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What CFOs Need To Do To Save Their 340B Program

The State of 340B

"340B has become the most important funding mechanism for hospitals and clinics to care for patients who can't afford the cost of care," says Bill von Oehsen, a 340B Drug Pricing Program expert and principal at law firm Powers Pyles Sutter & Verville.

Von Oehsen says every healthcare CFO needs to know that the 340B program saves money and generates revenue, but it carries compliance risk. Von Oehsen should know. He played a role in drafting the legislation that created the 340B program in 1992 and, during the process, led the charge to get hospitals added.

"We're headed toward more requirements, more detailed reporting," remarks Ted Slafsky, publisher and chief executive officer of 340B Report. Slafsky has 30 years of experience with 340B. Before publishing the 340B Report, he was an award-winning journalist. He was also CEO of Washington, D.C.-based 340B Health, an organization of more than 1,500 public and private nonprofit hospitals and health systems participating in the federal 340B drug pricing program.

Through the federal 340B program, hospitals and clinics that provide a vital safety net to stretch scarce federal resources can buy outpatient prescription drugs at a significant discount. According to U.S. Health Resources and Services Administration data released last August, discounted drug purchases via 340B reached $44 billion in 2021.

Since 2020, pharmaceutical makers have increasingly restricted 340B discounts for drugs distributed through 340B contract pharmacies. The move has led to court battles between HRSA and the drug makers. Both sides continue litigating. Hospital finance and pharmacy executives say drug makers continue rapidly imposing new limitations on how covered entities tap the program's benefits on behalf of patients.

"We're in this vagueness, and we have to plan budgets and projects for the next five years, but we don't know what's going to change," says Todd Karpinski, chief pharmacy officer for West Virginia University Health System. Karpinksi's purview covers pharmacy operations, strategic planning and creating opportunities for his lines of services.

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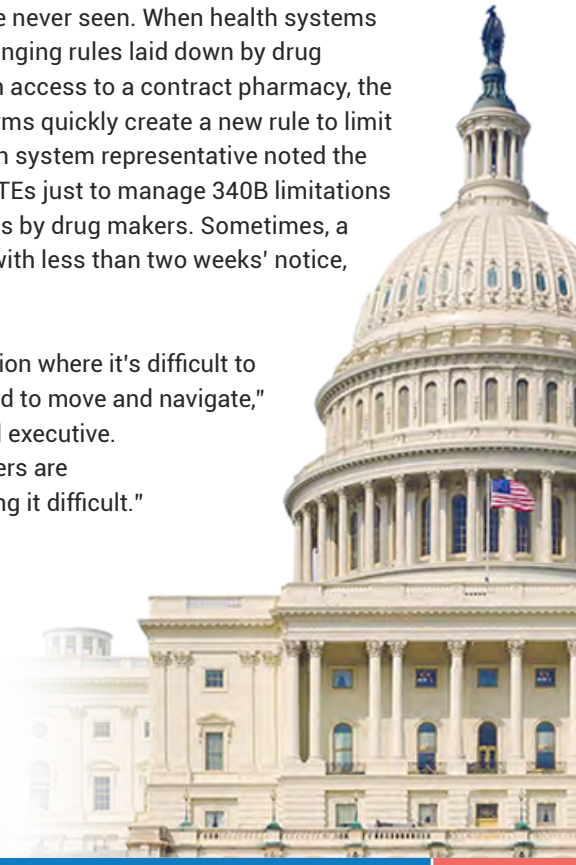
>
> — **Garrick Stoldt, Chief Financial Officer**
> St. Peter's University Healthcare System

Health systems like Karpinski's rely on 340B contract pharmacies to dispense medications purchased through the 340B program. Healthcare executives say drug makers want to limit the number of contract pharmacies covered entities can use, placing restrictions on the number and distance between locations. Industry experts say CFOs, particularly those serving smaller community hospitals, are fearful about the developments. For small community hospitals, losing just one or two contract pharmacies can flip their balance sheet from black to red.

In the last few years, 340B program and compliance experts remark that drug makers have grown brazen to a degree they have never seen. When health systems meet the ever-changing rules laid down by drug makers and regain access to a contract pharmacy, the pharmaceutical firms quickly create a new rule to limit access. One health system representative noted the need to add two FTEs just to manage 340B limitations and policy changes by drug makers. Sometimes, a change happens with less than two weeks' notice, another says.

"It creates a situation where it's difficult to operationalize, hard to move and navigate," remarks a hospital executive. "Drug manufacturers are intentionally making it difficult."



340B Risks and Benefits

"The big thing about 340B is we can expand treatments and access to underserved populations that we couldn't think about without the program," says Garrick Stoldt, CFO for New Brunswick, N.J.-based St. Peter's University Healthcare System. "It's a very complex program, and it's the compliance and due diligence that make it so."

To illustrate his point, Stoldt, who is also a lecturer for Rutgers University's Bloustein School of Planning and Public Policy, recalls Johnson & Johnson inviting him to speak with its attorneys about healthcare. The conversation pivoted to the 340B program. The lawyers complained to Stoldt about what they felt was the program's lack of oversight. Stoldt shocked the attorneys by relating how St. Peter's was spending 20 percent of its 340B program savings just to comply with requirements from HRSA.

Echoing Stoldt's point is Justin Gibson, vice president of finance for the Northern Region of West Virginia University Health System, which is the state's largest health system with 20 hospitals and five institutes. Gibson says, "You need to invest in checks and balances. There are risks if a CFO doesn't keep up with compliance.

"Every program we consider adding through 340B has a material impact for our underserved patients," Gibson adds.

According to another hospital system CFO, when his organization first ventured into the 340B program, they were hit with a HRSA audit and found to have a partial failure. Managing compliance for the program was too complex for the pharmacy staff, says the CFO. The team relied on an outside consultant to vet its program, the CFO notes, but a consultant alone wasn't sufficient. The hospital system had to pay back $500,000 to the drug makers for duplicate discounts and go through a corrective audit.

For Stoldt and St. Peter's, the benefits of 340B equate to more patient encounters, which he notes will climb from 60,000 to 100,000 over the next few years across three programs: internal medicine, pediatrics, and obstetrics. With 340B savings, Stoldt says St. Peter's will expand its family health facility to see even more charity care and Medicaid patients and add offerings like lab services and a food pantry.

"Our metrics include growing our stewardship to the underserved population, and 340B dovetails with our mission and helps give us resources to expand," Stoldt notes.

Karpinski says his health system's priority with the 340B program is ensuring continuous compliance. But along with that, he and his colleagues focus on how to work within the program to stretch limited resources as far as possible to care for underserved populations. The health system's total uncompensated care in 2021 was over $334 million, which is over three times more than the 340B benefit achieved through the WVUHS 340B program. The mission of WVUHS is to improve the health of West Virginians and all those the health system serves through excellence in patient care, research, and education. The 340B program enables WVUHS to achieve its mission by stretching scarce federal resources as far as possible, while delivering high quality health care services to vulnerable patient populations, including low-income, uninsured, underinsured, and homeless patients as well as those living in rural communities.

WVUHS is committed to providing comprehensive medical services to all patients regardless of their ability to pay, including a full spectrum of inpatient services, surgical services, and outpatient services such as emergency medicine, trauma, cancer care, infusion services, specialty pharmacy services and behavioral health services. The 340B program has allowed WVUHS to expand access to care across the states it serves, while focusing on safe, cost-effective care that results in improved patient outcomes.

> "The savings from the 340B program drive many of our operation's initiatives, whether that's our pharmacy or other outside projects we want to pursue," Karpinski notes. "The savings for us accounted for our entire operating margin, without 340B we would have lost money."
>
> — **Todd Karpinski, Chief Pharmacy Officer**
> West Virginia University Health System

For small rural hospitals, which play a vital role in serving patients, 340B is a lifeline, too. WVU Medicine St. Joseph's Hospital became a critical access hospital in 2014. Located in a town of approximately 5,000 people, the hospital's service area is twice the size of an average critical access hospital. Before becoming a CAH, St. Joseph's finance director Russ Plywaczynski says the hospital had very low cash on hand and existed hand to mouth with good years and some bad.

"Day to day it was a struggle, but our president focused on the 340B program," Plywaczynski remarks. "That funding was really the biggest factor in keeping us solvent and able to deliver quality healthcare to all our patients, insured or not. A hospital with my volume in a rural area can't survive on fee for service."

Building a 340B Team and Asking Questions

To manage the risks of the 340B program, hospital CFOs must have a knowledgeable team (ranging from a few people to dozens of 340B experts), administrative structure, well-oiled processes, and technology that objectively vets the work of TPAs. While a consultant or TPA can help a CFO, the responsibility for and risks with compliance rest with the organization's finance head.

"We have an advisory council made up of senior leadership who meet quarterly about 340B," says Karen Famoso, regional director of Pharmacy at WVU Medicine. "We also have an affinity council made up of our directors of pharmacy, IT, and other key stakeholders who meet quarterly to discuss the future of 340B, how to manage the program and present savings. The groups discuss compliance results, identification and resolution of technical issues, while maintaining a continuous quality improvement culture."

With a team in place, there are questions every CFO should continue asking about 340B. Answering these questions, especially the ones related to continuous compliance, takes technology.

"You can't run a 340B program without software like SectyrHub," Stoldt says. "Hospitals have to meet their eligibility every year. And you need software for that. That's the building block toward a compliant program."

Technology, like SectyrHub, for maintaining continuous compliance is often mistaken for something third party administrators offer. And while some TPAs offer similar services, health leaders say TPA-agnostic software like SectyrHub plays a unique role.

"If a TPA is doing this, then they may be making money on it per each claim," Karpinski says. "[CFOs] want unbiased opinion."

? Stoldt and other CFOs say software like SectyrHub 340B helps answer questions such as:

How can we prove we're ready for an audit, right now?

SectyrHub provides a dashboard that a CFO and team can use to see for themselves – right now – just how audit-ready their organization is. If there are gaps, hospital leaders can drill down to see what they are and, most importantly, what's being done about them.

Are we optimizing our program benefit?

Optimizing the 340B benefit is all about managing the risk of non-compliance. With SectyrHub, a healthcare team gains confidence with identifying qualified transactions because everything is standardized and documented. Hospital quality management is more than clinical--it permeates all the hospital's functional areas. SectyrHub supports financial quality outcomes.

How do we confirm the accuracy of our TPA's qualification process?

SectyrHub helps establish and standardize audit processes and documentation across the audit team and TPAs. The software also provides visibility to easily confirm this. With SectyrHub's Smart Audit functionality, a team can audit more transactions in the same amount of time by deploying a closed-loop system for identifying audit concerns, requesting a stakeholder's support, and resolving issues. And with the SectyrHub dashboard, executives can quickly see how many issues they have with each audit, how many findings there are, and performance trends.

Protecting the Program

Once CFOs understand the 340B program as well as its risks and benefits, von Oehsen and Slafsky say, financial chiefs play a valuable role protecting the program. Both experts recommend CFOs get engaged by testifying before Congress and include their stories drawn from the economics of helping the underserved.

“CFOs are concerned that 340B will get diluted by legislation," adds Stoldt. “It's important to help legislators understand the benefit to their state. It's not a Republican or Democrat issue; there are people on both sides for and against 340B."

To illustrate how CFOs can get involved, Famoso points to 340B Health, which hosts fly-in days for health leaders to meet their representatives in Washington and discuss the importance of the 340B program.

She attends these sessions with her government relations team. By meeting with members of Congress, she says health leaders can educate legislators and their staff about what is happening with manufacturer limitations that constrict access to 340B pricing.

“There's a misconception that 340B costs patients or government, it doesn't cost anyone other than drug makers," says Karpinski. “Hospitals aren't using 340B to drive up the cost of healthcare, quite the opposite."

As Karpinski frames it, hospitals need CFOs publicly speaking because drug makers are shaping the agenda.

Sectyr provides software solutions that help healthcare and other regulated businesses maintain Continuous Program Compliance with ever-changing regulatory requirements. Used by hundreds of hospitals, health centers, and pharmacies across the country, Sectyr's cloud-based compliance platform, SectyrHub, helps protect compliance programs from risk by maintaining Continuous Program Compliance, and thereby eliminating the overwhelming manual effort typically required to prepare for, prove, and respond to an audit.

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