



- Speaker 1: Welcome to the ASHP Official podcast, your guide to issues related to medication use, public health, and the profession of pharmacy.
- Tom Kraus: Thank you for joining us for the ASHP Advocating for Impact Podcast, where every episode covers a policy issue impacting the practice of pharmacy. We'll do our best to translate the politics and the policies so you can understand how these issues impact your practice and your profession. Today we're going to be discussing the role of the 340B Drug Pricing Program in supporting patient care and some threats that we see facing the program.
- Tom Kraus: I'm Tom Kraus, Vice President of Government Relations for ASHP. Today I'm joined by Kathryn DiBitetto. Kathryn leads the government relations team at 340B Health, a nonprofit organization of more than 1,400 hospitals and health systems participating in the 340B Drug Pricing Program. She plays a critical role in educating policy makers about the 340B program and the work it enables participating hospitals and health systems to carry out with their patients. Thanks so much for joining us today, Kathryn. Let's start with the basics, what is the 340B program?
- Kathryn D.: Great. Thank you so much, Tom. Really appreciate your invite and I'm excited to get right into everything related to the 340B program. Yeah, the basics, 340B is a federal drug discount program created in 1992 that helps safety net providers access outpatient drugs at a discounted price. What it really does is it helps to serve the needs of patients who have low incomes or who live in rural communities, so those who are uninsured, underinsured, or have public health coverage such as Medicaid.
- Tom Kraus: Where do the resources from the program come from, where do they go, how do hospitals access those resources?
- Kathryn D.: Yeah. By law, the pharmaceutical companies who participate in Medicaid or Medicare Part B have to provide front end discounts on outpatient drugs who are purchased by providers. Those providers are more than just hospitals, they are what HRSA, the Health Resources and Services Administration, calls covered entities. They include public hospitals, nonprofit hospitals, community health centers, hemophilia treatment centers, and other federal grantees. Really together they make up our nation's healthcare safety net.
- Tom Kraus: So I understand and just for context for the listeners, my sense is about half of ASHP's members practice in a 340B covered entity and I think roughly half the hospitals in the U.S. are-
- Kathryn D.: Participate in it? Yeah, mm-hmm (affirmative). Yeah, a good portion of our nation's hospitals do participate in 340B, yep. It's really important, you talked about resources, it's important to remember that 340B, while it is a federal program, it doesn't cost taxpayers a single cent. The discount does come from the pharmaceutical companies.



Tom Kraus: How do they determine what hospitals are those safety net hospitals that qualify?

Kathryn D.: Yeah. This is a great question, it often comes up on Capitol Hill. There are really strict eligibility requirements that hospitals have to meet in order to participate in 340B program. At a high level, they must be either public or a private nonprofit hospital or contract with a state or local government to provide care to low income individuals. There are no for-profit hospitals, for example, that can get into the program. Secondly, they must serve high volumes of low income patients to qualify for 340B. Those are frequently referred to as Disproportionate Share Hospitals. They also have to meet a certain threshold of serving high volumes of low income patients.

Tom Kraus: Okay. Just approximately, what's the percentage of the population that has to be?

Kathryn D.: For the DSH hospitals, that's 11.75.

Tom Kraus: Okay.

Kathryn D.: They have to meet that DSH percentage threshold. Then also if you are a rural hospital, because you are a rural hospital in a rural community, you can participate in 340B. Typically those are the hospitals that are 25 beds or less.

Tom Kraus: Okay. So those smaller rural hospitals are, by default, qualified to be in the program?

Kathryn D.: Yes, mm-hmm (affirmative), mm-hmm (affirmative). Yeah. 340B is really important to them, especially since ACA, a lot of hospital consolidation and some rural hospital closures, of course in the last few years. In some instances, 340B has helped the rural hospitals keep their doors open.

Tom Kraus: Okay. Yeah, I hadn't realized how acute the impact was for those rural hospitals, that's really interesting.

Kathryn D.: Mm-hmm (affirmative), mm-hmm (affirmative).

Tom Kraus: How do those percentages get determined and is there an evaluation of that?

Kathryn D.: On top of all of these eligibility requirements, hospitals must certify through HRSA every single year and it's a very rigorous process that hospitals go through to re-enter the program at the beginning of the year. That happens annually as well.

Tom Kraus: Okay, got it. Okay, thanks for explaining who qualifies and where the resources come. I think the question that's often asked on Capitol Hill is how do those resources get used and how do we make sure that they're benefiting patients?



- Kathryn D.: Yeah, absolutely. Hospitals use 340B savings in a number of different ways, each use the savings to meet the unique needs of their community. For example, a hospital in rural Oklahoma may use a savings differently than a hospital in downtown Detroit. That's really the beauty of the 340B program. On the national level we have data that shows that 340B hospitals provide 60% of uncompensated care in our country while representing just about 38% of acute care hospitals. They're really doing a lot to put it back into patient care.
- Tom Kraus: That's sort of consistent with the intent when Congress authorized the program?
- Kathryn D.: Exactly, yes, yes. If we look at the report language from 1992, the intent of the program was to, "Help entities stretch their scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." That's exactly what hospitals are doing today.
- Tom Kraus: Does the program provide any direction on how those resources get used or does it really give flexibility to the programs to help the the patient population as best they see fit?
- Kathryn D.: Exactly. There is no requirement in the law that says that hospitals have to use the savings in a certain way and so they use it to best meet the needs of their community.
- Tom Kraus: Great. Let's talk about some examples of how this actually plays out in real life. Can you tell us more about the specific ways that hospitals use these resources?
- Kathryn D.: Yeah, absolutely. It's a number of ways, like I said, it's a flexible program. But ultimately it's used to help enhance patient care for low income and rural patients. We did a survey recently of our membership and 70% of our hospitals say that they help fund free and low cost medications to treat diabetes, cancer care, and much more. Some hospitals use it to extend pharmacy hours, perhaps hire clinical staff, or generally support uncompensated care.
- Tom Kraus: I know there was an example of an innovative way that Intermountain Health was using those savings to benefit the diabetic population in their community.
- Kathryn D.: Yeah, yeah. This is a really compelling story out of Intermountain Health in Utah. They have a voucher program for diabetes, which is supported by the 340B program. They've shared with us and with lawmakers on the Hill that they had a patient who had been admitted to the hospital 32 times in 14 months, this was a diabetic patient. 340B savings actually allowed Intermountain to provide this patient with her insulin at a steep discount. Since, the patient has not been admitted again. It's incredibly helpful in lowering hospital readmissions. It is benefiting the hospitals in all levels, especially keeping patients out of the hospital, which we all can support.
- Tom Kraus: Those are resources that these hospitals would not otherwise have access to.



- Kathryn D.: Yeah, yeah.
- Tom Kraus: I think pharmacists may not always know which programs within their hospital are supported by the 340B program. How do hospitals document the work that they're doing and how can pharmacists learn about that?
- Kathryn D.: Yeah. I learned that that's such a true statement, Tom, especially with hospital systems that have so many departments that are really doing their own important work. Sometimes it's only in the pharmacy where everyone is well versed around the 340B program. More and more, as 340B is becoming more of a household name within the four walls of the hospital, you're seeing departments come together and meet on 340B regularly and talk about how it's helping the patients. We've seen a shift in the last few years with hospitals being more conversant about their 340B savings.
- Kathryn D.: 340B health has actually created a handbook to help hospitals along the way. It's a very detailed guide which takes everyone through the steps of collecting your data around 340B. It covers everything from who do you talk to within your various departments, pharmacy, finance team, government relations team, how do you get everyone together to really calculate the number and say, "Okay, our 340B savings number is X." Then come up with your narrative on how it is helping your patients in your community. Another thing to closely look at is what would you have to change if 340B were scaled back or limited?
- Tom Kraus: So what patient services would you have to cut?
- Kathryn D.: Exactly, yeah. We're really dedicated to that and making sure that hospitals are putting that on paper, giving it to their lawmakers, sharing it on social media to the extent that they can, and really talking about it and providing that data to policymakers on Capitol Hill so that they are aware of the impact in their district.
- Tom Kraus: Great, thank you. We talked about a lot of the benefits and the intent of the program, but there are also some threats to the program. Occasionally we hear of lawmakers or advocacy groups that have concerns about the 340B program. What are the threats that the program faces?
- Kathryn D.: Sure, yeah. There's actually a lot of bipartisan support for the program, it has had bipartisan support since it was created in 1992. That's something we're really proud of. Members from all different types of districts and makeup are coming out in support of 340B. You saw that as policymakers were doing a number of hearings on the program for the last few years. The Health Committee did three hearings in one year, Energy and Commerce did a series of hearings.
- Kathryn D.: A lot of those hearings were looking at asking really fair questions about the program. What we just talked about, what are hospitals doing with their savings? How are they documenting? What is HRSA doing to oversee the program? They were asking good questions. As part of those hearings, we saw a lot of new



champions get on the record in support of 340B as well. Yes, oversight of any federal program is really important and we absolutely support that and we welcome it. But we just want to be careful of proposals that might limit the scope of 340B so that it would impact hospital's ability to provide care.

Tom Kraus: Okay. I understand that another potential threat is that we've seen some payers try to take advantage of the resources intended to support patient care at safety net hospitals by paying lower rates to 340B hospitals. But I also understand that states are actively pushing back on this practice, what are some of the states doing to prevent payers from abusing the 340B program? How can health systems take action to support those states?

Kathryn D.: Yeah, and that's something we've been watching very closely and we're observing this as a trend in the 340B program. With less interest at the federal level, we're seeing the state start to engage in 340B. With regard to discriminatory reimbursement, we've seen some private payers reduce payments or attempt to reduce payments to 340B providers, and it's not just hospitals. We've pushed back tremendously as a community on this. Some payers have successfully just said, "Okay, we're not going to go down this road."

Kathryn D.: Then as you mentioned, the states have actually taken action to make it illegal to carry out such practices in their states. The states that have taken action to prohibit such practices from happening in their state include West Virginia, Minnesota, South Dakota, Montana, Oregon, and something is actually starting to move forward in Ohio as well.

Tom Kraus: That's great. It sounds like state legislators are recognizing the value of the program and doing what they can to protect those resources for their patients.

Kathryn D.: Exactly, yeah. My recommendation would be to start paying attention to your state legislatures and if you see 340B activity, flag it for Tom or myself, and we'll get to the bottom of it to see what's going on and what the impact could be for 340B hospitals.

Tom Kraus: Yeah, that's a great point. Please do let us know if you hear about threats to the program in your state. Or if you're experiencing some of that payer behavior and you want to engage with us on what's going on there, it'd be helpful for us to be able to learn about that and share that with others. Please do share.

Kathryn D.: I will also add that currently there is no federal legislation to push back on this. It was in the last Congress, but it's not something that is moving forward or active at the federal level.

Tom Kraus: That's great. I understand that there's also been some challenges in the Medicare program in that the Medicare program has tried to benefit from some of those 340B savings by reducing its payments to 340B hospitals. I know that the hospitals



have pushed back very hard and there's ongoing litigation there, but can you tell us a little bit more about what the hospitals are doing?

Kathryn D.: Yeah, absolutely. These cuts are a big cause for concern. They went into effect in 2018 and when CMS proposed this back then, there was a lot of pushback from Capitol Hill. There was a bipartisan letter with dozens of signatures to CMS asking them not to finalize this proposed rule. Nonetheless, they moved forward with it and the cuts did go into effect in 2018. Then there was bipartisan legislation along those same lines that would have reversed the cuts from going into effect. Unfortunately, the bill did not move forward but again, strong bipartisan support, which was really fantastic to see on this issue.

Kathryn D.: Legislative route wasn't exactly successful at the time. Yes, as you mentioned, there is a federal court case that is still ongoing. The federal court have ruled in the hospital's favor saying that CMS acted in an unlawful manner and the government is actually appealing that decision. We're currently awaiting a verdict. Meanwhile, the hospitals are being paid less and working hard to maintain their services. It is an ongoing fight in the courts right now.

Tom Kraus: Yeah. Thank you for explaining some of those steps that the hospitals are taking. ASHP is also very concerned about the cuts to the 340B program that had been proposed, we are pushing back actively with, with CMS. We've also discouraged CMS from moving forward with requests to hospitals to share information about the acquisition prices they pay for 340B drugs for two reasons. Number one, it's very intrusive and burdensome to hospitals to generate those information. Two, the courts have said that that information is something that CMS would have to have in order to effectuate its proposed cuts. We don't think that CMS should be seeking that information with the clear intent to be reducing resources available to those safety net hospitals.

Tom Kraus: Kathryn, 2020 is an election year, do you think Congress will make any changes to the 340B program prior to the elections or is that even an issue that we should be considering?

Kathryn D.: Okay, let me dust off my crystal ball for this one. I'm never surprised when it comes to the 340B action on Capitol Hill, so I say this with caution. I think that we have to remain vigilant no matter what is going on in the political realm. That said, I really don't anticipate legislation being introduced that would "reform or change" the 340B program. We're always watching what's going to happen in this drug pricing debate. Last year, as the committees were marking up their respective bills, 340B kept coming up. There was an amendment that would have been pretty harmful over in the Senate, some discussion in the House markups. The point is that it could still resurrect in some way, shape or form, but I don't anticipate any direct hits to the program via legislation in 2020. I think that's a safer way to put it.



- Tom K.: Just to summarize some of what we've discussed today, it sounds like the 340B program really is core to providing access to services, particularly at safety net hospitals. Those hospitals, through some of the work that that your organization is doing, really should be taking the effort to document the resources that they have from their program, how they're using those resources, how they impact patient care, and what services would be lost if the program were reduced in some way. Thank you for explaining that. It sounds like there are some of these threats that are out there, but they're not legislative so much as things that are happening in the courts and behind the scenes at CMS, which we are actively advocating to prevent from moving forward. Is there anything else listeners should take away?
- Kathryn D.: Yeah, I agree with everything you had just said. I think it still underscores the need to make sure you're keeping in touch with your lawmakers even when the threat isn't so red alert. Still connect with your health LAs and their offices and say, "Hey, this is important. Remember, without it, we might have to scale back this program." Just keeping it on their radar, touching base periodically always helps so that they know if there is a bill or any proposal that mentions 340B, they'll go to their local hospital and ask them what the implications may be. You want to make sure that you're still touching base regardless of the threat level.
- Tom Kraus: That's right, thank you. Again, if you have concerns about something that's going on in your community, a potential threat to programs at your facility, please reach out to ASHP or 340B Health and we'll be happy to work with you to identify some potential solutions and help you with some resources. When speaking of resources, 340B Health has provided some links that listeners can find in the show notes of this episode, including a quick reference document summarizing the 340B program and a helpful explainer video about how the program works.
- Tom Kraus: Kathryn, thank you so much for taking the time to speak with us today and explain the 340B program.
- Kathryn D.: Thank you and thank you for all the good work you do here, Tom. We're so thrilled to be partnering with ASHP on this podcast. Thank you so much for having me.
- Tom Kraus: Thank you.
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