Welcome to 340B Insight from 340B Health.

David Glendinning (00:15):
Hello from Washington D.C., and welcome back to 340B Insight, the podcast about the 340B Drug Pricing Program. I'm David Glendinning with 340B Health. This episode is sponsored by Sentry Data Systems. Since 2003, Sentry has been providing health care organizations with 340B management and compliance solutions that help you make better business decisions. They bring you more than just software solutions and technology. They deliver passion, expertise and partnership every step of the way.

Our guest today is Maureen Testoni, the President and CEO of 340B Health. We first had Maureen on the podcast for our second episode back in May to discuss the current state of the 340B Program. Since that time there has been no shortage of important developments for the program. They include a major decision in a federal court case, a preview of how much Medicare might pay covered entities in 2021, and some legislative news from Capitol Hill.

But before we go to that interview, let's take a minute to answer one of your questions about 340B. One of our listeners asks, "I hear that 340B recertification is going to look different this year than it has in years past. What is changing this time?"

For the answer, we went to our own Steven Miller, the Vice President of Pharmacy Services here at 340B Health. Steven notes that 340B recertification is an annual process that all hospitals must go through to attest their continued eligibility for discounted drugs and ensure that their registration information on file is accurate. It is one of the most important ways the Health Resources and Services Administration conducts oversight of the 340B Program. This year, recertification starts today, August 17th, and runs through September 14th.

In one new element to the process, hospitals that are changing their current classification will need to submit documentation for this change during recertification, instead of through a follow-up request. HRSA also is adjusting the way covered entities indicate whether they will be using 340B drugs for out-of-state Medicaid patients. As part of that clarification, some hospitals might need to identify the states associated with certain national provider identifiers listed in the hospital’s Medicaid exclusion files. Steven tells us these changes are designed to cut down on the potential for duplicate discount findings involving the use of 340B for out-of-state Medicaid patients.

If you are a member who missed our recertification webinar last week, you can find out more information about this year's process in the show notes for this episode.

Now for today's feature interview with Maureen Testoni. Our own Myles Goldman sat down with Maureen to talk about some of the big 340B developments that have occurred since we last had her on the show. Let's listen in to that conversation.

Myles Goldman (03:16):
Thank you, David. I'm Myles Goldman with 340B Health, and I'm joined by Maureen Testoni, the President and CEO of 340B Health. Maureen, welcome back to 340B Insight.

Maureen Testoni (03:28):
Thank you, Myles.

Myles Goldman (03:30):
Congratulations on the recent 340B Coalition Virtual Summer Conference. It looks like it was a big success.

Maureen Testoni (03:37):
Yes, we were very pleased. There were more than 50 sessions and more than 150 speakers. And many of these sessions are now available on-demand for people who registered. They can also get CE credits.

Myles Goldman (03:49):
And there certainly was a lot discussed at the conference. Since we had you on in May, Maureen, there have been some significant developments involving the 340B Program, and I know our listeners will value hearing your perspective on it, which is why we have you on today. A federal court upheld the administration's deep cuts in Medicare part B payments to many 340B hospitals that started in 2018.

What is your take on the ruling and what happens next?

Maureen Testoni (04:16):
Well, Myles, the ruling was very disappointing. So this is a situation where CMS has decided to pay many 340B hospitals less than they pay to non-340B hospitals by significant amounts and it’s been in place for two years and has been very harmful to hospitals. The issue is that we do not believe that the government was following the statute when it made those cuts, to the degree that several hospital organizations and hospitals sued the government, making that case saying, "You went too far, you do not have the authority to make those cuts." And twice the district court agreed with the hospitals and said, "You know what, HHS, you did go too far. You should not have made those cuts." But HHS appealed to the D.C. Circuit Court of Appeals and a three-judge panel came out with the decision that you're referencing and said, "No, we think that that was appropriate. We think that the law does give HHS the authority to do the cuts the way they did them." And so what that means is right now, the cuts can continue and they're saying that HHS has the authority to do that.

But there are some options ahead. The plaintiffs in this case, the hospital groups and the individual hospitals in the decision, have the ability to request a rehearing by the D.C. Circuit Court of Appeals. So a rehearing en banc is how it would be referred to. And basically what they would be saying is, "We would like the full appeals court to hear our case and consider vacating the decision that was issued by the three-judge panel." If they make that request, then the D.C. Circuit Court of Appeals gets to decide whether or not they're going to grant it. And if they don't grant it, then the decision stands unless there's going to be an appeal to the Supreme Court. And if they do grant it, then there will be another hearing and the D.C. Circuit Court of Appeals can vacate the decision by the three-judge panel and issue a different decision. So those are all potential actions that are still ahead of us.

Myles Goldman (06:24):
And just a few days after the court decision came out, CMS issued its proposed rates for Medicare's Outpatient Prospective Payment System for 2021. I understand Medicare cuts will continue next year, no matter what happens with the courts.

Maureen Testoni (06:41):
Yes, we expect Medicare cuts will continue next year. I think one of the big concerns though, is that it's not just the regular cuts that we were used to, that we've been seeing since 2018. Instead, it's cuts that go much deeper than what we are seeing right now. So as a comparison of average sales price minus 22.5, which is what we currently get, to average sales price minus 28.7, which is what you would be getting under what is being proposed by CMS. But CMS also says in their proposal that they are considering perhaps staying with the ASP minus 22.5. So they're not saying, "Absolutely, we are definitely going to go to this deeper cut." Instead, they're saying that when they did a survey a few months ago, their survey results lead them to believe that doing the deeper cut would be a more accurate reflection of actual 340B costs.

But they are acknowledging that their survey might not be 100%. So they haven't said exactly what they're going to do. It's in a proposal right now, and everybody is able to submit comments and they seem to be suggesting that you can submit comments to urge them to stay with the current amount. Now, 340B Health will be doing an analysis of this rule, which we will share with our members. We will also obviously be submitting comments. We think there are a lot of legal problems with the rule, especially since they relied on what we believe to be a legally flawed survey. And we will also be preparing templates for our members. We're going to be really strongly encouraging our members to submit comments on this rule as well. And the comments, Myles, will be due on October 4th.

I just also want to mention just for our listeners on this, that this does not apply to all 340B hospitals. I get this question a lot. So critical access hospitals, rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are not now subject to the cuts and they would not become subject to the cuts in 2021 under CMS' current proposal.

Myles Goldman (09:03):
The situation in the courts and with CMS isn't the only news that has been on the radar of 340B Health and the 340B community. In the past month, several pharmaceutical companies have taken steps to limit the availability of 340B discounts. Can you fill us in on those actions and discuss what it means for 340B safety-net providers?

Maureen Testoni (09:25):
We have been working with 340B allies in terms of other members of our 340B Coalition, where they are also very concerned these letters from drug manufacturers apply to them as well. So as soon as this stuff started coming out, the 340B Coalition, we mobilized very quickly and we sent a very strong letter to Secretary Alex Azar at HHS, asking him to stop these actions and to actually enforce the statute. So basically when you're talking about, when you're saying limiting discounts, there are several drug manufacturers that are saying that they do not have to comply with contract pharmacy guidance. So that means they're saying they do not have to offer 340B discounts for drugs that are going to be sold through contract pharmacy. That's a very, very big deal. Very big concern.
It started with Lilly. Lilly said straight up, "For our drug Cialis, for three NDCs associated with that drug, we are not going to offer you the 340B price if you try to buy it for your contract pharmacy." And they're very clear in saying, "We don't think we have to comply with the guidance." Right after that Merck, and then Sanofi issued a directive, sort of an ultimatum to 340B covered entities and saying, "You need to share with us all of your claims data. Not just claims data relating to Medicaid, which has some relationship to 340B, but all of your claims data, including all of your commercial claims data. So millions and millions of pieces of data, you need to share with us." And Sanofi is saying, "And if you don't, we aren't going to honor contract pharmacy anymore either."

So very, very concerning to see manufacturers, just take it upon themselves to say, "We don't have to comply with the statute." And we do believe at 340B Health that these statements do directly violate the statute. That the statute requires that drug manufacturers offer covered entities their drugs at the 340B price. There's nothing in the statute that says that manufacturers decide to give you the 340B statute only if they like what you're going to do with it. There's HIPAA concerns with sharing the data. There's concerns with a lot of provisions in the legally enforceable terms of use that covered entities would be subject too. And the bottom line is they have absolutely no legal authority to request all of this data that they're asking for. It's something that 340B Health is looking into very closely because we do think this is a situation where litigation might be in order.

Myles Goldman (12:11):
And could this be part of a trend among drug companies and either way, what can 340B hospitals do in response as they're receiving these letters?

Maureen Testoni (12:22):
It definitely could be a trend and that is a big concern of ours. In terms of what hospitals can do, we are strongly encouraging hospitals to pay careful attention to the agreements that are being sent to them by Merck and Sanofi. Those are the only two that are sending agreements at this time, and really carefully consider the HIPAA concerns and the other terms that are in the terms of use, the legal binding terms. We are reminding people, they do not have any legal requirement to comply with Merck and Sanofi's requirements, but there is a risk that Merck and Sanofi will stop recognizing or stop providing the 340B price through contract pharmacies.

We are asking hospitals to look for situations where they are actually getting overcharged by Lilly when they do try to buy one of the three NDCs through one of their contract pharmacy accounts. So if in fact, as a hospital, you are trying to purchase one of the three Lilly NDCs and you are not charged at 340B price, we're strongly encouraging people to let HRSA know. There is a process you can go through. There's a form you fill out by Apexus. So fill out that form as fast as you can, and send that into Apexus, forward it to HRSA. Also, please contact 340B Health. That goes for whether you're overcharged, but also if you submit ... if you are trying to purchase the drug through your contract pharmacy account and it's not listed. So if they are not making the 340B price available, that is also something that you can record and submit to HRSA on this form. And we're really asking people to do that because we have to be able to show that this action is really happening and it is really hurting hospitals in order to be able to pursue any potential legal action.

Myles Goldman (14:24):
And switching gears now, when you were on the podcast in May, you flagged the issue of some 340B hospitals potentially losing eligibility for the program due to the COVID-19 pandemic. Has there been any progress on 340B Health's efforts to protect 340B hospitals on this issue?

Maureen Testoni (14:43):
Yeah. Myles, there actually has been some progress. I mean, the concern is that with the pandemic, hospitals have had to really change how they operate their inpatient units. And so many of them have had to stop taking inpatients so that they can have their beds open for people that have COVID. So the concern was this could really change their disproportionate share adjustments, which is a measure of how many Medicaid and low-income Medicare patients that you have in a given year. And if that number does not hit a certain threshold, then you are out of the 340B Program and you have to wait a whole other year before you can apply to get back in. So there are some hospitals that because of the pandemic and all the changes, are potentially at risk of not meeting that threshold.

We have taken this to Capitol Hill and we’re so pleased by the support of the 340B champions on Capitol Hill that we now have a bill introduced by Senator Thune. It’s a bipartisan bill with three Democrats, three Republicans introduced in the Senate to address this issue. And then similarly, in the House, another bipartisan bill by Congresswoman Matsui and Congressman Stewart, which would address this issue if people fell below their DSH adjustment percentage, so they wouldn’t lose eligibility. And then the House bill actually goes a little further, it also protects hospitals if there was any problems adhering to the 340B statute’s GPO exclusion.

And I should point out the names of the other original sponsors of the Senate bill, which is Senators Portman, Capito, Baldwin, Stabenow and Cardin. I would strongly encourage hospitals to reach out to their senators and their representatives and urge them to co-sponsor these bills.

Myles Goldman (16:45):
Well, we have certainly covered a lot of topics in a fairly short amount of time, Maureen. We’ll be sure to watch all of these developments throughout the coming weeks and months. Thank you so much for joining us today.

Maureen Testoni (16:59):
You’re welcome, Myles. Thanks for having me.

David Glendinning (17:01):
Our thanks again to Maureen Testoni for bringing us up to speed on some of the big news that has been happening in the 340B world.

As always, if you have any questions or comments about any of the items we cover here at 340B Insight, please email us at podcast@340bhealth.org. We will be taking a short summer break here at the podcast, while we plan an exciting lineup of fall content for you. We will be back with our next episode in about four weeks. By then, Congress will be back in town for its final legislative push prior to the November elections. So we will still have plenty to talk about. Until then, thanks for listening and be well.
Announcer (17:46):
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