Align the Team
With Better Workflow

Improve staff efficiency

Eliminate repetition mistakes

Do more MTM

Lower wait times

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Cash is king, especially in a pharmacy. With tight margins, DIR fees, generic effective rate fees, and the delay in receiving third-party reimbursements, it’s easy to find yourself faced with cash flow pressures.

Although several factors might contribute to tight cash flow, the following three red flags are common.

1. **Poor Accounting Fundamentals**
   Without a fundamental accounting system built with integrity, any financial metrics used to analyze cash flow essentially have little to no value. How can you determine what is causing poor cash flow if you don’t know what the metrics are and how the numbers reconcile on your financial statements? If you don’t know where you stand, then you cannot know what the issues are that could impact your cash flow. If you are not confident in your accounting system and are facing cash flow problems, bringing those fundamental numbers into focus should be your first course of action.

2. **Low Gross Margin**
   Once the accounting fundamentals are in place, it’s all about gross margin. How does your margin stack up against your peers in the industry and with national averages? Margins that are below the averages without a valid reason are key contributors to poor cash flow. Because “cost of goods sold” is your biggest expense, how well you buy is a key metric. Margins are directly associated with inventory; poor inventory management can be a contributor. Issues with adjudication can result in the pharmacy facing delays in receiving payments from third-party payers, or worse, billing below what third parties typically pay.

3. **High Payroll and Benefits Expenses**
   Outside of cost of goods sold, payroll and benefits are your biggest expenses. Pay attention to your payroll as a percent of revenue. Are you above or below average for your pharmacy type? Above average payroll and/or benefits will eat right into cash flow. Determine what the average payroll is for your size and type of pharmacy and work from there. Do you make money on those extra hours on Saturday or Sunday? Are your internal operations maximizing your payroll dollars? Your pharmacy peers running lean payroll are feeding their bottom line and cash flow.

Those are three common red flags that point to poor cash flow. Surprisingly, another area of poor cash flow is growth. It seems strange, but strong growth in a pharmacy means larger cost of goods purchases. That requires more cash flow. The twist is that your wholesaler bills are usually due before you collect from third parties. This is an inherent cash flow issue inside a pharmacy. If you find yourself in this situation, you will want to assess your liabilities and debt load to find the right ways to help finance your growth. If any pharmacy owner is not careful, a pharmacy can literally grow into bankruptcy.

Taking a step back, pharmacy owners need to know how to track and benchmark their cash flow. Assuming your accounting fundamentals are in place, the “current ratio” will be your go-to cash flow key performance indicator. You find that by dividing your current assets by your current liabilities. Proper classification of your current assets (mainly cash, receivables and inventory) and current liabilities is key. You want to strive to maintain a ratio above 2:1, and the higher that ratio, the better your cash flow will be. Any ratio below 2:1 is a clear indicator of problems in your pharmacy.

Stay sharp with strong accounting fundamentals, and increase your understanding of your pharmacy purchasing, inventory, and payroll to turn these red flags into green flags.

Scotty W. Sykes, CPA, CGMA, is with Sykes & Company in Edenton, NC, which specializes in accounting for pharmacies.
Current healthcare culture is being likened to a dangerous concoction of excessive prescriptions in a recent report published by the non-profit Lown Institute.

According to “Medication Overload: America’s Other Drug Problem,” 750 adults over the age of 65 are hospitalized every day due to side effects from one or multiple medications. Over the past decade, these adverse drug events (ADE) resulted in more than 35 million requests for treatment and 2 million hospital admissions.

ADEs, as described in the report, are most often a result of polypharmacy. With each medication added to a drug regimen, whether it is the first medication to treat a disease or subsequent medications to alleviate side effects, the risk of an ADE increases between 7% and 10% with each additional prescription.

More than four in 10 adults are taking more than five prescription medications per day, according to the report. Twenty percent of those adults are taking more than 10 drugs per day. If supplements and OTC products are included, nearly 67% of all older Americans are taking medications — a 300% increase when compared with previous decades.

The Lown Institute cites three aspects of the current practices in medical treatment that have led to the culture of polypharmacy: an emphasis on prescriptions as one of the easiest and more

Continued on facing page

4 in 10 adults are taking more than five prescription medications per day

With each additional prescription risk of an adverse drug event increases

7% $>$ 10%
During the Congressional Pharmacy Fly-In on April 10th, HHS Secretary Alex Azar addressed the audience of community pharmacists and praised the work of pharmacists. Compared to other professions in the healthcare industry, Azar said community pharmacists know best how to put patients at the center, provide them with peace of mind, and treat them like a person and not a number.

“We know the burdensome nature of the DIR system can be a real challenge for community pharmacies, while a lot less of a burden for pharmacies owned by the PBM itself.”

Azar Praises Community Pharmacies, Outlines Initiatives in NCPA Address

Test strips for conditions like diabetes, or those used to measure warfarin levels, have been sold online or directly from a seller. The FDA warns these may yield inaccurate results.

No deaths or other serious injuries were reported to the FDA; however, use of unauthorized strips could lead to infections which would subsequently result in harm or death.

Test strips should only be purchased from a trusted source like a local pharmacy or directly from the manufacturer. Check packaging and expiration dates to ensure boxes have not been opened or altered and are still good to use.

— Valerie DeBenedette, managing editor

“Polypharmacy” continued effective ways to help patients and reduce pain, information and knowledge gaps between physicians and patients, and the fragmentation of care among specialists and primary care physicians. Recognizing the growing threat to patients, the Lown Institute—based in Brookline, MA—has made it their mission to address instances of poor healthcare value and emphasize the threat to patients, while simultaneously working with healthcare practitioners to develop better healthcare practices.

The group plans to release a more comprehensive report—the National Action Plan for Addressing Medication Overload—by early 2020.
Th e CDC is currently conducting inves-
tigations into a Michigan-based compre-
hensive hypertension control program to
determine whether it has the potential for
nationwide implementation.

The program consists of a cooperation
between Michigan Medicine Clinic (MMC)
pharmacists and Meijer stores to increase
accessibility to patients. According to the
CDC, MMC served 1,332 patients with hy-
pertension in 2017, while an additional 514
patients were able to be served in three
local Meijer stores.

Within the cooperation, pharmacists
move through the five-step Pharmacist’ Pa-
tient Care Process and used blood pressure
alerts to ensure all patients with hypertension
are referred to a pharmacist.

As a result, the CDC reports hy-
pertension management control
rates in the area increased to 77%,
up 5% from the previous year.

Rate increases have been attributed to
various aspects of the cooperative, including:
the five-step Pharmacists’ Patient Care Pro-
cess; implementing blood pressure alerts to
patients; granting pharmacists greater con-
trol over administration; and new onboard-
ing protocols, practice guidelines, shadowing
experiences, and EMR system training.

The program originated at Michigan
Medicine, the clinical facility formerly the
University of Michigan Health System. Mich-
igan Medicine provides preventive and acute
health care services to diverse populations
across southeastern Michigan and has re-
cently expanded the use of its ambulatory
services to three Meijer community phar-
macy locations in Washtenaw County.

Specialty Pharmacies—particularly in
healthcare settings—continue their rapid
growth. More than 900 unique pharmacy
locations received specialty pharmacy ac-
creditation by the end of 2018, a 25% in-
crease from 2017, according to a DCI report.

The 911 specialty pharmacies operating
in 2018 is more than double the number of
specialty pharmacy locations in 2015, a
new Drug Channels Institute (DCI) re-
port shows. DCI released the report ahead of
Asembia’s Specialty Pharmacy Summit,
April 29-May 2 in Las Vegas.

Continued on facing page
Pharmacy locations owned by healthcare providers — hospitals, health systems, physician practices, and providers’ group purchasing organizations — account for more than a quarter of all accredited specialty pharmacy locations, DCI finds. But, independently-owned specialty pharmacies account for almost half of accredited specialty pharmacies.

“Most hospitals and health systems are aggressively pursuing specialty pharmacy dispensing revenues. They want to provide integrated, comprehensive care for patients with complex, chronic conditions and integrate specialty pharmacy services with ACOs,” Adam Fein, PhD, CEO of DCI, tells Drug Topics.

Hospitals and health systems can also generate substantial profits by acquiring discounted specialty drugs under the 340B Drug Pricing Program, he adds. “Like smaller retail pharmacies, health systems are not always able to join manufacturers’ limited specialty pharmacy dispensing networks. Health systems, however, can influence manufacturers’ pharmacy network strategies far more significantly than can specialty pharmacies. Their physicians can demand that the hospital’s pharmacy gain access to a limited dispensing network. This influence has increased, because hospital and health systems have been acquiring physician practices,” Fein says.

DCI’s location data do not necessarily correspond with the market share of specialty prescriptions or specialty dispensing revenues. The top four companies—all of which are fully or partly owned by a PBM—accounted for more than 70% of prescription revenues from pharmacy-dispensed specialty drugs, according to DCI.

Despite significant growth in 2018, the specialty pharmacy market is reaching maturity as PBMs and insurers dominate specialty drug dispensing channels, Fein tells Drug Topics. “The go-go growth years are fading. It’s becoming harder to enter the industry and more challenging to scale a business.”

DCI identified unique pharmacy locations that had achieved specialty pharmacy accreditation from the Accreditation Commission for Health Care, the Center for Pharmacy Practice Accreditation, and/or the Utilization Review Accreditation Commission (URAC).

DCI found 606 locations accredited by only one of the three organizations, and 305 pharmacy locations accredited by two or more of the three, a rise of 70% from 2017.

— Christine Blank, contributing writer
Looks Matter, Neatness Counts

Is the look of your pharmacy impeding your success?

My wife hates it, but whenever we travel, I drop in on any independent pharmacies I happen to notice. For me, it is a fun way to meet new people and discover new ideas. I wish I could say that most of what I see is impressive, but it’s not. Too many independent pharmacy owners fail to give the exterior and interior look of their pharmacy the attention it deserves. This is unfortunate for, as pharmacy migrates into providing new, more, and better professional services, they need to upgrade and improve the look and feel of their pharmacy, inside and out.

Why? Because, looks matter and neatness counts. The look, feel, and layout for a pharmacy striving to provide more profitable services must be different—indeed, better—than that of a traditional community pharmacy.

Between 1995 and 1997, it was my privilege to help lead a major industry project called “The Concept Pharmacy.” The project was supported by APhA and the National Wholesale Druggists’ Association. Our task was to search out and interview cutting edge pharmacists and then document and share how they had profitably implemented enhanced care services.

Not surprisingly, one key element of success each of these innovative pharmacists mentioned was the decision to upgrade the physical layout of the pharmacy so that it provided an environment conducive to the new services they were offering. Most pharmacists mentioned adding private or semiprivate counseling areas, but some also stressed the importance of rearranging the layout and product assortment of the front end. In addition, some pharmacists even suggested displaying high-end supplements and other items that directly tie in with the new services you’re looking to provide.

As I reflect on the things I see successful pharmacy owners doing to improve the look and feel of the pharmacy, I think of the analogy of producing a play. For a play to be successful you need actors, a script, and props. For your new services to be well received, you need people that can provide the service, a carefully prepared way to tell patients what you are doing, and you need to make sure the look and feel of your pharmacy sets the stage for the services you plan to provide.

Andrew Finney, RPh, owner of Perkins Drugs recently built a brand-new building in which he opened a second pharmacy in Gallatin, TN. The new pharmacy was built with a private counseling area and with a store layout that supports his professional services. It looks great, inside and out!

In looking at the pictures of his new pharmacy I was impressed that he upgraded the will-call bin area by installing an LED light-supported prescription retrieval system. When a patient picks up their medication the clerk types their name or phone number into the point of sale, which causes the bag handle containing that person’s prescription to light-up. The clerk can quickly spot the patients’ bag, retrieve it, scan it and check the patient out. Finney adds that with all the technology in his pharmacy it is nice to have something that is visible to his customers and supports his professional image.

As you strive to find new, better, and more profitable ways to serve the people of your community, give some thought to improving the exterior and modernizing the interior. Upgrading your physical facility just may be the most important thing you do to prepare for the future. For, as my 10th grade English teacher said when I turned in my book report, looks matter and neatness counts.
As the U.S. opioid addiction crisis continues, the pharmacy industry’s role in addressing the epidemic increases. Around 68% of more than 70,200 drug overdose deaths in 2017 involved an opioid, according to the CDC. Moreover, about 80% of people who use heroin first misused prescription opioids, according to the Substance Abuse and Mental Health Services Administration. Since the next patient standing across the counter could be an at-risk patient, or a potential perpetrator of fraud or abuse, are pharmacies doing everything possible to vet each patient interaction?

The Power of Observation
There are obvious situational markers that pharmacists flag and follow-up on, including cash-only buyers, late-night fills, and group approaches. Provider information; authenticity of the script; and the proximity between provider, patient, and store are all things that can prompt a pharmacist to ask questions.

Technologies exist that allow pharmacists to confirm prescriber eligibility, patient identity, as well as query a state prescription drug monitoring program database. However, the databases are not interconnected or not sufficiently integrated in pharmacists’ workflows.

Pharmacies have begun to implement policies and technologies to help reduce or eliminate opioid fraud. Whether limiting opioid prescriptions to a seven-day supply or consulting with patients for opioid prescriptions about addiction risks and safe storage and disposal, pharmacies are taking a more proactive role in addressing the obstacles.

Mining Big Data for Meaningful Data
Despite these steps in the right direction, there is more the industry can do to accurately safeguard patients who are at risk and identify potential fraudsters.

The primary avenue for opioid abuse is drug diversion. Because drug diversion is a social phenomenon, with little to no indication found in medical data, adding public records data to transactional prescription data can deliver potential diversion indicators that no data set can reveal on its own. Such technology can identify connections among individuals and their interactions with providers, pharmacies, or even other patients; flag aberrant behavior patterns; and help pharmacists accurately determine who may be at risk for potential fraud or abuse.

Data and analytics tools can detect provider prescriptions for excessive quantities, prescriptions to family members or large social groups, or prescriptions that do not correspond with a medical event and flag them as risks.

Likewise, technology can correctly flag individuals who are potentially at risk for overdose, abuse, or diversion. Some patients doctor shop and get many prescriptions filled by various providers in a relatively short amount of time and subvert current process communication windows.

Working Towards Industry Collaboration
While a pharmacy can benefit from insights about what happens in its stores, in many cases it misses the big picture of what substances the patient has received from other pharmacies, whether the patient demonstrates other potential signs of addiction, whether the patient’s connections are also visiting the same prescriber, and whether they’ve all attempted to obtain the same script. For the safety of patients and betterment of the industry, a contributory prescription database for information-sharing is the goal and would bring immense value in addressing this epidemic.
Big Storm Brewing for Specialty Pharmacy

New prescriptions in a pharmacy “go through what is often a very slow prescriber credential verification process.”

Specialty pharmacies dispense some of the most expensive, sensitive, and life-saving medications to patients, the kinds that can cost more than $100,000 a year. Unfortunately, the way these prescriptions are being filled today is often chaotic and ripe for fraud, is different in each state, and might be about to get even worse for patients.

Before we get into the details of this brewing crisis around the dispensing process, let’s take a quick look at the sector. There were 729 accredited specialty pharmacy locations in 2017, a number that doubled from 2015 according to Drug Channels research. These pharmacies account for 40% of the $450 billion annual pharmaceutical market, with a rapidly increasing share of the 4.25 billion retail prescriptions in the United States each year.

“Of the $181 billion in 2016 sales of specialty drugs, $45 billion in sales was in the oncology market, the largest single therapeutic category. Medications for autoimmune issues came in second at $37 billion,” according to a 2018 article in Drug Topics.

Specialty pharmacies are a major part of the American medication experience for many patients, including those navigating cancer, blood disorders, liver disease, and infertility. When new prescriptions come in to these pharmacies, they go through what is often a very slow prescriber credential verification process that can involve manually calling or looking up licenses for the prescribers on various board websites. When refills arrive, the pharmacies usually don’t verify prescriber licenses at all. That license could have expired, or the physician moved to a new state, had their license revoked, retired, or passed away.

This means patients are sometimes getting drugs from unlicensed prescribers or are being kept waiting for medications because of slow verification. It’s a process that lets through a lot of fraud and abuse. The process has regulations that vary significantly from state to state. In our research, eight states have ruled that all refills are void when the prescriber’s license becomes inactive; another 20 states limit the number of refills allowed after license inactivity.

This is a serious issue for patients and for anyone concerned about medication fraud and abuse. Now, the problem is potentially getting bigger.

CMS has been accelerating what is called “clawbacks.” It is requiring medical organizations to return payments they made for earlier services tied to expired or fake provider credentials.

This kind of attention to fraud and errors is healthy because we all need to focus on making healthcare more affordable, safe, and fair. However, it means that specialty pharmacies can face big bills from CMS if they have dispensed medications to patients without properly confirming prescriber credentials. We know the rate of those mistakes is high—we’ve seen it as high as 40% on some rosters—and that specialty pharmacies don’t have the technology and credential verification processes in place to do the verifying that would protect them from these cases.

What can be done? How do we update the predispense verification process for specialty pharmacies so that patients get their medications quickly and accurately while combating fraud and helping specialty pharmacies avoid huge penalties?

It’s time for specialty pharmacies to take action. It is an easy problem to fix with predispense verification technology that is ready to be implemented. It’s a problem we should all want to fix for a medical system that fights abuse and protects patients.
Provider Status Is Crucial to Fight the Opioid Crisis

On April 5, state law SB 265 formally recognized pharmacists as healthcare providers in Ohio, allowing them to practice as part of a patient’s care team and to bill health insurers for their time. This progressive law adds the pharmacist as a key player to a patient care team by improving medication management, including opioid misuse, a major health crisis in the United States. SB 265 aims to knock down the barriers that have stood in the way of health plans, hospitals, and healthcare teams from integrating and using the expertise of the pharmacist.

With the passage of the new law, Ohio pharmacists will be more present in clinical settings where they can work with patients to manage their medication regimen and be reimbursed by insurers for their time and services. Pharmacist services that may be covered include drug therapy management and vaccine administration. This long-awaited status comes after years of legislative effort without resolution. Ohio hopes to gain recognition as a trendsetter for national adoption of the law in the years ahead.

SB 265 will be extremely beneficial for patients with chronic conditions who need regular monitoring of their medications, as well as for patients taking multiple medications, to ensure no adverse effects occur. But how can pharmacists under this new legislation help combat the opioid epidemic?

**Pharmacists Combat the Opioid Crisis**

According to the CDC, every 11 minutes someone dies from an opioid overdose in the United States. SB 265 comes at a crucial time where the front line of defense against the opioid crisis are those educated at the highest level about these dangerous drugs—pharmacists. With the heavy toll of opioid drugs crippling the United States, the use of pharmacists in a patient’s care plan may be most important.

A pharmacist is one of a patient’s most qualified team members when it comes to addressing complicated medication-related challenges. When you have a legal problem, you want a lawyer. When you have a drug problem, you want a pharmacist. They are the professionals who have the most in-depth knowledge in evaluating drugs and the effect drugs have on the human body.

Ohio has one of the highest rates of opioid-related overdose deaths. Many cases of opioid-related abuse stem from chronic conditions; patients start taking a dangerous drug as part of their recovery plan and escalate their use in conjunction. Pharmacists may be the first to suspect opioid abuse and misuse. Because of this, many pharmacists have altered the way they interact with patients who take opioids. Ohio pharmacists can now actively reduce the negative effects of substance abuse on communities and improve healthcare outcomes in the state.

Pharmacists are keenly aware of best practices in drug prescribing and of when opioids may not be necessary because another medication could be equally effective without risking addiction. Switching to nonaddictive medications could theoretically decrease the number of opioids dispensed. If pharmacists nationwide continue to gain provider status, laws such as Ohio’s SB 265 will be a critical component to improving patient care and tackling the opioid crisis one prescription at a time.

**What’s Next?**

Only time will tell exactly how much pharmacists will influence and assist in combating the opioid epidemic, but it is likely their contribution will be influential. Adding pharmacists as a critical part of a patient care team will be essential in not only preventing opioid abuse from starting, but in identifying ways to help those suffering from addiction.
EPA’s New Rules on Drug Disposal Begin in August

By David Frabotta, executive editor

The U.S. Environmental Protection Agency has passed new hazardous waste pharmaceutical disposal rules that ban disposing of drugs into sewer systems, but the approved regulations allow some flexibility for drugs that can be redistributed or that qualify for manufacturer credit.

The new rules, established in 40 CFR part 266 subpart P, the Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities, go into effect in August with variable implementation deadlines in each state. Healthcare facilities will be able to accumulate hazardous waste pharmaceuticals onsite without a Resource Conservation and Recovery Act permit for 365 days, which is an increase from 275 days in the current regulation. The rule also removes over-the-counter nicotine replacement therapies from the acute hazardous waste listing, thereby classifying it as non-hazardous waste.

Pharmacies and healthcare facilities will not be classified as a large-quantity generator when they create more than 1 kilogram of acute hazardous waste pharmaceuticals in one month, and thus will not need to comply with satellite accumulation area regulations.

In a welcomed and unusual departure from ubiquitous paperwork, pharmacies will not need to specify hazardous waste codes on manifests, will not need to keep track of how much hazardous waste is generated each month, and will not need to segregate acute and non-acute hazardous waste pharmaceuticals.

The definition of hazardous waste pharmaceuticals are established in Title 40 Code of Federal Regulations part 261.2 subpart C and D. Two major exceptions are if a pharmaceutical product can be lawfully donated or reclaimed, and OTC products that have reasonable expectations of lawful reuse or redistribution. Drugs that do not have a reasonable expectation to be eligible for manufacturer credit, a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be reused, dietary supplements, and homeopathic drugs must be disposed of by a hazardous waste treatment, storage, and disposal facility. This includes:

- Investigational drugs
- Free samples of pharmaceuticals received by healthcare facilities
- Residues of pharmaceuticals remaining in empty containers
- Contaminated personal protective equipment
- Floor sweepings
- Clean-up material from the spills of pharmaceuticals.

What Pharmacies Need to Do

As the new regulations come into force this summer, pharmacies will need to check state laws and state regulatory activities to determine compliance deadlines before the federal deadline in August. Subpart P compliance deadlines will include a one-time notification.

The new regulations require all personnel to be trained on non-creditable hazardous waste pharmaceuticals. A system will need to be created to determine whether drugs are creditable or non-creditable. Storage protocols will need to be established for each category. The pharmacy must also distinguish between prescription and nonprescription products. Storage cannot exceed 365 days onsite, and healthcare facilities must adhere to labeling requirements, container standards, and shipping standards.

EPA has also passed new empty container standards for dispensing bottles, syringes, IV bags, and other acute and nonacute hazardous waste pharmaceuticals. One notable change is a ban on triple rinsing containers with acute hazardous waste.

Exemptions exist for DEA controlled substances, which must be managed in compliance with DEA regulations and destroyed by a method that meets the agency’s nonretrievable standard, including approved waste combustors or incinerators.

The final rule can be read in The Federal Register. More can be found on EPA’s website, including a free webinar (https://clu-in.org/conf/tio/HazWaste-Pharmaceuticals/).
CBD—cannabidiol—is suddenly everywhere and is being touted as a cure-all ingredient in lotions, tinctures, salves and balms. The dramatic proliferation of CBD products has led analysts at the Brightfield Group to predict the market will reach $22 billion by 2022, "outpacing the rest of the cannabis market combined."

CBD oil is a booming business, but is it legal? That depends. Should pharmacists recommend CBD oil? That depends, too.

The variables involved in answering both questions includes the evolving and often puzzling patchwork of state and federal laws that govern products made from the cannabis plant. "You've got all sorts of state laws with some states approving marijuana, some only medically, some medically and recreationally, and some approving only certain products," said Timothy Welty, PharmD, professor of pharmacy practice at the College of Pharmacy and Health Sciences, Drake University in Des Moines, IO. "The other confusing part is the whole issue of licensure that varies from state to state.

Then we have the 2018 Farm Bill. Everyone still trying to sort out what that means. It's extremely confusing."

Medical marijuana is now legal in 33 states, with 10 states and Washington DC, also legalizing recreational use. Legislation varies regarding the role pharmacists can—or have to—play in dispensing marijuana. In Arkansas, Connecticut, Minnesota, Pennsylvania and New York, pharmacists must play a role in dispensaries, while in other states they are excluded by law. Whether a pharmacist can recommend CBD oil also depends on the state.

"In Iowa there are two state-approved manufacturers of CBD products, but a pharmacist cannot be involved with dispensing or selling these state-approved products," said Welty. "Over the border in Minnesota, the law is different. They actually require pharmacists to be in the dispensary. Pharmacists have to be careful about what states allow with the range of CBD products. "In some states it’s clearly a violation that could lose them their license," he adds.

In 2018, the Agriculture Improvement Act—the Farm Bill—removed the hemp plant from the Controlled Substances Act. Cannabis derivatives with less than 0.3% of the psychoactive compound delta-9-tetrahydrocannabinol (THC) are no longer considered an illegal substance. CBD is derived directly from hemp plant, a close cousin of the marijuana plant, but which usually contains a low percentage of THC, so the act may not cover all CBD products.

"If CBD is derived from a U.S.-grown hemp plant that has a license to be grown and a company that has a permit to manufacture CBD, then that is legal," said Alex Capano, DNP, a faculty member at The Lambert Center for the Study of Medicinal Cannabis and Hemp at Thomas Jefferson University in Philadelphia, and medical director for Ananda Hemp, which manufactures hemp-based products. As part of the Farm Bill, hemp was permanently removed from the controlled substance list. "However, if CBD is derived from a marijuana plant or flown from overseas or comes from an unlicensed hemp plant then it’s Schedule I," she said. Months before the bill passed, the FDA approved Epidiolex (cannabidiol) to treat seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. Epidiolex is the first FDA-approved drug containing a purified drug substance derived from marijuana.

“A lot depends on what the state board approved and what is going to potentially get a pharmacist in trouble. Even a foot balm with CBD in it can technically be a controlled substance.” —TIMOTHY WELTY, PHARM.D
PHARMACY PRACTICE

What Are the Uses?
Research continues into the use of cannabis-derived drugs to treat degenerative diseases such as Parkinson’s disease and multiple sclerosis, or to decrease symptom severity and the frequency of flares associated with autoimmune diseases. Cannabidiols might also be useful in treating opioid addiction. So far, double-blind randomized controlled studies are scant and, except for the studies supporting Epidiolex, much evidence remains anecdotal. But anecdotal evidence carries some weight.

“I deal with patients every day and I’ve observed people having pretty profound responses across the board,” said Capano. Not everybody has had the opportunity to see those kinds of results, she adds.

“Pure CBD is really expensive. If you’re paying a lot of money for it. What we’ve seen in Colorado many times is that what they say is in there is not actually in there.”

JACCI BAINBRIDGE, PHARMD

The FDA does not regulate the safety or purity of CBD products sold as supplements, making it harder for consumers to know what they’re getting. CBD products are commonly used to alleviate pain, induce sleep, and improve mood, but some products being marketed might not have been extensively tested.

“Pure CBD is really expensive,” said Jacci Bainbridge, PharmD, FCCP, professor of clinical pharmacy at the University of Colorado. “If you’re getting what they say you’re getting, you’re paying a lot of money for it. What we’ve seen in Colorado many times is that what they say is in there is not actually in there.”

If a pharmacy plans to carry CBD products that are not FDA- or state-approved, it’s essential to consider the source, Capano says. Work with a reliable company that can guarantee their product and provide counseling on how to use it. Always advise customers to start with a low dose and inform them about potential interactions.

What About Bioavailability?
Bioavailability must be considered when dealing with CBD products.

“The bioavailability of CBD in a tablet is less than 10% of whatever CBD you might have taken,” said Welty. “If you put it in oil like Epidiolex or into a tincture, then the bioavailability may go up as high as 20%, which is still pretty low. How much are you actually getting into your blood? With topical application, CBD has to go through the skin’s fat layer and that slows absorption. The whole issue of being able to give a high enough dose to be absorbed is a concern.”

Taking a significant dose of purified CBD may subject patients to potential interactions with drugs such as cyclosporine, benzodiazepines, calcium channel blockers, atorvastatin, and simvastatin. “We don’t know about all of them, but most of the interactions we can find in the package insert of Epidiolex,” said Bainbridge. “Everything we know for sure is on that label.”

It’s hard to know how much CBD oil is too much without well-controlled toxicology studies, and given the lack of regulation there’s no way to know if the products or the plants they’re derived from are contaminated with herbicides, pesticides, heavy metals, or fungus.

To add another concern into the mix, CBD products are not supposed to contain more than 0.3% THC, but some formulas do, and that THC may register on a pre-employment drug test.

“You do have to worry about very sensitive drug testing, say for law enforcement,” said Bainbridge. “Since it’s absorbed systemically, a person can test positive for THC.”

If a pharmacy plans to carry CBD products, the important first step is learning what the state regulations are. “A lot depends on what the state board approved and what is going to potentially get a pharmacist in trouble,” said Welty. “Even a foot balm with CBD in it can technically be a controlled substance.”

What Are the Options?
Pharmacists can offer patients safe options. Although Epidiolex is FDA-approved for only two rare syndromes, doctors can prescribe it for other things. “They are not restricted to treating seizures. It’s up to a physician. If they feel it’s appropriate, they can prescribe it for Parkinson’s, pain, you name it,” says Welty. “My feeling is that if you’re going to recommend it, the safest way is with Epidiolex, a product that we know has been monitored for quality. If that’s not an option, go with a state-approved product like you can get in Iowa or Minnesota, where there’s some control.” Be suspicious of “artisanal” CBD products, he warns. “Some commercial products are reputable, but you don’t always know what you’re getting.”

Despite concerns, patients are likely to experiment with CBD on their own, without the benefit of any professional counseling. “The reality is people are going to use CBD. It’s out there; the industry is booming. If people are going to use it, there’s a benefit to getting counseling from a licensed pharmacist,” said Capano. “If patients are going to be using it they might as well use it well.”
How Pharmacy Closures Impact Medication Adherence

By Tracey Walker, contributing editor

When a pharmacy shuts its doors, it can negatively impact medication adherence.

A new study, published in *JAMA Network Open*, found that when pharmacies close, people stopped taking widely used heart medications that have known cardiovascular and survival benefits.

Researchers from the University of Illinois at Chicago used information from a national all-payer pharmacy dispensing database that links patients across retail and nonretail channels. They analyzed data collected from more than 3 million adults aged 50 years and older who filled at least one statin prescription at a pharmacy between 2011 and 2016. They compared medication adherence among people who had filled a prescription at a pharmacy that later closed—about 93,000 people—with adherence among those whose pharmacy stayed open.

Patients filling a statin, beta-blocker, or oral anticoagulant prescription at pharmacies that closed were found to have an immediate statistically and clinically significant decline in adherence during the first three months after closure compared with their counterparts. This difference persisted over 12 months and was greater among older adults living in neighborhoods with fewer pharmacies.

Among statin users, about 23.8% of people in the pharmacy closure cohort did not refill their prescription at any point during the 12-month follow-up period, compared with only 12.8% in the nonclosure cohort. A decline in adherence also was observed among people who had been adherent to their medications the year prior to the closure. Among those who were fully adherent at baseline, 15.3% in the closure cohort discontinued their statins, compared with only 3.5% in the nonclosure cohort.

The findings show declines in adherence—including the complete discontinuation of medication—were highest among people who used independent pharmacies, filled all their prescriptions at a single store, or lived in neighborhoods with fewer pharmacies. “Pharmacy closures contribute to nonadherence to prescription medications, particularly for older individuals living in neighborhoods that have fewer pharmacies,” says lead study author Dima M. Qato, PharmD, MPH, PhD, associate professor at the University of Illinois at Chicago.

Implementing strategies that target patients most at-risk for experiencing a pharmacy closure is important, according to Qato. “These include pharmacy outreach to patients in advance of a planned closure, more flexibility from health plans on which pharmacies are preferred and expanding coverage to include home-delivery by pharmacies to offset potential access barriers,” she says.

Policies should consider the role of pharmacy benefit managers (PBMs), the report suggests. “For example, Medicare Part-D and Medicaid managed care plans should pay attention to the role their PBMs have not only on the cost of prescription drugs to patients but also on the impact of PBM contract on pharmacy reimbursement and maintaining convenient pharmacy access and preventing pharmacy closures,” Qato says.

She outlined four things about the effect of pharmacy closures on adherence:

- **System-level factors on nonadherence and access to prescription medications extend beyond the cost of prescription drugs.**

- **Declines in adherence were most pronounced among older adults using independent pharmacies, living near fewer pharmacies, or using a single store for all their prescriptions.**

- **Pharmacy closure may undermine adherence benefits.**

- **Sufficient reimbursement rates may help prevent some pharmacies from closing.**

“Pharmacy closures contribute to nonadherence to prescription medications, particularly for older individuals living in neighborhoods that have fewer pharmacies.”

DIMA M. QATO, PHARMD, MPH, PhD

Tracey Walker is senior content manager for Managed Healthcare Executive, a sister publication to Drug Topics.
In a competitive environment, it’s more important than ever for independent pharmacies to increase patient care and decrease costs. They cannot afford high overhead costs or inefficiencies behind the counter.

“Today, pharmacies have to be at the top of their game,” says Ryan Summers, PharmD, owner of Summers Pharmacy in Clinton, MO.

At the same time, patients expect more from their pharmacies. “Patients don’t just compare pharmacies to other pharmacies,” Summers says. “They compare us to nonpharmacy organizations that have a high level of customer satisfaction.”

One important way to improve customer service and staff efficiencies is to incorporate a workflow management process. The pharmacy will be more organized. Prescriptions will be filled by priority. Technicians and clerks will have a better sense of their individual responsibilities.

From the patient perspective, workflow management helps improve medication safety since there is an orderliness to filling prescriptions. The pharmacist, because he or she is less involved in the filling of prescriptions, has more time to counsel patients about their medications, which can lead to improved adherence and less side effects.

“Workflow management is important to both the pharmacy staff and patients,” says Stephen A. Brown, JD, PharmD, adjunct professor in the Department of Pharmaceutical, Social, and Administrative Sciences at Samford University in Birmingham, AL. “With the correct workflow management process, pharmacists and nonpharmacist personnel can operate at the top of their abilities. There is a sense of well-being among the staff.”

Many software programs are available to help independent retail pharmacies increase efficiency and improve patient care.
implement a workflow management system—each distinct in their own way. But they have a number of common traits.

- Each system clearly orders and prioritizes the tasks at hand, from the time the prescription comes into the pharmacy through to checkout.
- Employees, whether they are pharmacists, technicians, or clerks, know their individual responsibilities during their shifts.
- Prescriptions are prioritized so the pharmacist knows which ones to verify immediately and which can wait.
- There are checks and rechecks to ensure the proper medication is getting to the right patient.

“"The main objective of workflow management is to align the team,” says Ghada Abukuwaik, RPh, president and head pharmacist of CureMed Pharmacy in Clifton, NJ. Employees better understand what they’re doing and the tasks they are expected to perform. “It’s essential to running a successful pharmacy.”

A successful pharmacy breeds customer trust. “The last thing you want as a pharmacist is to have customers watching as the staff tries to locate their prescriptions,” says Michael Fapore, RPh, owner of The Medicine Shoppe in Somerset, PA. “Workflow builds patient confidence.”

Greater Confidence in Patient Safety
Patient safety was the No. 1 issue that prompted Fapore to implement a new workflow management system.

In the old workflow system at his pharmacy, the pharmacist would enter all data into the computer, and the technicians would count, fill, and place the prescription at the end of the counter for the pharmacist to check. With a large amount of prescriptions coming in at any one time, Fapore wasn’t always sure at the end of the day that everything was done correctly. “It was hectic,” he says.

In the new system, the process of filling prescriptions is broken down into various subsets. Technicians, working at their own workstations, know their individual responsibilities—entering prescription information, assembling the prescription or troubleshooting insurance questions.

There are several safety checks before the technicians would count, fill, and place the prescription at the end of the counter for the pharmacist to check. With a large amount of prescriptions coming in at any one time, Fapore wasn’t always sure at the end of the day that everything was done correctly. “It was hectic,” he says.

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RYAN SUMMERS, PHARMD
the prescription gets to the pharmacist for a final check. For example, the technician filling the prescription identifies the medication by bar code. The system prevents the prescription from being filled if the incorrect bar code is scanned.

When the medication gets to the pharmacist for the final check, its image appears on a computer screen, along with its drug utilization review data. “This is something the old system did not have,” Fapore notes. “It’s a big plus for patient safety.”

Repetitive mistakes are less common with the new workflow management system. That’s not to say mistakes are a thing of the past.

“We usually catch something every day, and although 99% are minor errors, we are able to correct them and educate our staff to reduce these errors in the future,” Fapore says.

“The last thing you want as a pharmacist is to have customers watching as the staff tries to locate their prescriptions. Workflow builds patient confidence.”

MICHAEL FAPORE, RPH

When there is a mistake, Fapore can see where it occurs, and he can discuss the steps to take to avoid similar errors in the future with the responsible employee.

The new system gives Fapore peace of mind. “I want to be confident that all prescriptions are correct,” he says. “I know there is no guarantee we will be mistake-free. However, our new workflow management system gives us the best opportunity to safely deliver prescriptions to our patients.”

When Michael Fapore, RPh, decided to implement a new workflow management system in his pharmacy, The Medicine Shoppe, in Somerset, PA, he stressed patience with his staff. “I’m glad I did because we had some rough times at first,” he says.

Part of those rough times stemmed from the fact that his old software program could not support the improvements in the pharmacy’s workflow that Fapore wanted, despite assurances from the developer that it could.

The results were not pretty.

“The day we opened, we had a mess,” Fapore says. “The system wouldn’t work as we wanted.”

Fapore and his staff were able to muddle through on a temporary fix for several months before he purchased a new software program that could accomplish everything he wanted.

Once the new system was implemented, Fapore began to see the changes in patient safety and staff efficiencies he had envisioned through workflow management.

While it was a tough lesson, Fapore learned that there must be demonstrable proof that a software program can handle the type of workflow management system the pharmacist wants.

“The first thing I would tell [pharmacists] is before they start, make sure their software can support the objectives,” he says. “Demand a demo to make sure it will work the way they want it to work. We did not do this, and it made it a lot tougher for us in the beginning.

“We found out the hard way that not all computer systems are set up to manage workflow,” Fapore maintains.

Building a Better Operation

Independent pharmacies have to offer an array of services that appeal to the customer to remain competitive, says Summers, who opened Summers Pharmacy in 2013 after being employed at large retail chain. He has since added five more pharmacies through acquisition or openings.

While offering more services sets independents apart, it creates challenges that can only be overcome with proper workflow management procedures, he points out.

“There are so much more that employees have to learn and be able to do in an independent pharmacy,” Summers notes. “To take care of patients today, there has to be more services such as multidose packaging and medication synchronization. Each service offered is another point where employees have to be trained and another point where something could go wrong.”

Workflow management makes other changes easier, he adds. “It’s much easier to add systems, services, and processes, as well as to make adjustments, when there is a workflow process. There is no worry that employees will feel stressed, overworked or overloaded when we add to our customer offerings.”

When Don Grove, RPh, was building his new store, J&D Pharmacy in Warsaw, MO, a decade ago, he experimented with workflow, even though he was unfamiliar with the concept. But he had a vision of how he wanted the pharmacy
to operate. "I was mentally doing workflow," he says.

He designed a system that includes inventory carousels, prescription bags that hang instead of being placed in bins, separate pharmacy and technician workstations, video counseling kiosks, and urgency color-coded transparent bundling bags. At the same time, the pharmacy was redesigned to reduce interruptions by patients and allow for more transparent interactions among employees.

Grove’s goal is to make it possible for one pharmacist to fill as many as 400 to 500 prescriptions a day.

As a result of the workflow management system, J&D Pharmacy achieved what Grove refers to as a "double oxymoron." Not only was there an increase in volume, but also in accuracy and employee satisfaction. "It isn’t easy to achieve an increase in all three," he stresses.

Involving Employees

Employee buy-in is critical. Without it, there isn’t much chance that workflow management, or any new system, will succeed. Buy-in might be the hardest part of implementing a workflow process, Summers says.

While buy-in can be reached in different ways, with or without employee input, the workforce needs to be brought into the process at an early stage. Every employee should know why workflow management is important and its ultimate goals once implemented.

Pharmacists will find that some employees will resist change for as long as possible. "Change is hard," Summers says. "Employees have to be able to trust the process. Sometimes, that’s not the easiest thing.”

One aspect is that employees must come to terms with no longer being able to pick and choose the tasks they perform. For a workflow management system to be successful, technicians and clerks should know all tasks and responsibilities. "They need to be able to step into someone else’s role without a loss of productivity," Summers notes.

Regularly scheduled meetings with staff to discuss successes and where improvements can be made ensures that buy-in will continue long after implementation.

"Our team preferred to be on the same page in terms of goals and productivity numbers," Abukuwaik says. "They wanted to see our progress and discuss the next goals, and they wanted to know how they could raise their own productivity scores. The meetings gave our team members a sense of ownership in mastering workflow management.”

In the day-to-day work of the pharmacy, workflow management delivers improvements.

"The system really helps with the relationship between the pharmacist and technicians and clerks," Summers says. "Everyone knows what they’re supposed to do. It makes for a great workplace environment.”

Enhancing Customer Service

Customer service is paramount. The traditional view of customer service is based on quick, reliable, and accurate service.

The customer has been to the doctor’s office, sometimes waiting for a long period of time before being seen. Or they have sick children, or they themselves are sick. Whatever the case, they don’t want to spend a lot of time in the pharmacy.

"We have time to visit with our patients and take care of other patient care situations. We can do whatever we can to take care of their needs for OTC and prescription products.” MAX CALDWELL, PD

"Our main goal is to get them in and out as quickly as possible," says Max Caldwell, PD, owner of Caldwell Pharmacy in Wynne, AR. "But in a high-volume store, pharmacists must utilize as much technology as they can to make that waiting time as short as possible.”

Workflow management allows independent pharmacists to extend customer service into the area of counseling. Because the pharmacy’s workflow is orderly, where technicians and clerks take care of their areas of responsibilities, pharmacists have the time to counsel patients.

"We have time to visit with our patients," Caldwell says. "We can do whatever we can to take care of their needs for OTC and prescription products.”

In-depth counseling—more than just repeating label instructions—can mean better medication adherence, fewer side effects and improved safety, because patients will have a better idea of how to take their medications properly. There is also time for follow-up conversations to discuss any other medication issues.

"The pharmacist can counsel patients who haven’t started taking their medications because they’re afraid of the side effects, or point them in the right direction if there are side effects," Summers says. "This type of customer service not only can improve the health of the patient, it can create a patient-pharmacist relationship based on trust. "If we can meet the expectations that scripts are filled quickly but also provide high-quality counseling, then we have satisfied patients,” Samford’s Brown stresses. Patients will come back and grow to appreciate the role of pharmacists and staff in improving their health.

"Workflow management is the key,” he adds. "It makes the dispensing quicker and frees up the pharmacist for quality patient interactions.”
Health System Pharmacists Reduce Readmissions

Health systems recognize value of pharmacists in readmission reduction programs

By Mari Edlin, contributing writer

Hospitals are working hard to improve their readmission rates. The Affordable Care Act’s 2012 Hospital Readmission Reduction Program (HRRP) imposes penalties for higher-than-expected risk-standardized 30-day unplanned readmissions for six conditions.

The Medicare Payment Advisory Council (MedPac) estimates that 12% of readmissions are potentially avoidable. Preventing even 10% of them could save Medicare $1 billion.

As pharmacists increase their status as healthcare providers and take responsibility for medication therapy management (MTM), hospitals are leveraging their expertise and placing them at the forefront of readmission reduction programs.

Role of Pharmacists in Readmissions Programs

Eric Maroyka, PharmD, director of the Center for Pharmacy Practice Advancement at ASHP, believes that pharmacists could play many roles in readmission reduction programs:

- Conducting full medication reconciliation from hospital admission through discharge.
- Offering recommendations to a medical team, such as eliminating unnecessary or harmful medications, optimizing dosing, and suggesting alternative therapies.
- Making changes independently to medication therapy based on practice scope and collaborative practice agreements.
- Assisting with care coordination before discharge, providing patient education, and scheduling follow-up visits for MTM.
- Coordinating with pharmaceutical assistance programs, insurance, and community or outpatient pharmacies to access affordable medications.
- Ensuring medication adherence.

“An interprofessional and complementary approach using the pharmacist as the medication expert will add a necessary dimension to ensure an experience every patient deserves to improve access, cost, quality, and overall interprofessional team resilience,” Maroyka says.

Maroyka is aware of the challenges of such endeavors. “Electronic health record interoperability remains a significant barrier across patient care settings,” he says. “This contributes to communication breakdowns and making less-informed decisions about patient care when accessing disparate data systems with incomplete or incorrect patient information.”

The health system pharmacy has to have the capability and capacity to consistently support interprofessional care transition efforts across a continuum of care, Maroyka says.

Here are the ways that three health systems use pharmacists in readmission reduction programs.

BayCare Health System

BayCare Health System, a not-for-profit healthcare system in Tampa, FL, introduced its Pharmacy Transitions of Care Program (PTOC) as a pilot in 2014, with two pharmacists in one of its 15 hospitals. The program has since grown to 23 pharmacists and expanded to all its hospitals. It targets Medicare A and B beneficiaries who have a primary diagnosis of a CMS core measure and who are discharged from a hospital to home or an assisted living setting.

Timothy L’Hommedieu, PharmD, director of pharmaceutical services, East Region, BayCare Health System, credits...
the healthcare industry’s shift to value-based care for the initiation of PTOC.

“The program’s goal is to decrease 30-day hospital readmissions. With drug therapy as the best way to treat acute and chronic conditions, the program provides an opportunity for pharmacists to play a significant role in transitional care,” he says.

Participating pharmacists are specially trained in ambulatory and transitions of care and hired just for that role, L’Hommedieu says. They are board certified and/or have received residency training.

Collaborating with inpatient and outpatient care teams—including social workers, home care experts, and physicians—pharmacists conduct two patient visits after discharge and telephone encounters within 7 and at 21 days after discharge, providing comprehensive medication review, MTM, and counseling.

They also evaluate patient clinical status, help identify and solve any problems with medications—side effects, wrong dose, or inappropriateness or ineffectiveness—and ensure patients understand their medications and can afford and access them.

“The objective is to address an aging population within the community, ensuring a safe and appropriate level of care for patients after discharge and promoting self-care management.”

JASMEN ESFANDI, PHARMD

“Clinical pharmacists have always assumed these responsibilities, but not in the transitional setting. BayCare has specifically invested in them to provide these services,” L’Hommedieu says.

BayCare conducted a study using data from September 2016 to May 2017, comparing 2,200 patients eligible for
a readmission penalty enrolled in PTOC with a control group of 1,335. The readmission rates were 8.3% versus 23.7%, respectively. The program demonstrated a 63% relative reduction in all-cause readmission rates during that time.

Although L’Hommedieu says HRRP is not the primary reason for developing the program, he is aware that results are publicly reported and can influence which hospitals patients select. “The law serves as justification for our investment in the value-based PTOC, which serves as a support program offering optimal patient outcomes,” he says. “If we deliver best practices, we set our patients up for success, and we can reduce readmissions.”

He emphasizes the importance of the team-approach to reducing readmissions, but admits it isn’t always easy to coordinate such a group and provide a seamless experience for patients.

**Dignity Health Northridge**
Dignity Health-Northridge (CA) Hospital Medical Center’s chronic disease transitional care program involves a team of physicians, nurse practitioners, nurses, social workers, and pharmacists who collaborate with an inpatient care team. They provide clinical oversight and discharge planning for a chronic disease population during a hospital stay and for 30 to 90 days after discharge.

After discharge, the team provides clinical oversight to patients in conjunction with external community partners, such as home health agencies and local pharmacies, and focuses on patient safety, health, satisfaction, and mitigation of avoidable readmissions.

By using an interdisciplinary approach to care, pharmacists can reach out to other experts on the team to help develop an individualized care plan and assist in creating strategies to support positive patient outcomes, says Jasmen Esfandi, PharmD, clinical pharmacist for the program.

Northridge in Southern California initiated the program in 2015, as an enhancement to its palliative care program. “The objective is to address an aging population within the community, ensuring a safe and appropriate level of care for patients after discharge and promoting self-care management,” Esfandi says. The number of patients affected by the program has nearly doubled to 7,300 since its inception.

Through MTM, pharmacists and nurse practitioners provide recommendations for changes in medication regimens based on patient diagnoses. Pharmacists also perform discharge medication reconciliation for patients returning home or transferring to one of Northridge’s skilled nursing facilities. If discrepancies or errors in medications—incorrect doses, drug interactions—are found, physicians join pharmacists in resolving problems.

Pharmacists also make home visits to help patients understand their medications and how to administer them, ensuring they have access to their medications and can account for any missing drugs.

Like pharmacists in similar programs, Esfandi says data collection is one of her biggest challenges; prompting the hospital to engage data coordinators to collect measures that communicate productivity, efficiency, and positive outcomes of the program.

She also agrees that while HRRP has helped drive the transitional care program, the estimated Medicare penalty savings indicates the effectiveness and value of the program.

Northridge has experienced a yearly decrease in readmission rates of 10% over the previous year. Esfandi says these rates are aligned with California state goals.

**Einstein Medical Center**
Einstein Medical Center in Philadelphia developed its Medication REACH (Reconciliation, Education, Access, Counseling, Healthy Patient at Home) intervention in 2012, with a single pharmacist.

Since then, Einstein has incorporated...
transition-of-care services into existing clinical pharmacist roles. Pharmacists collaborate with physicians, residents, and nurse practitioners from admission through postdischarge. The center added two pharmacy technicians, one to complete medication reconciliation in the emergency room and one as a discharge liaison to facilitate access to medications at the time of discharge.

The goal is to reduce hospital readmissions by improving medication management in the hospital, home, and during transition from these settings.

A 667-patient study, which appeared in the *American Journal of Health-System Pharmacists*, evaluated whether REACH was feasible as part of routine care at a safety net hospital and could reduce hospital readmissions for Medicare fee-forservice. Einstein sought to improve medication management through direct pharmacist involvement and communication between pharmacists and a clinical team. Pharmacist intervention included reconciling medications, patient-centered education, ensuring access to medication, and follow-up at patients’ homes.

The study compared 30-day readmissions in patients with full and partial intervention with those receiving standard care. It showed 9.8% unplanned readmissions for the managed group versus 20.4% for the control group.

“It is important to establish collaboration not just between pharmacists and a medical team but also with care managers, insurers, and community pharmacists,” says Mariel Shull, PharmD, pharmacy utilization management coordinator for NYU Langone and the dedicated pharmacist and coauthor in the Einstein study.

She sees pharmacists as an ideal fit for their role in a transition of care program that demands continuous coordination because of its complexity. “It is important to measure impact to support expansion of services and advocate for resources, but efficient documentation is difficult or challenging in many existing electronic medical records,” says Shull, concurring with Esfandi.

A readmissions program helps make a case for the involvement of pharmacists and the program, she says. “Hopefully, pharmacists and other team professionals will adapt this kind of transition of care model to other programs used in everyday care,” Shull says.

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Lack of Deprescribing Harmful and Expensive

By John Schieszer, contributing writer

A new study from Sweden is suggesting that many older adults with cancer are being prescribed preventive medications at the end of their lives that may harm their quality of life while providing questionable clinical benefits. The problem may stem from inadequate deprescribing.

The study, published March 25, 2019, online in Cancer, found that deprescribing strategies need to be more widely adopted to help reduce the burden of drugs that have limited clinical benefit near the end of life.

There is little published research on how much overprescribing occurs in patients with advanced cancer during the final months and weeks of their lives. Lucas Morin, and his colleagues found the average number of drugs prescribed to them increased from 6.9 to 10.1 during the last year of life. The percentage of patients taking 10 or more drugs doubled from 26% to 52%.

Preventive agents, including antihypertensives, platelet aggregation inhibitors, anticoagulants, statins, and oral antidiabetics were frequently continued until the final month of life.

The Costs of Not Deprescribing

The study showed that the median drug costs during the last year of life were $1,482 per individual, including $213 for preventive therapies. Approximately one-fifth of the total costs of prescribed drugs were for preventive medicines. This proportion only decreased slightly as death approached.

Costs for preventive drugs were especially high in older adults who died from specific tumor types. These costs were higher among older adults who died of pancreatic cancer (adjusted median difference, $13; 95% confidence interval, interquartile range [IQR] $5 to $22) compared with older adults who died of lung cancer (median drug cost, $205; IQR, $61 to $523). The same was true for gynecologic cancers (adjusted median difference, $27; 95% confidence interval, IQR $18 to $36). The study showed no decreases in the costs of preventive drugs during the last year of life.

This large study suggests that a substantial number of older adults who die with solid tumors are receiving preventive drugs until their final four weeks of life, accounting for approximately 20% of total drug costs.

The authors of the study note that drug prices in general are much higher in the United States, with total U.S. pharmaceutical expenditures almost triple compared to expenditures seen in Sweden.

Geoffrey W. Brown, PharmD, with the University of Buffalo and the State University of New York, Buffalo, says the pharmacist’s role in deprescribing is to help weigh risks versus benefits of medications. While this is done throughout the patient’s lifetime, it requires a different approach at the end of life.

“Pharmacists are experts on side effects, monitoring parameters, drug interactions, dose-response, and routes of administration of medicines. All these details about a medication can affect a patient’s quality of life. A complex medication regimen should be reviewed by a pharmacist and each medication scrutinized,” Brown tells Drug Topics.

Reduce Meds, Reduce Side Effects

The findings suggest that reducing the use of preventive medications in patients with cancer near the end of life may reduce unnecessary side effects,
improve patient quality of life, and reduce financial burdens for patients.

Mark Ratain, MD, professor of medicine and the director of the Center for Personalized Therapeutics at the Comprehensive Cancer Center at the University of Chicago, says polypharmacy is the problem: patients age 65 and older in the United States are on too many medications.

"The oncologists are not paying attention to non-oncology drugs," Ratain tells Drug Topics. "It is the tip of the iceberg that nobody is paying attention to medications. Most U.S. Medical schools don't even have a department of pharmacology anymore."

Tanya M. Wildes, MD, associate professor of medicine in the Division of Medical Oncology at Washington University School of Medicine, St Louis, says deprescribing involves intentional, thoughtful discontinuation of specific medications, including those that likely will not benefit the patient or those that may increase the risk of adverse effects.

"Deprescribing is difficult, particularly when patients have been on medications for a long period of time and no one stops to question whether it continues to provide benefit, especially when that risk/benefit ratio may have shifted in the setting of a cancer diagnosis," Wildes tells Drug Topics.

She cites a trial published by Kutner et al. in 2015 in JAMA Internal Medicine that randomized patients with life-limiting diagnoses to either continuation or discontinuation of a current statin. The study highlighted how quality of life can be improved.

"Patients who stopped their statin lived just as long as patients who continued it, but they reported better quality of life. In addition, the group who stopped their statin tended to discontinue other medications as well. Presumably, in the process of stopping their statin, they became more intentional about each of the medications that they were taking, carefully considering its benefits," says Wildes.

**A Failure to Communicate?**

Patricia A. Ganz, MD, professor of health policy and management and medicine at UCLA Fielding School of Public Health and director of the Center for Cancer Prevention and Control Research at the Jonsson Comprehensive Cancer Center, Los Angeles, CA, says the findings in the Swedish study are intriguing, but not surprising.

"It is particularly interesting because it comes from one of the Nordic countries where they have very good medical record data and other information, along with the ability to link cancer cases to that data. What is more interesting is that, generally, patients in these health care settings have good access to primary care physicians, who would be the doctors prescribing most of the preventive care medications," Ganz tells Drug Topics.

Physicians and patients may be afraid to "rock the boat," Ganz says. If a patient has been on one of these medications for many years, the medications often are not stopped even though the patient is failing.

"It is really an oversight. Stopping some of these medications could make life a lot simpler for patients and their families as there would be fewer pills to take," says Ganz. "I think this speaks to the need for cancer doctors and primary care physicians to communicate with each other and to stop medications that clearly have no benefit when a patient is dying."

Pharmacists need to review each medication and ask if it is providing true benefit or just making life more difficult for the patient, Brown says.

"Doctors and providers are pretty well versed on the benefits of medications, but pharmacists bring a different perspective. We’re more attuned to the details of medications and the hidden drawbacks they may have."

The goal of palliative care is to reduce symptoms and maximize the quality of life, but sometimes what is used as palliative treatment decreases quality of life and that’s troubling, Brown says.
According to the National Diabetes Statistics Report from the CDC, an estimated 30.3 million Americans had diabetes in 2017, 7.2 million of whom were undiagnosed. Approximately 5% had type 1 diabetes, and the remaining 95% had type 2 diabetes.

Over the last 20 years, the number of adults with diabetes has more than tripled, and the total direct and indirect estimated cost of diagnosed diabetes in the United States in 2012 was $245 billion.

“Diabetes is the highest traditional overall drug spend category for commercial, Medicare D, and Medicaid clients; and among all drug categories, only autoimmune has a higher drug spend,” says April Kunze, PharmD, senior director for clinical formulary development and trend management strategy, Prime Therapeutics.

“Given the prevalence and the opportunities where diabetes care can go wrong, it can be an ideal area connected to outcomes-based contracts,” explains Mark Ginestro, a principal from KPMG Strategy. “The proper management of the condition can lead to major savings in overall medical costs.”

**Pipeline Promises**

“With an aging population, the prevalence of diabetes and the number of medications to treat the disease are anticipated to grow,” Kunze says. “There have been many new therapies introduced to the market in the past few years, which has caused a rise in the use of branded medications in combination or as a replacement to older lower-cost generic drugs.”

While there are some exciting promises in the pipeline, recent activity has cast doubts on that pipeline’s future. The FDA recently denied approval for the investigational drug Zynquista (sotagliflozin, Sanofi and Lexicon Pharmaceuticals) for type 1 diabetes.

Zynquista works by inhibiting both sodium-glucose cotransporter 2 (SGLT2), a transporter responsible for most of the glucose reabsorption performed by the kidney, and sodium-glucose cotransporter 1 (SGLT1), a transporter responsible for glucose and galactose absorption in the gastrointestinal tract.

The agency issued a Complete Response Letter (CRL) in March, following an eight to eight vote by the FDA’s advisory committee in January in favor of the drug’s benefits outweighing its risks.

“Given the advisory committee’s vote it is not entirely surprising that the FDA has issued a CRL for the Zynquista New Drug Application,” Kunze says. “Other SGLT2 inhibitors are being studied for use in type 1 diabetes. Currently, SGLT2 inhibitors are approved for the treatment of type 2 diabetes.”

Farxiga (dapagliflozin, AstraZeneca), one of the SGLT2 inhibitors currently approved for type 2 diabetes, was recently approved for type 1 in Europe and is currently undergoing studies in the United States—but Zynquista’s rejection has cast doubts on its future in the United States.

Manufacturers of SGLT2 inhibitors are also studying overall health outcomes, such as major cardiac events and sub-populations within diabetic patients, including those with chronic
kidney disease or heart failure, to show potential benefit and expand labeled indications, according to Kunze.

Technology and Diabetes
Technology also has an important role to play, with wearable devices, such as continuous glucose monitors (CGMs) that aid in the diagnosis, treatment, and self-management of diabetes. Ginestro also says that medical device makers have introduced different variations of an artificial pancreas, an automated insulin pump with a CGM for management of patients with type 1 diabetes.

As far as additional technology innovations beyond the artificial pancreas, more digital tools are being introduced that will help with the diagnosis, management, and treatment of diabetes.

“We expect to see more type 2 diabetes patients opting for use of CGMs and other monitoring devices.”

MARK GINESTRO

“Another opportunity is tied to using tech to connect the doctor or patient to warn of elevated A1C levels or blood sugar readings to engage a patient to prevent a trip to the emergency room. The use of predictive analytics can also be applied to stratify patients by risk so the ones most vulnerable to repeat hospitalizations can get the help they need.”

Proactive Management
With remote patient monitoring now being reimbursed by CMS, Ginestro expects more players to emerge in proactive health management.

“We expect to see more type 2 diabetes patients opting for use of CGMs and other monitoring devices,” says Ginestro. “We can even foresee the broader consumer community using CGMs when they may be deemed prediabetic or even for those who are simply health-conscious consumers.”

Future of diabetes
The demographic of tens of millions of prediabetics and the obesity epidemic mean there will be no shortage of patients, according to Ginestro. “Medications are aimed at making diabetes management easier with longer acting medications. Technology is helping with the management of these conditions and addressing unmet medical needs,” he says.

“We expect to look closely at preferred product opportunities to help manage spend,” says Kunze. “In addition, payers will be looking for the real-world experience to match the clinical trial outcomes.”

Erin Johanek, PharmD, RPh, is a staff pharmacist at Southwest General Health Center in Middleburg Heights, OH.
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Specialty Drugs Need Close Management to Control Costs

By Mari Edlin, contributing writer

The cost of specialty drugs compared to the volume used is a bit like the long-supported statistic that 20% of patients represent 80% of healthcare costs.

While specialty drugs constitute only 1.9% of total prescription volume, they account for 37.4% of spending within the retail and mail order distribution channels, according to a report by the IQVIA Institute.

PBMI estimates that by 2020, specialty drugs will account for half of total U.S. drug spend. They have increased 55% under the medical benefit since 2011.

“Specialty pharmaceuticals are the fastest growing and most expensive segment of pharmacy care. As a result, specialty conditions drive a disproportionate segment of total health care costs,” says Michael Zeglinski, RPh, senior vice president of specialty pharmacy at OptumRx, a pharmacy care services company owned by UnitedHealthcare.

“Specialty pharmaceuticals are the fastest growing and most expensive segment of pharmacy care.”

MICHAEL ZEGLINSKI, RPH

Tools/Strategies to Lower Costs

Industry players continue to seek ways to manage specialty pharmaceutical costs in light of the factors pushing prices well above those for other drugs.

PBMI says many employers have introduced high-deductible plans to encourage members to make better decisions; create specialty drug tiers; use coinsurance for cost sharing; place prior authorization and step therapy on certain drugs; and exclude certain specialty drugs.

Benefit design is one of the most efficient ways to keep drug prices in line, says Ken Majkowski, PharmD, pointing to closed formularies that exclude certain medications. Majkowski is chief pharmacy officer at FamilyWize, a discount prescription program partnership.

For example, when new hepatitis C drugs began entering the marketplace in 2014, the PBM Express Scripts, only covered Viekira Pak (ombitasvir/paritaprevir/ritonavir and dasabuvir), but added Harvoni (ledipasvir/sofosbuvir) in 2017. Its National Preferred Formulary (NFP) now lists Epclusa (sofosbuvir/velpatasvir), Harvoni, Vosevi (sofosbuvir/velpatasvir/voxilaprevir), and Zepatier (elbasvir/grazoprevir) for hepatitis C. CVS Health recognizes Sovaldi and Harvoni.

Express Scripts rolled out its National Preferred Flex Formulary this year to provide a way for plans to cover lower list price products, such as new authorized alternatives with less reliance on rebated brands.

Majkowski says 10 years ago, it cost about $1 billion to bring a drug to market, which has jumped to $2.7 billion today, partially attributable to the high cost of conducting safety and immunogenicity trials on biologics that have a smaller test population. He notes that some biologics are worth their weight in gold: List prices for Sovaldi ($84,000 per course of treatment) and Harvoni ($94,500) tip the scales, but can cure hepatitis C. The alternative would be a liver transplant, at an estimated $812,500, including surgery, care, and immunosuppressants.

Newer tools in the industry are copayment accumulator programs, in which a drug coupon will not count toward a patient’s deductible or out-of-pocket cost limits, with patients having to pay more for their drugs once a coupon expires.

“From a tactical perspective, prior authorization, including documentation of a particular condition and eligibility for the treatment are essential,” says Bruce Sherman, MD, chief medical officer, National Alliance of Healthcare Purchaser Groups. “Because some of the identified treatments address only one specific mutation, it’s critical that genetic abnormality has to be in evidence for the treatment to be effective.”

He sees novel contracting approaches as one solution to nibbling away at costs. “Most of these contracts are value-based, in that the patients have to respond to treatment for the drug manufacturer to be paid,” he says. “Amortized payments are another potential solution.”

“We are continually looking at claims and trends for safety and appropriateness...”
Contributors to the High Costs of Specialty Drugs

Michael Zeglinski, RPh, of OptumRx highlights several factors that contribute to the high cost of specialty drugs:

**New product entry and drug price inflation**
A recent study published in *Health Affairs* found that rising specialty drug costs were due to a combination of new product entry and existing product price inflation. Average costs of specialty drugs increased 13 times faster than general inflation.

**Lack of competition**
Zeglinski is looking at biosimilar drugs to foster greater competition and increased savings as specialty drug patents expire. He expects that after several years of competition, biosimilars would be priced as much as 40% below their reference products.

**Scientific advances**
Referring to another study in *Health Affairs*, Zeglinski says pharmaceutical companies can set prices however they want when entering new categories. The study found that premiums pharmaceutical companies earn from charging substantially higher for their medications in the United States compared to other countries generates substantially more than what the companies spend globally on research and development.

“Lowering the magnitude of the U.S. premium to a level where it matches global R&D expenditures would have saved U.S. patients, businesses, and taxpayers approximately $40 billion in 2015,” he says.

“Adding to the cost of biologics are the multiple drugs taken by people with chronic disease, making it important to focus on total costs, not just the cost of a single drug,” Ken Majkowski PharmD, of Family-Wize says.

Jennifer Fuhrman-Berger, PharmD, of Benecard says that specialty drugs consume about 30% of her employers’ drug spend, but that the specialty drug trend has slowed to 8.91% in 2018. She prefers to look at drugs with the highest utilization, not the most expensive drugs that are often taken only by a small population.

issues,” says Jennifer Fuhrman-Berger, PharmD, senior vice president, clinical services, at Benecard, a pharmacy benefits administrator. To overcome what she considers potential issues related to specialty drugs, such as fear of injections; lack of adherence; switching drugs, but continuing to get both prescriptions; and improper drug storage, she says Benecard communicates with pharmacists and nurses to monitor these issues, along with potential side effects, and contacts physicians if nonadherence becomes a problem.

Benecard relies on pharmacogenetics to determine whether a patient can metabolize a drug or not. “If one doesn’t work, then we choose a different drug or dosage,” she says. “We believe that putting the client at the center of care and pharmacists at the point of sale, enabled by clinical edits, keeps our trend down.” Benecard manages specialty drug pricing by passing through the acquisition cost to payers, thus providing savings to plan sponsors.

The company also works closely with plan sponsors to determine which drugs should be reimbursed through the medical versus the pharmacy benefit.

OptumRx uses a variety of strategies to manage the continuing high cost of specialty drugs:

- **Therapy solutions model**, which provides patients with healthcare specialists and counselors who offer education and support via routine medication monitoring, personalized follow-ups, and in-home onboarding for patients new to treatment.

- **The oncology Split Fill program**, which takes an individualized approach to patients who take cancer medications that may cause severe side effects by providing half a month’s supply to patients for the first six fills. Pharmacy care providers check in with them often to manage potential clinical side effects, discontinuations, or adherence issues.

Early results from these programs have shown 96% of enrolled patients are more likely to tolerate therapy. For those who don’t, OptumRx helps them through discontinuation, resulting in pharmacy savings of $2,500 per patient per year.

OptumRx’s PreCheck MyScript helps prescribing physicians identify equally effective lower-cost alternative treatments, view a patient’s drug coverage, and determine if prior authorization is required. The provider chose the recommended alternative one in five times, resulting in savings to patients and payers, Zeglinski says.
By Keith Loria, contributing writer

A look at common HIPAA mistakes in pharmacies, and how to avoid them

B rian McCullough, PharmD, BCPS, assistant professor at Husson University School of Pharmacy in Bangor, ME, remembers an incident from his pharmacy residency.

He was on an elevator with colleagues, when one of them said, “You should see my patient Mr. Jones. He is huge! He must be at least 500 pounds. I’m surprised they found a bed big enough for him!”

“Our residency director called an impromptu meeting that afternoon. The resident who made the comment was already in the room; eyes puffy, tears streaming down her face.

It turns out that the other people on the elevator were Mr. Jones’s family, including his wife,” he says. “They had filed a complaint soon afterward, and our director was very clear that this behavior was not tolerated.”

Fortunately, the family allowed the complaint to stay internal to the hospital. Had they not, a large fine, a lawsuit, and possible job termination could have been the result.

The Health Portability and Accountability Act (HIPAA) was signed into law in 1996. It enacted penalties if a patient’s health information is shared with anyone not authorized to obtain this information.

While this law is more than 20 years old, it is still good for providers and pharmacies to remember that the impacts that words and actions can have on patients’ health information and that this information must be protected or penalties may be incurred.

The Name Game

Yana Paulson, PharmD, chief pharmacy officer for L.A. Care Health Plan, says a big cause for HIPAA violations in a pharmacy is filling prescriptions for two patients with the same name in a rush and dispensing the medication to the wrong person.

Not only are the two patients getting the wrong medication, but also...
confidential information about the patients’ medical condition is disclosed to unauthorized individuals,” she says. “To prevent this mistake from happening, pharmacists usually have checklists in place to verify the patients’ date of birth and address.”

For example, a pharmacist once prepared and released a prescription that was for a different patient with the same name. The patient took the blood pressure medication that was not intended for them and, after three months, complained to the pharmacist of dizziness and light-headedness. “The pharmacist checked the records and discovered the error. The pharmacist informed the patient’s doctor and directed the patient to get a check-up to ensure they were not harmed, and an incident report was filed,” Paulson says. “The other patient with the same name was also contacted and the pharmacist made sure they also had a checkup to confirm the need for the blood pressure medication and to let the doctor know that the patient has not been taking it for three months.”

Additionally, when in a rush to minimize the wait time, a pharmacist who types a prescription label can, by mistake, choose the incorrect prescriber, especially if there are multiple prescribers with the same name in the database the pharmacist is using (i.e., Dr. John Smith), “The HIPAA violation occurs when the pharmacist or the plan decide to contact the prescriber because they need to communicate with him/her and the information is faxed to the wrong prescriber who is not authorized to see it,” Paulson says.

“‘To prevent this from occurring, the pharmacists usually have a checklist to remind them to verify that the address and phone number of the prescriber in the database matches with the information on the prescription,’” Paulson adds.

Policies and Procedures
Jay Hodes, president of Colington Consulting, which provides HIPAA consulting services for healthcare providers and businesses, notes inadequate policies and procedures often lead to HIPAA violations, citing three noteworthy examples.

In February 2009, in a case involving CVS, media reports alleged that patient information maintained by the pharmacy chain was being disposed of in industrial trash containers outside selected stores—containers that were not secure and could be accessed by the public.

Hodes says the investigation found CVS failed to implement adequate...
“The HIPAA violation occurs when the pharmacist or the plan decide to contact the prescriber because they need to communicate with him/her and the information is faxed to the wrong prescriber who is not authorized to see it.”

YANA PAULSON, PHARMD

policies and procedures to appropriately safeguard patient information during the disposal process; and failed to adequately train employees on how to dispose of such information properly.

“This is a common theme in the healthcare sector, not training one’s workforce in general and on organization-specific policy and procedure,” he says. “This CVS case is clearly human error and could have been prevented with comprehensive policies and procedures along with holding the workforce accountable.”

In July 2010, a case involving Rite Aid stemmed from an investigation after television media videotaped incidents in which pharmacies were shown to have disposed of prescriptions and labeled pill bottles containing individually identifiable information in industrial trash containers that were accessible to the public.

“The investigation found Rite Aid failed to implement adequate policies and procedures to appropriately safeguard patient information during the disposal process; failed to adequately train employees on how to dispose of such information properly; and did not maintain a sanctions policy for members of its workforce who failed to properly dispose of patient information,” Hodes says. “Again, the training issue along with inadequate policies and procedures caused the problem.”

In April 2015, a case involving Cornell Prescription Pharmacy a compliance review and investigation were opened after receiving notification from a local Denver news outlet regarding the disposal of unsecured documents containing the protected health information (PHI) of 1,610 patients in an unlocked open container on Cornell’s premises.

The documents were not shredded and contained identifiable information regarding specific patients.

The investigation revealed Cornell’s failure to implement any written policies and procedures as required by the HIPAA Privacy Rule. Cornell also failed to provide training on policies and procedures to its workforce as required by the rule.

“And once again, the same training issue along with inadequate policies and procedures,” Hodes says. “These cases represented two large corporate pharmacies along with what appears to be a small, independent. I see the Cornell case as sending a message that enforcement actions will happen even to small companies and just not large corporations.”

In general, any “covered entity,” which any pharmacy would be regardless of size, must have comprehensive HIPAA policies and procedures in place to address all the HIPAA Security Standards and Implementation Specifications found in the Code of Federal Regulations (CFR).

The CFR requires workforce training to cover security awareness and applicable HIPAA Privacy Rule requirements.

Proper Information Exchange

Matt Fisher, partner at Worcester, MA-based Mirick O’Connell and chair of the firm’s health law group, says for pharmacists, HIPAA is often used, either mistakenly or intentionally, to deny the provision of information or hinder the exchange of information.

“There could be some degree of reluctance to interact with other providers or coordinate care without an authorization or consent,” he says.

“However, HIPAA allows uses and disclosures for treatment, payment, and healthcare operations, all of which pretty much enable the use of patient information for most purposes related to smooth operation of a pharmacy or other healthcare entity” he adds.

Additionally, there could be a reluctance to allow an individual’s family member, caregiver, or other person to pick up a prescription or obtain information. Unless the patient has specifically objected, another person can pick up a prescription or obtain information so long as there has been an opportunity to object.

“That could potentially be challenging to determine, but circumstances can be informative,” Fisher says. “Overall, the key is to remember that HIPAA does not prohibit common sense operations in most instances.”

Additional Violations

HIPAA violations usually occur when the team is in a rush to complete tasks quickly so as to minimize wait time. In such situations, Paulson says, mistakes will happen.

One common violation occurs, she says, when the pharmacist consults the patient about his or her medication, and the consultation can be overheard by people standing in line. To prevent that privacy breach, pharmacies should have a consultation area away from the cash register or check out area.

“An example of a larger scale HIPAA violation can occur when a health plan...
or a clinic wants to send a letter to all patients who are on medication that is being recalled,” Paulson says. “If the data is pulled from the database incorrectly, all the letters could be sent to wrong addresses, causing a large-scale privacy breach. To prevent this, health plans and clinics must have quality controls in place to ensure all data is verified before it is used.”

**Penalties and Warnings**

In most pharmacies, the system is programmed to walk the pharmacist through multiple points to double-check all the information on a prescription before it is finalized. However, Paulson says, when these are missed and mistakes are made, the penalties can include termination from employment for repeated mistakes, or referral to the State Board of Pharmacy, which may result in discipline such as a suspension of license to practice.

“There can also be civil financial penalties to the business if a large number of patients are impacted,” he says.

Penalties for a HIPAA violation for a pharmacy can range from $100 to $50,000 per violation (or per record), with a maximum penalty of $1.5 million per year for each violation. The HHS Office for Civil Rights (OCR), the office that enforces the HIPAA regulations, has levied criminal charges in conjunction with the U.S. Department of Justice for HIPAA violations in the past.

As of December 2018, OCR has settled or imposed a civil money penalty in 62 cases resulting in a total dollar amount of $96,581,582.00. OCR has investigated a great deal of complaints against many different types of entities including national pharmacy chains, major medical centers, group health plans, hospital chains, and small provider offices.

“There are no warnings,” Hodes says. “If a breach occurs, there is a self-reporting notification requirement that is made to OCR. In some less egregious cases as part of the investigative process, OCR will issue a corrective action letter with technical guidance to the organization that had the violation. It will detail the required and necessary mitigation to resolve the noncompliance issue(s).”

**Staying Compliant**

The pharmacy at Atlantic Health System, headquartered in New Jersey, is responsible for verifying, dispensing, and monitoring more than three million medication doses per year. Cliff Moore, RPh, MS, director of pharmacy services at Atlantic Health System (AHS), says AHS has implemented barcode scanning at each step of the medication dispensing process — from pharmacist verification of the prescription to loading the medication into the automated dispensing cabinet to nurses scanning the drug before administration to the patient — in an effort to curtail mistakes.

“These steps allow the pharmacy team to proactively monitor medication bar coding compliance and correct any potential errors in real-time at all of our six sites,” he says.

Training is an annual requirement for pharmacists so HIPAA violations should be few.

“Whether a pharmacy purchases a HIPAA training DVD and makes the staff watch it or utilizes some type of web-based or instructor-led training, the bottom line is it has to be done, completed, and most importantly, documented,” Hodes says. “Cover routine items like paper document disposal with specific procedures. If investigated for a breach, there is a good possibility documentation of training provided will be requested.”

He adds that a HIPAA compliance program will take some work and should not be considered a “one and done” scenario. Best practices include training the workforce, conducting the required security risk assessment, and making sure there are HIPAA policies and procedures to cover the HIPAA Security Standards and Implementation Specifications.

“After a reportable breach occurs, it is too late in the game to see if an organization’s HIPAA compliance program can stand up to OCR scrutiny,” he says. “OCR will always want to determine what the organization had in place prior to the breach occurring, not after it was reported.”

Paulson says pharmacists must develop a habit of following all the controls that were put in the workflow to prevent HIPAA violations, using all checklists and alerts, and ensuring that all the information is correct before dispensing the medications.
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McKesson Pharmacy Systems
Cybersecurity: Safeguarding Your Pharmacy from Hackers

By Joe Dysart, contributing writer

Independent pharmacies that are uneasy about the increasing frequency of hacking in today’s business world can take heart: With a bit of planning, you can significantly reduce your vulnerability to a computer break-in via the internet.

“In this climate, I believe we all need to be on ultra-high alert,” says Kari VanderHouwen, RPh, owner of Duvall Family Drugs Health Mart in Duvall, WA. “Naively, I would like to believe that we are so small we wouldn’t be worth their time,” VanderHouwen says. “But I do know that they are looking for the low-hanging fruit.”

Some of the most notorious hacks during the past few years have been, and most likely will continue to be, perpetrated by a shadowy group of computer wizards known as Anonymous. “Anonymous is heroic to many people who are sick of government lies,” says Sharon D. Nelson, president of Sensei Enterprises, a computer security consulting firm. “They have become very much like— in ‘The Terminator’ movies—the Resistance fighting Skynet,” she says. “Many are ‘script kiddies,’ casual computer users without deep knowledge of computer code, or amateur hackers. But there is a core group of hackers who have extraordinary skills. They present one of the greatest security threats in recent years. And we have not, so far, done a lot to counter their intrusions.”

Perhaps even more sinister than Anonymous is the professionalization of hacking that has emerged in recent years—scores of hackers have become 9-to-5 workers in today’s world, with jobs that include holidays, vacations, and many of the other trappings associated with legitimate employment. Kevin Haley, director of Symantec Security Response, says, “advanced criminal attack groups now echo the skill sets of nation-state attackers. They have extensive resources and a highly-skilled technical staff that operate with such efficiency that they maintain normal business hours. We are even seeing low-level criminal attackers create call center operations to increase the impact of their scams.”

Ransomware

One of the preferred ploys of these organized crime rings is ransomware: malware that downloads onto your PC or business network. It then secretly encrypts all your business data and the hackers demand a ransom for your files to be restored.

Rich Conklin, an IT security consultant and owner of Executive Computer Solutions, says one of his clients was recently hit with ransomware that brought down 28 of its computers. “Because they had a formal data back-up program for their business—which I recommended and maintain—I
If there is one thing I want to strongly recommend to all pharmacies is that they all need a disaster recovery plan, security awareness training, and have daily offsite backups of their data.”

JASON CARTER

Avoid Custom Software

Staying a step ahead of hackers also means being careful with any custom-made software, Nelson adds, since these programs are rarely subjected to the rigorous security testing that popular established software undergoes.

Content management systems (CMS)—software designed to enable independent pharmacies to easily update their web sites—for example, are often custom-made. “A custom CMS is usually a bad idea,” Nelson says.

Guard Passwords

Many employees also tend to get lazy about passwords. Surprisingly, one of the most commonly used passwords is still “password,” a seemingly trivial oversight that has spelled the undoing of otherwise stellar computer security systems.

Nelson recommends complex passwords of more than 12 characters, both letters and numbers, which are tough to crack even by software specifically designed to crack passwords. And she reminds people to use different IDs and passwords to enter different applications and networks.

Independent pharmacies looking to be especially vigilant about passwords can also use free online password generators, like Secure Password Generator, which will instantly generate long complicated passwords for you.

As an alternative, pharmacies can purchase password management software such as Dashlane 4 or LastPass, which auto-generate complicated passwords, and centralize all your IDs and passwords into a single easy-to-use program.
Independent pharmacies also need policies in place to establish lock-outs after a system user has entered a predetermined number of incorrect IDs or passwords, Nelson adds. The same lock-out fail-safe needs to be activated the moment an employee departs or is terminated from your pharmacy.

For protection of especially critical data, Winkler also advises multiple authentication, such as the use of two or three passwords to access a web site maintenance account, rather than just one. Businesses whose data privacy is especially critical should consider investing in data leakage prevention software, he says.

Keep Data Off the Internet
You also may want to consider keeping patient data and credit card data on a separate system that is always completely disconnected from the internet. "Restricting web access to a separate network—isolated from patient records and credit card transactions—is a good idea," says Michael Deninger, RPh, PhD, owner of Towncrest Pharmacy in Iowa City, IO.

Employees should also stay on the lookout for "social engineering" ploys—when a hacker tricks someone at your pharmacy into surrendering digital information with a phone call or innocuous email, as opposed to online hacking tactics.

Regular meetings, e-newsletters, or memos about security vigilance also offer an opportunity for you to update pharmacy staff about the latest smoke-and-mirrors tricks that are in vogue among hackers.

A popular recent hacker ploy, for example, is to regularly spam employees with marketing emails that seem to originate from a legitimate business and include a handy unsubscribe link at the bottom. Unbeknownst to the recipient, clicking that link activates an invisible download of malware to their PC or other computer device—software that can be used to steal IDs, passwords, credit card numbers, client data, and more.

“Look at the link, and see where it’s coming from,” Winkler advises. If you don’t recognize the company, or the link seems hinky, don’t click it.

You should run any security solution you choose past your attorney or any personnel hired to ensure that the software you use complies with all government regulations for pharmacies.

Get Insurance
You’ll also probably want to consider buying insurance against a cyber attack and data breach. "Since most policies do not have sufficient coverage, I recommend purchasing additional coverage to protect your assets," says RxXpress’ Grisnik. "We must all continuously review and update our policies and operating procedures for our employees to ensure we protect our own and our patients’ information."

Mona Ghattas, BSPharm, owner of Duran Central Pharmacy in Albuquerque, agrees: "My business has a separate insurance policy that addresses cyber security, both externally and internally. Every business must own a policy like this in today’s world."

If all else fails, you’ll also want a backup plan—just in case your pharmacy gets hit by a hacker despite all your efforts. "If there is one thing I want to strongly recommend to all pharmacies, it is that they all need a disaster recovery plan, security awareness training, and have daily offsite backups of their data," says Jason Carter, chief technology officer for Best Value Pharmacies.

There are of course other ways to further toughen your security and protect your pharmacy. But at a certain point, you’ll probably need to concede that your Internet security will never be perfect.

"Anybody who sells you ‘perfect security’ is a fool or a liar," Winkler says. "What security is about is risk management. The more you elevate security, the more you’re raising the bar, and the more exponentially you’re decreasing your risk."
The Latest FDA Approvals

By Drew Boxler, associate editor

Scott Gottlieb, MD, energized the rate of new drug approvals at the FDA. He may have resigned as commissioner, but new product approvals continue to flow at a good pace. Here are the latest since our last update in February.

JEUVEAU
(PrabotulinumtoxinA-xvfs, Evolus)
Indications: Temporary improvement in appearance of moderate to severe wrinkles associated with corrugator and/or procerus muscle activity in adults.
Dosage: 0.1 mL by intramuscular injection into sites on the face.
Contraindications: Infection at the injection site.

EGATEN (triclabendazole, Novartis)
Indications: Treatment of fascioliasis in patients age 6 or older.
Dosage: Two oral 10-mg/kg doses given 12 hours apart in patients age 6 years of age or older, to be taken with food. Round dose upwards if unable to adjust exactly. Product can be swallowed whole, divided in half and taken with water, or crushed and taken with applesauce.
Contraindications: Known hypersensitivity to benzimidazole derivatives.

ZULRESSO (brexanolone, Sage Therapeutics)
Indications: Postpartum depression in adult women.
Dosage: Continuous intravenous infusion over 60 hours (2.5 days).

MAYZENT (siponimod, Novartis)
Indications: Treatment of relapsing forms of multiple sclerosis, including relapsing-remitting disease, secondary progressive disease, and clinically isolated syndrome.
Dosage: Assessments are required prior to initiating Mayzent; maintenance dose is 2 mg; for patients with a CYP2C9*3/*3 or *2/*3 genotype, maintenance dose is 1 mg. First-dose monitoring is recommended for patients with sinus bradycardia, first- or second-degree [Mobitz type I] atrioventricular (AV) block, or a history of myocardial infarction or heart failure.
Contraindications: Patients with a CYP2C9*3/*3 genotype or patients who have experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure within the past 6 months.

SUNOSI (solriamfetol, Jazz Pharmaceuticals)
Indications: Adults with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).
Dosages: Once daily upon waking, avoid use within 9 hours of intended bedtime. Narcolepsy starting dose: 75 mg once daily. OSA starting dose: 37.5 mg once daily. Doses may be increased in three-day intervals, maximum being 150 mg daily. For patients with renal impairment: Starting dose: 37.5 mg once daily. Maximum: 75 mg once daily after 7 days. Severe impairment: 37.5 mg once daily. Not recommended for patients with end stage renal disease.
Contraindications: Concurrent treatment with a monoamine oxidase inhibitor (MAOI) or use of an MAOI within the preceding 14 days.

DOVATO (dolutegravir and lamivudine, ViV Healthcare)
Indications: Adult patients with HIV-1 but not hepatitis B, who have not taken previous antiretroviral treatments, and who do not have any...
suspected substitutions associated with resistance to either dolutegravir or lamivudine.

**Dosages:** One 50-mg tablet once daily. If Dovato is coadministered with carbamazepine or rifampin, take one tablet of Dovato once daily, followed by an additional dolutegravir 50-mg tablet, approximately 12 hours from the dose of Dovato.

**Contraindications:** Coadministration with doxetilde.

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**SPRAVATO**

*esketamine, Janssen*

**Indications:** Adults with treatment-resistant depression, to be used in conjunction with an oral antidepressant.

**Dosages:** 28 mg intranasally. Patients must remain under healthcare supervision for at least two hours after receiving administration.

**Contraindications:** Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation, intracerebral hemorrhage, or hypersensitivity to esketamine, ketamine, or any of the excipients.

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**SKYRIZI**

*risankizumab-rzaa, AbbVie*

**Indications:** Treatment of moderate-to-severe plaque psoriasis in adults who are also candidates for systemic therapy or phototherapy. Patients must be screened for tuberculosis and other infections prior to treatment initiation.

**Dosage:** 150 mg administered in two subcutaneous injections at weeks 0 and 4, and then every 12 weeks thereafter.

**Contraindications:** None

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**IBRANCE**

*palbociclib, Pfizer*

**Indications:** Adults with hormone receptor positive, HER2-negative advanced or metastatic breast cancer in combination with either an aromatase inhibitor as initial endocrine-based therapy, or fulvestrant in patients with disease progression following endocrine therapy.

**Dosages:** Recommended starting dose is 125 mg once daily taken with food for 21 days followed by 7 days off treatment. Dosage interruptions or reductions are recommended based on individual safety and tolerability.

**Contraindications:** None

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**BALVERSA**

*erdafitinib, Janssen Pharmaceutical Companies*

**Indications:** adult patients with locally advanced or metastatic urothelial carcinoma that has susceptible FGFR3 or FGFR2 genetic alterations and progressed during or after at least one line or prior platinum-containing chemotherapy.

**Dosage:** Initial dose is 8 mg orally once daily, increase to 9 mg if criteria are met.

**Contraindications:** None

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**DUOBRII**

*(halobetasol propionate and tazarotene, Bausch Health)*

**Indications:** Adults with plaque psoriasis

**Dosage:** Thin layer of Duobrii lotion applied topically to affected areas once daily.

**Contraindications:** Pregnancy. Avoid application to skin with eczema, as severe irritation may result.

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**ETICOVO**

*(etanercept-ykro, Samsung Bioepis)*

**Indications:** Treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA) in patients aged 2 years or older, psoriatic arthritis (PsA), ankylosing spondylitis (AS), and plaque psoriasis in patients 4 years and older.

**Dosage:**
- Adult RA and PsA: 50 mg to be administered once weekly in conjunction with methotrexate.
- AS: 50 mg administered once weekly.
- Adults with plaque psoriasis: 50 mg administered twice weekly for three months, followed by 50 mg once weekly for the remaining treatment cycle.
- Pediatric patients with plaque psoriasis or JIA who weigh 63 kg or more: 50 mg once weekly.

**Contraindications:** Sepsis
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Spravato for Treatment-Resistant Depression

By Shyam Patel, PharmD, and Lisa M. Holle, PharmD, BCOP, FHOPA

In March, the FDA approved intranasal esketamine (Spravato, Janssen), when used in conjunction with an oral antidepressant, for treatment of depression in adults who have not benefitted from other antidepressant medications. Esketamine is the S-enantiomer of racemic ketamine and functions as an N-methyl-D-aspartate (NMDA) receptor antagonist that leads to alleviation of treatment-resistant depression (TRD).1

**Efficacy**

Esketamine was evaluated in two phase 3 randomized double-blind multicenter placebo-controlled trials. In one trial, patients meeting DSM-V criteria for TRD (defined as treatment with at least two different antidepressants trialed for adequate dose and duration) were randomized to receive flexible dose (56 mg or 84 mg) intranasal esketamine plus an oral antidepressant or intranasal placebo plus an oral antidepressant. Esketamine and oral antidepressant was significantly better at controlling depression; a significant reduction (-4) in the change from baseline score in the Montgomery-Asberg Depression Rating Scale (MADRS) at week 4.2 In the second trial, patients who were responders or remitters to esketamine after at least 16 weeks of therapy were randomized to either continue receiving intranasal treatment and an oral antidepressant or placebo and an oral antidepressant for long-term variable duration. The primary efficacy measure was time to relapse. Both responder and remitter patients experienced a statistically significant longer time to relapse with esketamine compared to the placebo.3

**Safety**

The most common adverse events were dissociation (41%), dizziness (29%), nausea (28%), sedation (23%), vertigo (23%), headache (20%), dysgeusia (19%), hypoesthesia (18%), lethargy (11%), and increased blood pressure (10%). Drug-related side effects could affect driving; patients should not drive or operate heavy machinery until the next day, after a restful sleep.

Geriatric use of esketamine was supported by data from clinical trials. No significant differences in safety were observed between the 65 and older group and younger groups.

Physical dependence is reported with prolonged use of large doses of ketamine; no withdrawal symptoms were reported with recommended esketamine use up to 4 weeks after discontinuation. However, dependence may occur in patients who abuse esketamine or take doses larger than recommended.

**Dosing**

Esketamine induction phase dosing is 56 mg intranasally on day 1, then twice weekly administration of 56 mg or 84 mg weeks 1 through 4. During weeks 5 through 8 of the maintenance phase, patients are administered 56 mg or 84 mg intranasally once weekly. During weeks 9 and onwards, patients are maintained at 56 mg or 84 mg intranasally once weekly or once every 2 weeks.4

A healthcare provider must administer this drug in a clinic. The patient must remain for at least 2 hours and have prearranged transportation home. Patients must also enroll in the risk evaluation and mitigation strategy program. Blood pressure should be monitored before and after treatment. If blood pressure is under 140/90 mmHg, consider waiting for blood pressure to fall before administering esketamine. After administration, blood pressure should be monitored for 2 hours. If blood pressure remains elevated 40 minutes postdose, refer patient for immediate emergency care.

Patients using a nasal decongestant or nasal corticosteroid should administer medications at least 1 hour before esketamine use. Because nausea and vomiting are common side effects, patients should avoid eating food for at least 2 hours and avoid drinking liquids for at least 30 minutes before administration.

Dose adjustments are not recommended for patients with renal or hepatic insufficiency. Use of esketamine is not recommended in patients with Child-Pugh C hepatic dysfunction.

**References**

2. ClinicalTrials.gov. Identified NCT02418585; A study to evaluate the efficacy, safety, and tolerability of flexible doses of intranasal esketamine plus an oral antidepressant in adult participants with treatment-resistant depression (TRANSFORM-2). Available at https://bit.ly/2sHj6ia.
3. ClinicalTrials.gov. Identified NCT02493868; A study of intranasal esketamine plus an oral antidepressant for relapse prevention in adult participants with treatment-resistant depression (SUSTAIN-1). Available at https://bit.ly/2sj1ifD.
Workflow: Staffing, Phone Lines, and Drive-Throughs

The profession of community pharmacy presents an interesting dichotomy, one that requires business skills as well as clinical skills. Not much infuriates me more when I hear dispensing pharmacists say, “I don’t get involved in that clinical stuff. I focus on the business side.”

I’d like to tell them to go sell shoes. Pharmacy is a healthcare profession and clinical skills are of paramount importance. Someone decided a very long time ago that dispensing pharmacists needed a college degree to run a drug store as a pharmacist. Dispensing information is as important as dispensing product.

I’ve been doing this amazing profession for 38 years, and one thing I am always working to improve is management of workflow. I always say, “There are too many bottles and too many sheets of paper for a pharmacy to be disorganized.” Organization is critical to operate a pharmacy. Nothing disrupts workflow more than “looking for stuff.”

The most important job of any pharmacist is verifying the accuracy of prescriptions. I wrote a column about my technique of using the red pen, to provide me a physical way of checking prescriptions and “pull the trigger” so I can efficiently move to the next.

Unless he or she is an owner, there are three parameters in a pharmacy that are out of the managing pharmacists’ control: staffing, phone lines, and the drive-through window.

I’ve written several articles about staffing, and the different formulas chains use to determine staffing. I’m waiting for the day that state boards of pharmacy or the pharmacy organizations take a stand on inadequate staffing, the No. 1 gripe for most pharmacists.

The number of phone lines is another challenge. When a pharmacy has three phone lines and only two busy techs to answer them, the pharmacist gets interrupted. Pharmacists answering the phone and answering the questions like “What time do you close?” or “Do you have chocolate milk up front?” is utter nonsense, but often with both techs on the phone, line No. 3 rings and only the pharmacist is available. The number of phone lines should never exceed the number of technicians available to answer it.

Of all the customer conveniences that frustrate the pharmacist, the drive-through window is the most challenging. Most drive-throughs are attached directly to the pharmacy space. Patients can gawk in and observe the staff answering phones, and processing orders. I remember when the small chain I worked for in the 1980s installed the first drive-through in our area. A seasoned pharmacist and I were talking, and he said “Buddy, when you have a drive-through, one clerk should be assigned to that spot, and that should be their only responsibility.” Most drive-throughs in the pharmacy world do not have such luxury, and often the pharmacist is the one to walk over and tend to the window. I’ve seen patients want to buy lottery tickets, soda, and stamps, while interrupting pharmacy staff from their life-saving work.

I counsel patients on every new prescription by flagging the bag with a fluorescent green sticker. I bring them to the small private area and discuss the use, side effects, directions, and any other information I may have. My opioid patients get special counseling for appropriate use, security, constipation concerns, and are handed a drug disposal bag to properly destroy any unused meds. This can’t possibly be done over the intercom system in a drive-through. Patients standing in the parking lot can hear every discussion with the patient in the drive-through. What ever happened to privacy and HIPAA? That certainly went out the (drive-through) window.

“There are too many bottles and too many sheets of paper for a pharmacy to be disorganized. Organization is critical to operate a pharmacy.”

Pete Kreckel, BSPharm, practices community pharmacy in Altoona, PA. He welcomes your emails at editors@drugtopics.com.
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