started implementing reductions in payment a couple of years ago. Hospital organizations and hospitals sued CMS, and they have won twice in court, in the lower court. And now it is at the appellate court where it's been argued and we're just waiting for a result.

Maureen Testoni (11:18):
So there is a chance that that CMS could lose that lawsuit. That lawsuit, much of it is based on the fact that when CMS cut the payments to hospitals, they did not follow the right procedures. So CMS seems now to be saying, "Okay, we're going to try to follow some of the requirements that the law requires that we do." One of which is to really try to come up with an accurate estimate of what the costs would be for a 340B hospital, before we try to set prices.

Maureen Testoni (11:52):
Now CMS had made clear though, it doesn't seem like they're just trying to get the costs, it seems that they really want to establish a payment level at those costs or very close to those costs. We and other
organizations had asked CMS to postpone issuing this survey during this COVID-19 pandemic, because it is just so burdensome. There are literally thousands of pieces of information that hospitals would have to review in order to be able to really complete the survey.

Maureen Testoni (12:23):
They are giving an option to hospitals to be able to do a quick survey instead, where you just basically press a button. But as part of that, you're agreeing to certain things that I think many hospitals have told us they are not comfortable with agreeing to. We could see CMS try to act on the data they get from the survey, the earliest we would see that would be July when CMS proposes changes in reimbursement for outpatient drugs. That would come out in July and then it would be finalized in the fall. So 340B Health will certainly provide analysis for our members and we will provide template letters for our members to be able to communicate with CMS on this. And we'll be looking at potentially other advocacy and legal recourse as well.

Maureen Testoni (13:15):
The second issue that is also being considered by Congress has to do with cutting Medicaid reimbursement to 340B hospitals. And there is a proposal that has been passed that would do that, that would reduce Medicaid reimbursement for Medicaid managed care to 340B hospitals across the board.

Myles Goldman (13:37):
We're in the early months of a new decade, one that's had of course, a lot of surprises already. But what trends in healthcare do you see affecting 340B over the next few years?

Maureen Testoni (13:50):
So that's a great question. Certainly one of the big issues, one of the big trends, is the push to move care out of an inpatient hospital setting to outpatient settings. So the fact that more care can be done on an outpatient basis just makes 340B that much more important, because 340B applies only to outpatient drugs. When 340B was enacted in 1992, a lot of things had to be done on an inpatient basis. I mean, chemotherapy was largely done on an inpatient basis. If you had an organ transplant, you have to get drugs regularly to help with that. And that was on an inpatient basis. That has all, or much of it, has moved to outpatient. So that has had a big impact on 340B.

Maureen Testoni (14:38):
Also, as we are moving away, another trend that we're seeing, is drugs sometimes taking the place of invasive procedures. So again, done on an outpatient basis. And one thing with a lot of these drugs that we're seeing is they're coming out at a really high price. I mean, they're the drugs, they're the miracle drugs. They can do things that we wouldn't have thought with the way things could be done 50 years ago, but they're just so, so expensive. Those are some of the trends that I see playing a role around 340B in the coming decade.

Myles Goldman (15:16):
Well, it'll certainly be interesting to see how those evolve over time. I wanted to end today with a more personal question. What might 340B Health members be surprised to know about you?

Maureen Testoni (15:31):
340B Health members might be surprised to know that I am fluent in Spanish, that I used to live in Argentina. My father was from Argentina. He came over here as an adult where he met my mother, who also came to this country as an adult from Northern Ireland. So I am first-generation, and I went to middle school in Argentina and still have a lot of family over there.

Myles Goldman (16:00):
Maureen, thank you so much for taking the time to speak with us today.

Maureen Testoni (16:05):
Thank you, Myles. Thank you very much for having me.

David Glendinning (16:07):
Our thanks again to Maureen Testoni for joining us on 340B Insight. We plan to have regular segments on this podcast where we answer some of your questions about the 340B Program. You can email us at podcast@340bhealth.org. Again, that's podcast@340bhealth.org. And if you have a topic you'd like us to cover on a future episode, please email us as well.

David Glendinning (16:31):
If you missed our first episode of 340B Insight, Maureen Testoni spoke with Admiral Krista Pedley, the Director of the Health Resources and Services Administration's Office of Pharmacy Affairs, which oversees the 340B Program. Be sure to check that out in your feed or on our website. We'll be back in just a couple of weeks with our next episode. Thanks for listening and be well.

Speaker 1 (16:57):
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