Future of Chains
What it means for pharmacy
Are you offering your patients with diabetes a cost-effective insulin option?

You can if you stock Lilly’s Insulin Lispro Injection U-100. It’s the same molecule as Humalog® U-100, but at a lower list price that may be more affordable for some of your customers.*

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• Same safety profile and clinical efficacy
• Same manufacturer and molecule
• Same KwikPen® and vial

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†State laws vary.

For customers who need help paying for their Lilly insulin prescription, encourage them to call Lilly Diabetes Solution Center at 1-833-808-1234, Monday through Friday, 9 AM to 8 PM ET.

Indication for Humalog and Insulin Lispro Injection
• Humalog and Insulin Lispro Injection are rapid-acting human insulin analogs indicated to improve glycemic control in adults and children with diabetes mellitus.

Select Important Safety Information

Contraindications
• Humalog and Insulin Lispro Injection are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of its excipients.

Please see Important Safety Information for Humalog U-100 and Insulin Lispro Injection U-100 on the next page and Brief Summary of Prescribing Information on the following pages.
Important Safety Information for Humalog and Insulin Lispro Injection

Contraindications

- Humalog and Insulin Lispro Injection are contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of its excipients.

Warnings and Precautions

- Never Share a Humalog or an Insulin Lispro Injection KwikPen or Syringe Between Patients: Humalog and Insulin Lispro Injection KwikPen must never be shared between patients, even if the needle is changed. Patients using a Humalog or Insulin Lispro Injection vial must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.

- Changes in Insulin Regimen: Changes may affect glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made cautiously under close medical supervision and the frequency of blood glucose monitoring should be increased.

- Hypoglycemia: Severe hypoglycemia may be life threatening and can cause seizures or death. Hypoglycemia is the most common adverse reaction of Humalog or Insulin Lispro Injection. The patient’s ability to concentrate and react may be impaired as a result of hypoglycemia. Hypoglycemia can happen suddenly and symptoms may vary for each person and may change over time. Early warning symptoms of hypoglycemia may be different or less pronounced under conditions such as long-standing diabetes, diabetic nerve disease, use of medications such as beta-blockers, or in patients who experience recurrent hypoglycemia. These situations may result in severe hypoglycemia and possibly loss of consciousness prior to the patient’s awareness of hypoglycemia. Timing of hypoglycemia usually reflects the time-action profile of administered insulins which may vary in different individuals or at different times in the same individual. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may increase the risk of hypoglycemia. Educate patients to recognize and manage hypoglycemia. In patients at higher risk for hypoglycemia and patients with reduced symptomatic awareness, increased frequency of blood glucose monitoring is recommended. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia.

- Hypersensitivity Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with Humalog or Insulin Lispro Injection. If hypersensitivity reactions occur, discontinue Humalog or Insulin Lispro Injection and treat per standard of care until signs and symptoms resolve.

- Hypokalemia: Hypokalemia may be life threatening. Insulins, including Humalog and insulin lispro injection, cause a shift in potassium from the extracellular to intracellular space possibly leading to hypokalemia, which, if untreated, may result in respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia (eg, patients using potassium-lowering medications or medications sensitive to serum potassium concentrations).

- Hyperglycemia: The most common adverse reaction of Humalog or Insulin Lispro Injection is hyperglycemia. Changes may affect glycemic control and predispose to hypoglycemia or hyperglycemia. In patients at higher risk for hyperglycemia, changes in insulin requirements, and the risk for hyperglycemia may be increased.

- Drug Interactions: Some medications may alter glucose metabolism, insulin requirements, and the risk for hypoglycemia or hyperglycemia. Signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs. Particularly close monitoring may be required.

- Use in Specific Populations: Humalog and Insulin Lispro Injection have not been studied in children with type 1 diabetes less than 3 years of age or in children with type 2 diabetes.

- Dosage and Administration: Humalog and Insulin Lispro Injection should be given within 15 minutes before or immediately after a meal.

- Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction: Malfunction of the insulin pump device, infusion set, or insulin degradation can rapidly lead to hyperglycemia and ketoacidosis. Patients using subcutaneous insulin infusion pumps must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure.

Please see Humalog and Insulin Lispro Injection Brief Summary of Prescribing Information on the following pages. Please see Instructions for Use included with Humalog and Insulin Lispro Injection products.
INDICATIONS AND USAGE
Humalog and Insulin Lispro Injection are rapid-acting insulin analogs indicated to improve glycemic control in adults and children with diabetes mellitus.

DOsing
- Subcutaneous Injection: Humalog or Insulin Lispro Injection should be given within 15 minutes before or immediately after a meal.
- Continuous subcutaneous infusion (insulin pump): Humalog U-100 or Insulin Lispro Injection U-100 can be administered using an insulin pump. Do not administer Humalog U-200 in a subcutaneous insulin infusion pump.
- Intravenous Infusion: Administer Humalog U-100 or Insulin Lispro Injection U-100 only after dilution and under medical supervision with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia. Do not administer Humalog U-200 intravenously.

CONTRAINDICATIONS
Do not use Humalog or Insulin Lispro Injection:
- During episodes of hypoglycemia.
- In patients who are hypersensitive to Humalog or Insulin Lispro Injection or any of the excipients in Humalog or Insulin Lispro Injection.

WARNINGS AND PRECAUTIONS
- Never share prefilled pens, needles, cartridgues, reusable pens compatible with Lilly 3 mL cartridgues, or syringes between patients: even if the needle is changed. Patients using vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.
- Hyper- or Hypoglycemia with Changes in Insulin Regimen: Changes in insulin strength, manufacturer, type or method of administration may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Make changes cautiously under close medical supervision and increase the frequency of blood glucose monitoring.

Hypoglycemia: Is the most common adverse reaction of Humalog and Insulin Lispro Injection. Severe hypoglycemia may be life threatening and can cause seizures or death. The patient’s ability to concentrate and react may be impaired as a result of hypoglycemia. Hypoglycemia can happen suddenly. Symptoms may vary for each person and change over time. Early warning symptoms of hypoglycemia may be different or less pronounced in patients with long-standing diabetes or diabetic nerve disease or in patients who use medications such as beta-blockers or experience recurrent hypoglycemia. These situations may result in severe hypoglycemia and possible loss of consciousness prior to the patient’s awareness of hypoglycemia.

Timing of hypoglycemia usually reflects the time-action profile of administered insulins which may vary in different individuals or at different times in the same individual. Other factors such as changes in food intake, injection site, exercise, and concomitant medications may increase the risk of hypoglycemia.

Educate patients to recognize and manage hypoglycemia. Self-monitoring of blood glucose is essential for patients receiving insulin therapy. Increase monitoring frequency with changes to insulin dosage, use of glucose-lowering medications, meal pattern, and physical activity. In patients with reduced symptomatic awareness or that have a higher risk for hypoglycemia, such as those with renal or hepatic impairment, increased frequency of blood glucose monitoring is recommended.

ADVERSE REACTIONS
Adverse reactions associated with Humalog and Insulin Lispro Injection include hypoglycemia, hypokalemia, allergic reactions, injection-site reactions, lipodystrophy, pruritus, rash, weight gain, and peripheral edema.

- Insulin Initiation and Intensification of Glucose Control: Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

- Lipodystrophy: Long-term use of insulin, including Humalog and Insulin Lispro Injection, can cause lipodystrophy at the site of repeated insulin injections or infusion. Lipodystrophy includes lipoatrophy (thinning of adipose tissue) and lipohypertrophy (thickening of adipose tissue) and may affect insulin absorption. Rotate insulin injection or infusion sites within the same region to reduce the risk of lipodystrophy.

- Weight Gain: Weight gain can occur with insulin therapy, including Humalog and Insulin Lispro Injection, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

- Peripheral Edema: Insulin, including Humalog and Insulin Lispro Injection, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

- Allergic Reactions: Local Allergy—As with any insulin therapy, patients taking Humalog or Insulin Lispro Injection may experience redness, swelling, or itching at the site of the injection. These minor reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation of Humalog or Insulin Lispro Injection. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic Allergy—Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin, including Humalog and Insulin Lispro Injection. Generalized allergy to insulin may cause whole body rash (including pruritus), dyspnea, wheezing, hypotension, tachycardia, or diaphoresis. In controlled clinical trials, pruritus (with or without rash) was seen in 17 patients receiving regular human insulin (n=2969) and 30 patients receiving Humalog or Insulin Lispro Injection (n=2944). Localized reactions and generalized myalgias have been reported with injected metacresol, which is an excipient in Humalog and Insulin Lispro Injection.
**DRUG INTERACTIONS**
Certain drugs may alter glucose metabolism, insulin requirements, and the risk for hypoglycemia or hyperglycemia. Signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs. Dose adjustment and increased frequency of glucose monitoring may be required.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**—Published studies with the use of insulin lispro during pregnancy have not reported an association between insulin lispro products and major birth defects, miscarriage, or adverse maternal or fetal outcomes. However, these studies cannot definitively establish or exclude the absence of any risk because of methodological limitations in the study design. Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, perterm delivery, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity.

**Lactation**—There are no data on the presence of Humalog or Insulin Lispro Injection in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for insulin, any potential adverse effects on the breastfed child from Humalog or Insulin Lispro Injection, or from the underlying maternal condition.

**Pediatric Use**—Humalog and Insulin Lispro Injection are approved for use in children for subcutaneous daily injections. Only the U-100 formulations of Humalog and Insulin Lispro Injection are approved for use in children by continuous subcutaneous infusion in insulin pumps. Humalog and Insulin Lispro Injection have not been studied in pediatric patients younger than 3 years of age or in pediatric patients with type 2 diabetes.

**Renal or Hepatic Impairment**—Patients with renal or hepatic impairment may be at increased risk of hypoglycemia and may require more frequent Humalog or Insulin Lispro Injection dose adjustment and more frequent blood glucose monitoring.

**OVERDOSE**
Excess insulin administration may cause hypoglycemia and hypokalemia. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

**PATIENT COUNSELING INFORMATION**
See FDA-approved patient labeling and Patient Counseling Information section of the Full Prescribing Information.

See Brief Summary of Prescribing Information on adjacent page. See Instructions for Use accompanying the pen or vial. Additional information can be found at https://www.humalog.com/hcp/, https://www.lillyinsulinlispro.com, or The Lilly Answers Center at 1-800-LillyRx (1-800-545-6979).
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Drug Topics  
Year of the Pharmacist

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Drug Topics
Voice of the Pharmacist
Much like the weather at this time of year, chain pharmacies are in a state of change, and these changes will likely have ripple effects for all of pharmacy. Everything that happens with the larger chain pharmacies affects every other part of the business, including the independent community pharmacists. To help you keep up with all of these changes, this issue features a number of high-touch, clinical care articles that focus on the future of pharmacy.

This issue features an article with practical tips for helping to manage medications for senior patients, an article on new treatment options for patients with rheumatoid arthritis, and a content piece that centers on why providing diabetes care makes sense for both helping patients and your bottom line.

This issue also features a great look at how vaccination should be a part of every pharmacy—and why it doesn’t have to be so stressful. You’ll learn how to prepare for a pharmacy inspection—saving you time and headaches. As in other issues, you’ll find the latest clinical news and studies to help you practice at the top of your game—no matter what setting you work in.

This issue also underscores that independent pharmacists are in a position to shape the future of pharmacy as well. As long-time independent Dispensed As Written columnist Peter Kreckel, BSPharm, writes, chains can learn a few things from independents too! “Come to my pharmacy when I’m staffing,” he said to a member of a chain, “and then head down the street to their chain and see the difference.”

Pharmacy can’t exist in a vacuum! Chains should be learning from independents and independents should be learning from chains.

After all, when it comes down to it, it’s really all about how to make sure everyone who comes through your door leaves with the information and treatments they need to get healthier.

As you anticipate the changes that fall brings and the changes that healthcare will keep bringing, Drug Topics will be there to help you along the way. It’s an exciting time for pharmacy, and we can’t wait to be there with you for it.

Mike Hennessy, Sr.,
Chairman and Founder
Profiting from Vaccination Programs

How you can increase revenue while improving public health.

By Jill Sederstrom

The majority of pharmacies in the United States now offer vaccinations, but there is still significant opportunity to turn a well-run vaccination program into a profitable endeavor that benefits both patient and pharmacy.

Many adults still fail to get the recommended vaccinations each year. According to the CDC, just 37.1% of adults received the flu vaccine during the 2017-2018 flu season. This presents a significant opportunity for pharmacies to improve these numbers by expanding their immunization efforts, marketing their programs to the community, and relying on what makes a pharmacy a unique healthcare setting.

"Pharmacies have a huge advantage right off the bat of being readily available and accessible," says Beverly Schaeffer, RPh, of Katterman’s Sandpoint Pharmacy in Seattle, WA.

Katterman’s was one of the first to offer vaccines—starting their program back in 1996. Schaeffer says the pharmacy had been hoping to give 300 vaccines but found themselves administering 1,200. Since then, the program has continued to grow and the pharmacy now offers all available vaccines in the state and can even administer to children and infants.

"All pharmacists could be doing more immunizations than they are if they wanted to," she says.

Expanding immunization efforts can not only improve public health, but it can also serve as an increased revenue stream for community pharmacies. Close to 100 million Americans get the flu shot each year, translating to $4 billion to $5 billion in revenue, PBA Health reports.

Immunizations outside the influenza vaccine can often bring in even larger administration fees for pharmacies. "Almost all immunizations pay an administration fee that varies from plan to plan, but you get paid for the vaccine plus an administration fee," Schaeffer says.

Vincent Hartzell, PharmD, president of Hartzell’s Pharmacy in Catasauqua, PA, says successful immunization programs not only provide revenue for a pharmacy on their own, but they also often drive other areas of business. "Vaccines have allowed us to provide marketing and attract new customers," he says.

The most effective marketing strategies, he says, don’t always have to be costly and can be as simple as an effective social media post, informing local physicians and area senior centers of the pharmacy’s immunization services, or using banners and signs.

Schaeffer has found one of her best marketing tools is a sandwich board placed outside the pharmacy each day that highlights different services such as its tetanus shots, travel vaccines, or the highly sought-after shingles vaccine.

Her pharmacy does a significant amount of business in travel vaccines, so she also tries to drive other store business through a separate travel aisle where customers can find everything needed for an upcoming trip—anti-diarrhea medications, rehydration packets, eye drops—all in one convenient area.

Hartzell believes it’s important that all the pharmacists in a community pharmacy be trained to give immunizations so that there is always an available staff member whenever a customer arrives at the store.

To improve the workflow, he says, non-pharmacist staff should also be a critical aspect of vaccination programs. Those workers should have ways to identify patients who may be behind on immunizations or could benefit from annual vaccines such as the influenza and pneumococcal vaccines.

"Make sure that your technicians know how to do the billing, make sure your technicians know how to fill out the consent forms because that’s stuff that you don’t need a pharmacist for," he says.

Overall, Schaeffer and Hartzell agree, successful vaccination programs can yield big rewards for community pharmacies and their patients.
Authorized Generics
What you need to know. By Mari Edlin

Authoried generics might just be the answer for drug manufacturers whose patents for their branded drugs have expired. Instead of risking the loss of market share when other drug companies enter the generics marketplace, the brand name manufacturers could develop their own generics.

An authorized generic is exactly the same product as an approved branded drug, but is marketed without the brand name on the label. Usually sold at a lower price, it can be marketed by a branded drug company or by another company with the brand company’s permission. “By making an authorized generic, a brand manufacturer gets a jump start on the competition as generics start to appear,” says Karen Berger, PharmD, a staff pharmacist at Plymouth Park Pharmacy in Fair Lawn, NJ.

“Authorized generics, which are identical to the brand, should not be confused with a branded generic that has gone through the abbreviated new drug application (ANDA) process and is assigned a name other than its chemical name,” she says.

Leaving Nothing to Chance
“While a separate NDA is not required for marketing an authorized generic, FDA requires that the NDA holder notify the FDA if it markets an authorized generic. The NDA holder may market both an authorized generic and its brand name product at the same time,” says Charlie Kohler, spokesperson for the FDA.

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By making an authorized generic, a brand manufacturer gets a jump start on the competition as generics start to appear.

KAREN BERGER, PHARM.D

A regular generic should do just fine as well as save money,” Berger says. David Lassen, PharmD, chief clinical officer, Prime Therapeutics, has seen an increased trend in manufacturers releasing authorized generics, primarily for two reasons:

1. Recent market pressures around high drug costs have prompted them to provide cost relief, and
2. Manufacturers can maintain market share of product through authorized generics.

“Prime takes a ‘lowest net cost’ approach to managing drugs with our clients, which in some cases means encouraging the use of originator brands over authorized generics when the net cost (with rebate) is lower than the authorized generic price,” he says.

“In doing so, the objective is to help ensure members aren’t penalized by higher out-of-pocket costs. For those members with coinsurance and high-deductible plans, we override benefits to help ensure the member isn’t penalized,” Lassen says.

Pfizer, which has the broadest portfolio of authorized generics in the United States, stated its position on authorized generics in an August 2018 report. The company believes that authorized generics “help advance public health and the broader healthcare system by increasing competition, improving access, and helping patients adhere to high quality, affordable medicines.”

Pfizer attributes increased adherence to greater ease in switching from a branded product to an authorized generic that looks similar to the original drug. As reported in a 2018 issue of BMJ, in an FDA-sponsored study of 210,000 patients, switching from a brand to an authorized generic was associated with lower “switchback” rates compared to switching from a brand to a regular generic.

Increased Competition

“For generic drug companies, there is a strong incentive to be the first to file a Paragraph IV certification under Hatch-Waxman and market their products during the 180-day exclusivity period, even if there is shared generic exclusivity, because competition with other generic products is more limited during that period,” says Andrew Powaleny, director, public affairs, PhRMA.

### Authorized Generics vs. Generics

<table>
<thead>
<tr>
<th>Authorized Generics</th>
<th>Generics</th>
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<tbody>
<tr>
<td>Usually made by brand name manufacturer</td>
<td>Made by separate manufacturer</td>
</tr>
<tr>
<td>Same inactive ingredients</td>
<td>Possibly different inactive ingredients</td>
</tr>
<tr>
<td>Same active ingredient</td>
<td>Same active ingredient</td>
</tr>
<tr>
<td>No ANDA required</td>
<td>ANDA required</td>
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<tr>
<td>Usually very similar in appearance to branded drug</td>
<td>Usually different in appearance to branded drug</td>
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The Hatch-Waxman Act of 1984 allows the first manufacturer that comes out with an ANDA to have 180 days of exclusivity, at which time the FDA can’t approve another generic, often resulting in lawsuits and counter suits. However, if an authorized generic avoids a lawsuit while holding tight in its 180-day exclusivity period, the manufacturer will make money on both the brand and authorized generic, Berger says.

After the 180-day period, other generics might start to hit the market at a lower price, urging large chains and buying groups to send these to their stores from wholesalers.

**Cost Savings**

According to the Federal Trade Commission, consumers and the healthcare system could benefit from an authorized generic on the market during an 180-day exclusivity period because of increased competition that reduces generic prices and results in significant cost savings.

An FTC report notes that “competition from an authorized generic during the 180-day exclusivity period is associated with retail generic prices that are 4% to 8% lower and wholesale generic prices that are 7% to 14% lower than prices without authorized generic competition.”

In addition, the FTC found that, following the 180-day exclusivity period, the presence of an authorized generic “tended to be associated with lower prices in markets where an exclusivity period had expired” as retail prices post-exclusivity were found to be 10% to 11% lower and wholesale prices were 6% to 13% less.

“As such, Congress should reject attempts to delay, restrict, or prohibit authorized generics,” Powaleny says.

Berger says a patient’s insurance determines if authorized generics could save money. “Usually generics should have a lower copay so technically an authorized generic should have a lower copay for the patient than a brand would. Because every insurance has different structures and rebates and different technicalities, it is hard to generalize, but I would venture to say that most generics—whether it is a regular old generic, branded generic, or authorized one—should be less expensive than a brand,” she says.

Both Berger and Powaleny agree that drug rebates could influence the true cost of a drug. Berger says rebates play a role in price savings from authorized generics that can be more profitable than a brand name drug because they usually aren’t subject to rebates that flow from a drugmaker to PBMs and lower a brand’s revenue.

“If an authorized generic is not more cost effective than a brand discount (cost) minus the rebate, the plan (employer) may be better off with the brand; however, the member would likely pay less with the authorized generic as it has a deeper discount (cost), and the member pays a generic copayment or a lower cost in the deductible phase,” she says.

Medicaid, however, requires manufacturers to calculate and pay mandatory Medicaid rebates on AGs taken by Medicaid patients, Powaleny says.

**Preventing Drug Shortages**

Berger and Lassen agree that authorized generics have not filled the void during drug shortages. “It seems that when a drug is unavailable, it’s unavailable from every manufacturer whether it is a regular generic, authorized, or branded,” Berger says.

“To date, we have not seen the use of authorized generics play a significant role in helping to eliminate drug shortages,” Lassen says.

Sanofi, however, says that in 2015, it developed an authorized generic version of leflunomide for rheumatoid arthritis—17 years after the launch of Arava, its branded version—to meet demand left by a drug shortage from generic makers of leflunomide.

Berger predicts that the next big step for authorized generics will occur when companies that make biologics, such as AbbVie’s Humira (adalimumab), try to extend their profitability by making an authorized generic when their patents expire.
Training pharmacy staff—and yourself—to make the most of a new technology shouldn’t be a major challenge. Vendors provide training along with their new products. Don’t they?

Yes and no, says Carlie Traylor, PharmD, associate director of Strategic Initiatives for the National Community Pharmacists Association. She was previously director of clinical services for an independent pharmacy group and oversaw staff training.

“Yes, vendors provide training, but vendor trainers go home eventually,” she said. “Training tasks fall to the store in the end. What you have to remember is that training, including technology training, is never done.”

So what’s a store owner or manager to do?

For starters, rethink the term “training.” Talk of staff training raises too many visions of tedious sessions trying to learn a task or a skill that is totally impenetrable. The problem isn’t the subject, but the way it is presented.

“It is all about your approach,” says Beth Tomac, owner of Broad Street Pharmacy in Chesaning, WI. A longtime pharmacy technician, she became a pharmacy owner when a prior workplace sold to a chain and the working atmosphere changed dramatically.

“You can tell your staff they have to learn something, and it won’t go very well,” she explains.

“Or you can talk about the excitement of a new technology and how it is going to solve a specific problem that everybody knows about and make their lives easier. And about how utterly cool this new tech is going to be. When everyone knows that a new technology isn’t going to interfere with their position but will enhance it, attitudes change. You just gave them reasons to succeed instead of reasons to fail.”

No argument from pharmacy management system PioneerRx. The company prides itself on on-site customer training, says education manager Will Tuft. Training teams spend a week at each pharmacy on every installation. But the pharmacy’s approach to training has a lot to do with the success of new management software.

“It is a huge expense to implement new technology in the pharmacy, so there’s a good reason you are making that investment and making that huge change in the way you and your staff work,” Tuft says. “If you look at it like

Training Resources

Most pharmacy associations have a training department, but many are focused on clinical and business services such as medication therapy management or expanding immunization programs. Staff training materials can be harder to find.

The National Community Pharmacy Association devoted multiple sessions at its 2019 convention to staff training and training techniques. The group will release a new series of staff training videos later in 2019.

NCPA also has a training webinar, Management Techniques to Increase the Pharmacy’s Financial Success. A six part online course, Comprehensive Motivational Interviewing Training, can help staff train patients in a new technology or help change behavior as part of tobacco cessation or diabetes education program. Both are available through the NCPA Innovation Center.

The Association for Talent Development (TD.org) trains trainers—and pharmacy owners/managers.

Every CE session is a training seminar. Don’t just listen to the content, watch how the presenter structures the information and the mechanics of their teaching techniques. Some work well, some don’t—and all can help you to brush up your own teaching skills.
'Hey, here’s this new technology you have to learn; you just made the new technology a roadblock instead of an opportunity.

“If you focus your team on the why—why we are implementing this new technology, why we’re climbing this learning curve and how much it is going to help—you can get buy-in from your team to make that big push. Your attitude, and their buy-in, makes all the difference.”

Patients are part of your team, too, Tomac says.

It becomes clear when staff are training patients on a device like a new glucose meter or talking through familiar issues such as medication adherence. Staffers can make mastering that new patient-facing technology easier for the patient.

“It’s all about making their life better, not making it more complicated,” Tomac says. “If the patient isn’t comfortable with that new insulin pen or glucose monitor or whatever, they won’t use it. It’s all about helping them understand the advantages to learning that new device, how it is going to help them. It’s all about your attitude.”

One way to help acclimate patients to new technology is to talk about it. When Broad Street Pharmacy installed their ScriptPro robots, Tomac encouraged staffers to talk about it with patients, letting them know the pharmacy was installing the latest and greatest technology to make filling scripts faster and safer. Those conversations drove home the idea that the pharmacy cares enough to make a significant investment to make life better for patients.

That’s a double message, Tomac says. “Talking with customers about the wonderful new tech helps shape public perception of the pharmacy.

When patients have to do the learning, they better understand the rewards technology can bring.

“Talking about what we do behind the counter with technology just reinforces the message that we care and that we are always available to help,” Tomac says. “And it reminds the staff what a difference they are making, too. Just by changing your approach you have changed a task (learning new technology) into a goal (making your life better).”

That kind of attention to attitude plays out in larger pharmacy organizations, too. Tabula Rasa HealthCare doesn’t let new technicians anywhere near a dispensing line until they have finished a training program. For managers who focus on the bottom line, training is a dollars and cents issue.

“Pharmacy techs used to be readily available and now not so much,” says Steve Gilbert, Tabula Rasa vice president, Performance Improvement. “You don’t want to create a revolving door with constantly bringing people on board. We can either prepare them to succeed or prepare them to fail. Preparing people to succeed is the right thing to do, but it’s an economic decision at the same time.”

Training staff to succeed helps them be more comfortable in their role, Gilbert adds, which can ultimately lead to better productivity. Better training also means fewer mistakes. Minimizing errors improves patient safety. And it’s cheaper to fill a script correctly the first time than to have to replace something that was misfiled.

“Every time you teach a system or a device, you become more competent yourself,” Traylor said. “Tech vendors have great training videos, but the staffer who actually uses the system is the best one to help the trainee translate the video to the specific system they will be working with. Don’t ignore vendor resources, but it’s up to you to make their resources work within the system as configured for your store.”

Pharmacy owners and managers are responsible for training, but they shouldn’t be doing it all personally. Leave training to the operational expert. The manager is seldom the most knowledgeable person about any specific system or technology; let the staffer who knows more about the system than you train the newcomer.

NEW PHARMACY TECH

The Equashield Pro automated compounding unit is in beta testing in several US sites. The company says its closed system reduces surface contamination with antineoplastic agents, is faster to compound, and covers more routes of exposure than alternative compounding robots.

QS/1 introduced its new SharpPOS and a new register during the summer. Improvements include automatic SIGIS file updates, checking and issuing a refund in the same transaction, and unlimited department keys.

The new register runs both the current POS system and the SharpPOS with dramatically reduced footprint compared to current registers.

HBS has released the integration of its Pharmacy Services Portal with PickPoint’s will-call retrieval and bagging systems. The integrations mean a single application can help pharmacy staff cut wait times and improve service.

Capsa Healthcare released the new Kirby LesterKL-SR robotic dispenser for busy retail and hospital outpatient pharmacies. It manages filling of a pharmacy’s most common scripts using universal cassettes that require no technician calibration, eliminating an important source of error when changing the medication in a cassette.
liability insurance is like every other kind of insurance—you hope you never have to use it, because it usually means something has gone wrong.

For pharmacists, when something goes wrong, chances are it’s giving a patient the wrong dose or wrong drug—but mistakes in the pharmacy go far beyond that.

That’s according to the 2nd edition of the Pharmacist Liability Claim Report from healthcare insurance companies CNA and HPSO. The report analyzes claims over several years, from January 1, 2012 through December 31, 2016, that resulted in at least a $1 payment. Claims were included regardless of when they were filed, but must have closed during that time period.

Overall, the report looks at 184 closed claims. This is compared to the first edition of the report, released in 2013, that tracked claims over a 10-year period from January 1, 2002 to December 31, 2011, that resulted in at least a $1 payment. Claims were included regardless of when they were filed, but must have closed during that time period.

The total amount incurred in the 2nd edition is $25 million with an average claim of $124,407, compared with a total of $18 million and an average of $101,269 in the 1st—an increase of 22.8%.

Breaking Down the Numbers

So, where do all of these claims come from? The vast majority of claims are against pharmacists (96.2%), compared to just 3.8% against pharmacy technicians. According to the report, this is likely due to the fact that technicians operate under the supervision of pharmacists, and “therefore, the lower severity of pharmacy technician claims is commensurate with the scope of their licensure.”

The report also breaks down where those pharmacists worked and the average claims in each of those settings: the largest claims came from hospital pharmacies, with an average claim of $273,338 (more than twice the overall average of claims). The lowest average comes from pharmacists and technicians working in homecare environments, with an average payout of just $5,063.

The most common pharmacy types for claims were, perhaps unsurprisingly, from independent or individually-owned pharmacies (55.4%), compounding specialty pharmacies (17.9%), and national/regional chain pharmacies (12.0%).

And what were these claims for?

Pharmacy Mistakes and Why They Happen

Perhaps the biggest takeaway from the report, however, is the most common claims. By far, the most common claims were the result of the wrong drug (36.8%) and wrong dose (15.3%).

According to the report, a major reason for this is the problem of sound-alike and look-alike drugs (Table 1). Failure to separate out sound-alike drugs using methods like color separation and tall man lettering accounts for 15.1% of wrong drug dispensing errors. In one claim, a pharmacist dispensed minoxidil instead of methotrexate, resulting in the patient’s congestive heart failure and permanent partial disability.

Other risk factors include failure to check drug against label and actual prescription (9.8%) and failure to review prescription with patient (1.7%).

<table>
<thead>
<tr>
<th>Table 1 Wrong Drug Mistakes</th>
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<tbody>
<tr>
<td><strong>Drug Prescribed</strong></td>
</tr>
<tr>
<td>Abilify 15 mg</td>
</tr>
<tr>
<td>Labetalol 200 mg</td>
</tr>
<tr>
<td>Lexapro 10 mg</td>
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<tr>
<td>Methadone</td>
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<td>Methylphenidate</td>
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<tr>
<td>Pantoprazole 40 mg</td>
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<td>Pravastatin 80 mg</td>
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<td>Ropinirole 2 mg</td>
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It’s no secret that healthcare is in a state of rapid shifts—it has been for a long time, and it shows no sign of slowing in its evolution—and pharmacy is no exception. From independents to big box to large chains to hospitals, every pharmacist is going to feel (and is already feeling) significant changes.

Perhaps the greatest shift in recent years, however, has come from chains. Changes in chains affect not only the pharmacists working in those chains, but show how pharmacy as a whole is evolving.

**Major Shifts**
Pharmacy is continuing its shift away from solely dispensing medications to providing total care of a patient through drug therapy management, active patient engagement, and the ability to expand clinical services like administering flu shots and vaccines. The major chains are expanding the coverage of healthcare services from pharmacy to incorporating retail healthcare clinics into their locations and having pharmacists practice at the top of their licenses, such as strep testing and treatments.

Ramzi Yacoub, chief pharmacy officer at RxSense, a Boston-based healthcare tech company, believes pharmacy chains...
of the future will be offering more convenience in healthcare by expanding their in-store clinics, partnering with health insurers and health systems and providing a one-stop shop for patient care.

"With the retail chains already having pharmacists on-site and incorporating diagnostic services through clinics, they can provide a multi-disciplined team of clinicians who can manage the patient holistically," he says.

He also notes patients are shifting how they consume healthcare. They are more educated about the costs of medications and services as a way to save money.

"Patients are comparative shopping for their medications and taking advantage of prescription savings through services like SingleCare to save money on their medications," Yacoub says. "Pharmacists play a vital role in helping patients become consumers of medications, as they are well informed of the cost of medications and less costly alternatives. I think you will see more transparency in pharmacy both demanded by the consumer but also by state and federal requirements, which will result in a more educated consumer."

Thomas R. Bizzaro, RPh, vice president, health policy and industry relations, at San Francisco-based FDB, which provides drug and medical information, says in the coming years, chains—like independents—will continue to develop and deepen the important role of pharmacists within the value-based care delivery framework, especially as it relates to primary care delivery and identifying and addressing social determinants of health.

"As we have already seen, retail chains will expand pharmacy services beyond medication dispensing by addressing a growing number of basic healthcare needs, enabling pharmacists to practice at the top of their licensure," he says. "Of course, pharmacists will continue to serve their communities as the most trusted source of medication and drug information."

Meanwhile, he believes, automation and technicians will manage more of the pharmacy's dispensing—while pharmacists will become more involved in routine primary care, especially if it supports medication adherence and better outcomes.

"These changes will elevate not only pharmacists—but also pharmacies—to a larger and more meaningful healthcare delivery role in their communities and in patients' lives," Bizzaro says.

"In the future, when we talk about the care continuum that includes community physicians, inpatient, and post-acute care, pharmacies also will be included as one of those pillars."

Alam Hallan RPh, CDE, director of pharmacy at Guelph General Hospital and a registered pharmacist in Ontario, Canada and also the owner of several independent community pharmacies, says the major chain will be a complete health solution with a focus on chronic disease management in 10-20 years.

"We are seeing a lot of these employ nurse practitioners and will continue to see the build on this trend and offer other services, including telehealth," he says.

Retailers Evolving

Last year, CVS Health completed its acquisition of Aetna, after the health insurer agreed to sell its Medicare prescription drug plan business to WellCare Health Plans. Meanwhile, Walmart has been adding Walmart Health Clinics, offering healthcare services and providing basic healthcare needs.

As Larry Merlo, the CEO of CVS Health has publicly stated, the "Retailization of Healthcare" will continue to expand and evolve.

"I believe you will continue to see more pharmacies adopting a healthcare model similar to CVS’s," Yacoub says. "Retailers today are evolving their strategies but, at the end of the day, they are providing a convenient service where customers are the center of care and convenience is top of mind."

There are many analogs, such as the recent launch of Walmart Health, the Walgreens partnership with Humana specific to Primary Care Services, and the Rite Aid expansion of RediClinic. This model provides additional convenience to patients receiving healthcare services in a convenient location—including expanded hours such as nights and weekends.

Alexandra Brown, communications manager for Walgreens, says the company is focused on creating a modern, differentiated retail offering that makes shopping easier and more convenient for its customers, while also providing greater access to pharmacy and healthcare services to become more of a neighborhood health destination.

"Through this approach, and a 'store-in-store' model, we’re able to give our patients and customers affordable access to a broad range of important healthcare services, such as diagnostic lab testing, hearing, optical, and dental care—all conveniently located in local Walgreens stores," she says.

Moving forward, it will be critical for drugstore chains to keep up with the pace of rapidly changing customer expectations. While it’s hard to speculate what this "experience" may look like 10 to 20 years down the road, Brown notes that technology will be a key driver. That’s why Walgreens is digitalizing and innovating for the future by combining its expansive physical store footprint with the latest technology, as well as partnering with leading technology companies such as Microsoft and Verily.

"With this future focus, we’re working with partners to harness data, analytics,
In order for retail pharmacies to be fully integrated into the value-based care continuum, there must be greater momentum among regulators and technology companies to achieve true interoperability of systems, including giving pharmacists access to patients’ EHRs. “More patient information needs to be automatically shared with pharmacists in a standardized format, using interoperable vocabularies like SNOMED, LOINC, RxNorm, and others that can help these healthcare professionals better understand patient conditions and make crucial medication decisions with greater context,” Bizzaro says. “Too often, retail pharmacists are left out of care transition discussions as patients are discharged from hospitals and into long-term care facilities or back to their primary care physicians.”

Involving pharmacists and speaking the same language through standardized, codified information would strengthen care continuity, prevent avoidable readmissions or adverse health events, and ultimately improve outcomes, which benefits all stakeholders.

Hallan believes the move away from dispensing and the technical aspects of operations will continue and maybe in 10 to 20 years would completely defragment itself from it. “The new responsibilities will focus on the patient care, outcome-oriented care plans, and working closely with the patients to help them accomplish these goals to lower healthcare costs quality of life,” he says. “Artificial intelligence and machine learning would be a key player in this entire prediction as well. As it becomes more integrated within the healthcare system, its impact may be significant. Whatever happens, one thing is for sure, pharmacy is going to become a high-touch health profession.”

What Needs to Be Done? Experts Weigh In

and artificial intelligence to give our customers and patients a unique advantage,” she says, adding that Walgreens is working “to develop more personalized health care experiences across a range of needs, from preventive self-care to chronic disease management.”

Merger Mania

Yacoub says it’s likely there will be more mergers in the future, versus roll up of retail pharmacies, as healthcare needs to be delivered more efficiently and conveniently with an omnichannel strategy. Healthcare in general, he says, is evolving and patients are challenged with the friction and the inconveniences even today. “As an example, you may have to go to one place to get lab work, then to the doctor to get diagnosed, then to the pharmacy to pick up medication,” he says. “This process is likely repetitive if you have a chronic disease. I suspect there will be more consolidation in services to provide a more convenient experience to consumers such as improving the omnichannel experience, expansion of clinical services, and a more efficient local delivery model.”

Hallan says there’s an increased focus right now in lowering the prescription cost, both from a pharmacy’s perspective to increase profit and for the PBMs to lower their costs.

“Naturally this is going to create a system where mergers have to happen in order to grab a larger share of the market so they are able to lower their costs and maintain profitability,” he says. “The market forces are ideal to make these happen.”

Industry-wide, Bizzaro says it’s unlikely that we will see any major activity with mergers in the near term, noting what is more likely to happen is independent local and regional chains will continue to be acquired by major national retailers—which may pose challenges for some communities, since often these acquisitions result in store closings and consolidation.

“If a local pharmacy closes, traveling to another location to access medications may become a challenge for some patients, and some pharmacists may lose their jobs,” he says. “Because pharmacists are central to the communities they serve, it’s important to keep an eye on social determinants of health issues such as transportation challenges that could have an impact on medication adherence when these acquisitions result in store closings.”

Brown notes part of Walgreen’s strategy entails focusing on establishing new partnerships and furthering existing ones with other industry leaders to transform its offering, organization, and infrastructure.

For instance, most recently, Walgreens partnered with brands including Microsoft, FedEx, LabCorp, Birchbox, Kroger, Humana, and Verily to create new healthcare and retail experiences.

Online Worries

The industry has already witnessed how online prescription refills, as well as over-the-counter ordering, have impacted retail pharmacies. Bizzaro notes those services will likely continue to grow in popularity, especially with the increasing popularity of mobile apps that increase access, convenience and adherence.

“Online technologies will have a more meaningful impact in the coming years by providing patients with trusted, objective, and reliable information about their medications, including how and why they need to adhere to their prescribed regimens,” he says. “There is so much misleading and false drug information on the internet, and patients are looking for reliable and authoritative data, especially if they are directed to it by their pharmacist or other trusted healthcare professional.”

For that reason, an increasing number of pharmacies are accessing authoritative sources to provide complete drug and dosing information to their patients that they can access online.

“Ideally, this information should be
provided at a fifth- to eighth-grade reading level in multiple languages for maximum comprehension, and to meet patients where they are when it comes to health literacy,” Bizzaro says. “Online technologies also enable video demonstrations of proper medication administration for more complex delivery methods such as inhalers or injectables.”

Access to this type of information online also allows pharmacies to reduce their complete reliance on paper-based educational materials, which patients may forget about or throw away.

Having customized patient education content available on-demand through desktops or apps, where it can also be integrated with a patient’s digital calendar, can encourage adherence and ensure that patients take their medications correctly.

Yacoub thinks there will continue to be an increase in online consumers of healthcare as well as more telehealth services being utilized, especially in rural areas of the country and where there is a lack of clinicians in a particular segment such as behavioral health.

“The demand for online services will continue to increase as the younger generation accesses healthcare services like they consume products and services today,” he says. “Retailers will need to continue to increase their presence online and allow patients to be consumers of healthcare online, but there will always be a need for a combined brick and mortar strategy along with a mobile presence.”

Hallan notes that with the acquisition of PillPack by Amazon, pharmacy received a lot of focus and a lot of new players. Many are focusing on key areas such as erectile dysfunction and then slowly expanding to other areas.

“But a lot of them are the same basic thing—lowering the cost of prescription medications while satisfying the customer expectations of fast and convenient shipping and good customer service,” he says. “I think a company that is planning to enter this area needs to know that while price is important, they need to have a plan on what they have to offer once prices become a non-competit ing factor. The customer service differential will always be there but it would be nice to see how they introduce the pharmaceutical expertise in this mix.”

**Role of the Pharmacists**

In the years ahead, pharmacists will need to continue to evolve in providing their clinical expertise in treating patients and being an integral part of the healthcare team.

“As we are seeing technology advance, and a continued shift to e-Prescribing, the dispensing of medications will be less of a focus for pharmacists,” Yacoub says. “Pharmacists will be providing more medication therapy management (MTM) services and consultations to patients on how to improve their care. As we see more integration of healthcare services, we will see a multi-disciplinary model of a healthcare team to deliver care to patients.”

In that model, pharmacists will continue to provide their guidance and expertise in medications to deliver the best possible outcomes to patients.

As healthcare moves toward value-based care and retail pharmacies evolve their role within the ecosystem, it’s projected that more pharmacists will be stepping out from behind the counter—with a focus on delivering some components of primary care as non-physician providers.

Bizzaro says services that pharmacists provide will increasingly include the administration of immunizations—already commonplace in most pharmacies—as well as chronic care management, which may include services such as helping patients with diabetes interpret their HbA1c readings and giving them advice on lifestyle changes that will support better outcomes in combination with their drug therapy.

“With the personal touch that pharmacists have always had with patients—one of the key benefits of having so many pharmacists in neighborhoods—they will also help patients overcome social determinants of health challenges and will help connect them to social care agencies to address issues such as transportation, food insecurity and social isolation,” he says. “The pharmacist is ideally suited to address these concerns, considering they often interact with patients more frequently than their physicians do.”

What must also evolve, he notes, is a payment mechanism that recognizes the time and expertise pharmacists will be spending on these important care services that go beyond medication dispensing.

“Payers already recognize the important ROI pharmacists can bring, especially in a value-based care environment, to improve outcomes, lower healthcare costs, and improve patient satisfaction,” Bizzaro says.

Talha Sattar, founder of NimbleRx, a prescription delivery service, sees fewer brick-and-mortar pharmacies in the years ahead, with a huge uptick in delivery.

“I think the pharmacist is an underutilized resource today and the utilization will increase more towards drug management and counseling, which you are already seeing in CVS, with building basically a physician’s office in-store,” he says. “It will be much more about managing the health and relationships, and less about filling the prescriptions.”

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**It will be much more about managing the health and relationships, and less about filling the prescriptions.**

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An estimated 47 million adults living in the United States were age 65 and older in 2017, according to research conducted by SeniorLiving.org. The Population Reference Bureau projects that number will more than double to nearly 100 million individuals by 2060. The combination of the expanding elderly population taken together with an average lifespan of 78.6 years for men and slightly more than 81 years for women highlights the need to improve medication-related outcomes in this population. Facilitating how senior citizens manage their medications by engaging technology, support systems, healthcare providers, and other resources are good places to start.

Geriatric patients face many challenges in managing their medications, which is sometimes very complex due to their medical conditions,” says Jin Seon Kim-Paglingayen, MD, an assistant clinical professor of health sciences in the department of family medicine at University of Southern California Riverside.

Complex Challenges
Experts have varying opinions when it comes to pinpointing the biggest hurdle in helping senior citizens manage their medications. However, polypharmacy appears to be a recurring theme—especially as prescription medication use continues to rise.

Prescription medication use among the geriatric population has more than doubled over the last 20 years. A 2015 study published in The Journals of Gerontology that evaluated data from 13,869 adults ages 65 and older in the National Health & Nutrition Examination Survey (1988-2010) found that older patients took a median number of two medications in 1988; by 2010, that number had doubled to four medications with 40% of the patients taking 5 or more medications.

Jessica Triboletti, PharmD, assistant professor of pharmacy practice at Butler University College and ambulatory care clinical pharmacy specialist at Eskenazi Health in Indianapolis, notes the medication management is not exclusive to prescription medications. Comprehensive medication management should also include over-the-counter medications, dietary supplements, and herbal products.

According to Jacqueline Hagarty, PharmD, BCGP, an ambulatory clinical pharmacy specialist at Banner Pharmacy Services in Phoenix, taking multiple medications can have serious consequences. A high pill burden contributes to low adherence rates, but poor understanding or lack of education on the medications also hinders patient adherence.

“I find that many of my patients do not know the indications for all of their medications, so they do not understand the importance of taking them every day,” she observes.

Hagarty also finds that some patients may feel overwhelmed by managing their medications. Many patients are also worried about side effects and interactions, but they do not always express these concerns to their health care providers.

Polypharmacy, the need for increased collaboration among healthcare professionals, and the importance of education are among the key challenges. However, technology and support systems can play a significant role in helping senior citizens manage their medications effectively.
professionals, and improving communication are not the only challenges in the world of medication management. Kim-Paglingayen points out that particular circumstances such as language barriers, lack of transportation, and physical or mental disabilities require unique solutions.

Older patients who are disabled or without access to transportation may also lack social support, such as having a family or friend to pick up their medications and refill requests promptly. Those who have mental or physical disabilities may not be able to adhere to high-maintenance medication regimens, such as increased fatty tissue, decreased bodily fluid, and overall weight-loss can alter the volume of distribution, warranting the need to adjust medication doses.

Special populations, such as homebound patients—both young and old—may face a greater risk for adverse drug events associated with complex medication regimens. Frequently, these individuals live with multiple chronic conditions and take multiple medications to treat each condition, increasing the risk for complications and costly medication regimens and poor medication adherence.

**Best Practices For Managing Medications in Seniors**

- Use larger-font prescription vials and medication guides for patients with decreased vision
- Educate patients and their caregivers on medication indications, side effects, and administration tips
- Consider mail order for patients who lack transportation
- Work with other healthcare providers to coordinate daily home health visits for patients who have physical and mental disabilities. Family or friends may help manage medications.
- Always involve a medical translator for patient encounters and arrange insurance-provided transportation services if a family member or friend is unable to help

Collaboration Is Key

Melissa Morgan-Gouveia, MD, a geriatrician with Christiana Care Health System’s Department of Medicine who specializes in home-based primary care with Christiana Care’s Visiting Nurse Association says that open lines of communication between all healthcare providers involved—including caregivers—is imperative to improving the patient experience and outcomes.

She cites the increased potential for OTC drug interactions as an example. Many OTC medications are combination products with multiple different medications, which can increase the risk for unintentional overdoses of medications such as acetaminophen.

Triboletti agrees. “Communication is key, and pharmacists are in a unique position to provide accessible and consistent medication support,” she says. “Conversation with patients and caregivers are important to help identify concerns, barriers, and underlying causes for nonadherence.”

Hagarty emphasizes the importance of reviewing medications with the patient can help increase their understanding. Doing so could potentially improve patient adherence while facilitating the pharmacist’s ability to identify opportunities to optimize their medication therapy. Examples of this include discontinuing unnecessary medication and duplicate therapy, identifying new drug interactions, and finding solutions to barriers to access such as transportation or cost. Sometimes, healthcare providers must adjust the solutions to suit the patient’s environment.

“Home health providers should identify the over-the-counter medications a patient is taking when conducting a medication review, including asking about medication bottles seen during the visit that the patient may forget to mention such as the over-the-counter sleep medication on their nightstand,” Morgan-Gouveia says. “They alert the patient’s primary care provider [and the pharmacist] about any over-the-counter medication a patient is taking that is not on their medication list.”

**Technology: Help or Harm?**

Healthcare is no stranger to new technologies designed to engage users—in this case, patients. While some stereotypes regarding senior citizen’s affinity for and ability to use technology persist, internet use among senior citizens is on the uptick. The number of senior citizens who own smartphones more than doubled from 23% in 2013 to 47% in 2016.
to roughly 50% in 2017, depending on the age range, according to a report from Pew Research. As many as 59% of senior citizens aged 65-69 years reportedly owned smartphones and 49% of 70- to 74-year-olds owned smartphones in 2017. While lower, those numbers still remain relatively high for the 75+ group: 31% of 75-79-year-olds owned a smartphone and 17% of seniors aged 80 years and older having owned smartphones in 2017.

Similarly, internet use among this population has soared. Only 14% of senior citizens used the internet in 2000, but that number soared to at least 67% by 2017. Furthermore, the usage statistics pattern those of geriatric smartphone owners, with the 65-69-year-old-age groups being the most robust internet user, followed by those in the 70-74-age group; usage drops off after that point. However, recruiting technology to solve medication management problems may require insight that transcends the gadget and the application.

“These hurdles are not just technological—they’re life hurdles,” says Maureen Williams, marketing solutions manager, consumer and physician experience for Meditech. For Williams, a healthcare technology industry professional who also cares for her aging mother, the reality hits home. “Any technology that gets deployed needs to be easy-to-incorporate into that patient’s daily life.”

For patients who might benefit from technological interventions, Williams recommends that healthcare professionals work with patients to ensure the technology is something the patient finds easy-to-use, easy-to-understand, and easy-to-incorporate into their daily life. It is also crucial that the patient finds the technology both meaningful and useful enough to continue using it.

“If an alarm is going off every 2 minutes, the patient is just going to cut it off,” Williams cautions, referencing a phenomenon known as alert fatigue. In addition to addressing the patient’s ability to manage medications, Williams says that providers frequently encounter challenges helping patients address costs. Meditech has a patient portal that facilitates real-time communication between all interested parties. Both printable and downloadable, patients can access the list to share with healthcare providers and family members. However, not all platforms offer the same features. Williams’ mother must phone in refill requests for certain prescriptions, and subsequently, call the pharmacy to ensure the script went through. For patients who have a portal to refill prescriptions (as well as their care providers that leverage real-time benefit check and Electronic Prior Authorization), the refill process is much more efficient and smoother.

Kim-Paglingayen says that, while technology offers an opportunity to help seniors better manage their medications, it may not be a suitable choice for every member of the golden-years community.

“There are tech-savvy elders who have a list of their medications and dosages in their smartphone ‘note’ section,” says Kim-Paglingayen. “But most elders I know would rather have a handwritten list in their wallet or note pad that they bring along with them to the hospital or the clinic.”

In cases where a patient’s medication list is unclear, Kim-Paglingayen’s staff usually places a call to the patient’s family, pharmacy, or PCP for collateral information. However, there are times when phones come in handy, as she says some patients come in with pictures that they took of their pill bottle.

Ultimately, using technology depends on the patient’s reception, comfort level, and access to specific resources.

“Depending on the person, apps and online resources can be a great tool to keep patients engaged in their own health care,” says Triboletti.

Any technology that gets deployed needs to be easy-to-incorporate into that patient’s daily life.

MAUREEN WILLIAMS

These apps may have slightly different features, but the key is to find an app that fits the needs of your patient population.

JACQUELINE HAGARTY, PHARMD, BCGP, AMBULATORY CLINICAL PHARMACY SPECIALIST AT BANNER

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**Smartphone Apps for Medication Tracking and Adherence**

- **MyMeds**
- **Mango Health**
- **Medisafe Medication Management**
- **Pill Reminder-All in One**

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**Technology** / Small Doses
Chains Implementing Tech to Help Track Opioid Misuse

Rite Aid and Walmart utilize new platform to manage patients.

By Christine Blank

Rite Aid is the latest pharmacy chain to utilize Appriss Health’s NarxCare platform to more efficiently identify and manage patients at risk for controlled substance abuse and misuse.

NarxCare equips pharmacists with advanced analytics, tools, technology, and invaluable insights that are presented and accessed directly within Rite Aid’s pharmacy management system, according to a statement. NarxCare also provides machine learning and artificial intelligence-based patient risk analysis in a visually interactive format to support pharmacists’ dispensing decisions and state law compliance.

Rite Aid has already implemented NarxCare, which analyzes and presents information from state PDMPs, in 12 states, the retailer says in a statement.

Walmart also began using NarxCare last year, NPR reports, soon after it announced restrictions on filling opioid prescriptions. In addition, NarxCare reports are in use at more than 35,000 pharmacy locations across the US.

Appriss Health also has NarxCare agreements in place with 20 states and with the Boards of Pharmacy in the 43 states as their prescription drug monitoring program (PDMP) technology provider via its AWARxE platform.

"NarxCare is another efficient and effective solution to help our pharmacists make responsible dispensing decisions, while mitigating possible controlled substance misuse or abuse,” says Jocelyn Konrad, executive vice president, Pharmacy and Retail Operations at Rite Aid. “The integration of NarxCare and PDMP information into our pharmacist’s workflow empowers them to focus more on building relationships with patients and improving health and wellness across the communities they serve.”

While pharmacists have access to PDMP information, it can be difficult to navigate and analyze, Rite Aid says. NarxCare helps pharmacists “identify potential problems up front, in real-time, for every customer, every time they consider a controlled substance dispensation,” Rite Aid says.

"Pharmacists also have the support they need to better engage with their customers and determine the best course of action for them, while fulfilling their corresponding responsibility to ensure all controlled substances are filled for a legitimate medical purpose pursuant to a valid prescription within the scope of the prescriber’s practice,” Rite Aid adds.

"NarxCare encourages pharmacies to utilize their PDMP, even when not required by legislation, and enables pharmacists to perform clinical evaluations that may otherwise be impractical to perform. In some instances, David Griffin, vice president of marketing and communications for Appriss Health, tells Drug Topics.

In July, Appriss Health also partnered with the Texas State Board of Pharmacy (TSBP) to integrate PMP information into the electronic health record systems of all prescribers and pharmacy management systems for all pharmacies in Texas with its PMP Gateway solution. In addition, Appriss said TSBP it will make available the NarxCare platform, “designed to deliver additional clinical content to help identify patients at risk of an opioid overdose.”

Prior to this integration initiative, prescribers had to log in to separate systems to query patient information, “which took important time away from patient care,” Appriss Health says.
According to the CDC’s 2017 National Diabetes Statistics Report, 30.3 million individuals in the U.S. have diabetes, and 7.2 million people living with the disease are undiagnosed. This showcases the need for diabetes management programs and continuous patient education and monitoring.

According to a study published in Diabetes Spectrum, pharmacist-led interventions in a rural primary care clinic were associated with the majority of patients experiencing an A1C reduction of at least 1%, which has the potential to reduce the risk of complications and decrease diabetes associated costs. Pharmacists’ have a unique skillset as drug experts and play an integral role as part of the healthcare team—not only improving patient outcomes, but also expanding business opportunities.

Exploring Business Opportunities
Pharmacists can play an integral role in establishing diabetes management services in the community and health system settings. According to a study published in American Health & Drug Benefits, 96% of the providers approved of the collaborative practice agreement for pharmacist-led diabetes services.

Additionally, pharmacists’ satisfaction with the new protocol was high. The majority (89%) of patients were referred by providers who received a personalized provider report card, which identified patients who met the criteria (A1C > 9%) for pharmacist referral under the protocol. Pharmacists can use these personalized provider report cards to establish a relationship with physicians and expand diabetes management services. This may lead to expanded patient care opportunities and enhanced communication with prescribers.

The CMS offers reimbursement for Medicare beneficiaries for diabetes self-management training (DSMT), provided that individuals have been recently diagnosed with diabetes or are at risk for complications. Pharmacists first need accreditation to provide DSMT. The National Community Pharmacists Association (NCPA) has teamed up with the American Association of Diabetes Educators to provide an educational program known as “Diabetes Accreditation Standards-Practical Applications” (DASPA), which provides the necessary requirements for accreditation to be recognized as a certified program provider. Approved program instructors may include pharmacists, registered nurses, and registered dietitians, which demonstrates the importance of interprofessional patient care programs. The DSMT programs should include education on self-monitoring blood glucose (SMBG), diet and exercise counseling, an insulin treatment plan, and motivation to use skills for diabetes self-management.

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Pharmacists can also participate in the program From Prevention to Pump Training for opportunities and ideas for diabetes services like wellness coaching and insulin pump training. Various programs exist for the certification of pump training and offer reimbursement for different services provided to patients. The CDC’s Rx for the National Diabetes Prevention Program helps pharmacists get involved in prevention by identifying and reaching out to patients at risk for developing type 2 diabetes. This resource provides pharmacy case studies and how pharmacists can play an integral role through raising awareness; screening, testing, and referring; and delivering the program.

Ultimately, managing medications is about building trust and makes a much deeper impact on the patient than dispensing a medication without counseling. Mutha says patients who have diabetes will in turn be grateful for the medication management and counseling points for their health. Even if there is not always a profit, the pharmacist-patient relationship is continually enhanced to promote disease state management, which will in turn advance the business side.

Many deaths seen in the news have resulted from various factors affecting access to insulin, (i.e. cost), and have caused patients to turn to rationing or going without the important drug therapy. Pharmacists can play an important role in addressing these timely issues to ensure patients have access to these life-saving medications. "Personally, I have undertaken such cases and made life changing impacts in many ways by providing education, counseling, and teaching patients the A1C targets, glycemic index, lifestyle modifications, body mass index, symptoms of hypo and hyperglycemia, and guidance to personalize cost effective solutions for diabetes," says Mutha.

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Mutha adds that "the current trend of telehealth care could play a vital role in helping the community with diabetes management." Pharmacists as drug therapy experts can play a vital role in disease state management remotely as technology is continuously expanding. The CPT codes 99453, 99454, and 99457 may be used by pharmacists in the future for reimbursements through remote patient monitoring or telehealth.

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Diabetes Care as a Business Opportunity

Diabetes management goes beyond making patients healthier.

By Jennifer Gershman, PharmD, CPh

According to the CDC’s 2017 National Diabetes Statistics Report, 30.3 million individuals in the U.S. have diabetes, and 7.2 million people living with the disease are undiagnosed. This showcases the need for diabetes management programs and continuous patient education and monitoring.

According to a study published in Diabetes Spectrum, pharmacist-led interventions in a rural primary care clinic were associated with the majority of patients experiencing an A1C reduction of at least 1%, which has the potential to reduce the risk of complications and decrease diabetes associated costs. Pharmacists have a unique skillset as drug experts and play an integral role as part of the healthcare team—not only improving patient outcomes, but also expanding business opportunities.

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Health Conditions Influence Insulin Use

Study shows patients in poor health more likely to use insulin.

By Briana Contreras

Patients with type 2 diabetes who were in poor health were more likely to continue taking insulin after age 75 years than their counterparts in better health, according to Kaiser Permanente research published recently in *JAMA Internal Medicine*.

As people with type 2 diabetes age, the risks of insulin use can outweigh its benefits, creating the need for increased provider and patient education, the research says.

"Leading medical specialty organizations recommend reducing diabetes treatment intensity for older patients, particularly when they have multiple, life-limiting health conditions," says Richard W. Grant, MD, MPH, research scientist with the Kaiser Permanente Division of Research in Oakland, California. "But in current practice we found that these sicker patients were less likely to stop taking insulin."

Insulin is a hormone that helps the body regulate sugar in the blood and is a key component of treatment for many patients with type 2 diabetes. Older adults who continue to use insulin are at greater risk of dangerously low blood sugar, or hypoglycemia—this can happen when people take too large a dose of insulin, Grant says.

In the study, *The Use and Discontinuation of Insulin Among Adults Aged 75–79 with Type 2 Diabetes: A Longitudinal Cohort Study*, researchers followed 21,531 Kaiser Permanente members age 75 and older in Northern California who had type 2 diabetes. Nearly one-fifth of the patients used insulin at the beginning of the study, and among them, about one-third discontinued its use over the next four years.

The researchers grouped patients into three categories of health (poor, intermediate, and good) using information in the medical record about the number of chronic conditions, functional status, and indicators of end-stage disease.

Insulin use was highest among older adults in poor health, (29% of them used insulin) with a serious end-stage disease, or intermediate health (28% used insulin) with at least two other health conditions.

In contrast, just 11% of those in good health used insulin, the research says.

The findings were similar even when researchers took into account how well patients were controlling their blood sugar.

"Revisiting the need for potentially harmful medications such as insulin when the risks outweigh the benefits can help to reduce adverse events like hypoglycemia and improve the quality of care in older patients," Grant says.

Pharmacists, primary care physicians, geriatric specialists, and others are working together to address "polypharmacy"—when older patients take five or more medications for multiple conditions—and to "de-prescribe" medications by reducing doses or taking people off them, he adds.

A recent Kaiser Permanente study showed discontinuing diabetes medications reduced the risk of hypoglycemia in elderly patients with well-controlled type 2 diabetes.

"We’re raising awareness about the need for physicians and patients to have conversations and reconsider medications that may lose benefit or add more risk as patients age," says Misha S. Draves, MD, medical director of pharmacy for The Permanente Medical Group at Kaiser Permanente in Northern California.
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As the vaping crisis continues, pharmacists are being called upon in growing numbers to help counsel patients about recent deaths and how individuals can protect themselves. Research into the pathology of vaping-associated lung injury is in its infancy. However, a study published in *The New England Journal of Medicine* has found that lung injuries from vaping are most likely caused by direct toxicity or tissue damage from noxious chemical fumes.

Researchers at the Mayo Clinic reviewed lung biopsies from 17 patients, all of whom had vaped and were suspected to have vaping-associated lung injury. The study found no evidence of tissue injury caused by accumulation of lipids, which had been suspected as a possible cause. In recent months, CDC has received almost 2,000 lung injury reports associated with vaping and dozens of deaths.

Thomas Ferkol, MD, pediatric pulmonologist at Washington University School of Medicine in St. Louis, Missouri, has thoroughly investigated the threat of electronic cigarettes in children and adolescents and helped develop a position statement. “We are not certain what anyone is inhaling when they use electronic cigarettes. Their vapors can contain ultrafine particulates, volatile organic compounds, and heavy metals, such as nickel, tin, and lead. Other reports have shown that these products can be contaminated with bacterial and fungal toxins,” Ferkol says.

He says electronic cigarettes were designed to deliver nicotine, and the nicotine content in vapors can be as high and often higher than combustible cigarettes. Other chemicals he says are common in these products are propylene glycol and glycerin—solvents for nicotine and flavorings.

“A growing literature has shown that e-cigarette exposure causes acute inflammation, injury, oxidative stress, and other toxicities in the lung,” says Ferkol.

Vaping among American middle school and high school students is also on the rise. Ferkol cites preliminary data reported by the National Youth Tobacco Survey which shows continued increase among high school students: 30-day nicotine vaping rates are at 28% this year, compared to 21% last year and 12% in 2017. “The warning signs for chronic [e-cigarette] use are the same as those seen in nicotine addiction. In addition, bronchitic symptoms have been associated with e-cigarette use in adolescents, manifested as a persistent, daily productive or ‘wet’ cough for several weeks,” says Ferkol.

**Changing Laws**

Recent deaths and illnesses linked to vaping prompted New York in September to become the first state to ban flavored e-cigarettes; since then other states have imposed temporary bans on the sale of e-cigarettes or the flavored liquids used in them until more is known. The CDC recommends that e-cigarettes should not be used by children, young adults, pregnant women, or adults who don’t already use tobacco products.

Many young and pregnant women are using e-cigarettes as a safer alternative to smoking, but little is known about the effects on fertility and pregnancy outcomes. In a mouse model, researchers at the University of North Carolina at Chapel Hill found that e-cigarette usage prior to conception significantly delayed implantation of a fertilized embryo to the uterus. They also discovered that e-cigarette usage throughout pregnancy changed the long-term health and metabolism of female offspring.

Sean Callahan, MD, assistant professor in pulmonary and critical care medicine, University of Utah, says pharmacists have to be concise and direct when counseling individuals. He said the message needs to be clear that the potential lung damage and other sequelae is still unknown.
As more states legalize marijuana for medical and/or recreational use, people who have been diagnosed with chronic obstructive pulmonary disease (COPD) may wonder if marijuana use is safe or perhaps less harmful to their lung health than smoking tobacco.

While it is estimated that 85% to 90% of COPD cases are caused by smoking cigarettes, studies report conflicting outcomes regarding marijuana use. In the meantime, The American Lung Association, the American Thoracic Society, and the National Institute on Drug Abuse caution the public, particularly those with respiratory problems, against smoking marijuana.

Although the risks of respiratory problems associated with marijuana may be lower than those associated with smoking tobacco, studies to date have shown that it is not risk free.

According to The American Lung Association, the danger has much to do with how marijuana is generally used, as it’s often smoked using pipes, bongs or paper wrapped joints. Inhaling smoke is harmful to lung health, whether it is smoke from burning wood, tobacco, or marijuana. Toxins, irritants, and carcinogens are released when these materials combust, all of which can harm the lungs of those who smoke and those who inhale secondhand smoke. While marijuana smokers may inhale less smoke per day than cigarette smokers, they may inhale deeper and hold the smoke in longer, greatly increasing the amount of tar that remains in the lungs.

According to the American Thoracic Society, regular marijuana smoking is likely to cause lung damage, which could potentially increase a person’s risk of developing COPD. A 2013 study showed that regularly smoking marijuana injures the cell linings of the lungs’ airways, which interferes with the ability to filter out germs and dust.

Research has not yet concluded whether marijuana use affects the immune system, potentially depressing the body’s ability to fight disease. Marijuana use can make an already weakened immune system more vulnerable to respiratory problems associated with aspergillus, a fungus that grows on marijuana and which may be inhaled when marijuana is smoked.

According to the National Institute of Drug Abuse, those who smoke marijuana regularly report more symptoms of chronic bronchitis than those who do not smoke. In younger smokers, marijuana smoking has also been associated with the development of large air sacs, called bullae. Ruptured bullae can leak air and potentially lead to a collapsed lung.

Pharmacists may want to urge patients who are considering marijuana use to discuss that use, and potential delivery systems, with their doctor, especially if they have COPD and/or other breathing problems.
Drug store chains and health officials are urging individuals to get the influenza vaccine as soon as possible since the flu season has hit earlier this year and has already caused the death of one 4-year-old.

"As does the CDC, we recommend everyone 6 months of age and older get their annual flu vaccine by the end of October. It takes about two weeks to develop the antibodies to fight the flu after getting your flu shot, so it’s important to get it before the flu spreads in your community to best protect yourself and loved ones," Alex Novielli, PharmD, manager of immunizations in Pharmacy and Retail Operations for Walgreens tells Drug Topics.

"While the severity of the flu season is unpredictable, it’s important to not wait until flu season is in full swing or there is an outbreak in your area to get the vaccine," adds Papatya Tankut, vice president of pharmacy affairs at CVS Health.

A 4-year-old boy died in California from the flu in early September, according to the Riverside University Health System in Riverside, CA. While the child had underlying health issues, he tested positive for influenza, health officials said in a statement.

"We should never forget that the flu still kills. I always recommend people get their flu shots every year, but a death so early in the flu season suggests this year may be worse than usual," said Cameron Kaiser, MD, public health officer for Riverside County, in the statement.

Meanwhile, Maryland Secretary of Health Robert Neall urged individuals to get vaccinated after the Maryland Department of Health reported 11 laboratory-confirmed influenza cases since September 1. "Get your flu shot now. Don’t put it off," Neall said in a press release.

A number of people headed to Walgreens to get the flu shot as soon as it was available and the retailer has "continued to see people coming in to get the vaccine," Novielli says.

The flu shots are free to patients with most insurances, Novielli says. Plus, the drug store chain is offering customers who get a flu vaccine before November 30th $5 off an eligible purchase of $20 that day in certain stores.

"We are also leveraging marketing tactics, including broadcast, radio, out-of-home, email, paid social, and more to encourage everyone to be a Flu Fighter and fight for the ones they love by protecting themselves with a flu vaccine," Novielli says.

Similarly, CVS Pharmacy and MinuteClinic are rewarding flu shot recipients with a coupon for $5 off a $25 purchase in most states. For CVS Pharmacy locations in Target, a $5 Target coupon will be rewarded.

"CVS Pharmacy and MinuteClinic Target locations also all have prominent signage to ensure we’re getting the word out that customers should get their flu shot, and we are also using several media channels to drive awareness," Tankut says.
Physicians’ attitudes toward herpes zoster (HZ) and vaccination to prevent it appear to be more favorable after a decade of availability of a vaccine, according to a newly published study.

Researchers at the CDC and the University of Colorado Denver’s Vaccine Policy Collaborative Initiative analyzed data from three surveys administered to primary care physicians in 2005, 2008, and 2016. Over those years, Zostavax was licensed by the FDA in 2006, and Shingrix was approved by the FDA and recommended by the CDC Advisory Committee on Immunization Practices in 2017 as the preferred vaccine for people 50 and older.

Researchers also discovered that while a similar percentage of surveyed physicians reported stocking the vaccine in their offices in 2008 and 2016, a significantly greater number of them indicated in 2016 that they had stopped administering the vaccine as a result of cost and reimbursement issues. Physicians were also more likely to refer patients to pharmacies to purchase and receive the vaccine in 2016 (77%) than in 2008 (33%).

Mitchel C. Rothholz, RPh, MBA, and chief strategy officer at the American Pharmacists Association (APhA) says many community pharmacists are already benefiting from physicians’ changing practices.

“About 60 to 70% of community independent pharmacies are doing immunizations, and all of the chains are doing immunizations,” he notes. “It’s critical that community pharmacies provide access for the public for these important vaccines that prevent disease.”

Regarding the payment model, Rothholz adds that pharmacists also have an advantage, particularly when it comes to Medicare patients. “The shingles vaccine is paid under Part D, so that’s a drug benefit payment versus a medical payment. Of course, pharmacies are involved in that, but it’s a lot more work for physicians that they don’t want to do,” he explains.

APhA recognizes the importance of vaccinations across the patient’s lifespan, Rothholz continues, noting that the organization has spent the last 25 years preparing community pharmacists for and supporting them in their role as valued healthcare providers and administrators of vaccinations.

“We coined the term ‘immunization neighborhood’, which is built around the three Cs: collaboration, coordination, and communication,” he says.

“Pharmacists must be knowledgeable across all vaccines so that they’re a knowledgeable resource for public health departments and others in the community,” he concludes. "When there’s misinformation out there about vaccines, they can help educate their patients and guide them through their needs. They can either administer it, offer it, or refer the patient to a practitioner who can administer it.”

of the physicians surveyed in 2016 strongly agreed that HZ and complications like postherpetic neuralgia cause a significant burden of disease for older patients. Just 35% of those surveyed in 2005 held the same view.

of the 2016 respondents strongly agreed that the burden of HZ and its complications in patients 60 to 79 years old was sufficient to make vaccination important, compared to just 34% in 2005.

of those surveyed in 2016 strongly recommended the HZ vaccine to eligible patients 60 or older, compared to 41% in 2008.

Physicians who participated in the studies also identified patient cost as the biggest barrier to vaccination. Their concerns over safety and efficacy diminished over the course of the three surveys.
FDA and DEA issued joint warning letters to several websites for illegally marketing unapproved and misbranded versions of opioids such as tramadol. The warning letters issued to Meds4U, Divyata, Euphoria Healthcare Pvt Ltd, and JCM Dropship, which operate a total of 10 web sites, say that they must immediately stop illegally selling the opioids, FDA and DEA said in a statement.

The agencies say the illegal sale of these opioids is particularly concerning because tramadol carries a boxed warning for significant risk of serious or even life-threatening side effects.

“As the FDA works to forcefully tackle the opioid crisis on all fronts, we cannot allow rogue online pharmacies to continue to fuel the crisis by illegally offering opioids for sale and circumventing the important safeguards that have been put in place for opioids to help protect the public health,” said acting FDA Commissioner Ned Sharpless, MD. “Today’s effort is also noteworthy because while the FDA partners regularly with the DEA, this is the first time we have issued joint warning letters with them. This action further strengthens the warning to the operators of these websites. We remain committed to using all available regulatory and enforcement tools to stop the illicit flow of opioids online.”

The FDA remains concerned that the easy availability of opioids online further fuels the crisis, the agency says. The networks also violated the Controlled Substances Act (CSA) by failing to register their online pharmacies with the DEA, despite knowingly or intentionally advertising the sale of controlled substances, including opioids. The FDA issued a similar series of warning letters earlier this year and in 2018.

In addition, the FDA hosted internet stakeholders and thought leaders, government entities, academic researchers, and advocacy groups at its second Online Opioid Summit to discuss ways to collaboratively take stronger action in combatting the opioid crisis by reducing the illicit availability of opioids online.

“The FDA remains committed to addressing the national crisis of opioid addiction on all fronts, with a significant focus on decreasing exposure to opioids and preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain treatment therapies and opioids more resistant to abuse and misuse; and taking action against those who contribute to the illegal importation and sale of opioids,” the agency says.

The FDA will continue to evaluate how opioids currently on the market are used, in both medical and illicit settings, and “take regulatory action where needed.”

NIH Awards $945 Million for Opioids Research

Among the research grants and contracts awarded, a total of $945 million from the National Institutes of Health (NIH) were directed toward research on novel medication options to combat opioid use disorder and overdoses.

The grants, contracts and cooperative agreements were awarded for fiscal year 2019 across 41 states through the Helping to End Addiction Long-term Initiative (NIH HEAL Initiative). “The trans-NIH research effort aims to improve treatments for chronic pain, curb the rates of opioid use disorder (OUD) and overdose, and achieve long-term recovery from opioid addiction,” said NIH in a statement.

An estimated 50 million U.S. adults suffered from chronic pain and in 2018, an estimated 10.3 million people 12 years and older in the United States misused opioids, including heroin, NIH said.

The “historic investment” by NIH was made possible by funding secured from Congress by President Trump, said HHS Secretary Alex Azar.

“We need to ensure that people with chronic pain have effective treatment options that don’t expose them to the risk of opioids,” says Rebecca G. Baker, PhD, director of the NIH HEAL Initiative. “Preventing opioid misuse and addiction through enhanced pain management and improving treatments for OUD and addiction are both critical parts of our trans-NIH response to the opioid crisis.”
Migraine: What to Know

By Karen Berger, PharmD

Migraine is a very common neurological disease—as the third most prevalent illness worldwide, it affects 39 million women and children in the US, according to the Migraine Research Foundation. Despite its prevalence, migraine often goes undiagnosed and undertreated.

Every year in the US, $36 billion is spent on migraine-associated healthcare and lost productivity costs, and 157 million days of work are missed due to migraine. More than 4 million adults suffer from 15 or more migraine days monthly, known as chronic daily migraine. Medication overuse often contributes to chronic migraine. Chronic migraine is also associated with depression, anxiety, and sleep disturbance.

According to The American Headache Society, preventive treatment for migraine is an important part of the treatment plan. Drugs with established efficacy include anti-epileptic drugs (divalproex sodium, topiramate), beta blockers (metoprolol, propranolol), and BOTOX.

Drugs categorized as probably effective include the antidepressants venlafaxine and amitriptyline, and beta blockers atenolol or nadolol. Several other drugs are categorized as possibly effective, including carbamazepine, lisinopril, and clonidine, among others.

Currently, four injectable drugs are available for prevention, including BOTOX and monoclonal antibodies. BOTOX (onabotulinumtoxinA) is approved for chronic migraine with a recommended total dose of 155 units.

Another migraine drug, lasmiditan (Reyvow, Eli Lilly), was approved last month. Lasmiditan tablets were approved for acute (active/short-term) treatment of migraine with or without aura in adults. The most common side effects are dizziness, fatigue, paresthesia, and sedation. The drug may cause driving impairment; patients are advised not to drive within eight hours of taking the medication.

Monoclonal antibodies are approved for episodic and chronic migraine and may be promising in patients who have failed prior preventive treatments; three are currently available with another, epitinezumab, in the pipeline. All three are administered subcutaneously.

**Emgality** *(galcanezumab-gnlm)*
240 mg loading dose, followed by monthly doses of 120 mg.

**Aimovig** *(erenumab-aooe)*
available in 2 doses (70 mg and 140 mg, either can be used as a starting dose), given once monthly.

**Ajovy** *(fremanezumab-vfrm)*
dosed as 225 mg monthly or 675 mg every 3 months.

An acute migraine should be treated immediately. For a mild/moderate attack, NSAIDs, acetaminophen, or combination drugs with caffeine (aspirin/acetaminophen/caffeine) can be used.

For a moderate/severe attack, or if the above treatment does not provide relief, triptans or dihydroergotamine are recommended.

The American Academy of Neurology does not recommend opioids or butalbital in the treatment of migraine, except as a last resort, as routine use of these medications often causes more frequent and severe headaches.

Patients regularly using medications for acute headache should be evaluated to ensure they are receiving preventive treatment to help avoid development of medication overuse (rebound) headaches.

Patients who prefer nondrug therapies or have failed to respond to or cannot tolerate medications may be candidates for neuromodulation. Neuromodulation, which can be used as an acute or preventive treatment, uses an electric current or magnetic field to stimulate the nervous system. FDA-approved devices include Cefaly, Spring TMS, and gammaCore.

As accessible healthcare professionals, pharmacists can be a valuable resource to patients who suffer from migraine. In addition to counseling patients on medications, pharmacists can help patients with nonpharmaceutical advice.
California Governor Gavin Newsom signed into law last month new legislation that allows pharmacists in the state to initiate and dispense HIV medication without a prescription.

The law, SB-159, was amended to say that “a pharmacist may initiate and furnish HIV preexposure prophylaxis” and “a pharmacist may initiate and furnish HIV postexposure prophylaxis.” Previously, only pharmacists in specific collaborative practice agreements were able to dispense the drugs independently.

In order to dispense either preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP), pharmacists will need to complete a board-approved training program, according to the law.

According to the non-profit Equality California, pharmacists will be able to dispense at least a 30-day supply (up to a 60-day supply) of PrEP and a complete course of PEP, making California the first state in the country to allow pharmacists that authority.

The law also prevents insurance companies from requiring step therapy or prior authorization and will take effect starting January 1.

Advocates for the law say it is a step in the right direction to remove stigmas and increase access to a potentially life-saving medication. “The HIV epidemic is still a pressing issue today—especially for LGBTQ people of color and folks in rural communities. But with Governor Newsom’s signature, SB 159 is a giant step forward in getting to zero transmissions, zero deaths, and zero stigma,” said Rick Zbu, executive director of Equality California, in a statement.

The California Health Benefits Review Program (CHBRP), which provided analysis for the bill, found that overall, rates of increased access to PrEP and PEP would be relatively modest—at least at the beginning. The organization found that PrEP access would increase post mandate by 588 enrollees (from 29,395 to 29,982) in commercial and CalPERS plans and by 180 enrollees (from 9,000 to 9,180) in Medi-Cal. Access to PEP would increase by 121 enrollees (from 6,055 to 6,176) in commercial and CalPERS plans and by an unknown number in Medi-Cal.

However, while initial access gains will likely be slim (an estimated 25 fewer HIV cases will result in the first year), CHBRP says utilization will increase over time as more pharmacists complete the training and more patients and healthcare professionals are aware of PrEP and PEP (in a 2015 survey, 34% of primary care doctors and nurses had never heard of PrEP). CHBRP says awareness remains lowest among groups most likely to contract HIV (men who have sex with men, transgender women, blacks, and Hispanics).

Therefore, CHBRP concluded in their report, “In order for independent furnishing of PrEP by pharmacists to increase utilization, patients need to be engaged in HIV prevention and seek PrEP from pharmacists.”

The new law is part of the trend seeing pharmacists gain increased authority, something pharmacy groups have long advocated for.

APhA CEO Thomas E. Menighan, BSPharm, MBA, ScD (Hon.), FAPhA tells Drug Topics, “Pharmacists are uniquely positioned in communities to serve the public where they work and live. The opportunity to provide preventative, public health services is a natural extension of what we’re trained to do. We congratulate Californians on their new law that permits pharmacists to serve an important role in the prevention of HIV AIDS.”
How Pharmacists Can Help Rheumatoid Arthritis Patients

By Joan Vos MacDonald

As with many chronic conditions, rheumatoid arthritis (RA) needs to be managed even when there are no symptoms.

“When providing consultation to patients with RA, pharmacists should remind patients that even though they may feel fine, daily management with medication helps lessen the impact of RA,” says Prem Shah, PharmD and EVP of specialty pharmacy at CVS Health. “In addition, pharmacists should discuss activity and the importance of regular exercise and movement, as well as ensure patients keep up with routine monitoring such as blood tests and x-rays recommended by their physician.”

RA medications include NSAIDS, corticosteroids, disease-modifying antirheumatic drugs (DMARDs), and biologic agents.

“The medication regimens are fairly complex and require very close monitoring for safety,” says Jessica Farrell, PharmD, associate professor of pharmacy at Albany College of Pharmacy and Health Sciences. “It is important that patients are being treated by a rheumatologist or at least co-managed by their doctor and a rheumatologist.”

Potential side effects of RA medications may require immediate attention.

“Some of the RA drugs have some pretty severe side effects, so that’s always something that the pharmacist can help the patient understand,” says Lisa Schwartz, PharmD and senior director of professional affairs, National Community Pharmacists Association (NCPA).

Dispensing Pain Relief Advice to Patients

“You may need to speak to patients about their pain level and additional medications to manage the pain they’re experiencing, what is appropriate with their other medications, as well as the supplements they can take and their diet,” said Elise Damman, PharmD, executive resident, NCPA.

A non-inflammatory diet, which has been shown to help moderate RA severity, features ample fruits, veggies, and cold water fish, plus whole grains, beans, and lentils.

Data suggests that fish oil and turmeric may help treat inflammatory disease, while RA patients may also benefit from vitamin D supplementation to prevent bone loss.

“Everyone experiences bone loss as they age, but if someone is taking medication, a steroid in particular, to control RA flares, long term use can accelerate that bone loss,” said Schwartz.

Regular physical activity is recommended, but in moderation.

“Weight bearing and strenuous exercise can sometimes cause an exacerbation or flare-up of their disease,” said Farrell. “Water exercises are really good because they are not weight bearing and strengthen muscles around the joints to help stabilize them.” Preventing joint deformity and protecting mobility are important goals in managing RA.

On a practical level, pharmacists can help RA patients cope with limited mobility through gestures as simple as fitting medication with easy open caps. “One of the things we teach patients with inflammatory joint disease is that they really have to listen to their bodies.”

Jessica Farrell, PharmD, Albany College of Pharmacy

“IT is something the patient has to request, but it is helpful to remind folks with RA medications that it might be a good conversation to have,” said Schwartz. “A lot of community pharmacies tend to carry unique medical equipment that will help RA patients as their disease progresses, such as reachers, grab bars, and raised toilet seats. We have things that may make daily living a little easier when you are having a bad day with your RA.”

By Joan Vos MacDonald
Dozens of recent articles have attempted to deconstruct the root causes of the opioid epidemic, asserting that the pharmaceutical supply chain failed to recognize a growing crisis as it was happening. What these stories gloss over is the role of the supply chain’s regulatory body, the DEA. The DEA has myriad regulatory tools and enforcement avenues at its disposal, which were underutilized in the midst of a growing opioid abuse crisis.

**DEA Set Manufacturing Quotas**

There was significant attention to the fact that 76 billion opioid pills were distributed across the nation from 2006 to 2012—given the DEA production quotas, the number shouldn’t have been surprising at all.

Given the DEA production quotas, the number shouldn’t have been surprising at all.

Production quotas are approved annually by the DEA and published on the agency’s website. During this time period, the DEA quotas permitted the manufacture and distribution of nearly 1 trillion milligrams of oxycodone and hydrocodone—with an average strength of just under 7.5 milligrams per pill (as revealed by the ARCOS, Automated Reports and Consolidated Ordering System, data), that’s enough to create 130 billion pills.

Experts have highlighted that the DEA production quotas reduced supply of amphetamines in the 1970s by 90% and then similarly cut Quaalude production by 74% in the 1980s, drastically impacting abuse issues with those substances.

What’s interesting is that during the 2006 to 2012 time period, the actual supply of opioids distributed amounts to just 57% of the DEA-established quotas. Breaking it down even further, my company’s shipments during this period amounts to only 4.8% of DEAs opioid quotas. Yet the DEA raised opioid quotas annually for decades, only beginning to reduce them in 2016.

In fact, Sens. Kennedy (R-La.) and Durbin (D-Ill.) recently issued a public letter, urging the DEA to utilize its increased authority granted by the Opioid Quota Reform Act of 2018 to adjust opioid quotas to reflect diversion, overdose deaths and public health. The letter chided the agency’s previous increases, stating, “between 1993 and 2015, DEA allowed aggregate production quotas for oxycodone to increase 39-fold, hydrocodone to increase 12-fold, hydromorphone to increase 23-fold, and fentanyl to increase 25-fold.”

**Licensing and Registration**

Every pharmacy in the nation that dispenses controlled substances must maintain a DEA registration. In fact, all orders from pharmacies to distributors for opioids are placed in a DEA-managed web portal called Controlled Substance Ordering System (CSOS) to ensure that the pharmacy requesting to purchase opioids has an active registration with the DEA. However, it doesn’t seem to be used for data analytics or to identify potentially bad actors.

That means pharmacies had an active license with the DEA while they were receiving the opioids they ultimately dispensed. State Boards of Pharmacy also license every pharmacy and are yet another safeguard against bad actors, meant to public health and safety.

This begs the question: why have federal registration and state licensing programs if they aren’t used to limit access or to curb bad actors?

**ARCOS Data**

The recently-released DEA ARCOS data show not only the amount of opioids that were distributed in the U.S. but also reveal detailed information on where each and every pill was legally sold in the United States as the crisis was growing. This was information that only the DEA had access to. A Congressional investigation even noted that the DEA didn’t proactively use ARCOS data to identify bad actors.

It defies logic that the law enforcement and regulatory agency responsible for policing controlled substances failed to do just that. As the organization that determines the quantity of drugs produced—with full access to a comprehensive database of where every pill was sold and dispensed, as well as its own system to register every entity that plays a role in the supply chain of controlled prescription medication—DEA had the responsibility to address the crisis of opioid abuse and misuse as it took hold.

Perhaps even more confounding is that the former head of the DEA Office of Diversion Control not only didn’t use these tools effectively, but instead joined private trial attorneys as a consultant to support their contingency-fee fueled efforts to litigate the supply chain he had
The aggregate production quota set by DEA each year ensures that patients have the medicines they need while also reducing excess production of controlled prescription drugs that can be diverted and misused. 

UTTAM DHILLON, ACTING DEA ADMINISTRATOR, ON DEA’S PROPOSAL TO LIMIT OPIOID PRODUCTION IN 2020

been tasked with regulating.

Thankfully, new leadership at DEA has been taking the right steps. DEA has begun lowering production quotas for opioids and has been increasingly working to identify bad actors who had access to patient information. But more work is necessary. The additional transparency into ARCOS data for companies in the supply chain is just the beginning—real-time access to the database will be key in aiding distributors’ ability to see the full picture of a pharmacy’s ordering history.

Regulators and law enforcement should make use of the tools at their disposal to address the causes of rising overdose deaths. Ultimately, the opioid epidemic will continue to rage unless government, the supply chain, and the medical community work collaboratively.

Gabe Weissman is senior vice president of communications, AmerisourceBergen

Editor’s note: The Justice Department released a report that comes to many of the same conclusions—that the DEA knew about the problem but did not react.
Inspection Checklist: Are You Ready for the Board of Pharmacy Inspection?

While a visit from the Board is not something you look forward to, the pharmacy should nevertheless be ready for it at all times.

What does it mean to be ready for an inspection? You might be surprised: not only does it include proper record-keeping, inventory maintenance, and drug security; but also such apparently trivial things as, among other things, dust-free shelves, staff appearance, and bathroom functionality (yes, bathrooms are often inspected too).

If the inspector concludes that the pharmacy provides sub-standard services and does not comply with pharmacy regulations, the Board may commence an administrative action against the pharmacy or issue a citation/fine (depending on the inspector’s observations). Therefore, it is important to anticipate an inspection and prepare the pharmacy and its staff for the process.

The inspection process differs from state to state, but most pharmacy boards focus on a few common things. For example, virtually all boards require that the inspectors introduce themselves and state the purpose of their visit prior to commencing an inspection. Most states allow the inspectors to take pharmacy records off-site (provided they issue a receipt to the pharmacy). And the inspectors are required to provide the pharmacy with the inspection report or written observations after the conclusion of the inspection.

The inspection report is the most important document during the inspection because it lists potential violations, suggestions for improvements, and other concerns of the inspector. An experienced pharmacy attorney, for example, can simply glance at the report and tell you whether it is likely that the Board will commence an administrative action against the pharmacy, issue a citation/fine, or if no further actions would follow.

Therefore, it is imperative for the pharmacy to review the inspection report and address its allegations or observation, if applicable. If, for example, the inspection report states that the pharmacy has no policies and procedures on dispensing controlled substances, the pharmacy should draft such policies and send them to the inspector shortly after the conclusion of the inspection. On the other hand, if the inspector notes that there is expired inventory in stock, prepare a corrective action plan on how this issue had been addressed. I cannot stress enough the importance of the inspection report as an opportunity to avoid a costly license defense in the future.

The inspector may ask you for additional information and documentation as required by your state laws. I had cases where inspectors asked for financial business information (tax returns, billing records, etc.). However, most states provide that pharmacies must only provide access to 1) all stock of dangerous drugs and devices, and to 2) all records of manufacture, sale, acquisition, receipt, shipment, and disposition. Therefore, if the inspector asks anything that is not on the above list or not expressly authorized by a statute, you should discuss the request with your legal consultant to analyze the validity and the Board’s authority for such request.

Words of Wisdom from Don McPherson:

“True prevention is not waiting for bad things to happen, it’s preventing things from happening in the first place.”
What Chains Can Learn from Independents

Although the quote “take the time to walk a mile in his moccasins” is often attributed to the Native American culture, it in fact comes from a poem written by Mary T. Lathrap in 1895, originally titled Judge Softly. I feel we can adapt this to our profession: “take the time to work a shift in his/her lab coat.”

I joined my son-in-law Mark for a conference in Las Vegas, where he gave three presentations for PAIN WEEK. One evening we attended a show, and we were seated next to a patron who told us she worked in marketing. She named the pharmacy chain, one the bigger ones.

She said her focus on marketing is the “store experience.” She described how they fit people with contact lens and glasses and send them into the store and track their eye movements. Amazingly, most eyes seemed to focus on finding a trash can! She described how they focus on signage, color, music, lighting, shelf placement, and anything that could improve the “store experience.”

She also described how a bunch of her colleagues are traveling to London to witness how British pharmacies operate. When they get back to the U.S., they are going to implement ideas gained from watching their British counterparts in this chain’s “wellness centers.”

Finally, the independent pharmacist couldn’t resist: “I asked, did you ever spend a day in one of your pharmacies to see why your pharmacists are so unhappy? Did you ever see the overworked pharmacist, technicians, and cashiers answering phones, staring at computer screens, and trying to accomplish all 10 plus metrics?” I have a few colleagues that work for said chain, and they are the most unhappy healthcare professionals anywhere. I advised her to come to my pharmacy when I’m staffing, and then head down the street to their chain and see the difference.

Imagine one of the biggest drug chains spending millions of dollars, when this community pharmacist knows the obvious. I call their store for a prescription transfer, and it takes at least six minutes for a pharmacist to get to the phone. Through the wizardry of electronics and social media, I can save this chain a bundle of money so they can use that money to get more staffing.

First off, their CEO makes almost 23 million dollars a year. That equals 184 pharmacists’ salaries. For my pharmacist colleagues, the 23 million could hire an almost 1000 technicians, full time at $12.00 per hour. Secondly, let’s cancel your marketing staff’s trip to London. I can tell you what works to increase customer satisfaction. Third, start paying attention to your store staff, if they are too afraid to speak up, don’t be surprised.

I told this member of your marketing team “the only reason most people go to your chain is because they are forced by your PBM.” Your chain’s pharmacists work extremely hard and get less technician hours every year.

They are told to do more with less. Cancel your marketing trip to London, and come to Altoona, PA, where this 61-year-old passionate pharmacist is more than willing to help rescue the 12,000 plus careers of your pharmacists. Not that Altoona PA is an expensive place to stay, you can save even more money by staying at our house. I can accommodate four of you in one of our three empty bedrooms!

Give me a call, I can assure you the phone will be answered within 4 rings! Show up in your white lab coat and sturdy shoes, and you’ll learn so much more than you would taking a trip to London.

“Your chain’s pharmacists work extremely hard and get less technician hours every year. They are told to do more with less.”

Peter Kreckel works in an independent pharmacy in Pennsylvania. You can reach him at editors@drugtopics.com.
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