

Challenges and Solutions for Pharmacy Supply Chain Management



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Challenges and Solutions for Pharmacy Supply Chain Management



The pharmaceutical supply chain is complex and it faces a number of challenges. In our cover story we look at best practices to manage the uncertainty of drug shortages, cost pressures, and cash flow by implementing technology efficiencies and automating as much of the process as possible.

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Testing Generative Artificial Intelligence

USING GOOGLE'S AI CALLED BARD, WE ASKED THE QUESTION: What supply chain management challenges do pharmacies face?

What we got was the standard fare on how technology helps pharmacies improve efficiency, reduce costs, comply with regulations, and better manage the inventory of drugs on hand. As an example, it stated, "Pharmacies can use technology to carefully track on-hand inventory, ensure they have the most cost-effective purchasing, and to carry the minimum inventory in store that can still meet prescription demand." That's true.

Cost pressures were a subcategory in the reply. Here Bard mentioned the rising cost of pharmaceuticals putting pressure on pharmacies' bottom line. Somewhat true. It isn't just the rising costs, but also the DIR (direct and indirect remuneration) fees that are pressuring the bottom line. Also contributing are the slim profit margins on generics.

The conclusion is that the pharmaceutical supply chain is a complex and challenging system. That's true.

From what I have read AI can help physicians make better diagnoses, leading to better outcomes. This will avoid costly medical mistakes, which a recent *Wall Street Journal* article (April 8–9) pegged at a quarter of a million deaths a year in the United States

Al isn't entirely new. The insurance industry has been using Al algorithms in its predictive modeling to set rates for some time now. Al algorithms are also used to decide which ads to deliver to your phone. And Al has been the force behind our Google searches. What's new is that Al is now generating well-written text on any subject we throw at it.

Bill Gates says he equates Al to the first graphical user interface introduced to the Windows and Macintosh operating systems. We all know the impact this has had on how we use computers. The phase "user friendly" resulted from this.

All that said, generative Al is considered a breakthrough in allowing a search on a topic and getting a well-written response. This is clearly another demonstration of how computers are changing our daily lives. **CT**



If you're a pharmacist looking to make a technology investment, this is a chance to meet top management of key technology companies.

If you're a company looking to network in the industry, consider becoming a member and attending the 2024 Annual Conference.

ASAP conferences attract a small group of high-level decisionmakers who attend not only for the programming, but for the valuable networking opportunities as well.

What to Learn More?

To view presentations from the last conference visit asapnet.org/2023-conference

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Save the Date and plan to attend the 2024 Annual Conference at the historic Don CeSar, St. Pete Beach, Fla., Jan. 10-12.

ASAP's mission is to foster understanding of the role that technology plays in assisting pharmacists to promote patient safety and the proper use of medications, comply with laws and regulations, and operate their practices more efficiently by providing a forum for sharing diverse knowledge and perspectives on the modern practice of pharmacy.



kneeland's notes: APHA recap

Musings on the APhA Annual Meeting



by Bruce Kneeland

THE AMERICAN PHARMACISTS ASSOCIATION'S (APHA) annual meeting is unique in

that it is the only pharmacy event geared to meet the needs of all pharmacists, no matter their practice setting. Pharmacists come by the thousands to learn from the general session and CE programs, and to explore a truly impressive exhibit hall.

This year's event was held in Phoenix in March. I live in Prescott, about 100 miles north, so I took a day and drove down to see what was new. Here are a few things I learned.

A few months after last year's event, the fairly new CEO of the organization departed unexpectedly. After several months with an interim CEO, it was generally expected APhA would use this event to announce a replacement, but no such announcement was made. One highlight for me was being able to see my long-time friend and exceptional pharmacy owner, Theresa Tolle, R.Ph., deliver her remarks as the outgoing president of APhA. Last year she had played a major roll in encouraging me to apply for the 2022 APhA Honorary Membership. I was honored to receive that award on the same stage Tolle began her one-year journey at the helm of the organization.

In her remarks this year Tolle reported that APhA has worked with government officials, nonprofit organizations, and private companies to move the profession forward. Their message is that pharmacists are uniquely qualified to help improve outcomes and lower the total cost of healthcare, not just medications. She stated that while frustratingly slow, progress is being made on PBM (pharmacy benefit manager) reform, provider status, and test-to-treat authority, on both the state and national level. And, Tolle said, the association is finding success in helping payers understand the unique value pharmacists can play in helping people deal with social determinants of health.

Speaking of PBM's. I had a hallway conversation with Rob Tinsley, CEO of the Kansas-based pharmacy support organization, Currus. He says the organization has formed a subsidiary PBM called, Prescription Network. According to Tinsley this new company

is helping employers, patients, and pharmacies by providing a truly robust prescription benefit where pharmacy providers are reimbursed at NADAC (National Average Drug Acquisition Cost) plus a dispensing fee. The model also includes a pass-through of all rebates to the benefit of the payer, and the formulary is not prioritized based on maximizing rebates but on saving costs.

I am familiar with several "pharmacist friendly" PBMs and hope they find success in the marketplace. One of Tinsley's goals is to work with pharmacy owners to introduce his pharmacy benefit experts to business owners in their communities.

The APhA trade show flow was busy. I counted almost 200 vendors. Many, such as ScriptPro, Micro Merchant, Transaction Data Systems, and RxSafe will be familiar to *ComputerTalk* readers. And I enjoyed visiting with several companies I had not yet heard about.

Pyrls, pronounced "pearls," is a young technology company bringing easy-to-navigate medication information designed for pharmacists to use in counseling sessions and while providing other clinical services. Another company new to me, Quidel, was demonstrating a point-of-care testing device that interfaces with several pharmacy management systems. It tests for flu, COVID-19, RSV (respiratory syncytial virus), strep, and others. Also new to me was Insulet Inc., makers of Omnipod, a wearable insulin delivery device that helps monitor and then deliver insulin without the need for patients to do injections.

My takeaway from attending this meeting is that creative pharmacy leaders, dedicated pharmacists, and innovative companies are finding new and better ways for pharmacists to practice their profession and operate a profitable pharmacy. But for that to happen they will need to learn new skills, plug into new technology, and provide new services. **CT**

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feature: DSCSA compliance

Why You Need to Know About GS1 and EPCIS for DSCSA Compliance



by J. Randall Hoggle, B.Pharm., D.Ph., M.B.A.

AS YOU PROBABLY KNOW, THE NEXT

requirements of the Drug Supply Chain Security Act (DSCSA) "track and trace" are coming soon, and pharmacies must be prepared for and compliant with these new reporting requirements by Nov. 27, 2023. That means starting now to ensure you are compliant, if you are not already. Please see the action steps that I outline here to be able to receive Electronic Product Code Information Services (EPCIS) advance shipment notices as product leaves your supplier's warehouse to ensure you accurately receive the prescription products you ordered.

Soon after the DSCSA was enacted, the pharmaceutical supply chain industry came together in many different forums and agreed on using GS1 standards as the platform for DSCSA compliance efforts, a practical decision based on the need for trading partners from manufacturers to pharmacies to use one set of common standards.

You need to register your pharmacy with GS1 to set up a Global Location Number (GLN) and Serialized GLN (SGLN).

The GLN and SGLN will be needed for three reasons:

- DSCSA-compliant EPCIS transmissions require your supplier to have your GLN/SGLN or they cannot forward those transmissions for your purchases from that supplier.
- 2. The GLN and SGLN will be needed to send salable returns back through the supplier's verification router service.
- 3. The GLN and SGLN can be used as dispenser validation credentials.

GS1 is a not-for-profit international organization developing and maintaining its own standards for barcodes and the corresponding issue company prefixes. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically.

Here are the action steps you need to take with GS1 over the next couple of weeks:

- 1. Register with GS1 to set up your Global Location Number (GLN), which is required of all pharmacies for current DSCSA compliance components and conversion from advance ship notices (ASN) format to EPCIS format. See "Steps to complete GS1 registration of your pharmacy" below.
- 2. Once you have received your GS1 registration information to set up your GLN and SGLN, forward it to your DSCSA compliance service provider, if you have one, to assist you in completing the process. Otherwise, just contact Advasur and we will assist you, as this is mission critical to your practice and business.
- 3. Once you complete your sign-up with your DSCSA compliance service provider, you can respond to your supplier's request to test EPCIS transmissions; all such tests require you to have a GLN/SGLN to do an EPCIS transmission test. Once the test is successful you or your DSCSA compliance service provider will start to receive EPCIS rather than ASNs.

Steps to complete GS1 registration of your pharmacy:

Starting in early 2023, the data format used by suppliers for sharing ASNs will be migrating from EDI 856 to EPCIS. Advanced ship notices are the digital data files that each dispenser should be receiving from their suppliers (not printed packing slips) at the time of order shipment. Dispensers (pharmacies) are required to retain these transaction documents for a full six years to achieve full DSCSA compliance. To receive EPCIS files for advanced ship notices, all trading partners (including dispensers) will now be required to obtain a Global Location Number (GLN) from GS1.org. This requirement is based on the FDA guidance for DSCSA compliance

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feature: DSCSA compliance

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requirements. Most dispensers have not yet created their location number, but it is going to be a must.

Follow this GS1 website link if you have a single pharmacy and pay the one-time fee of \$30 at the time of checkout: https://my.gs1us.org/product/1366/single-gln.

If you don't have a DSCSA compliance services provider and cannot set up the GLN and SGLN yourself, then GS1 offers an option to set those up for you for a higher initial fee and an annual maintenance fee.

If you are a multipharmacy owner, go to this GS1 website registration link: GS1 Company Prefix - UPC - GS1US Ecommerce. The initial pricing for multipharmacy locations is shown in the table, with initial and annual renewal fees.

GS1's website often refers to GLNs interchangeably with the term barcodes. You will not need to purchase a company prefix from GS1. Just pay the fee to set up the GLN. If you purchase the prefixes too, then prefixes would require registration fees and renewal fees every year.

With suppliers (direct-selling manufacturers and wholesalers) already starting to test EPCIS transmissions with some dispensers, time is of the essence to complete the GS1 registration and GLN/SGLN setup.

I am always available to assist my pharmacy colleagues who are trying to be compliant with these regulations. My email is r.hoggle@advasur.com. I will try to respond to any questions within one workday for *ComputerTalk* readers. **CT**

J. Randall Hoggle, B.Pharm., D.Ph., M.B.A., is the managing director of Advasur, LLC, the Advasur Audit & Supply Chain Resource Center in Rockville, Md.

Number of Pharmacies Needing a Barcode	Initial fee	Annual Renewal Fee
1–10	\$250	\$50
1–100	\$750	\$150
1–1,000	\$2,500	\$500
1–10,000	\$6,500	\$1,300
1–100,000	\$10,500	\$2,100

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Comply with DSCSA Requirementswhile Protecting Your Business

- ✓ Set Up ASN/EPCIS Connections and Maintain Dynamic Supplier Database
- ✓ Customize ASN/EPCIS Repository Service
- √ Validate and Certify Suppliers
- ✓ Customize DSCSA Compliance SOPs
- ✓ Inspect Shipping Notices for Complete Data Required
- ✓ Set Up GS1 Connection for EPCIS and VRS Utilization
- ✓ Aggregate and Provide DSCSA Compliance Reports
- ✓ Validate, Store, and Retrieve ASNs within 48-hour Inspection Clock
- ✓ Live Audit Support
- ✓ Enhanced Drug Distribution Security (EDDS)
 Services

Challenges and Solutions for Pharmacy Supply Chain Management





by Will Lockwood VP | Senior Editor Will can be reached at will@computertalk.com

Keeping a handle on inventory is essential in pharmacy. Not only does effective inventory management directly impact patient care,

ensuring that the right medications are on hand, but it is also key to a healthy cash flow and increased ordering efficiency.

The typical pharmacy has moved well beyond manual inventory management, for example using software systems to set reorder points based on minimum and maximum (min/max) stock levels, using electronic data interchange (EDI) to place orders with suppliers, and scanning barcodes to check in deliveries.

Here we'll take a look at ways pharmacies can raise their game by deploying the latest inventory management best practices and making sure that they are automating as much of the process as possible.

WHERE TO START

Even considering labor, inventory is likely a pharmacy's biggest investment. It's a major asset, and one you want to focus on managing to ensure the best return, according to Larry Stephenson, VP of strategic sales at Transaction Data Systems. "It's not always just the cost of goods," notes Stephenson, "but how you manage the flow of these goods effectively as you stock the pharmacy and dispense medications also has a major impact."

The first area you want to look at is how to go beyond relatively simple min/max rules, which are often set by intuition or based on a limited set of data. This often leads to either overstocking or understocking medications. Not to mention that it is next to impossible to keep min/max rules up to date for all drugs a pharmacy dispenses, unless you really let your software drive the process. This allows you to use what Stephenson calls

software-driven days'-supply-based inventory, which is the most efficient way to manage ordering that takes historical trends such as seasonality into account. "You want to allow your pharmacy management system to really calculate for you what your demand is," says Stephenson. "Our Rx30 pharmacy software can look at historical trends by individual drug or class of drug. It can more quickly recognize when demand is shifting. And you don't have to sift through reports yourself or rely on your intuition to set minimums and maximums."

Ryan LaVarnway, R.Ph., offers a real-life example of just how important it is to bring technology to bear on inventory management. He owns three pharmacies in New York: Brooks Pharmacy in Hamburg, Attica Pharmacy in Attica, and Island Prescription Center in Grand Island. "Inventory is one of our biggest expenses," says LaVarnway, "and between my three locations I'm managing thousands of different NDCs [National Drug Codes]." Even using the inventory management tools within his pharmacy system was too labor-intensive, so LaVarnway brought Datarithm in to streamline the process. "We can run nonmovement reports from our DRX pharmacy software that look back 90 days," says LaVarnway, "But that still means a lot of manual work going through the lists and checking inventory against them."

The decision to add Datarithm made an immediate impact. "The first thing I did with Datarithm was to run an analysis of historical dispensing data that produced a report that gave suggestions for stock to return to the wholesaler and medications that I could move among my locations to improve turns," says LaVarnway.

It was difficult for LaVarnway to keep up with maintaining optimized on-hand levels for all of his inventory, considering the large number of NDCs spread across his three locations. "Especially for a multistore owner," says LaVarnway, "one of the most valuable things that Datarithm brings is a highly efficient way to stay current on what, at each location, is a return opportunity and what can be moved to a different pharmacy if it's in higher demand there." Datarithm identifies drugs for which there is a full package

continued on next page

cover story: supply chain

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quantity as opportunities for returns to a wholesaler. For drugs that aren't eligible for a return, LaVarnway gets recommendations for which of his locations can best use the inventory.

"There was a long list of items on this report to begin with," says LaVarnway, "because our manual process led to a lot of overstock and dead stock." Now he runs the report once a week. "We've found this is the right interval for us," he says, "and we continue to see a benefit from suggested returns. And there are usually 10 or 20 suggestions for balancing inventory among my three locations."

Getting these transfers done is easy too, according to LaVarnway. A staff member simply clicks to accept Datarithm's suggested amounts to transfer, which then automatically decrements that inventory from the pharmacy management system at the originating pharmacy. Then the receiving store checks the medications in to add them to its inventory. "The way that Datarithm and DRx are integrated makes it seamless," says LaVarnway.

Finally, Datarithm also provides a list of 20 drugs for cycle counting each day, which ensures accurate on-hand quantity data in LaVarnway's pharmacy system, but without the all-out effort of a full inventory. These cycle counts started out with high-dollar and brand-name drugs, since these offer the best opportunity to reduce cash tied up in inventory.

JUST-IN-TIME INVENTORY

You've certainly heard about the concept of just-in-time inventory, and pharmacies — with their typically daily deliveries from wholesalers — are a perfect place for this. "Once you've got a data-driven decision process for ordering drugs, the next step is that your technology should really allow you to run just-in-time based inventory," says Larry Stephenson.

This can have the biggest impact in cases such as a branded product that you are dispensing to one patient. "Let's say that a product like this costs the pharmacy \$900," says Stephenson. "What Transaction Data Systems pharmacy software can do is identify this drug and automatically suggest it for order just ahead of the refill date. So you, as a pharmacist, don't have to remember to order it, and you are then keeping your cash flow in your pharmacy instead of keeping it in inventory on your shelves."

LaVarnway, certainly, has found that just-in-time ordering is very important. Rather than have the minimum inventory level in his pharmacy software trigger a reorder immediately after

More on Supply Chain

PharmSaver's Mike Sosnowik, P.D., on how a technology-driven approach gives pharmacies the tools they need to identify profit-enhancing opportunities. **pg. 12**

Advasur's Randall Hoggle, B.Pharm., D.Ph., M.B.A., on what pharmacy needs to know about GS1 and EPCIS for DSCSA compliance. **pg. 5**

And online at bit.ly/3MO6Vdf, **Invistics's Beth Richter, Pharm.D., VP of business development,** looks at artificial intelligence's ability to identify diversion faster and more accurately than traditional methods.

dispensing, he uses order alerts from Datarithm that prompt him to be sure he's getting drugs delivered just a few days before refills are due.

BUYING SMARTER

Not everything benefits from just-in-time ordering, however. You will also want to make sure you can take full advantage of other opportunities to purchase as efficiently as possible.

One way to do this is forward buying. This is when a partner such as a wholesaler or group purchasing organization (GPO) offers bulk advanced purchases at a discount — for example, a big monthly generic special order. "I've had many pharmacies tell me that smart forward buying has a big positive impact on their financials," says Stephenson. But it can be time-consuming to take full advantage of the opportunity, with a pharmacy owner often spending substantial amounts of time looking through a giant spreadsheet and going through existing inventory to figure out how much he or she really needs from a GPO's recommended forward buy. "We can automate that process," says Stephenson. "We push inventory data from the Rx30 pharmacy software out to the GPO, and then it's so much more efficient to participate in a forward buy when your partner knows what you can actually use. Pharmacies can optimize their forward buying and get it done in a fraction of the time."

Being able to buy at the lowest cost is so critical, notes Stephenson, because every extra dollar of margin available to a pharmacy helps to make up for the bad claims and the direct and indirect remuneration (DIR) fee clawbacks.

One wrinkle that's actually quite important is handling the fact that generics are often sourced from a rotating list of

manufacturers. This is particularly the case with bulk buys. Stephenson notes that your software should have tools to maintain a master drug for a group of generics. "This way you are able to continue to see the dispensing trends for that drug," he says, "even though you may be buying from different manufacturers over time."

Another way to buy smarter is by taking advantage of class-of-trade discounts, for example, for the long-term care (LTC) market. "So many of our successful community pharmacies work with GeriMed, MHA, and others to be able to buy smart for their LTC dispensing, and really expand their business in this area," says Stephenson. If you are going to do this, then it's critical to be able to maintain virtual inventories. "You use a virtual inventory," explains Stephenson, "so that you can have separate LTC and retail inventory data without having to keep the drugs physically separate. We're helping our clients recover every penny possible for serving the LTC market as combo shop pharmacies." Virtual inventory is important for other areas of pharmacy, such as 340B and, as we'll see, specialty.

SPECIALTY CONSIDERATIONS

Specialty pharmacy in particular comes with its own set of inventory considerations, and success will depend heavily on

having the right tools in your technology to address them. Karen Silverblatt, VP of business development for pharmacy at Inovalon, which owns the ScriptMed specialty pharmacy management software platform, points to several areas of attention for specialty pharmacy inventory management.

Specialty drugs are expensive. According to the Sept. 28, 2021 AARP Public Policy Institute's *Rx Price Watch Report* (bit.ly/ 3OZkmd5), the average annual cost for a specialty prescription drug was \$84,442 per year, and has been increasing significantly faster than the overall rate of inflation. These high costs make it absolutely critical that pharmacies use all the tools we've talked about so far to ensure that specialty medications are stocked at the right levels and dispensed as efficiently as possible.

"ScriptMed uses historical data to intelligently project demand," notes Silverblatt. "It's an intelligent system that can notice changes in trends and use that to adjust reorder points. For example, you may start dispensing more of a product because you brought on a new payer client or a drug picks up additional indication approval," she says. "You need software that can track velocity and align suggested order levels so that the pharmacy staff can focus on servicing patients." Returning to the topic of virtual inventories, another area of specialty inven-

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cover story: supply chain

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tory that can be tricky without the right technology, according to Silverblatt, is tracking multiple drug inventory types and the associated acquisition costs. A pharmacy dispensing specialty drugs may have to manage inventory acquisition costs for commercial insurance, pharmaceutical manufacturer free programs, 340B, or clinical trials, for example. "You have to know your acquisition cost for inventory in every category and be able to store and capture receipts at the patient level to be able to accurately apply the right cost and manage margins for the dispense," says Silverblatt.

The level of inventory detail may go further to aligning specific potency lots to specific patients in the case of some plasma products. "We have the ability in ScriptMed to handle these multiple inventories virtually," says Silverblatt, "so the pharmacy doesn't have to manage multiple physical locations of the same product. The system will do it."

SPECIALTY AND CONTRACT COMPLIANCE

The cost of specialty therapy raises an important point for Larry Stephenson. "These specialty products are branded

products with very high cost compared to many of the generics," he says. "So a pharmacy building its specialty pharmacy dispensing needs to work with its wholesaler to understand how this will impact generic compliance and rebates. If you all of a sudden start introducing very high-cost drugs on the branded side, then it makes it look like you're not compliant on the generic purchase side, even though you are." Many pharmacies count on generic compliance rebates, so it's of the greatest importance to understand your wholesaler contracts and have the right conversations to make sure a valuable new line of business and clinical opportunity is ending up a net positive.

YOU WILL SEE RESULTS

Getting a handle on your inventory brings results. Ryan LaVarnway reports reducing his inventory costs by six figures, with most of that amount coming from identifying surplus inventory. He's also increased his turns by four points, which combines with his lower inventory investment to significantly improve cash flow.



Getting started on improved inventory management isn't hard. When Larry Stephenson talks with Rx30 users, he always suggests that they begin with the fastest-moving drug groups and apply smart reorder functionality. "Move these to the days'-supply-based model," he says. "You will be able to see that you can trust the technology to successfully predict your demand."

Another idea is to start tracking the valuation of your inventory on a regular basis so that you know the rate at which your cost of inventory is increasing, a particularly important point when there are strong inflationary pressures. Then you also want to track your increase in turn percentage year over year. "It may be alarming to see a 10% to 15% increase in the valuation of your inventory," says Stephenson, "unless you can also see that you're running at a 20% increase in turns from the previous year. This tells you that you can afford to make the inventory investment because it's moving quickly." Stephenson notes that TDS is rolling out a business intelligence tool for its platforms this summer, called RXInsights, that is designed to make it easy for pharmacies to track these two critical metrics of inventory valuation and turn rate growth.

There's no need to wait, though. It's always a good time to focus on your inventory, according to Ryan LaVarnway, and

there's technology out there that will help you raise your game. "Pharmacy owners can't afford to have a bunch of money just sitting on the shelves," he says. "We got to a point where it was clear that we needed to eliminate manual processes. You can't manage inventory efficiently if you are going by feel and your best guesses. Once we brought Datarithm in, we saw immediately how much overstock and dead stock we were carrying. We cleaned all that up for a strong return on our investment right away."

The right inventory management tools may help you leverage payer and provider relationships to carve out a specialty patient niche. "Even if you are primarily in the retail pharmacy space," says Karen Silverblatt, "if you have the right technology, there may be opportunities for you to serve some specialty patients if you are positioned to meet payer, pharma, and patient requirements."

So a strong, technology-driven approach to stocking your shelves brings substantial benefits: It improves your patient service level, it supports participating in a wide array of markets, and it improves the pharmacy's financial footing. Technology is definitely your best friend when it comes to inventory. **CT**



MEET YOUR ALLY IN PHARMACY MANAGEMENT

Retroactive DIR Fees increased by

107,400% between 2010-2020.

Carry costs can

(CMS)

range from

20% to 30%;

an average of <mark>2%</mark> per month. *(NCPA)*

Every 1% change in an average pharmacy's costs of goods can shift profits by

> 20%. (PBA Health)

Datarithm

REDUCES INVENTORY

by an average of

20%



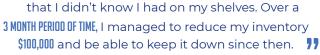
Customers experience an average Turn Rate improvement of

4-5 POINTS,

and an average Turn of 19X (compared to the industry average of 11X-12X).

Within 10 minutes of going live, I pulled





- Steve Spruill, Owner of Maddox Drugs

Control your pharmacy costs and let the cash flow. Datarithm will show you how.

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SPONSORED CONTENT

The Pharmaceutical Supply Chain: Tools to Help Navigate the Challenges

WITH THE PHARMACEUTICAL/HEALTHCARE

INDUSTRY, and more specifically the pharmaceutical supply



Mike Sosnowik, P.D., President, PharmSaver

chain, undergoing rapid change, the need for additional support and strong relationships is crucial. We are living through an unprecedented time of drug and supply shortages, regulatory compliance pressures, and cost and reimbursement challenges. At a time when you need stronger supplier relationships, we are seeing in many cases those relationships challenged or eroding. Profit constraints across the entire industry are driving wedges in the customer-supplier relationship. The prime vendor business model, despite all the industry changes,

remains static, and both contract management assistance and customer support are difficult to obtain or use.

However, one new area has opened that is actually supportive of pharmacies and provides tools to help manage contracts. This technology-driven approach provides purchasing analytics and regulatory support and aids in identifying profit-enhancing opportunities. The PharmSaver platform, now in its 10th year since inception, has steadily grown and enhanced business relationships specific to the pharmaceutical supply chain.

Let us identify industry challenges and elaborate on how the PharmSaver technology-driven approach supports solutions.

DSCSA (Drug Supply Chain Security Act) REGULATORY COMPLIANCE. With the upcoming regulatory changes, pharmacies are challenged to find mechanisms to both collect and store the data required for compliance. While a number of software companies are selling collection and storage solutions, the PharmSaver purchasing platform is the only one to date that sets up and provides data collection and storage services at no cost to the pharmacy.

REIMBURSEMENT AND COST OF GOODS. The aggressive nature of the insurance and PBM (pharmacy benefit manager) industries has created a situation where many drugs, if not purchased correctly, will result in a negative reimbursement and financial loss to the pharmacy. The PharmSaver platform creates a seamless and automated way to assure the most competitive cost of goods for products purchased. The "Reimbursement Alert" feature warns pharmacies of potential negative reimbursement prior to purchase.

PRIME VENDOR AGREEMENT MANAGEMENT. The prime vendor agreement (PVA) is the most important relationship a

pharmacy can have. Negotiating, managing, and complying with the PVA can be a "make or break" moment for a pharmacy. The PharmSaver platform allows pharmacies to load the specifics of their agreement within the PharmSaver system. With this information, which remains confidential to every pharmacy, PharmSaver gives pharmacies the tools to comply with, manage, and optimize their specific PVA. Using the PharmSaver system not only aids in contract compliance, but also assures appropriate product selection and assists pharmacies in maximizing rebates associated with their respective PVA.

GPO AND OTHER CONTRACT MAINTENANCE. More and more pharmacies today belong to multiple GPOs (group purchas-

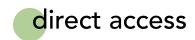
ing organizations). The task of correctly managing and identifying opportunities becomes challenging, and doing comparisons that factor in rebates is difficult. The PharmSaver platform not only allows pharmacies to identify and load multiple GPO agreements but also, in its automated analysis, identifies the best opportunities at dead net. The system takes into account rebates that may apply to some items but not others, and chooses those that will provide the lowest net price available.

ENHANCED PROFIT-GENERATING OPPORTUNI-

TIES. For many pharmacies with larger volumes, volume purchase incentives and short-dated product options can present a compelling opportunity. The PharmSaver platform has a unique short-dated opportunity application that will not only identify price opportunities, but, based on a pharmacy's volume, actually suggest purchase quantities. The system will then go so far as to block these items from reorder for a period, assuring that the short-dated product is used and not pushed to the back of the shelf.

OTHER FEATURES. Pharmacies using analytics and internal reporting can address inventory, profitability, and margin concerns, as well as many other day-to-day management issues. The PharmSaver platform provides dynamic tools and reporting, such as NDC (National Drug Code) or GPI (generic product identifier) matching, product size and volume opportunities, automated order and replenishment, and interfaces with pharmacy management and robotic systems. In today's Al-driven world, data is critical to managing your business and your business relationships.

While current industry challenges can be daunting, there are solutions out there that provide available tools to help manage your business, enhance profitability, and save staff time. Perhaps one of the best features is that the PharmSaver platform and all that it provides are absolutely free to pharmacies. In the 10 years since launch, we have grown to over 3,000 pharmacy users, which is the greatest validation available to the utility of the platform. **CT**



Datascan Pharmacy Software: Providing the Family Touch

ComputerTalk Publisher Bill Lockwood sits down with Kevin Minassian, president of Datascan Pharmacy Software, located in Bohemia, N.Y., to hear about the keys to the success of his company.

ComputerTalk: Let's begin by hearing how long Datascan has been serving the pharmacy market and what got you started.

Kevin Minassian: Datascan was originally started 42 years ago by my father. He was self-taught in IT and programming, as he was not even able to finish high school when my family fled Bulgaria after it became Communist. After failing with the first pharmacy system he attempted to resell, he later ended up buying the code for what was the basis for our first pharmacy software. Even though I did not come in to buy the company from him until 2009, I used to help out here when I was a kid. Back then I helped build computers from scratch and did onsite service calls from time to time. For a decade after college, I started and built an AV company that specialized in flat screens back when they were rare. I built that company from the ground up to over \$6 million a year in sales. In 2009, a year after we lost my brother, my father approached me one last time to get involved, and he agreed to sell the company to me. I used the prior decade of experience growing my business to come here with a fresh perspective to transform Datascan and our products into a new company. Today, we are nearly four times the size we were back then, but still continue to be a boutique pharmacy software firm concentrated on our clients and their needs.

CT: Datascan is one of the few remaining family-owned pharmacy software vendors. Why is that important, and what's the difference between you and the competition?

Minassian: I find it perplexing that independent pharmacy owners a: know what sets them apart from their local chain, which keeps their patients coming back, and b: want their community to support their privately owned business while they're bullied by the behemoth PBMs [pharmacy benefit managers] and chain pharmacies trying to put them out of business. Yet so many of them decide to work with pharmacy software vendors that are owned by billion-dollar hedge funds, or wholesalers.

Datascan is family owned and family focused. So many of our clients have been with us for decades, and for good reason. When you need to escalate an issue or concern, the vice president gets involved here, not some manager. And when needed, she sits down with me and the team to make sure we come up with a long-term resolution. We are no-nonsense here. We expect the best



"Our technology is always evolving — it's feature rich, and we are in the middle of revamping most of it from the ground up for longevity."

- Kevin Minassian

from our support team. All we ask of our clients is communication. If you feel unheard, if an issue keeps rearing its ugly head, simply tell the support team or email our VP that you need it escalated. The majority of our competitors are owned by private equity firms that are focused on raising prices, cutting costs, maximizing profits, and flipping the company every five or six years for the benefit of their investors. We are focused on giving our clients the fastest response times, the most up-to-date technology, and the best overall experience they can find on the market today.

CT: The pharmacy software landscape has certainly changed in recent years. What kind of changes are you seeing, and how are they impacting community-based pharmacies?

Minassian: My vice president, Sarah Callioras, and I speak about this frequently. She is our head of sales and interacts with folks constantly who are getting frustrated regarding the relationship with their current pharmacy software companies. Most are expressing a dire need for change. The most frequent reason we hear is simply customer support. They are seeing common wait times of 10 minutes or more, sometimes in excess of 30, just to speak with a support person. They now recognize that being one of thousands of customers means they've lost their voice. Customer ideas show up less and less in the software. Service levels are going down, yet, amazingly, the cost of these competing systems continues to go up. Let's face it, if you're a private equity firm, your focus is delivering your investors returns — otherwise you won't have investors for very long. In order for many of them to do so, they keep raising prices and cutting costs — and inevitably it is resulting in declining customer satisfaction.

I have no partners, no board of directors, and no investors. We own our software and control the direction and changes that occur to it. In order for my vision to work when I bought this company, we

continued on next page



had to set ourselves apart. We are proud of the reputation we have built. Search around the internet and you can easily find our reviews and what our clients think about us. Our average inbound support call waits are less than 60 seconds to speak with a live person who is trained in all areas of our business, from our products to IT. We have a structured program for accepting customer feature requests and ideas, with most coded into the software, especially if the idea will benefit others. I, the owner of the company, am involved day to day whether I am physically here or not. Our technology is always evolving — it's feature rich, and we are in the middle of revamping most of it from the ground up for longevity.

CT: Now tell us about some of the features in your software that you see supporting the longevity of independent pharmacies.

Minassian: For independent pharmacies to thrive long term, they need to focus on efficiency through automation, profit centers outside of prescription drugs, and customer conveniences. The more you automate in your pharmacy, the less manual labor, the less labor expense you incur. Labor is one of the larger expenses, so why not put the technology to work for you? Auto refill is only scratching the surface, but what about automatic communication with patients? The ability to auto-send doctors new prescription requests when the last fill is used on a maintenance medication, for example.

Profits in the backend of pharmacy have been dwindling for decades, so the ability to build out profitability in areas like compounding, OTC [over the counter] sales, DME [durable medical equipment] and so on is important. Having a robust built-in compounding module in our software has helped us grow, and our clients run their compounding business without requiring additional software. The same with our LTC [long-term care] module. We built our integrated point-of-sale product 20 years ago from the ground up, and it helps build OTC sales through messaging, coupon discounts, a robust customizable rewards program, and more. Not to mention both our pharmacy software and POS [point of sale] systems save you from losses via insurance claims, but also have the ability to flag profits or losses below thresholds, including estimated DIR [direct and indirect remuneration] and GER [generic effective rate] fees; can help shop across vendors for best pricing when ordering; and give you a detailed profit picture of each patient across OTC and prescription sales.

I say it all the time: We live in an Amazon Prime and Netflix world. The days of searching countless stores for what you need are over. Knowing your customer base is spoiled with convenience everywhere they turn today, knowing the chain pharmacies are offering them all kinds of conveniences, how could you not focus on this? Patients should be able to log onto their mobile app,

see their prescription history, quickly queue up what they want refilled, and receive a notification when it's either ready for pickup or out for delivery. They should never have to call you — not for a refill, not for a new prescription on a maintenance drug, not to find out if they have refills left. Today, our software even gives you the ability to have two-way texting with patients — from the simple ability to autosend a text for a refill due that allows them the ability to choose yes or no to refill, all the way to the ability to receive and respond to questions from patients. The easier you make life for your patients, the less likely they are to leave you for someone else. That is the same philosophy we follow here with our clients, and it is definitely working.

CT: Software support plays an important role in vendor selection. Do you see an independent software vendor such as Datascan having an advantage here, and why is this?

Minassian: 1000% we do! Our support is night and day compared with the majority of our competitors. To begin with, we don't want you waiting. As I mentioned earlier, our average response time during business hours is 60 seconds or less. After hours, on weekends, and on holidays, we strive for 10 minutes or less, and if support gets backed up in a rare occasion during after hours, the entire team is there to chip in and assist. We have many members of our support team who have been with us for over a decade. We strive for low turnover, so you get to know our team, and they get to know you. It really is more like a family. Every single member of our support team is trained and constantly updated on all of our products and IT, including hardware and basic networking, operating systems, virus/malware symptoms, backup systems, and the list goes on. We don't want specialists who are separated by category answering the phones — that creates backup. We want anyone who responds to have the ability to assist at all times. We are seeing one of our competitors pushing more and more of their team overseas. Many of the larger corporate conglomerates are seeing turnover as their culture and management have changed after they were acquired.

CT: Is there anything else you would like to add in closing?

Minassian: As a dear family friend, who owned quite a successful business, once said, "I would rather be a big fish in a small pond, than a small fish in a big pond." That resonated with me even dating back to my first businesses in, and just after college. So, for any independent community pharmacy owners out there who are tired of being a number, tired of waiting to be helped, but are afraid of change, don't be. There are a few of us still left that are independently owned, that know our customers, and where you have a voice. And guess what — we not only have cutting-edge features and technology, but we are offering it at better pricing, and backed by the service you deserve. The same service you give to your customers day in, and day out. **CT**



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technology corner

Artificial Intelligence Chatbots: The Latest Developments



Brent I. Fox, Pharm.D., Ph.D.

THERE HAS BEEN CONSIDERABLE

INTEREST, discussion, and even concern about large language models over the last six months. Large language models? Some readers are likely thinking, "I am not familiar with this term. What are large language models?" If large language model doesn't resonate with you, maybe ChatGPT and Med-PaLM are familiar terms. If we scan the digital health landscape, these terms are unequivocally the hottest topic going.

The world of artificial intelligence (AI) encompasses tools, techniques, and models for using data with the end goal of allowing machines to think like humans. Similar to the goal of using AI, the field of AI is complex in that it includes subfields, terms that are used interchangeably, hierarchical technologies with varying levels of sophistication and capabilities, and constant evolution. These aspects of AI can make it challenging to make sense of advancements in the field. Considering the recent significance of ChatGPT and Med-PaLM, this column is devoted to those terms and their implications.

We will begin with a term that you may be more familiar with than large lanquage models: chatbots. Apple's Siri is the most widely used virtual assistant, with Amazon's Alexa and Microsoft's Cortana as other common examples. But I thought we were talking about chatbots?

THE AI FIELD

Chatbots and virtual assistants are

similar, with some suggesting they are essentially the same technology. Virtual assistants are sometimes referred to as "conversational Al" because of their ability to respond to spoken comments or requests and perform tasks asked for by the user. Chatbots are similar in that they respond to human questions (usually in written form) via messaging apps. The chatbots most of us are likely to encounter are commonly deployed by companies to interface with their customers, whereas virtual assistants are consumer oriented.

This is where the challenges of making sense of the Al field enter the picture. ChatGPT and Med-PaLM (more later) are at the core, chatbots. They respond to questions posed by the user. They are much different, however, from the typical chatbot you interact with when you click the "Chat" help window on a website, or talk to virtual assistants like Siri. Those

technologies are limited to a finite number of questions, requests, and answers.

Alternatively, ChatGPT and Med-PaLM are sometimes called "Al chatbots" because they enable human-like dialogue between the technology and the user.

Which brings us back to large language models. Large language models (LLMs) are a type of AI that creates natural language text in response to a user's question or request. Large language models are the engine, if you will, for Al chatbots like ChatGPT and Med-PaLM. How does a large language model actually answer a guestion? As a type of artificial intelligence, LLMs scan, analyze, and summarize large amounts of text. By large, we are referring to 570GB and 300 billion words (from the internet) in the case of ChatGPT-3 (https://bit.ly/43goVUs). By learning from such a large amount of text, LLMs allow prediction and generation of text to create a conversational experience for the user.

Simply stated, ChatGPT and Med-PaLM allow users to ask a question or provide a textual prompt, and the tool answers the question or prompt with a textual response. Well, that seems great, right? Who wouldn't want to ask a question

and receive an extensively researched answer? Apparently, a lot of people like that idea. Two months after its launch, ChatGPT reached 100 million users, compared to nine months for TikTok and two and a half years for Instagram to reach that same number of users (https://bit.ly/3Lpf6vN).

For those who write software code, ChatGPT is a viable source of support. ChatGPT can also be used for common documents like résumés or cover letters. But maybe the novelty of having a conversation with AI is partially driving interest.

CHAT LIMITATIONS

If ChatGPT is so popular, why was its use temporarily **banned in Italy?** And why are educators concerned about it? In Italy, the primary concerns were privacy and access (https:// www.bbc.com/news/technology-65139406). For privacy, the Italian data protection authority expressed concern over how ChatGPT uses personal data to develop the training algorithms for the software. In terms of access, the concern centers on the potential for minors to be exposed to inappropriate content. Broadly, legislation is being developed in the European Union to regulate artificial intelligence due to perceptions that they may "deceive" people.

Closer to home, in educational settings of all levels, educators have expressed concern that ChatGPT (and comparable tools) can be used to write essays or similar types of papers. However, a few relevant limitations are worth noting. First, at this time, ChatGPT's training data is current through 2021. So it cannot answer questions seeking factual answers based on information in 2022 or beyond. Second, questions or prompts need to be framed in a certain manner for ChatGPT to answer them. If the question isn't framed correctly, the tool guesses the intent. This

Learn More

A summary of the websites referenced in this column.

GPT blogs: https://bit.ly/43goVUs

ChatGPT sets record for fastest-growing

user base: https://bit.ly/3Lpf6vN

ChatGPT and privacy concerns in Italy: https://www.bbc.com/news/technology -65139406

How to make ChatGPT provide sources and citations: https://bit.ly/40V7gQi

For ChatGPT's self-identified benefits and limitations visit: https://bit.ly/3LpoaRm and https://bit.ly/41R0H2h

can lead to inaccurate answers. And last, according to the folks at ZDNet, it is more likely that the sources ChatGPT uses for an answer are wrong rather than right (https:// bit.ly/40V7gQi). This highlights an important limitation of Al chatbots in general — they do not truly understand questions. Instead, they use statistical procedures to construct responses.

Considering these limitations, why has ChatGPT's user base grown so quickly? Can you envision a high school or college student who procrastinated in writing a term paper? ChatGPT to the rescue! Or have you ever wanted to go deeper in the answer to a question than a simple Google search provides? For those who write software code, ChatGPT is a viable source of support. ChatGPT can also be used for common documents like résumés or cover letters. But maybe the novelty of having a conversation with AI is partially driving interest. Along those lines, I took a few minutes to test ChatGPT. I asked, "What are the benefits of ChatGPT?" and I also asked. "What are the limitations of ChatGPT?". For ChatGPT's self-identified benefits, go to https://bit.ly/3LpoaRm, and for limitations go to https://bit.ly/41R0H2h.

Maybe the novelty aspect is a significant factor influencing the number of users. But what if a large portion of users are relying on the information ChatGPT provides? In many cases, like trivia night, incorrect information from ChatGPT will not have significant impact. And maybe a high school student's grade isn't what they hoped due to ChatGPT providing incorrect, or partially correct, information. This is where Med-PaLM enters the discussion. Med PaLM is an Al chatbot specifically for healthcare-related questions. I will dig into Med PaLM in a future column. Please send your questions and comments to me. CT

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What You Need to Know About Maximum Fair Prices



Alan Sekula, Pharm.D.

ALMOST DAILY. One of the latest developments related to this topic is the Medicare Drug Price Negotiation Program, which is being established by the Centers for Medicare & Medicaid Services (CMS) for initial

WE HEAR NEWS ABOUT DRUG PRICES

Program, which is being established by the Centers for Medicare & Medicaid Services (CMS) for initial implementation in 2026 with the intent to reduce Medicare drug prices. These reduced drug prices will only apply to Medicare Part B and Part D. While this sounds like a laudable goal, pharmacies are left to wonder, "How exactly is this going to work, and how will it impact me?"

To achieve this goal, CMS must:

- Define the high-expenditure, single-source drug and biological product selection process.
- Complete the drug and biologic selections.
- Commence and complete manufacturer negotiations.
- Publish the prices to enable the pharmaceutical supply chain to use the maximum fair price (MFP) for Medicare Part B and Part D.

The law established a ceiling price for selected drugs and biologics to mitigate the increasing unit costs. The negotiation phase is designed to attain reduced drug prices. There are also penalties, which will be excise taxes on sales of the drug and/or biologic, for a manufacturer not agreeing to a negotiated MFP within the period. These penalties will be based on sales volume and start at 65%, but increase to 95% of sales as a deterrent to not agreeing with CMS to an MFP.

CMS PUBLICATION OF MFP

Once the MFP is determined between CMS and the manufacturer, it will be published for use by CMS. According to the current CMS guidance document, the MFP will

be a single price, even for a selected drug with multiple dosage forms and strengths. A single price will be assigned at the active ingredient level, and this price will represent the cost of the selected drug per 30-day equivalent supply.

CMS knows that this price is not sufficient for use in the market and has detailed 10 steps to calculate the MFP for each dosage form and strength. The steps provide additional detail to spread the final negotiated single MFP value across the dosage forms and strengths; this is done by weighting both dispensed metric quantity and strength-specific WAC (wholesale acquisition cost) prices to spread the MFP systematically. Pharmacies likely will not be required to use or verify these calculations. The weighting process could be guite simple if the strengths are all priced the same and have the same average daily dose, with an even utilization distribution among the strengths. Another point to highlight is that low-priced, low-volume dosage forms and strengths could become the low-priced option. The MFP will shrink the price for these products, and that can be beneficial to patients willing to take multiple doses to save additional funds. To help illustrate this concept, let's review an example of a product with a low MFP for a single strength. A fictitious brand is available in 100mg, 200mg, and 300mg tablets, where the 100mg is one-third the price of the 300mg and only 1% of the units dispensed lead to a small weighted portion of the negotiated MFP. If the single MFP value were \$500 for a 30-day supply, the weighting could lead to a \$5 MFP for the 100mg for a 30-day supply. If patients were willing to take three tablets to achieve the same dose as the single 300mg tablet, they would have a \$15 monthly cost, compared to a higher copay for the 300mg tablet (such as \$25 for a Tier 2 preferred brand).

USE OF MFP

CMS expects the drug compendia to publish MFP values. This will make for easy incorporation into pharmacy management systems and claims adjudication systems. The values will be available prior to the Jan. 1, 2026, effective date.

The law describes payment to the pharmacy as MFP plus "any dispensing fees for such drug" (this aligns with the transparency requirement). Unlike Medicaid, where NADAC (National Average Drug Acquisition Cost) was implemented and pharmacies were required to be paid professional dispensing fees, the MFP drugs lack this requirement. Pharmacies must understand this impact and negotiate to ensure that appropriate funds are included for the dispensing of these high-cost (and potentially high-volume) drugs. As Medicare Part D pharmacy network contracts are negotiated for 2024, pharmacies should consider that there will be no ingredient profit margin for MFP drugs starting in 2026.

Patient payment will be based on MFP and the copay/coinsurance structure (e.g., 25% coinsurance) defined by the plan. Manufacturers are responsible for ensuring dispensers have access to the products at the MFP value. Pharmacy acquisition is the MFP; therefore, there is currently no opportunity for pharmacy profit on the ingredient cost with the proposed process.

OPERATIONALIZING ACCESS TO THE MFP

CMS has offered its proposed process modeled on the generic drug chargeback process. This initiates with a Medicare Part D plan identified via BIN (bank identification num-

CMS Online Resources

Find the following at vwww.cms.gov/inflationreduction-act-and-medicare/medicare-drug-pricenegotiation:

> Medicare Drug Price Negotiation Program: Next Steps in Implementation for 2026

Drug Price Negotiation Timeline for 2026

Medicare Drug Price Negotiation Program Initial Guidance

Fact Sheet: Medicare Drug Price Negotiation Program Initial Guidance

According to the current CMS guidance document, the MFP will be a single price, even for a selected drug with multiple dosage forms and strengths.

ber) and PCN (processor control number) on a paid claim. The pharmacy dispenses the drug, and the patient pays the copay or coinsurance based on the MFP and dispensing fee. The pharmacy communicates the dispensing and request for chargeback to its wholesaler to reduce the acquisition cost of the drug to the MFP (within 14 days and without any billed fees for this service). This function could be performed by a pharmacy management system. As it stands today, there is no current process for a pharmacy to submit a chargeback claim to its wholesaler after dispensing a drug to a patient. The industry will need to develop a process to handle the MFP requirement before 2026. After the pharmacy submits the chargeback, the wholesaler and manufacturer complete the MFP reconciliation chargeback (this process currently exists for generic drugs). It is not too early for pharmacies to engage wholesalers to understand their plans to accommodate this new "transaction." This will likely require a new software release from pharmacy management system vendors to accommodate the new MFP fields and any related transactions

There is also the potential for a 340B-like process, with separate or virtual inventories for select Medicare drugs, not connected with those used for all other lines of business. The details and steps in this guidance review are subject to change pending comment review and CMS updates. Keep an eye out for additional updates later this year and in 2024.

Stakeholders will have to work together to determine the processes and validations needed to ensure timely compliance for 2026. Pharmacies must proactively engage CMS, federal legislators, and PBMs (pharmacy benefit managers) regarding reimbursement for products with an MFP value, and they should also understand and contribute to the process of acquiring the product at the MFP value. Pharmacy interactions with wholesalers and pharmacy management system vendors will be key to successful implementation. **CT**

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catalyst corner

PBM Reform Is Well Past the Tipping Point

RECENTLY, SEVERAL NEWS STORIES reported on federal efforts to reform pharmacy benefit managers (PBMs) as the Senate Committee on Health, Education, Labor and Pensions schedules hearings on numerous reform bills. The National Community Pharmacists Association (NCPA) members weighed in on these bills during their 2023 Congressional Pharmacy Fly-In in April. During that event, the NCPA released the results of a poll showing voters strongly supporting PBM reform (more on this later). That news did not surprise me, having worked on PBM reform in Minnesota while I served as interim executive director of the Minnesota Pharmacists Association (MPhA). At that time, five short years ago, there were a handful of states that had successfully passed PBM reform. Today, all 50 states have some type of PBM reform. PBM reform is well past the "tipping point" — the point at which a series of small changes or incidents becomes significant enough to cause a larger, more important change.

Data from the National Conference of State Legislatures (NCSL) Prescription Drug State Bill Tracking Database reflect this tipping point. I researched how many bills were related to "pharmacy benefit managers" in all states by year, and you can see the results in the table on the next page.

Adam Fein, Ph.D., of Drug Channels noted in his Feb. 28, 2023, blog (see https://www.drugchannels.net/2023/02/drug-channels-news-roundup-february.html) that while Congress is holding hearings, it is the states that have taken control of PBM reform: "From 2017 through 2022, forty-six states have passed 133 laws focused fully or partially on PBMs."The rampup in PBM reform efforts parallels continued consolidation in the PBM industry. The top three PBMs now control about 80% of the market, according to Fein.

The PBM industry has long operated with little transparency or regulation. As PBMs evolved from needed prescription processors to much more, their practices that harm patients,



Marsha K. Millonig B.Pharm., M.B.A.

pharmacies, and manufacturers have grown too. A good issue brief that outlines how PBM practices have evolved was done in 2015 by Applied Policy and can be accessed through the NCPA at www.ncpa.co/pdf/advocacy/concerns-pbm-issue-brief.pdf. The NCPA groups harmful practices into these buckets:

- 1. Network issues
- 2. Patient issues
- 3. Pharmacy anticompetitiveness
- 4. Reimbursement issues
- 5. Coercive contracting
- 6. Fraud, waste, and abuse
- 7. Recent and pending litigation

Many PBMs have preferred or restrictive networks that require their beneficiaries to use the pharmacy of the PBM's choice versus the pharmacy the patient would like to use. Even when pharmacies excluded from these networks are willing to accept the same terms and conditions of those within the network, they are still prohibited from participating in the network. PBMs often mandate patients' use of PBM-owned or -affiliated pharmacies. They may still require patients to fill certain prescriptions at their own retail, mail order, or specialty pharmacy.

PBMs directly harm patients with stringent step-therapy protocols, extensive prior authorizations, pharmacy gag orders, and retroactive claim adjustments that inflate copays. Anticompetitive practices contribute to pharmacy closures, indirectly impacting patients and their care. Industry consolidation has contributed to these anticompetitive practices, which include low reimbursement (underwater, nontransparent, and outdated maximum allowable costs), DIR (direct and indirect remuneration) fees and other clawbacks, use of patient data for steering, onerous audits, and restricting where patients receive pharmacy services. Pharmacies have little to no bargaining power with the PBMs, which can lead to coercive "take it or leave it" contracting.

Many states have changed how they contract with PBMs because

of fraud, waste, and abuse. A good resource to understand spread pricing was created by the NCPA: https://ncpa.org/sites/default/files/2022-11/spread-pricing-infographic-2022.pdf. The Congressional Budget Office estimates that more than \$1 billion would be saved over 10 years by eliminating spread pricing in state Medicaid managed care programs. States are also instituting reverse auctions to address PBM pricing. Looking at the "gross to net" spread overall, IQVIA's just-released report, "The Use of Medicines in the U.S. 2023," shows that the difference between list price (wholesaler acquisition cost, or WAC) spending and payer net spending reached \$255 billion in 2022, up from \$139 billion in 2017 — a nearly double increase in five years.

Finally, PBMs attempted to stall the tipping point by filing numerous lawsuits in states where early PBM reform laws were passed. Eventually the Supreme Court heard Rutledge v. Pharmaceutical Care Management Association, issuing a favorable opinion on Dec. 10, 2020, holding that federal ERISA (Employer Retirement Income Security Act) laws do not preempt states from enacting laws to address abusive practices by PBMs. This decision opened the door for further state legislative efforts to regulate PBM practices.

The recent NCPA poll mentioned earlier was conducted among a sample of nearly 2,000 registered voters weighted to a target sample by a number of demographics. Eighty percent of the voters surveyed were concerned that PBMs steer patients to pharmacies they own or control to maximize profit, with 78% concerned that PBMs require use of their mail-order pharmacies. Eighty percent were also concerned that PBMs keep negotiated drug discounts instead of passing them along to consumers. They also did not like the fact that PBMs have reimbursements less than the cost for pharmacies to acquire medications, and that they overcharge employer and taxpayer funded programs for medications and keep the spread.

Seventy-six percent of those surveyed said they support restrictions on patient steering, 75% say Congress should ban PBMs from penalizing patients for using pharmacies of their choice, and the same percent say Congress should require PBMs to reimburse pharmacies for at least what it costs them to purchase and dispense medications. Passing along negotiated discounts to patients is supported by 78% of voters.

Importantly, the poll shows that voters support more aggressive reforms over narrower options. As the press release for the poll states, "voters were asked to consider two plans: the first would ban patient steering; ban PBMs from excluding cheaper generic

THE TIPPING POINT

Year	Number of States	Number of Bills
2015	0	0
2016	0	0
2017	20	38
2018	44	167
2019	47	209
2020	42	185
2021	48	253
2022	39	149
2023 (to date)	47	223

Data from the National Conference of State Legislatures (NCSL)
Prescription Drug State Bill Tracking Database reflects the trend of
states introducing bills that call for some type of PBM reform.

drugs in favor of more expensive brand-names; require PBMs to share rebates with patients; and require broad transparency in PBM practices. The second plan would ban spread pricing; force PBMs to share discounts with health insurance companies instead of patients; and tell government agencies how much they're getting in discounts from drug manufacturers. Seventy-five percent of voters chose the first plan, a strong signal that Congress should focus on comprehensive reform that benefits patients directly."

Three-fourths of the voters also favored a rule requiring PBMs to report key financial information with government regulators versus one that would require them to simply share certain information with health insurance companies and employers.

NCPA CEO Doug Hoey noted, "Voters want real transparency, public accountability, and a non-coerced choice as to where they get their prescriptions." I agree. Finally, I was pleased at the news that in my state, Minnesota, the Department of Commerce has levied a \$500,000 penalty against CVS Caremark after alleging that Caremark violated a state law prohibiting the steering of patients to pharmacies or mail-order prescription services in which Caremark had an ownership interest. It's a great win for Minnesota patients and pharmacies. I look forward to seeing how other state and federal efforts evolve and look forward to more wins in the near future. **CT**

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