RX Retail Pharmacy

News

Publix Reaches Milestone

Publix Pharmacy recently filled the 100 millionth prescription under its free medication program. Introduced in 2007, Publix Pharmacy's free prescription drug program offers 14-day supplies of selected generic antibiotics and 90-day supplies of generic maintenance medications for hypertension and diabetes at no charge. "We are proud to provide a service that helps our customers afford their medications," said Publix vice president of pharmacy Dain Rusk.

CVS Completes Rollout

CVS Pharmacy recently completed the installation of time delay safes in all of its 353 CVS Pharmacy locations in Virginia, including pharmacies located in Target stores. The safes are intended to help prevent pharmacy robberies and the diversion of controlled substance narcotic medications by keeping them out of the hands of unauthorized individuals. In addition, the safes are expected to help CVS Pharmacy ensure the safety and well-being of its customers and employees.

Benzer Teams with AshHEALTH

Benzer Pharmacy has named AshHEALTH to spearhead its national GPO (group purchasing organization) and pharmacy acquisition strategy. Benzer is targeting aggressive growth as it aims to expand its fast-growing health-hub platform in every community the company serves.

BestRx' scripClip Interface

BestRx Pharmacy Software, an Oak Brook, Ill.-based provider of pharmacy management systems and other related technology, has developed an interface to support its customers using PerceptiMed's scripClip. ScripClip is the will-call management system developed by PerceptiMed that is said to improve workflow and patient safety by ensuring patients get the right prescription every time.

Oscar, Capsule Partner

Oscar and Capsule have announced a new partnership that will bring Capsule's same-day delivery pharmacy benefits to all Oscar members in New York.

Newsmakers

Rite Aid Appoints Robson

EnvisionRxOptions, a wholly owned subsidiary of Rite Aid and a leading pharmacy services and benefits company, announced last month the appointment of Dan Robson as the company's president. Robson will lead all aspects of EnvisionRxOptions operations. Most recently, Robson served as president of EnvisionRxOptions' subsidiary MedTrakRx.

Jeff George John Kiely Shlomo Yanai (Amneal)

Jeff George, John Kiely and Shlomo Yanai have been appointed to Amneal's board of directors. "It is a testament to the opportunities ahead for Amneal that we have attracted leaders of Jeff, John and Shlomo's caliber to our board. They each have deep knowledge of our industry, and we are confident they will help us capitalize on those opportunities. Moving forward, we will continue to add new expertise and fresh perspectives to our board," said Paul Meister, chairman of Amneal's board.

Brad Smith (HHS)

Brad Smith, who cofounded palliative care provider Aspire Health, is the new director of the Centers for Medicare and Medicaid Services' (CMS') Center for Medicare and Medicaid Innovation (CMMI). The Department of Health and Human Services said Smith will be the new leader of CMS' delivery model testing center, replacing Adam Boehler, who left in the fall after roughly a year when he was nominated for another position in the Trump administration.

Kate DeVarney (Titan Pharmaceuticals)

Titan Pharmaceuticals at its annual stockholders meeting last month elected executive vice president and chief scientific officer Kate DeVarney to the company's board of directors.

Craig Tooman (Vyome Therapeutics)

Vyome Therapeutics has appointed Craig Tooman as its chief operating officer and chief financial officer. Tooman brings more than 25 years of operating, financial and M&A experience in the biotechnology and pharmaceutical industries.

DSCSA Delays Raise Doubts

Focus

By Christopher Smith and John Linehan

Christopher Smith

John Linehan

Over the last six years, since the 2013 enactment of the Drug Supply Chain Security Act (DSCSA), late November has marked the introduction of new supply chain requirements for industry stakeholders, and this year the focus was on wholesalers. While some of the new provisions may present new burdens for wholesalers, the Food and Drug Administration has announced, as it has on numerous occasions in years past, a delay in enforcement for one statutory provision that will provide more latitude for wholesalers and manufacturers. Good or bad, the 2019 changes and enforcement delay will have significant consequences for the entire drug supply chain and the overall DSCSA implementation process.

The DSCSA is a federal law requiring tracking and tracing prescription drugs as they flow through the supply chain from manufacturers to dispensers. The law is designed to be phased in over a 10-year period, culminating in 2023, with the creation of an interoperable electronic data exchange to facilitate track-and-trace at the smallest saleable unit level. This year's phased-in provisions are geared towards moving wholesalers closer to the 2023 goal line with important implementation deadlines governing product distribution, returns and verification. However, the changes present critical operational issues for stakeholders, and the FDA's enforcement delays raise doubts about the overall implementation schedule.

The November 2019 effective statutory provisions mandate that wholesalers only transact in drug products encoded with product identifiers, unless the product is otherwise excluded from the scope of the DSCSA or is a grandfathered product. Generally, this means that wholesalers should only be purchasing and selling drug products with a product identifier. This same provision became effective for manufacturers in 2017, although FDA granted enforcement discretion to manufacturers until 2018.

That FDA did not provide a product identifier delay for wholesalers indicates the agency's confidence that manufacturers and repackagers are properly including product identifiers on their drug products. However, as recently as early 2019, industry insiders were reporting scanning problems with two-dimensional product identifier barcodes due to printing color issues and placement of the barcodes on the drug products. Wholesalers, likewise, have reported barcodes with data content problems, including missing data elements or erroneous data elements.

In regard to returned products, a major new requirement is that wholesalers may only accept returned drug products from dispensers or repackagers where the wholesaler can associate the returned product with a related transaction statement and related transaction information. In other words, wholesalers must only accept returned products that they originally distributed. This marks a substantial change from the status quo in which wholesalers are permitted to accept saleable returns regardless of who originally distributed the product.

If wholesalers are unable to accommodate this returns change, dispensers risk losing wholesaler credit on returns, and product flow disruptions are likely to occur through reverse distribution. This is a very real concern as, presently, it is unclear how wholesalers will associate returned product with its transaction information and transaction statement. Many wholesalers have complained of operational difficulties in this regard, as product identifiers will not be included in the transaction information until 2023. Recognizing this operational obstacle and to avoid supply chain disruptions, wholesalers may need to consider — and FDA may need to accept — alternative methods for demonstrating "association" until 2023.

The final two 2019 changes involve drug product verification. First, wholesalers must have systems in place to verify, at the package level, whether a product is a suspect product, including

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FDA Opioids Program Found Lacking

BALTIMORE — In 2012, the Food and Drug Administration established a risk-management program aimed at curbing improper prescribing of extended-release and long-acting opioids. That program, however, has come under scrutiny.

According to researchers at the Johns Hopkins Bloomberg School of Public Health, the program may not have been effective because of shortcomings in its design and execution.

Extended-release and long-acting opioids, which include oxycontin, account for a significant proportion of the prescription opioid market and are among the most misused, say the researchers in an online study published in December in *JAMA Internal Medicine*.

For their analysis, the researchers reviewed more than 9,000 pages of internal FDA documents, obtained through a Freedom of Information Act request, on the agency's Risk Evaluation and Mitigation Strategies program for extended-release and long-acting opioids. The authors concluded that the program never had proper evaluation procedures in place — essentially leaving the FDA without critical information about whether the program was working.

The assessment process was faulty from the beginning.

In their review, the authors found a number of critical design flaws in the evaluation program, including an over-reliance on surveys rather than other sources of health care information such as clinical records; use of nonrepresentative and self-selected patient and prescriber populations; and a failure to directly link prescribing behaviors with program participation.

"The FDA's Risk Evaluation and Mitigation Strategies program is a primary way to promote the safe use of these medicines, but we found that the mechanisms for assessing the program's effectiveness were deficient from the start," says the paper's senior author, Dr. Caleb Alexander, professor in the Bloomberg School's Department of Epidemiology and former chair of the FDA's Peripheral and Central Nervous System Drugs Advisory Committee.

The current opioid crisis in the U.S. originated largely from the wide availability and misuse risks of pre-

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How Technology Is Helping Improve the Prescription Journey

By Ken Whittemore

There's no question that e-prescribing has changed the way prescribers, pharmacists and patients interact with regard to medication therapy. It has improved efficiencies and patient safety. And not surprisingly, within the next few years, virtually all prescriptions in the U.S. will be transmitted electronically, including those for controlled substances.

But are the prescribing and dispensing processes as efficient and painless as possible? Thanks to new tools and technologies that are emerging almost daily, they're getting there.

For example, the new NCPDP SCRIPT Version 2017071 uses technology to drive the modernization of e-prescribing even further. Enhanced utility made possible via new and/or expanded data elements, plus new functionalities such as RxTransfer, which is an electronic way of transferring a patient's prescription from one pharmacy to another, and NewRxRequest, which allows a pharmacist to request a new prescription from a prescriber with either minimal information or expired prescription information, will be game changers. Ultimately, this new version of the standard will streamline and improve the e-prescribing process in hundreds of ways, creating more efficient and safer prescriptions, better patient outcomes and less pharmacist burnout.

Let's take a look at the prescription journey, along with some common — and not-so-common — pain points, and see how the right tools let pharmacists and their staffs do more, faster — without sacrificing accuracy:

Step 1: Prescription arrives at pharmacy.

Believe it or not, according to a study published in the *Journal for Managed Care & Specialty Pharmacy*, "Take one tablet by mouth two times daily" can be expressed more than 800 different ways — so it can be difficult for a pharmacist to know what the prescriber intends. Therefore, a margin for error is present right out of the gate. Standardized e-prescription language and the use of unique codes for specific data elements help pharmacists understand prescriber intent, avoid adverse drug events (ADEs) and reduce administrative burden for pharmacists.

Step 2: Pharmacist checks patient benefit eligibility for the medication prescribed.

Until recently, a patient without their benefit card meant wasted time and back and forth checking eligibility. But patient-matching technology now enables the pharmacist or their staff to check eligibility even when the patient is not able to present their benefit card. The pharmacist also can alert the prescriber to any potential insurance coverage problems with a prescription earlier in the process.

Step 3: Pharmacist checks for patient-specific therapeutic alternatives.

With cost a leading cause of prescription abandonment, the sooner one can identify out-of-pocket costs for patients, the more likely one will be able to get them to adhere to their medication regimen. To maximize adherence and minimize time to therapy, Real Time Prescription Benefit tools can give the pharmacist access to a patient's medication benefits and identify more affordable alternatives — all within the fulfillment workflow — thereby maximizing adherence and minimizing time to therapy.

Step 4: Pharmacist alerts prescriber to potential insurance coverage problems with the prescription.

No one likes delays at the pharmacy, and prior authorizations are not only a pain for pharmacists but also for patients and prescribers. Prior authorizations can cause treatment delays and trigger prescription abandonment. Additionally, completing a manual prior authorization is time consuming and frustrating. Automated prior authorization transactions can eliminate these extra hours on the phone or faxing with provider offices and payer help desks. The technology integrates directly with electronic health records, enabling health care professionals to easily obtain prior authorizations in real time at the point of care — helping to relieve this administrative burden. Additionally, when combined with Real Time Prescription Benefit tools, clinicians can quickly see if a prior authorization is required and view therapeutic alternatives, including those that don't require a prior authorization.

Step 5: Pharmacist electronically communicates and coordinates with other care team members

Gone are the days of having to break from the fulfillment workflow to call or fax another health care professional with a question or concern. For example, RxChange transactions eliminate hours on the phone with provider offices by enabling pharmacists to request a change, clarification or prior authorization from the prescriber electronically when: a therapeutic alternative is identified, a generic substitute is identified, the prescriber needs to initiate prior authorization, the drug use needs to be evaluated, the prescription needs clarification or the prescription is out of stock.

Ken Whittemore

In addition, smart messaging lets pharmacists efficiently sort and handle time-sensitive communications, including refills and questions from other providers. From medication management to collaborative practice agreements to addressing controlled substance abuse, digital clinical direct messaging enables seamless care collaboration.

Step 6: Patient receives a prescription optimized for affordability, adherence and effectiveness.

When prescribers can quickly access patient medical history and records and connect with other providers regardless of location or health information exchange, patients can afford their medication, which means they are more apt to take it as prescribed and experience therapeutic benefits sought by them and their health care providers.

More than ever, pharmacists and pharmacies are being recognized for the critical role they play in health care. But they must have the right tools in place to thrive as they're pressed to do more, faster — without sacrificing accuracy. The prescribing workflow is a challenging one, but technology is helping improve it by facilitating smarter therapeutic choices, alleviating stressors for pharmacists and enabling better care for patients.

Ken Whittemore is the vice president of professional and regulatory affairs at Surescripts.

DSCSA Delays Raise Doubts

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verification of the product's standardized numerical identifier. Verification is an important change as it requires a wholesaler to contact the manufacturer to determine whether the product identifier on the package corresponds to the standardized numerical identifier or lot number and expiration date assigned to that product. This verification requirement applies regardless of whether the wholesaler received the suspect product from a manufacturer or repackager or as a return from a dispenser. This added layer of responsibility regarding suspect product verification and the need for verification systems will require increased investments by wholesalers and manufacturers in manpower, time, resources, system development and funding.

Along with the suspect product verification requirement, a similar wholesaler verification requirement governing saleable returns was also set to commence in November 2019. This verification requirement requires wholesalers upon receipt of a saleable return, to verify the product identifier for each sealed homogenous case of drug product, or, if the product is not in a sealed homogenous case, verify the product identifier of each package — i.e., the same type of manufacturer-oriented verification as required for verification of suspect products. However, in September 2019, two months before the November start date, FDA granted one year of enforcement discretion as to this verification requirement. Accordingly, until November 27, 2020, FDA will not take enforcement action against wholesalers who further distribute saleable returns without having verified the product identifier. Likewise, FDA will not take enforcement action against a wholesaler for providing a transaction statement to a purchaser that the wholesaler has saleable returns verification compliance systems in place, where the wholesaler does not have such systems in place.

Wholesalers have embraced the last-minute reprieve.

Wholesalers and manufacturers have embraced this last-minute reprieve, which will give them more time to develop a system to verify saleable returns. Clearly, more time is needed, as at least one vendor was still testing a verification router service as part of the FDA's 2019 DSCSA pilot projects program and did not intend to complete testing until the end of 2019. Nevertheless, despite FDA's enforcement discretion, manufacturers still face saleable return verification obstacles not faced by wholesalers. FDA's enforcement discretion guidance made clear that manufacturers must still respond to wholesaler verification requests, even though wholesalers are not required to submit such requests until 2020. Accordingly, if wholesalers voluntarily seek saleable returns verification over the next year, manufacturers are still obligated to comply.

This year wholesalers were the primary target of newly effective DSCSA provisions, although dispensers and manufacturers are also impacted by provisions addressing returned products and/or suspect and illegitimate products. As has occurred in prior years, the rollout of newly effective 2019 DSCSA requirements is not entirely smooth. For example, wholesalers are being asked to implement provisions without the operational ability to do so, as with the wholesaler "association" requirement. Another reiteration of past years is FDA continuing to grant enforcement discretion for certain DSCSA provisions. Unsurprisingly, given industry operational difficulties, this year's provision du jour is the saleable returns verification provision. These developments reveal that ultimately — in fits and starts — the staggered phased-in DSCSA implementation continues to progress in some fashion. Nonetheless, the bumpy implementation along the way towards 2023 raises doubt for the supply chain and FDA as to the continuing viability of the 2023 deadline for the interoperable electronic data exchange, as well as for intermediate deadlines.

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Opioids Program Faulted

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scribed opioid painkillers. The crisis has now expanded to 50,000 opioid-related overdoses per year and millions of cases of opioid-use disorder. Among the more dangerous prescription opioids are extended-release and long-acting versions of oxycodone, morphine and other painkillers, designed to deliver opioids into the body over longer periods of time than immediate-release forms of these drugs.

Studies suggest that compared to immediate-release forms, extended-release and long-acting opioids are more likely to be used non-medically, and more likely to lead to opioid use disorder as well as overdoses.

The FDA's program required extended-release and long-acting opioid manufacturers to provide FDA-approved educational materials to both prescribers and patients in order to instruct them on the safe and appropriate use of these products.

During the program, extended-release and long-acting opioid manufacturers also were required to monitor and report annually on prescriber knowledge and behavior associated with these drugs, as well as on data related to patient access and safety.

The FDA documents suggested that Risk Evaluation and Mitigation Strategies' educational materials were consistent with FDA guidelines. However, the FDA documents also suggested that assessments of the impact of the program were, for the most part, inadequate.