IT’S NOT A JOB KILLER
Telepharmacy Offers New Frontiers to Grow Business

Expand Rx volumes ■ Create more jobs ■ Treat underserved populations

PBM Reform
THE END OF THE REBATE
IMPORTANT SAFETY INFORMATION AND INDICATIONS

Indications

FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:

- Clostridium difficile-associated diarrhea
- Enterocolitis caused by Staphylococcus aureus (including methicillin-resistant strains)

Contraindications

- FIRVANQ™ is contraindicated in patients with known hypersensitivity to vancomycin.

Important Limitations of Use

- Parenteral administration of vancomycin is not effective for the above infections; therefore, vancomycin must be given orally for these infections.
- Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections. To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Warnings and Precautions

- Significant systemic absorption has been reported in some patients (e.g., patients with renal insufficiency and/or colitis) who have taken multiple oral doses of vancomycin hydrochloride for Clostridium difficile-associated diarrhea. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. Monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
- Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with FIRVANQ™ to detect potential vancomycin induced nephrotoxicity.
- Ototoxicity has occurred in patients receiving vancomycin. It may be transient or permanent. It has been reported mostly in patients who have been
given high intravenous doses, who have an underlying hearing loss, or who are receiving concomitant therapy with another ototoxic agent, such as an aminoglycoside. Serial tests of auditory function may be helpful in order to minimize the risk of ototoxicity.

- Use of FIRVANQ™ may result in the overgrowth of non-susceptible bacteria. If superinfection occurs during therapy, appropriate measures should be taken.
- Prescribing FIRVANQ™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.
- Hemorrhagic occlusive retinal vasculitis, including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or intravitreal route have not been established by adequate and well-controlled studies. Vancomycin is not indicated for prophylaxis of endophthalmitis.

Adverse Reactions
- The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use FIRVANQ™ safely and effectively. See Brief Summary of Full Prescribing Information for FIRVANQ™ on the next page.

FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of:  
- *Clostridium difficile*-associated diarrhea  
- Enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains)

**Important Limitations of Use:**  
• Oral administration of vancomycin hydrochloride is not effective for treatment of other types of infections.
  
To reduce the development of drug-resistant bacteria and maintain the effectiveness of FIRVANQ™ and other antibacterial drugs, FIRVANQ™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

**Hypersensitivity to vancomycin**

- **WARNINGS AND PRECAUTIONS**
  - FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. Oral administration of vancomycin hydrochloride is not effective for treatment of other types of infections. Parenteral administration of vancomycin is not effective for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. If parenteral vancomycin therapy is desired, use an intravenous preparation of vancomycin and consult the package insert accompanying that preparation.
  
- Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of vancomycin hydrochloride for *C. difficile*-associated diarrhea. Some patients with inflammatory disorders of the intestinal mucosa also may have significant systemic absorption of vancomycin. These patients may be at risk for development of adverse reactions associated with higher doses of FIRVANQ™; therefore, monitoring of serum concentrations of vancomycin may be appropriate in some instances, e.g., in patients with renal insufficiency and/or colitis or in those receiving concomitant therapy with an aminoglycoside antibacterial drug.
  
- Nephrotoxicity has occurred following oral vancomycin hydrochloride therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. Monitor renal function.
  
- Otoxicity has occurred in patients receiving vancomycin hydrochloride. It may be transient or permanent. Assessment of auditory function may be appropriate in some instances.
  
- Use of FIRVANQ™ may result in the overgrowth of non-susceptible bacteria. If superinfection occurs during therapy, appropriate measures should be taken.
  
- Prescribing FIRVANQ™ in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
  
- Hemorrhagic occlusive retinal vasculitis (HORV), including permanent loss of vision, occurred in patients receiving intracameral or intravitreal administration of vancomycin during or after cataract surgery. The safety and efficacy of vancomycin administered by the intracameral or intravitreal route have not been established by adequate and well-controlled studies. Vancomycin is not indicated for prophylaxis of endophthalmitis.

**ADVERSE REACTIONS**

The most common adverse reactions (≥ 10%) were nausea (17%), abdominal pain (15%) and hypokalemia (13%).

<table>
<thead>
<tr>
<th>System/Organ Class</th>
<th>Adverse Reaction</th>
<th>Vancomycin Hydrochloride (%) (N=260)</th>
</tr>
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<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
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<tr>
<td></td>
<td>Vomiting</td>
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<tr>
<td></td>
<td>Diarrhea</td>
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<tr>
<td></td>
<td>Flatulence</td>
<td>8</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Pyrexia</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Edema peripheral</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Fatigue</td>
<td>5</td>
</tr>
<tr>
<td>Infectious and infestations</td>
<td>Urinary tract infection</td>
<td>8</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Hypokalemia</td>
<td>13</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Back pain</td>
<td>6</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>7</td>
</tr>
</tbody>
</table>

*Adverse reaction rates were derived from the incidence of treatment-emergent adverse events.

In addition to the information presented above from clinical trials, the following adverse reactions have been identified during post-approval use of vancomycin hydrochloride:

- **Otoxicity:** Hearing loss, vertigo, dizziness, and tinnitus have been reported.
- **Hematopoietic:** Reversible neutropenia, usually starting 1 week or more after onset of intravenous therapy with vancomycin or after a total dose of more than 25 g, has been reported. Neutropenia appears to be promptly reversible when vancomycin is discontinued. Thrombocytopenia has been reported.
- **Miscellaneous:** Anaphylaxis, drug fever, chills, nausea, eosinophilia, rashes (including exfoliative dermatitis), Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis have been reported with the administration of vancomycin.

A condition has been reported with oral vancomycin that is similar to the IV-induced syndrome with symptoms consistent with anaphylactoid reactions, including hypotension, wheezing, dyspnea, urticaria, pruritus, flushing of the upper body (“Red Man Syndrome”), pain and muscle spasm of the chest and back. These reactions usually resolve within 20 minutes but may persist for several hours.

**Geriatrics:** In patients over 65 years of age, including those with normal renal function prior to treatment, renal function should be monitored during and following treatment with vancomycin hydrochloride to detect potential vancomycin induced nephrotoxicity. Patients over 65 years of age may take longer to respond to therapy compared to patients 65 years of age and younger.

**Pregnant women:** There are no available data on FIRVANQ™ use in pregnant women to inform a drug associated risk of major birth defects or miscarriage.

**Nursing mothers:** There are insufficient data to inform the levels of vancomycin in human milk.

**OVERDOSAGE**

Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance.

**PATIENT COUNSELING INFORMATION**

**Antibacterial Resistance:**

Patients should be counseled that antibacterial drugs including FIRVANQ™ should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When FIRVANQ™ is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by FIRVANQ™ or other antibacterial drugs in the future.

**Important Administration Instructions:**

Instruct the patient or caregiver to:

- Shake the reconstituted solutions of FIRVANQ™ well before each use and to use an oral dosing device that measures the appropriate volume of the oral solution in milliliters.

- Store the reconstituted solutions of FIRVANQ™ in the refrigerator when not in use.

- Discard reconstituted solutions of FIRVANQ™ after 14 days, or if it appears hazy or contains particulates.

This is a brief summary of information from the prescribing information and does not include all of the information from the full PI. See the complete PI at www.FIRVANQ.com.

To report SUSPECTED ADVERSE REACTIONS, contact CutisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
EDITORIAL ADVISORY BOARD

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Voice of the Pharmacist

EDITORIAL MISSION: Drug Topics is the top-ranked pharmacy resource for community and health-system professionals. Since 1857, readers have turned to Drug Topics for coverage of issues and trends important to the practice of pharmacy, and for a forum in which they can share viewpoints and practical ideas for better pharmacy management and patient care.
Pharmacists Must Counsel on Cannabis Interactions

Most of us realize that the old image of stoner Jeff Spicoli in Fast Times at Ridgemont High is no longer the face of cannabis. Today, cannabis users are more likely to be average American grandparents seeking relief from arthritis or insomnia.

Whether or not we view this as progress, it is nonetheless extremely important that we as pharmacists accept the fact that cannabis—especially the nonhallucinogenic cannabidiol (CBD)—is in wide use among all age groups. It is difficult to ascertain its effectiveness as a pain reliever or anxiety-reducer, mainly due to the fact that, as a federally illegal substance, researchers run into layers of legal barriers to studying its use.

Regardless of what we know or don’t know scientifically, anecdotal and word-of-mouth evidence has fueled a dramatic surge in use. Products containing CBD are easy—and legal—to obtain either through local dispensaries or online. Regular, day-to-day conversations, especially among seniors, are increasingly likely to include comments about CBD in an ointment, tablets, or liquid that helps with muscle aches, relaxation, nausea, and a host of other common ailments.

Pharmacists’ Obligation

It is not up to pharmacists to endorse or condemn the use of CBD. The critical role I believe we must assume is to assure the health and safety of our patients, as we have always done. Today this means asking them if they are using CBD or other cannabis products, and educating them and ourselves about potentially dangerous interactions between cannabis and other drugs, both prescription and over-the-counter.

This will require effort since this information is not always easy to get. Many physicians are unaware of such drug interactions. And, as I mentioned earlier, research by the usual people and institutions is often nonexistent.

We have to use our training, instincts, and our networks to obtain the best, most current information. And we must regularly use our initiative to counsel our patients.

Public obligation

In addition to each pharmacist being mindful of the widespread use of CBD and the possible harmful interactions for each individual, I think it would be responsible and beneficial if each of the 33 states in which cannabis dispensaries operate pass laws requiring pharmacists be on site or available for consultation in these dispensaries. Five states have been wise enough to do this: Connecticut, Arkansas, Minnesota, New York, and Pennsylvania.

I would love to see my home state of California join this list. And I urge my fellow pharmacists to do what you can to bring this matter to your state board of pharmacy, and work to put pharmacists in this increasingly important position.

New Twist to the Ongoing Mission

Cannabis is one of the most omnipresent drugs in our professional landscape. It is up to each of us to pay attention, educate ourselves, and find the time to make our patients aware and keep them safe.

Seniors comprise only 12% of the population but consume 42% of all medicine, herbal remedies, dietary supplements, and over-the-counter products in the United States. They deserve our professional support in the form of counseling after we have carefully reviewed the possibilities of drug interactions—especially concerning cannabis.

“We have to use our training, instincts, and our networks to obtain the best, most current information. And we must regularly use our initiative to counsel our patients.”

Lack of regulation means protecting public health is our duty

Fred Mayer, RPh, MPH, FACA is CEO of Pharmacists Planning Services Inc. (PPSI) in San Rafael, CA. He is also a member of the Drug Topics Editorial Advisory Board. You can reach him at editors@drugtopics.com.
CMS Releases 2017 Drug Spending Dashboards

The Center for Medicare and Medicaid Services released updated, interactive dashboards to increase the transparency of drug prices. Drug spending grew highest in Medicaid, rising 14.8% between 2013 and 2017, while Medicare Part D retained the greatest total gross spending on prescription drugs in 2017 with $154.9 billion.

Initially released in May of last year, the dashboards are interactive digital interfaces that contain aggregated information on spending per dosage unit for prescription drugs paid under Medicare Parts B and D and Medicaid. Changes in average spending per dosage unit over time are shown on the dashboards as graphs, with information provided in an extensive table for consumers and researchers. The dashboards show manufacturer-level drug spending information as well as consumer-friendly descriptions of the drug uses and clinical indications.

"From 2013-2017, prescription drug spending grew at an average annual rate of 10.6% in Medicare Part D, 10% in Part B, and 14.8% in Medicaid—this is one of our fastest areas of growth," says Seema Verma, CMS Administrator.

Total gross spending on prescription drugs in 2017 was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.
Biosimilar Naming Change May Help End Consumer and Provider Confusion

After reviewing the potential cost of retroactively adding four-letter suffixes to all previously approved new molecular entities, the FDA has decided to limit the suffix addition to those products approved after March 7, 2019.

To further distinguish interchangeable biosimilars from originator and biosimilar products, the FDA says it will designate a proper name that is a combination of the core name and a distinguishable, four-letter suffix.

“We expect that as time goes on, and more biological products are introduced to the market with distinguishable suffixes, patients and providers increasingly will understand that the suffixes reflect a consistent naming convention and are not an indicator of product quality,” FDA Commissioner Scott Gottlieb, MD, says. “What’s important to remember is that biosimilars have been proven to be highly similar and have no clinically meaningful differences, and the FDA continues to engage in efforts to promote this understanding.”

The new naming system is anticipated to improve FDA post-market pharmacovigilance, increase specificity of adverse report tracking, and improve the distinguishability of products at the pharmacy level.

COPD CARE Reducing Veterans Readmissions and Increasing Access to Care

COPD CARE is a new program created by a pharmacist to lower the total hospitalizations of veterans with chronic obstructive pulmonary disease (COPD). It reduced 30-day readmissions from 18.4% to 0 and more than doubled access to physician care within 30 days of hospital discharge from 35.1% to 73.7%. Read the full story online.

Rite Aid Upends Corporate Team, Consolidates 400 Roles

Rite Aid Corp. cut 400 jobs in its corporate offices and shaken up the roster of its C-suite positions. The moves were part of what the company called a leadership transition plan and organizational restructuring.

CEO John Standley will be stepping down, but will remain in the position until Rite Aid finds a replacement.

Bryan Everett is replacing Kermit Crawford as chief operating officer of the company. Matt Schroeder is replacing Darren Karst as chief financial officer. Both Crawford and Karst are leaving Rite Aid. Brian Hoover, group vice president

Walmart Wrongly Fired Pharmacist with MS over Vaccinations

Lori Jacobs, who had MS and cerebral palsy, and worked for Walmart from 2007-2017, was awarded a $1-million compensation after a jury found Walmart violated the Americans with Disabilities Act.

Citing a U.S. Court of Appeals ruling in 2017, Walmart claims immunizations are a vital part of a pharmacist’s job and is considering appealing the decision. Walmart began requiring all pharmacists to give vaccinations in 2016.

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Acid Reflux Linked to Kidney Disease Risk

People taking protein pump inhibitors (PPIs) such as omeprazole (Prilosec), esomeprazole (Nexium) and lansoprazole (Prevacid) have a higher risk of developing kidney disease, a new study says.

Patients who took only PPIs were 28.4 times more likely to report chronic kidney disease and 35.5 times more likely to report end-stage renal disease than those taking histamine-2 receptor antagonists such as famotidine (Pepcid) and ranitidine (Zantac), the researchers found.

Patients who took only PPIs reported a kidney-related adverse reaction at a frequency of 5.6%, compared to 0.7% for patients who took only histamine-2 receptor antagonists.

— Christine Blank, contributing writer

Bayer, J&J Pay $775 Million in Xarelto Lawsuits

More than 25,000 plaintiffs have accused the drug makers of failing to warn of the bleeding risks associated with Xarelto and believe that their injuries could have been prevented with adequate information.

Injuries cited in the cases include the development of uncontrollable and irreversible bleeding, which has led to severe injuries and deaths. Anticoagulants as a category were linked with about 3,000 deaths in 2016, according to the Institute for Safe Medication Practices.

Xarelto has proven to be Bayer’s best-selling drug, earning $4.07 billion (€3.6 billion). J&J reported $2.47 billion earned from the drug.

FDA Requesting Data on Sunscreen Ingredients

The FDA is seeking further information on PABA, trolamine salicylate, and 12 other compounds commonly used in sunscreen to determine safety and effectiveness.

The request comes as a part of proposed rule to update regulatory requirements and establish a final monograph for non-prescription OTC sunscreens distributed in the United States. Scott Gottlieb, MD, commissioner of the FDA, says that formulations have evolved as manufacturers have innovated their products, warranting new considerations from the FDA.

Some products are allowed to be sold without specific FDA clearance as long as they are generally regarded as safe and effective. The new rules would clear sunscreens with two active ingredients—zinc oxide and titanium dioxide—as well as update dosage forms, increase the maximum proposed SPF value, and require product labels that better assist customers in identification of active ingredients and other critical information.

Before the proposed rule becomes final, the FDA is seeking public comment until May 28, 2019. Comments can be submitted electronically or by mail to the FDA.
CVS’ rollout of hemp-based cannabidiol (CBD) products at stores in select states is expected to open the CBD door for other pharmacy chains. But growth of the category could be hindered by complex regulations on CBD and similar products that differ from state to state and by consumer confusion.

CVS began selling topical CBD-containing products such as creams, sprays, lotions, and salves in California, Colorado, Illinois, Indiana, Kentucky, Maryland, and Tennessee. Walgreens said in March it will sell CBD products in 1,500 locations across the U.S., including Colorado, New Mexico, Kentucky, Tennessee, Vermont, South Carolina, Illinois, and Indiana.

“CBD is gaining popularity among consumers, particularly those looking for alternative care products,” Joseph Goode, senior director of corporate communications at CVS, tells Drug Topics. “Anecdotally, we’ve heard from our customers that these products have helped with pain relief for arthritis and other ailments, and we believe consumers will be looking for these products as part of their health offering.”

However, Goode clarified that the topical products are based on hemp, not marijuana, and CVS is not selling any supplements or food additives containing CBD. Hemp is a form of cannabis that contains very low amounts of tetrahydrocannabinol (THC). The 2018 U.S. Farm Bill redefined “marijuana,” a controlled substance to exclude hemp containing less than 0.3% THC. As a result, hemp and hemp-derived CBD are no longer controlled substances under federal law, Goode says.

The FDA has not as yet issued regulations on the marketing and sale of CBD-containing foods and topicals. Regulation of hemp-derived CBD varies by state and is often regulated by multiple agencies. For example, Alabama’s Board of Pharmacy does not agree with that state’s Attorney General’s assessment that CBD can be sold in pharmacies, Goode says, “so that complicates the sale of CBD products in our pharmacy stores [in Alabama].”

“We continue to actively monitor the regulatory landscape for CBD products and will expand product availability as appropriate and in compliance with applicable laws. State laws may be more restrictive than federal law and states can still prohibit or limit hemp,” Goode says.

CVS’s move into the sale of CBD products helps create trust among consumers and encourages other retailers to sell CBD topicals as well, Jessica Lukas, vice president of consumer insights at BDS Analytics, tells Drug Topics. BDS Analytics estimates the total U.S. CBD market, which includes products sold online and at dispensaries, will reach $20 billion by 2024. Around 40% of U.S. consumers say they would try CBD products under the right conditions, a separate new study says.

“It’s not surprising to see that topicals are the first products that retailers are carrying. They are not having to consider food products regulated by FDA. Other [pharmacy chains] will follow quickly and even grocery, mass, and other chains will start carrying them,” Lukas says.

Around 70% of U.S. adults 21 years and older don’t know the difference between CBD and THC, and around 65% believe any hemp product will provide some sort of psychoactive effect, BDS Analytics found.

Pharmacy retailers carrying CBD products could suggest that shoppers talk to their pharmacist if they have questions about the products. “Even if pharmacists relay the perceived benefits, that would be helpful, given the lack of understanding,” Lukas says.

Goode says the chain is working with CBD product manufacturers “that are complying with applicable laws and that meet CVS’s high standards for quality.”

At presstime, FDA Commissioner Scott Gottlieb expressed concern over the way these products will be marketed says the agency will continue to police product claims about medical benefits.

— Christine Blank, contributing writer
In-Store Retail Program Helps Cancer Patients

Walgreens new integrated support program aims to help patients with cancer manage the side effects of undergoing treatment

By Tracey Walker, contributing editor

A new program from Walgreens is providing personalized support to cancer patients by combining specially trained beauty consultants and pharmacists.

"Feel More Like You," a cancer side-effect management program rolled out in 100 stores in seven metro areas in 2018. It is available at more than 400 retail stores nationwide.

Cancer will soon be the leading cause of death in the United States, according to a new study published in the Annals of Internal Medicine.

"Cancer has a major impact on patients in the U.S. and across the world," says Rina Shah, PharmD, vice president of pharmacy operations and specialty at Walgreens. "It's more important than ever that healthcare organizations, and those who have a hand in shaping the future of patient care, look for new ways to address the evolving needs of patients. 'Feel More Like You' is an integrated approach to cancer care, with specially trained Walgreens beauty consultants and pharmacists working to provide personalized expertise to people living with cancer."

Both cancer and cancer treatment can cause the body to change, according to the American Cancer Society. Besides hair loss, chemotherapy can cause side effects. Radiation also causes hair loss, along with skin damage and other issues.

When a customer arrives in store, they will be able to receive on-site services from Walgreens beauty consultants and specially trained Walgreens pharmacists, according to Shah. Beauty consultants and pharmacists were also trained in collaboration with Look Good Feel Better, a non-profit organization that teaches beauty techniques to people living with cancer, and Cancer Support Community, the largest professionally-led nonprofit network of cancer support worldwide.

“The program was created in response to an increased number of oncology patients entering Walgreens pharmacies and the need for expert information,” says Shah. Walgreens is the first retailer to address the well-being of oncology patients by providing in-store pharmacy and beauty support to help people living with cancer manage both internal and external side effects of treatment. Caregivers and patients may be unsure where to go for help with holistic treatment both inside and out, and this program is focused on meeting that need.”

Currently, there is no health plan component to the program, but from this initial pilot program, Walgreens will be able to garner patient feedback and better assess what additional components are needed, according to Shah.

Here are five things to know about the “Feel More Like You” program:

1. The program is a first-of-its-kind retail offering and provides “in-store pharmacy and beauty support to help people living with cancer manage both internal and external side effects of treatment,” Shah says.

2. "Feel More Like You" is provided at no cost to Walgreens customers.

3. The signature component of "Feel More Like You" is an integrated approach to cancer care, with specially trained Walgreens beauty consultants and pharmacists working to provide personalized expertise to people living with cancer.

4. Approximately 500 Walgreens beauty consultants have completed specialized training to address the physical changes associated with cancer treatment, including hair loss and dry hair, dry skin and discolorations, sunlight sensitivity, and changes to nails and cuticles. More than 2,000 Walgreens pharmacists have received cancer-specific training to recommend over-the-counter products that may help manage side effects associated with cancer treatment such as skin rash, increased fatigue, mouth sores, and dry mouth. Additionally, beauty consultants and pharmacists at Walgreens "Feel More Like You" stores have completed empathy training from the Cancer Support Community to provide an enhanced level of emotional support to individuals with cancer.

5. Walgreens community-based specialty pharmacies will play a pivotal part in helping to provide support to coordinate care between individuals with cancer and their local Walgreens.

Tracey Walker is editor of Managed Healthcare Executive, a sister publication to Drug Topics.
340B Update

Recently, the U.S. District Court for the District of Columbia issued a permanent injunction to the Department of Health and Human Services to stop a major reduction in 2018 Medicare reimbursement to hospitals and other providers participating in the 340B Drug Pricing Program.

In its 2018 Outpatient Prospective Payment System (OPPS) final rule published on Nov. 13, 2017, HHS finalized a policy reducing the reimbursement rates for providers purchasing drugs through the 340B Program from 6% above the average sales price to 22.5% below the average sales price, effective Jan. 1, 2018.

Litigation
In American Hospital Association, et. al. v. Azar (Civil Action #18-2084), filed in the U.S. District Court for the District of Columbia in late 2017, plaintiffs American Hospital Association, other provider associations, and individual hospitals alleged that the Secretary of HHS Alex Azar’s reduction in reimbursement was arbitrary and capricious, contrary to law, and exceeded his authority. The plaintiffs moved for a preliminary or a permanent injunction to force the secretary to strike the change in payment methodology for 340B drugs and return to the OPPS rule and methodology used in calendar year 2017 for all future payments.

District Court Decision
In its decision on Dec. 27, 2018, the court denied defendants’ motion to dismiss and concluded that the agency’s action was outside the secretary’s discretion. The court noted that Congress’ limited grant of power to the secretary to adjust drug pricing under 42 U.S.C. § 1395d(t)(14)(A)(iii)(II) did not confer unbridled authority to make basic and fundamental changes to the statutory rate structure. The court held that in light of the nearly 30% reduction from the formula that Congress expressly set and the reduction’s wide applicability, the secretary had exceeded his authority in setting the 340B drug reimbursement rates in the 2018 OPPS Rule.

Court’s Remedy to Be Determined
Despite the plaintiffs’ success on the merits, the court declined to vacate the 2018 OPPS final rule and compensate plaintiffs retroactively for the underpayments. The court reasoned that increasing the 340B program reimbursement rates for 2018 would require offsets from the increased 2018 OPPS payments made for other nondrug items and services. Because this situation could wreak havoc on Medicare Part B’s OPPS system, the court ordered the parties to submit supplemental briefs on the issue of the appropriate remedy to implement the ruling. Similarly, the court declined to impose injunctive relief concerning the HHS rule setting the 2019 340B reimbursement rates, noting that the complaint had not specifically challenged the 2019 rule.

Challenge to the 2019 OPPS Rule
In November 2018, HHS issued a regulation requiring CMS to reimburse providers for drugs purchased under Section 340B in calendar year 2019, using the same discounted 2018 methodology found to be illegal by the court.

Plaintiffs subsequently filed an amended complaint and moved for a permanent injunction to stay the operation of this portion of the 2019 OPPS rule for the same reasons the court stayed the 2018 rule. Plaintiffs asked the court to order the defendants to issue an interim final rule providing for reimbursement of 340B drugs based on the statutory default rate of ASP plus 6%; and to order CMS to pay providers retroactively the additional amount to which they were entitled, plus interest, for drug claims paid before the effective date of the interim final rule.

This litigation is not over, and further orders are expected in coming months. In the meantime:

- Providers purchasing Section 340B drugs need to monitor ongoing developments in this litigation.
- Until the court orders repayment to providers for any past claims paid at the reduced 2019 OPPS rates, providers would be well advised to delay submitting claims as long as possible until a new injunction is in place that restores full reimbursement for 2019.
Your digital dispensary is on Twitter! Follow us for the latest news, views, and insights for your business and the profession.

Join our conversation today! @drug_topics
While progress toward provider status has been relegated largely to individual states, the opioid crisis could provide a path for movement at the federal level.

All but nine states have granted some sort of provider status for pharmacists, but the scope of services permitted by this state-by-state patchwork vary widely. More restrictive provider-status states permit the administration of influenza vaccines, while some have extended prescription authority for some classes of drugs.

While the scope of approved practices is widening, challenges remain in integrating pharmacist-delivered services into the healthcare system and establishing a codified framework to work with payers, including CMS, for reimbursement of services. Currently, reimbursement is limited generally to vaccinations, MTM, and chronic care management in most states. More progressive states have created reimbursement mechanisms for Medicaid patients for broader immunizations, birth control services, and initiating and dispensing naloxone, travel medications, and nicotine replacement therapies.

While reimbursement remains a challenge, scope of services is expanding. Some states allow pharmacists to perform patient assessments and wellness visits; order and interpret drug therapy-related tests; refer to other healthcare providers; and initiate, adjust and discontinue therapy. Idaho pharmacists, for example, can prescribe medications in 20 classes after several years of expansion that now allows the Idaho State Board of Pharmacy to determine drugs or devices that pharmacists may prescribe for certain conditions.

At press time, there were 109 active pieces of legislation in statehouses around the country that will either establish or expand provider status roles for pharmacists.

Lobbyists and industry advocates have been forced to make some hard choices during the last several years, the most consequential of which has been sacrificing direct reimbursement in order to establish new services for the profession.

In most current systems, pharmacists are not eligible to receive direct payment from Medicare, Medicaid, or other government payers, but they can partner with provider networks, employers, or with private insurers to provide care for a set population. If pharmacists are going to be part of a healthcare team, then they need to join a team that is eligible to get paid.

This clearly puts the responsibility of reimbursement squarely on pharmacists if they want to monetize the services they provide, and the one-off contract strategy is not ideal nor very likely to become widespread.
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The Next Step
to Reimbursement

However, expanded scope of services is widely considered a stepping stone to direct reimbursement. At the federal level, the Patient Access to Pharmacists’ Care Coalition is working to authorize reimbursement under Medicare Part B in medically underserved communities, which would reimburse pharmacists for approved services at 85% of the physician fee-for-service rate, similar to nurse practitioners and physician assistants.

A version of the bill was first introduced in 2014 and was reintroduced in 2017. Advocates are discussing a path forward under the new leadership, according to Ann Burns, RPh, vice president of professional affairs for APhA. “We’ve had good bipartisan support of the bills that we have in Congress, but unfortunately they have not moved to legislation,” Burns says. “However, there is a lot of movement and interest in the opioid crisis, so that could be the pathway for a national framework.”

As opioid use disorder continues to permeate the current political environment and public health debate, there is significant political will at the state and federal level to offer more access to care and interventions.

Drug overdose is the leading cause of death for persons under the age of 50, and prescription opioids are responsible for 40% of opioid overdoses, or about 46 per day. More than 51,000 people died of drug overdoses in the United States in 2015, according to the World Health Organization. England and Wales ranked No. 2 with 3,323 deaths. More than 70,000 drug overdoses occurred in 2017, and a whopping 47,600 were opioid related, outpacing suicides (47,173) and traffic accidents (40,100) for the first time.

“This is a uniquely American problem, and this is important to understand for society if we are going to make a difference because it really says something about our culture,” says Ron Friedman, an attorney who represents pharmaceutical firms and personnel in compliance matters. He discussed office-based addiction treatment options.

Fatalities continue to grow, and while prescription overdoses ebbed for the first time in 2017, prescriptions still contributed to more than 17,000 overdose fatalities.

In the current political climate and crisis surrounding the opioid use disorder, could motivate legislators to authorize pharmacist intervention programs that would qualify for reimbursement.
Bringing Vaccines, Information to the Fight Against Measles

Though requests for vaccinations are increasing, pharmacists might be limited by state laws.

By Fred Gebhart, contributing writer

Pharmacists nationwide are adding medically sound information and vaccinations to the fight against measles. Outbreaks were reported his year in New York, Washington, Oregon, Illinois, and Texas. Nearly all the infected individuals had not received the measles, mumps and rubella (MMR) vaccine.

“We are seeing increased demand for vaccination and pushback on anti-vaccine groups,” said Mitchel C. Rothholz, RPh, MBA, chief strategy officer for APhA. “At a minimum, pharmacies are serving as additional outlets for information to the public about the importance of MMR vaccine. They are a conduit to address some of the misinformation that is circulating.”

The CDC notes that among unvaccinated individuals, nine of every 10 who are exposed to measles will develop it. The virus can survive up to two hours in the air and on surfaces where an infected person has coughed or sneezed. A person is infectious up to four days before the rash appears.

About 10% of children with measles develop ear infections, and 5% develop pneumonia. Up to 2 in 1,000 die from measles complications, and 2 in 10,000 develop subacute sclerosing panencephalitis, usually years later, and die or suffer permanent impairment.

Interest in Measles Vaccine Spiking

Just what pharmacists can do is based on what individual states allow. In Oregon, for example, pharmacists are providing plenty of information, but relatively few MMR vaccinations. The state practice act limits pharmacists to prescribing and administering vaccines without a prescription issued by another provider to individuals seven years or older, noted Amy Valdez, RPh, immediate past president of the Oregon State Pharmacy Association. In neighboring Washington, another state with an outbreak, pharmacists have no age limit on vaccination.

“We usually administer about 50 MMR doses a year,” said Beverly Schaefer, RPh, co-owner of Ketterman’s Sand Point Pharmacy in Seattle. “We have done more than 50 doses in the first six weeks of this year alone.” The Washington Department of Health reported a 500% increase in MMR vaccinations for Clark County, the area most affected, between Jan. 1 and Feb. 16, compared to the 2014-2018 average.

Interest in receiving MMR vaccination runs from parents on behalf of newborns to senior citizens, Schaefer says. Older adults generally don’t need MMR vaccination because most who were born before the late 1950s had measles, and the infection confers lifetime immunity.

Measles Vaccine and Kids

The usual immunization schedule calls for a first dose of MMR at one year and a second dose between age 4 and 6, Schaefer noted. However, the second dose can be given as soon as four weeks after the first dose.

Many parents want the second dose ahead of schedule, she said. “And we are seeing uptake for people who are traveling with their kids and for previously unvaccinated children who need vaccination for school trips.”

Even parents who had refused vaccination are changing their minds as their children move into upper grades, Schaefer says. Many school travel abroad programs require MMR vaccination as a condition to participate.

“When they bring their kids in, I don’t have anything negative to say about the delay,” Schaefer says. “I emphasize what a good thing they are doing to protect the healthy status of their child.”
The Association of Affiliated Pharmacies and Apothecaries (AAPA) named Gerry Crocker as its first-ever CEO in December of 2018. The creation of this new position comes after a major organizational restructure for the group purchasing organization (GPO), to help grow and support independent pharmacies across the United States.

Crocker earned his Bachelor of Business Administration, Management, and Operations from Northern Michigan University in 1980.

He has previously served as the CEO and president of various pharmacy GPOs, as well as helped found the biotech drug development company CanPharmaRx.

Drug Topics talked with Crocker to learn more about the organization, its plans to expand, and what led him to the position in the first place.

DT: What attracted you to AAPA?

Crocker: This is my third role as a CEO for a GPO. I had worked with [one of the board members] in specialty pharmacy enterprise about 10 years ago, and we stayed in touch over the years. I was doing some consulting, and he asked me to come in and help them renegotiate their agreement with their wholesaler. Over that six-month process, I got to know the board really well. I learned a lot of encouraging things about the group and was quite impressed with them.

DT: What does the AAPA do for independent pharmacies?

Crocker: There’s a lot of components—payment terms, data sharing, supply-side, and buy-side. Primarily, all GPOs negotiate a prime vendor agreement with a wholesaler for their members, and the members all operate under the same purchase agreement with their wholesaler.

There are some pharmacy systems that have unique services, sometimes a part of the agreement, training support, and better pricing. We have seminars, workshops, CEs (continuing education) around each market segment that [independent pharmacy members] can participate in to help them better understand the market around them and their best opportunities—these are all things they don’t get in pharmacy school but are very important as you try to grow your business.

We are introducing a platform that will allow them to monitor their compliance within our agreement and optimize it to get better rebates and greater discounts by ending their sales data by the end of the month. [Independent pharmacy members] will be able to see where they’re at, where the next threshold of compliance is, and how to get there. They can work proactively to manage their discounts and optimization as opposed to operating reactively, which is where most independent pharmacies find themselves these days.

Advocacy is a big part of pharmacy, and this group is firmly entrenched in it.
The old company was a nonprofit organization—the Arab-American Pharmacist Association—and the previous owners retained that entity, but its sole purpose is legislative affairs, community service, and working with pharmacy schools to help pharmacy students with scholarships and loans.

We are engaged with the national associations to advocate for pharmacy in general, and CPAs specifically for independent pharmacies. We participate in all of the national initiatives and legislative affairs effecting pharmacies, and we ask our members to participate on their local levels as well.

The best thing we can do, on all levels for our independent pharmacy members, is to be their strongest advocate.

**DT:** You emphasize a “sustainable pharmacy business model,” could you explain how that looks to you?

**Crocker:** There’s only so much margin on the buy-side to protect yourself as an independent pharmacy.

There’s constant downward pressure from the PBMs on reimbursement—independent pharmacies get deeper discounting by growing their groups. It seems like there’s an equal pressure from the other side to reduce the reimbursements, which minimizes the gains the independent pharmacies just achieved.

The only answer is being a more efficient operator, buying smarter, and expanding your business. The sell-side of your business is really important.

Some pharmacies can survive as a traditional retail pharmacy, but most pharmacies that are growing have learned to open up to new markets. Those might be long-term care, compounding, 340B, or specialty.

**DT:** How do you plan to grow the AAPA?

**Crocker:** Besides our past network and my network, we are bringing on business development representatives in different markets. These are individuals that know the markets, know the owners, and probably have a market of 200 to 300 pharmacies each.

The group, as we’re building it out, is going to be more interesting to independent pharmacy owners because of the capabilities that we’re layering into the offering.

We’re also looking at consolidation in all markets, especially in healthcare and pharmacy. You see it on the highest levels — the PBMs and chains, and then their distribution and customers, all teaming up. Now you’re seeing consolidation between GPOs because size is typically a positive thing. We are in the top third of GPOs from a size standpoint.

We’re looking downstream at affiliation agreements and potential acquisitions, and upstream to see who we might want to align with to better enhance our position as we move forward. That’s going to be a constant in our space, and it would be foolish not to pay attention.

The AAPA has a great history of building a name for itself, and now they’re retooling for the future. We’re rebranding the company; going national; and layering in new technology, tools, and pharmacy services to help our members grow their business.

On the horizon, our continuing professional development is going to be a huge part. All the major wholesalers are looking to participate when it’s right to open the channel. There’ll be new revenue streams for pharmacy that will offset the losses in the transitional side of pharmacy.

“We’re rebranding the company; going national; and layering in new technology, tools, and pharmacy services to help our members grow their business.”

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**Current AAPA Vendor Organization Partners**

- McKesson
- TriState Distribution
- Rx HealthMart Pharmacy
- SAFE — Substance Abuse Coalition
- NCPA — National Community Pharmacists Association
- MPA — Michigan Pharmacists Association
- SRS Pharmacy Systems

*This article originally appeared online at DrugTopics.com in January.*

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**DrugTopics**

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When North Dakota opened the nation’s first community-pharmacy-based remote dispensing site in 2001, the case was simple. The state pharmacy association, board of pharmacy, and pharmacists wanted to reverse the tide of rural communities losing pharmacy services. The pilot program brought pharmacy services to 80,000 rural North Dakotans who were without a pharmacy.

Nearly two decades later, the case for telepharmacy is more inclusive. The goal is to bring pharmacy services to underserved areas. Telepharmacy can work in rural or urban settings, specialty clinics, hospitals, or anywhere else that needs but does not have ready access to pharmacist care.

That led Heather L. Bibeau, PharmD, director of outpatient pharmacy services at Bigfork Valley Hospital in Minnesota to open telepharmacies in three Federally Qualified Health Center clinics in Bigfalls, Floodwood, and Northome, MN, which had no community pharmacies in 2017. The state’s newest telepharmacies join 19 other remote dispensing facilities.

The latest move is bringing telepharmacy to underserved urban areas that lack a conventional brick-and-mortar pharmacy.

Meeting Unmet Needs

“There is a shift of telepharmacies for strictly rural areas to telepharmacies for medically underserved areas in urban settings, where patients may..."
“A lot of the communities we are in can’t support the salary of a pharmacist. But they can provide enough volume to support a telepharmacist.”

JEFF SHORTEN, PHARM D

have transportation issues, may be low income, and not have a convenient pharmacy,” said Adam Chesler, PharmD, director of regulatory affairs for Telepharm, a telepharmacy software provider owned by Cardinal Health.

Cardinal Health has identified multiple areas where a patient might need to take two or more buses to get to their doctor, then another two or three more to get to the nearest pharmacy, he said.

The focus is increasingly on providing access wherever it is needed.

Pharmacists are identifying other needs that telepharmacy can meet.

In West Texas, Micah Pratt, PharmD, needed a way to ease the skyrocketing costs of delivering medications to patients in Olton, about 30 miles from his pharmacy in Littlefield. He gained patients after a national chain bought out the sole pharmacy in Olton, closed the store, and moved prescriptions to an existing pharmacy another 30 miles away that did not offer delivery. With up to 25 deliveries to Olton daily, Pratt saw profits falling as delivery costs climbed.

In 2016, Pratt opened the first telepharmacy in Texas to give his Olton patients a local pharmacy outlet and provide a base for local deliveries. And to discourage potential expansion by the chain that had closed Olton’s brick and mortar pharmacy.

In Driggs, ID, Sally Myler, PharmD, wanted to expand to Victor, a nearby town that is small but growing as a bedroom community to nearby Jackson Hole, WY. And she wanted to deter an aggressive chain had already tried to buy out her third-generation Corner Drug, then threatened to undercut her prices and hire her employees when she declined to sell.

Telepharmacy helped Pratt and Myler move ahead of the competition. Both use Telepharm as their telepharmacy software provider, but their business models differ.

Pratt set up shop in what had been a large closet in a medical clinic in Olton, about 150 square feet. Existing Texas legislation allowed telepharmacy, but requirements were so onerous that no one had successfully opened a remote dispensing location. He spent months working with the Texas Board of Pharmacy to obtain waivers to open the remote location, then more months with the state legislature to create a more workable legislative framework for telepharmacy.
Telepharmacy

“With more favorable regulation in place, Pratt purchased a second brick and mortar pharmacy and opened a second telepharmacy. Texas allows up to two remote dispensing locations for each brick and mortar pharmacy and he is actively looking for two more telepharmacy locations.

Myler considered moving into the existing medical clinic in Victor, in a converted modular home. Instead, she worked with the clinic to build Victor’s first purpose-built medical facility. The clinic is her primary tenant and the building includes pharmacy space.

Victor is growing, like much of rural Idaho, which could improve prescription volume as well as front-end sales. At some point, it could make sense to convert the telepharmacy to a second brick and mortar pharmacy. Myler told Drug Topics that local real estate brokers warned that other operators were looking for pharmacy space, including Victor’s one grocery store.

“If we hadn’t come into Victor, it was clear that somebody else would,” she said, “either as a telepharmacy or a brick and mortar pharmacy. Either way, we would have lost the customers that are keeping our Victor outlet going.”

“Telepharmacy allows for new job opportunities for pharmacists,” said Jennifer Bingham, PharmD, BCAP, chair of APhA’s 2018-2019 Special Interest Group. “With the healthcare landscape shifting toward value-based care, it is a great opportunity for our profession to expand our services to provide more comprehensive patient care that can improve patient satisfaction. Knowing that telepharmacy can be used to drive new revenues and patient acquisition, the possibilities are endless.”

Business First

Telepharmacy is just as much a business as a brick-and-mortar pharmacy. The brick-and-mortar pharmacy has a pharmacist on the premises to oversee dispensing, counsel patients, provide advice, and answer questions. The telepharmacy pharmacist does precisely the same things, but from a remote location.

“The brick-and-mortar pharmacy needs sufficient prescription volume to justify the expense of a pharmacist. Telepharmacy allows a pharmacist to share time across multiple lower volume pharmacies.”

The Minnesota Pharmacists Association, among others, has how-to-get-started webinars and online educational materials, although access may be restricted to members or lie behind paywalls.

APhA has a four-part online CE program, The Role of the Telehealth Pharmacist, that defines different telehealth settings, explores the current technologies, discusses communication issues and lays out common regulatory considerations. Modules are free to nonmembers as well as to APhA members at elearning.pharmacist.com.

North Dakota State University, which helped launch the first telepharmacy pilot, has resources for community pharmacists, hospitals, and communities as well as a how-to guide and publications at https://www.ndsu.edu/telepharmacy/.

Telepharm, a Cardinal Health subsidiary, offers a variety of online information, tutorials, and state-specific information for different types of practice sites at https://www.telepharm.com/.

“There is a shift of telepharmacies for strictly rural areas to telepharmacies for medically underserved areas in urban settings.”

ADAM CHESLER, PHARM.D.

Like the idea of telepharmacy and not sure where to start?
"A lot of the communities we are in can’t support the salary of a pharmacist," said Jeff Shorten, PharmD, vice president of pharmacy operations for regional chain Thrifty White Pharmacy. Eleven of the chain’s 97 pharmacies are telepharmacies in North Dakota and Minnesota. "But they can provide enough volume to support a telepharmacist. We have pharmacists who are specifically telepharmacists helping these smaller communities. But it’s not a lucrative business model for us."

The break-even point for telepharmacy depends on location, but 30 to 45 scripts per day usually covers fixed costs such as technician staff, building, hardware, software, inventory, and other location-specific items.

"At 40 scripts per day, we’re not really paying back the pharmacist’s time that is going into the telepharmacy," said Brett Barker, PharmD, vice president of operations for NuCara Pharmacy, a 24-store regional chain that piloted two of the first telepharmacies in Iowa. The company now has five telepharmacies in North Dakota and Iowa.

"We want to get to 50 or 60 scripts per day to pay back the pharmacist’s time. The goal is to extend the reach of our pharmacists to places we wouldn’t otherwise be able to place them. We’d love it if we could grow them all to the point that the pharmacist is physically there full-time, but telepharmacy gives us a way to start in places where patients otherwise don’t have local access to pharmacists."

Telepharmacy location depends largely on local needs and availability. Thrifty White and NuCara use free-standing locations, but other telepharmacies operate in clinics, grocery stores, almost any location that can meet local regulatory requirements.

That flexibility gives regional chains and independent pharmacies a competitive edge. National chains and big box stores rely on standardized procedures. A pharmacy with 5,000 similar stores isn’t going to deviate significantly for pharmacy 5,001.

"CVS isn’t going to build a pharmacy in a town of 1,000 people," Shorten said. "And if the town isn’t big enough for a Walmart, they’re probably not going to put a random pharmacy in there. At the same time, as community pharmacies continue to be squeezed by thinning margins, there will be more and more pharmacies that are no longer viable as a traditional pharmacy with a pharmacist on site. That’s only going to increase the opportunity and the need for telepharmacy."

"With the healthcare landscape shifting toward value-based care, it is a great opportunity for our profession to expand our services to provide more comprehensive patient care that can improve patient satisfaction.”

JENNIFER BRIGHAM, PHARM.D., BCAP

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**PipelineRx**, which focuses on community hospitals, health systems and specialized care settings, has case studies, programs and solutions at [https://pipelinex.com](https://pipelinex.com).

The first stop in building a telepharmacy is usually the state board of pharmacy. About two-thirds of states have some sort of telepharmacy regulation or legislation in place, but the requirements vary widely. State pharmacy associations can be another useful entry point, but early conversations with your state board are essential.

Because telepharmacy needs vary widely from location to location, many pharmacists need variances or waivers to current telepharmacy regulations. State associations can often provide advice and support for the waiver process. Most state boards have a standard request form, and board surveyors may be available to discuss your variance needs before making a formal request.

Choose a type of location, whether it is a free-standing operation or part of some other medical space such as a clinic or another retail operation like a grocery store. Some states require telepharmacies to dispense from a medical facility while other states offer greater flexibility in location.

A telepharmacy is as much an independent business as a brick-and-mortar pharmacy and needs its own business plan. While financial specifics differ, 30 to 45 scripts per day seems to be the accepted break-even point. The business basics are no different from any pharmacy: acquiring the physical space; staffing, inventory and licensing costs; DEA registration if you plan to stock controlled substances; technology installation, operation and maintenance; wholesaler and payer contracts for the new location; insurance; advertising; staff scheduling and training; managing script deliveries, and so on. The biggest difference is coordinating pharmacist time at the main or hub pharmacy with open hours at the telepharmacy—most states require a remote pharmacist be available for prescription review and patient consultation whenever a telepharmacy is open.
Could We Be Nearing the End of the Rebate?

Legislators and regulators continue to scrutinize drug prices and PBM rebates, but reform is already underway

By Mari Edlin, contributing writer

Although the use of drug rebates has been under discussion for some time, “American Patients First: Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,” opened the door for a renewed debate.

“Today’s rebate system is set up in the shadows to serve entrenched interests—drug companies who set these prices so high and the pharmacy benefit managers who receive billions of dollars in rebates without patients ever knowing where the money goes,” said HHS Secretary Alex Azar.

The blueprint points a finger at PBMs and insurers who drive up drug prices by demanding high rebates in exchange for increased utilization. Among its proposals are requiring Part D plans to apply rebates at the point-of-sale (POS) and a rule to withdraw the “safe harbor” protection under anti-kickback laws, eliminating rebates in Medicare that have permitted manufacturers to negotiate with payers for formulary placement.

The blueprint also says that when prices are higher, PBMs, wholesalers, and plans receive higher rebates with little incentive to lower drug costs.

Questions include whether PBMs are double dipping by receiving payments from both insurers and drug manufacturers, whether rebates lower drug costs for consumers, and if rebates serve any other purpose than negotiating a position on a formulary by drug companies, among other issues.

“Manufacturers have chosen to negotiate price concessions with PBMs using rebates, which are paid months after a drug has been dispensed and are used by payers to reduce premiums and out-of-pocket costs for patients,” according to the Pharmaceutical Care Management Association (PCMA). “At this time, rebates are the only usable price concession available.

“As long as manufacturers are reticent to offer up-front discounts, fearing they will violate antitrust law, limiting or eliminating plans’ ability to negotiate price concessions after a drug is dispensed would only come at the expense of patients, who would face higher drug costs,” the organization says.

Joe Paduda, president of CompPharma LLC, a consumer and payer research organization based in Maggie Valley, NC, is not convinced that the administration is really tackling the issue.

“The government cannot negotiate prices with manufacturers, but it is a good faith effort for Congress to try to gain lower prices,” he says. “Competition needs to increase, and the FDA should speed up the development of generics.”

Do Consumers Benefit from Rebates?

On Jan. 31, the Trump Administration proposed that health plans and middlemen serving Medicare Part D and Medicaid beneficiaries in managed care plans be required to give consumers the benefit of discounts they receive on prescription drugs. Under this proposal, rebates from manufacturers to PBMs would be considered illegal kickbacks—essentially the end of the safe harbor protection ruling for discounts and rebates paid from manufacturers to PBMs.

In addition, the proposal creates a new safe harbor for prescription drug discounts offered to beneficiaries at POS and for certain fixed-fee service arrangements between drug makers and PBMs. While lowering out-of-pocket (OOP) costs for Medicare beneficiaries, the rule could generate unintended

Without rebates, manufacturers in competitive classes would need to find ways to distinguish their products, leading to value-based contracts. —MAGGIE ALSTON, MILLIMAN
consequences—increasing premiums from 8% to 22%, according to HHS.

Secretary Azar says rebates might be passed onto consumers, who could potentially realize reductions of 30% or more in their OOP costs for drugs, such as insulin and statins. Sicker beneficiaries with higher drug costs are expected to benefit the most.

The proposed effective date for the regulation is Jan. 1, 2020.

A white paper on drug rebates, coauthored by Senior Healthcare Analytics Consultant Maggie Alston and Principal Gabriel Dieguez of the actuarial and consulting firm Milliman, says eliminating the protection could “increase transparency in net pricing and improve the competitiveness of generic and bio-similar products, which could result in increased competition and lower prescription drug prices.”

“To the extent this action resulted in pharmaceutical manufacturers lowering their negotiated prices to a post-rebate level, some patients would benefit from lower OOP costs,” the paper says.

“Roughly 85% to 90% of drug claims are for generics, which for the most part are priced below their brand name counterparts and account for only 35% to 40% of U.S. drug costs,” says Mesfin Tegenu, RPh, president of PerformRx LLC, a Philadelphia-based PBM. “Pointing to rebates as a culprit is not accurate and does not solve the issue of high drug prices.”

“Specialty drugs, a category that incidentally has no or very low manufacturer rebates, is at the heart of the cost issue. Although specialty drugs comprise less than 1% of all pharmacy claims dispensed, they make up almost 40% of U.S. healthcare drug costs. These are the drugs that require a change in the price curve,” he says.

Express Scripts says drug pricing and rebates are not linked; thus, taking away rebates would not stop a drug company from raising its prices. The PBM points to registered price increases above 15% for nonrebated drugs treating infertility, depression, high cholesterol, and transplants as an indication that rebates aren’t a key driver of higher costs.

The End of Rebates

Mike Kolar, senior vice president and general counsel at Prime Therapeutics, a PBM based in Eagan, MN, doesn’t believe that complete elimination of rebates will result in lower drug prices. “Instead, we support exploring innovative approaches, such as designating a portion of rebates for use in lowering member out-of-pocket costs or premiums, or investing in programs to improve outcomes,” he says.

Armed with information on pairing the right drugs with the right patients and applying the most effective formulary strategies and clinical programs, the PBM can negotiate with manufacturers for the best possible pricing—whether through rebates or other avenues such as value-based contracts—to lower drug spend for clients, Kolar says. Prime also supports PBM transparency around rebate revenue to health plans and plan sponsors.

Kolar says rebate elimination will not result in dollar-for-dollar reductions from current list prices to net cost. “While some manufacturers are taking steps toward this with the introduction of authorized generics that are generally priced lower than their own brand drugs and carry no rebates, there is no guarantee that widespread decreases to true net will occur or would be sustained,” he says.

“If rebates are eliminated, health plans will likely experience increased drug spend, and member premiums may increase to offset the lost rebate savings,” he says.

Despite the energy being devoted to rebates, Paduda doesn’t think they will ever disappear and if so, not soon. “Other payment mechanisms will take their place,” he says. “We need to eliminate direct and indirect remuneration (DIR) fees and tie reimbursement to outcomes, to clinical levers, not financial ones.”

Bill Resnick, chairman and CEO of EmpiRx Health, a PBM headquartered in Montvale, NJ, agrees with Paduda that if rebates disappear, they will show up in another form of remuneration, such as discounts or value-added mechanisms.

“Rebates are embedded in the system, along with DIRs and manufacturers driving utilization to get their drugs on the best tiers,” he says. “They don’t help with cost and payment; they are just part of the economics of the drug industry and have no reason to be in the marketplace. They will never outpace the cost of drugs and don’t demonstrate lower overall drug costs.”

Resnick favors “optimizing” rebates over “maximizing” them—EmpiRx Health first looks at each drug’s clinical appropriateness and overall cost and then at what can be achieved in rebates for those drugs.

“The PBM industry tends to see the rebate as an opportunity to loosely manage utilization. Surprisingly to most outside the industry, many PBMs strive to maximize rather than optimize rebates, providing more units with rebates even when there’s not a medical need for the product,” Resnick says.
Rebates and DIR fees don’t help with cost and payment; they are just part of the economics of the drug industry and have no reason to be in the marketplace.

BILL RESNICK, EMPIRX HEALTH

If rebates should disappear, the distribution model would shift and become more of a direct-to-consumer distribution, along with a push toward value-based contracts away from fee-for-service, according to Alston.

“Without rebates, manufacturers in competitive classes would need to find ways to distinguish their products, leading to value-based contracts, and plans would need to better manage formulary decisions,” she says.

Glen Stettin, MD, chief innovation officer for Express Scripts, agrees that if rebates go by the wayside, some alternative will fill the gap—especially because the federal government is the largest beneficiary of rebates as a Medicare/Medicaid payer, he says.

“To manufacturers, rebates are a way to establish a differentiation by providing higher volume customers with larger discounts, but they could discount drug prices by just lowering them without a rebate,” he says. “Rebates offer different prices for different customers, an advantage for manufacturers. That’s why a flat fee would offer the wrong kind of incentive.”

Without rebates, Stettin says Express Scripts would use a management fee aligned with costs. “The objective is for us to provide the benefit of using affordable, effective drugs to control chronic conditions, improve adherence, and lower opioid use,” he says. “If we meet all guarantees, we will get a fee and if not, a lesser amount that puts the process at risk.”

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

Stettin says drugs that best fit the new formulary are those in categories that are competitive and appropriate for most members with the same indication. Harvoni (ledipasvir/sofosbuvir) is the first product managed through the new formulary. Some manufacturers are already participating, weaning them off rebates.

“Our program enables payers and health plans the option to choose a lower price option or the original branded drug, which might have a rebate, and provides cash-paying members and those with coinsurance or high deductibles immediate access to lower priced drugs,” Stettin says.

He says the PBM is straightforward in providing rebates—whether they are a percent of the cost of a drug for an amount per claim—because whatever a contract guarantees, the PBM lives up to those expectations or pays a client. Express Scripts says it returns 90% of the rebates it negotiates with drug manufacturers directly to its clients, a 100% pass-through for plan sponsors offering Medicaid, according to the PBM.

Resnick says most PBMs simply provide guarantees around discounts and rebates; thus, they have little to no accountability for actual utilization because more units equal more margin.

“It’s the concept of fee-for-service, the same misaligned structure that health care providers are proactively trying to move away from,” he says.

“The EmpiRx model offers discount guarantees and rebate guarantees, but where we differ is by adding in a client-specific, clinical guarantee that commits us to demonstrate appropriate utilization,” Resnick says. “Until we reach the guarantee, we are at full-risk for this amount; we begin to make margin only when we exceed this client commitment.”

An Alternative: Point-of-Sale Rebates

POS rebates have been suggested as a potential partial solution to the rebate debate. Resnick says POS rebates occur when the PBM places the approximate value of the rebate into the member/client cost share at the time the drug is dispensed, but is only applicable to co-insurance, not copayments.

“Right now, rebates don’t affect patients at POS as promised,” Milliman’s Dieguez says. “Members are buying drugs at sticker price, so they don’t receive the benefit of rebates. Although a PBM might claim 100% pass-through, it withholds hidden fees. Retention of rebates without transparency can legally make formulary decisions based on bottom line, but it should be the fiduciary responsibility of PBMs to act in the best interest of their clients.”

Alston cites the advantages of POS rebates as lowering cost sharing for beneficiaries filling scripts, potentially slowing down the pace for Medicare beneficiaries entering the gap where cost sharing is greater. For example, a 20% coinsurance on a $1,000 script with a 30% rebate is $140, while the same beneficiary would pay $200 without a POS rebate.

“On the other hand, by passing rebates to beneficiaries at the POS, plans lose a valuable source of revenue that keeps premiums low for all beneficiaries,” Alston says. “Premiums may increase, in the short run, if rebates are applied at the POS.”

This article first appeared in our sister publication Managed Healthcare Executive.
**What Works: Profiles of Four Travel Health Clinics**

By Joan Vos MacDonald, contributing writer

Adding a travel health clinic can be a good way for some pharmacies to boost revenue and, at the same time, offer a valuable service to the community. Customized travel consultations, which often include immunization and medication recommendations, can expand the services offered to existing customers, while potentially attracting new ones.

What works and what doesn’t? Every pharmacy is different, but the stories of four pharmacists who successfully opened travel health clinics, may inspire similar success. Each pharmacy offers advice based on what they learned.

**Katterman’s Pharmacy**

SEATTLE, WA

Set up a travel aisle to maximize profits.

When Katterman’s Pharmacy began offering travel health services five years ago, cofounder Beverly Schaefer, RPh, was surprised at the demand and its positive effect on revenue. “It has been hugely profitable for us,” Schaefer says. “We did over 12,000 immunizations last year, that’s 33 immunizations a day, so we’re busy.”

The idea for the clinic evolved from the vaccination services already offered. “People would see we were doing flu shots and ask, ‘Can you do a tetanus shot?’ ” Schaefer says. “Yeah, we can do that. ‘Can you do a hepatitis A shot? Can you do typhoid shot?’ We started doing everything.”

Eventually, the pharmacy set up an appointment-only clinic for one-on-one consultations.

“We review the health history and travel itinerary, and make recommendations for staying healthy while traveling. In Washington, pharmacists have prescriptive authority, so we can also write prescriptions.”

Travel prescriptions are sometimes needed for prophylaxis malaria medications or emergency antibiotics for foodborne or water-borne bacteria. Travelers seemed willing pay for this service, as an out-of-pocket expense. Charging $49 for a half-hour session, Schaefer found that because people often travel with a companion, they sometimes visit the clinic together.

“While it’s more work to look up two histories, they will have the same itinerary, so there’s the potential to earn $200 for just travel consulting, and that’s in addition to immunization and prescriptions.”

Many visitors have been so satisfied with the service, they return with trip souvenirs, which Schaefer displays.

To offer the benefit of one-stop shopping, the pharmacy set aside a travel aisle. “We can walk down the travel aisle and do over-the-counter stuff. But a travel clinic with a travel aisle has everything all in one place,” Schaefer says.

By informing a patient’s doctor about vaccinations that have been given, the pharmacy also markets the service. “The faxed form lists all the vaccines we offer and checks off the one we’ve given. Doctors then know what we offer, creating the potential for future referrals.”

Spreading the word required very little investment. “We put a sign on the door that says, ‘Leaving the country? Talk to us about vaccines.’ It costs nothing.”

**Hendricks Pharmacy**

CLAREMONT, CA

Get certified for yellow fever vaccination.

Karl Hess, PharmD, CTH, FCPhA, is an associate professor of clinical and administrative sciences at Keck Graduate Institute School of Pharmacy and Health Sciences. Since 2006 he’s also managed a successful travel health clinic at Hendricks Pharmacy. He attributes much of the clinic’s success to promotional efforts in and out of the pharmacy. Inside, something as simple as hanging up maps and pictures of far-off destinations has prompted customer conversations about travel and helped introduce the travel clinic’s resources.

“Word of mouth has helped quite a bit,” Hess says. The pharmacy also had a booth at a village health fair.
"We provided health information and gave away a lot of goodies to promote the clinic."

Depending on where a traveler is headed, a consultation at the clinic might offer tips on how to minimize altitude sickness when climbing Mt. Kilimanjaro or whether malaria protection is needed when traveling to Uganda.

Being certified to dispense yellow fever vaccine gives the pharmacy an advantage. "The CDC lists yellow fever vaccination sites on its website, which helps people find us. These are not vaccines any pharmacist can offer. You have to be trained."

A first step in launching the clinic was setting up a protocol for how vaccinations would be handled, including how shots are administered, how information is then registered, and how it is sent to a collaborating physician.

“We worked with the California Department of Public Health,” says Hess. "There was a lot of protocol and paperwork initially, then paperwork to get the word out to Hendricks customers. There were a lot of letters and faxes to physician’s offices."

Each state varies in terms of laws and regulations on what a pharmacist can do at a travel health clinic, so it’s important to learn the parameters, Hess says. "Check with your state board of pharmacy. Figure out what’s going on in your state and try to fill that service in creative ways.”

**Valu-Med Pharmacy**

**MIWED CITY, OK**

*Market to special interest groups.*

After hearing a presentation on how to set up a travel health clinic, Justin Wilson, PharmD, wanted to try it out. So he set up a clinic at one of his three pharmacies. "It kind of exploded from there," Wilson says. That was 12 years ago. Business has expanded every year since the service opened.

On a standard appointment, we do more than grab an arm and give them a shot," says Wilson. "Patients will call us and tell us they are going to Angola, and we use our system to figure out what the current recommendations are in that part of the world, compare shot recommendations with their medical history and make recommendations. We set an appointment, they come in and we do a full consult, giving them shots and a traveler’s health report." Not only does the clinic do individual consultations, Wilson often consults with groups.

"We market to several groups, churches going on mission trips, or businesses planning work-related travel," says Wilson. "If it’s a large group, we go there and do some education, immunize them, and give them all the documents they need."

Documentation is important if yellow fever vaccination is required. "One of the first things that contributed to our success was that we were certified to be a yellow fever clinic — the first pharmacy in Oklahoma, I believe. That differentiated us as a travel health center. Since yellow fever is the only shot that requires documentation, patients seek us out."

The pharmacy offers multiple clinical services, such as diabetes management. "Travel vaccination is probably the most successful clinical service we’ve added," Wilson says.
Team Building Activities for Your Pharmacy Staff

By Jennifer Gershman, PharmD, CPh, contributing writer

Team building activities can help enhance workplace performance and boost morale. These are activities that build trust and enhance communication outside of the practice setting and which can help staff members bond.

Activities should motivate staff to think outside the box and improve how they work with coworkers. Here are some ideas for team building activities that work well for pharmacy staffs.

Karen Berger, PharmD, now practicing at an independent pharmacy in Fair Lawn, NJ, served as the pharmacist-in-charge at a community pharmacy for eight years and used a personal approach to team building. Team building is an ongoing process within the pharmacy and should focus on the team aspect every day, she says. “Pharmacists would be lost without techs, so first and foremost treat them well. A little appreciation goes a long way,” Berger says. Pharmacists can be better bosses by focusing on personal touches like buying lunch or coffee for the staff occasionally. She also recommends “keeping a list of your staff and their birthdays, and be sure to make each person feel special on their birthday.” Other ideas to make the staff feel appreciated include having a snack drawer, hosting a holiday party or potluck at someone’s house, and restaurant outings.

Anyssa Garza, PharmD, BCMAS, is vice president of content and patient education programs at Digital Pharmacist Inc., in Austin, TX. Over the last few years, her company has gone on a variety of team outings. The product/engineering team took to table tennis to find a champion, and the build team went axe throwing. The Digital Pharmacist team went rowing on Lady Bird Lake and competed amongst each other. Scavenger hunts around Austin are another favorite activity. Garza says each December, all the departments create a 3-to-5-minute short film that is premiered at the company meeting.

Escape rooms have become popular and are popping up across the country as a fun activity for team building. These are themed rooms where participants must communicate and work together to find clues and solve puzzles in order to “escape the room.”

“Team building helps you form a different type of bond with your coworkers. With these activities, you get to really know your team from a different perspective. The work environment aspect has been removed, while fun and a little competition have been added,” Garza says. Building friendships with coworkers outside of work is one of the great outcomes of team building activities, she says. “The people you work with are the people you spend most of your day with, aside from your family, so our company really makes these activities a priority.”

“One of the most important aspects of team building is the selection of an activity that all team members are receptive to completing. It is also important that everyone keeps an open mind and be willing to participate in the activities,” says Michelle Clark, PhD, interim dean for Nova Southeastern University College of Pharmacy in Ft. Lauderdale, FL.

Clark, along with the pharmacy department chairs, has developed many team building experiences. Bowling, basketball, paint ball, and yoga are great ways for faculty to unwind and relax. Clark likes to encourage faculty to remove all electronic devices so that distractions are out of the way. She has some innovative team building activities planned for the future, which will include mini-retreats to enhance leadership and communication skills.

All of these team building ideas can be incorporated across different pharmacy practice settings. By finding an enjoyable activity that everyone can take part in, staff communication and morale can improve.
Talking to patients is an important part of a pharmacist’s job, and, as in any customer-service interaction, can occasionally subject a pharmacist to rude or unreasonable behavior. While it’s natural to feel upset when customers are irritable or impatient, the most effective way to defuse the situation is to act in a professional manner and focus on the problem, not the behavior.

“If someone comes in angry and rude, it’s easy to get angry, too,” says Marvin R. Moore, PharmD, owner of The Medicine Shoppe in Two Rivers, WI. “But that’s not going to make the situation any better. I tell my staff, ’Don’t throw fuel on the fire.’ When a patient is rude, take a step back. They are probably having a bad day.”

It’s rarely personal, says Moore, so there’s no need to get defensive. “One thing I’ve learned from dealing with people over the years is that rudeness is often due to something else that happened to them that day,” he says. “They just came from the doctor’s office after a long wait or got unexpected news. This is sometimes the last stop on a rough day.”

Patients may also act inappropriately if they don’t feel well and find it difficult to wait, or if they feel anxious about the prescribed treatment or how to pay for it. “Patients may be cranky and impatient as they enter pharmacies, especially when long wait lines are present,” says Nathaniel M. Rickles, PharmD, PhD, BCPP, associate professor of pharmacy practice at University of Connecticut School of Pharmacy in Storrs.

While it’s not possible to avoid every possible rude patient encounter, here are some things pharmacists can do to reduce how often they occur and react appropriately when they do occur.

Clarify Concerns
Pharmacists should develop strategic line control and crowd control practices and listen carefully to each patient’s needs, says Rickles, noting that after waiting in line, all patients rightfully expect to have all of their questions answered thoroughly. How you answer those questions matters. After listening to the patient’s concerns, try to understand the problem from his or her perspective.

Although it might seem counterintuitive, empathy can be the most effective way to manage the situation, says Roberta Cava, a customer service consultant and author of Dealing with Difficult People. Ignore the rude language and try to sort out the problem. “Assure them that you will do your best to help them,” says Cava. “They have come to you for advice and help. Do your best to try to understand what they want from you.”

To clarify concerns, Cava suggests using language that employs the patient’s own words. Use phrases such as, “It sounds as if the problem is...” and, “Is that what you mean?” to show you are working to understand their concerns. The feeling that someone is listening to them and understands their concerns is sometimes all that’s needed for patients to feel less irritable.

Cava also says something like, “I don’t blame you for being upset. I would be too if that had happened to me.”

If appropriate, apologize in an empathetic way, without admitting fault. A statement such as, “I’m so sorry you are experiencing this problem,” neither shirks nor accepts blame, but can go far to soothe an unhappy customer, she says.
Model Patience
It’s also essential to remember that you’re the expert in a subject many patients know little about.

“Often, patients do not understand their medications or insurance plans and may have a lot of questions,” says Rickles. “Pharmacists should keep this in mind and display patience. Going the extra mile to answer questions is a big part of serving others, and pharmacists should make it their goal to clear up any confusion a patient has about their medication.”

If your pharmacy does not offer the medication a patient needs or the medication is too expensive, still make an attempt to resolve the issue.

“If you can’t solve the problem on the spot, offer to call the patient when the issue is resolved.

“A helpful resolution may be to find another pharmacy that does carry the medication, or to find an alternative medication capable of producing similar results,” says Rickles. “Patients will recognize the extra time spent assisting them, which will increase the probability of their return.”

Explain Delays
The most important thing to remember when dealing with a rude customer is that the customer is always—the customer, says Beverly Schaefer, RPh, co-owner of Katterman’s Sand Point Pharmacy in Seattle. “The customer is not always right, so you need to sharpen your problem-solving skills to think of ways you can help them solve their problem.”

Patients may also have unrealistic expectations of what you can do to solve some of their problems. Explaining how the system works can help prevent future problems. There are many aspects that the patient may not understand.

“Prior authorizations take days,” says Schaefer. “Special products take a day or two to be ordered. Insurance companies are inflexible about refill dates. A change in directions needs a new prescription from the doctor. Vacation overrides need to be initiated by the patient. Calling in a refill from your car and then showing up doesn’t mean it will be ready. Payment is expected at time of service. Help your customers learn to help you serve them better. Everyone will benefit.”

Tone it Down
An unhappy patient may complain loudly and not pause to listen to your attempts to help or explain.

If the patient is yelling at you, Schaefer suggests lowering your voice. “Talk in a quiet voice. They will have to stop yelling to hear you.”

There are situations where a customer’s behavior may cross the line into verbal or physical abuse. While an important part of your job is customer service, you don’t have to let a customer verbally abuse you, or use insulting or racist language, and you should never ignore a threat.

If you feel as if you might lose control of the situation—and possibly display some irrational behavior of your own—take a deep breath, pause for a moment, or even excuse yourself briefly. Let the situation calm slightly and then speak in a quiet voice to see if you can make any progress toward a solution. If he patient is still abusive, you may need to get someone else involved, a coworker, manager, or even call 911 in the case of a threat.

“Dealing with rude behavior is part of customer service, but it doesn’t have to end badly,” says Schaefer. “It is your professional behavior in volatile situations that will help you manage the patient and the problem.”

10 Ways to De-Escalate the Situation
▶ Take a deep breath.
▶ Remain professional.
▶ Don’t take it personally.
▶ Try to ascertain what the problem is.
▶ Listen reflectively. Use their language so they know you are really listening.
▶ Apologize, if appropriate.
▶ Try to solve the problem.
▶ If you can’t solve the problem, refer the patient to someone who can.
▶ If you feel you are losing control, step back and ask for help.
▶ If the customer is being abusive, ask for help.
Dealing with Difficult Colleagues

By Mark Rowh, contributing writer

Nobody would characterize a pharmacy as a stress-free environment. With challenges ranging from avoiding prescription mistakes to dealing with unhappy patients, pharmacists face enough demands even when working with the best of teams. When difficult colleagues are part of the equation, stress levels may rise.

“Working in a pharmacy is usually busy and fast-paced,” says Laura Jones, MPharmS, clinical lead at Assured Pharmacy in Cheshire, UK. “You probably only have time to complete the tasks in front of you to make sure that patients get the treatment they need. When there are colleagues that make this more difficult you may notice that teamwork is also more difficult, and the effectiveness of the team suffers.”

In fact, dealing with challenging colleagues can be seen as a business imperative. At best, difficult colleagues make the work day less enjoyable. But the results may go much deeper.

“They can put the pharmacist under increased pressure, who in many cases will try and cover the areas that are underperforming,” Jones says. “How often have many of us stayed late or started early to try and keep up with work?”

Too often, she points out, a difficult colleague may not be asked to complete certain tasks as an easy way of avoiding conflict. This can increase workload on other team members and may be especially challenging when a change needs to be implemented.

“Difficult colleagues and coworkers cause a risk in safe and effective patient care and great customer service,” says Vinay Patel, PharmD, founder of Self Insured Pharmacy Networks, a benefit management firm in Raleigh, NC. “These colleagues, both pharmacists and techs, create barriers to open two-way communication which impedes maintaining efficient work flows.” He adds that the situation can be especially problematic in settings with two or more openly difficult colleagues, creating an unprofessional work environment.

Types of Difficult Colleagues

Even with the best staffing situation, some team members will be more challenging to work with than others. Here are some of the most common types of problem colleagues, along with tips for dealing with them.

**The slacker.**
Some people consistently do more than what is required. The slacker is just the opposite.

“This person tries to find ways to pass off work to others, never volunteers to help and is the first to abandon the team in a crisis,” says Shital Mars, CEO of Progressive Care, a health services organization in North Miami Beach, FL. A colleague who fits this profile doesn’t really care about the quality of work performed and thus can make frequent mistakes, leading to significant pressure to catch errors and make adjustments throughout the work flow process.

**The turf protector.**
Colleagues with this orientation like things the way they are, and will strive to keep them that way.

“They are very focused on self-preservation,” says Christopher K. Lee, a healthcare business consultant based in San Diego. “They are resistant to change and often react as though others are encroaching upon their turf.”

Such workers tend to be protective of what they see as their territory, he says. They work to maintain control and even if uncooperative actions are not overt,
may rebuff offers of assistance from others or drag their feet in implementing changes in operating procedures.

The pessimist.
Pessimists may do a decent job, but too frequently complain or take a negative position on virtually any issue.

"Pessimists don’t think highly of their job, their coworkers, or the company they work for," Mars says. "They often complain and drag down the morale of those surrounding them. This can lead to interpersonal conflicts, anxiety, high turnover, or quality problems in the work of those around them. "The hardest part of dealing with pessimists is that they project their negativity onto others, making it difficult to pinpoint the real source of a given problem," Mars says.

The complainer.
Everyone complains, but some people make it their specialty.

"These workers like to see the negative in everything," Jones says. "They often spread bad news that they’ve heard, or think they’ve heard, and enjoy seeing their colleagues share in the worry."

A typical stance taken by a complainer is to point out that a coworker has made a mistake or failed to follow a standard process. But the focus is on complaining rather than pitching in to correct the problem.

"They are quick to point it out and discuss the repercussions, but not very quick with possible solutions," Jones says. "This negative attitude can spread through the team and create an unhappy atmosphere for everyone."

The micromanager.
Although this label is often used when referring to a supervisor it can refer to any colleague, according to Jones.

"Micromanagers love the detail and the grandeur of having to deal with complex situations," she says. "This is so even when they are simple cases for everyone else."

She says the added drama can be particularly frustrating when pharmacies are busy and a colleague slows things down by taking unnecessary steps. It can also present problems when processes that are in place are not followed because the colleague wants to do things his or her own way.

The untouchable.
Some coworkers feel they enjoy a special status and as a result, can get away with actions that might not be tolerated in others.

"They may be the hardest to deal with because they are either great at their job, or they have a personal relationship with someone in management and, because of that, they feel a sense of entitlement," Mars says. They may put others down, expect special treatment, or become unreliable.

"They know they’re nearly impossible to let go of, which means they can get away with a lot of things without major repercussions like coming in late, taking long lunches, demeaning the work of others, gossiping, taking more time off than they are due, or demanding pay over and above what would be commensurate for the position."

Tips for Coping
Of course every individual is just that: an individual. Among other challenges, a difficult coworker may display any one of these traits or even a combination of them. But regardless of a colleague’s dominant workplace orientation, following these suggestions can help foster teamwork and limit confrontational situations.

Don’t delay in addressing problems.
"My personal philosophy is always to intervene early," Mars says. "When I first sense trouble brewing between me and my coworkers or even between coworkers themselves, I like to address it." She says that posing simple questions early can quash problems on the spot and help avoid lingering difficulties that are more difficult to manage down the road.

"Many people don’t like to handle interpersonal problems and would rather dismiss them to avoid conflict,"
Mars says, “You’ll never have a happy work environment unless you deal with people being people. By not engaging, a simple problem can become catastrophic.”

**Focus on safety.** Any worries about triggering a negative reaction from a coworker should never take a back seat to safety. Lee advises applying a practice borrowed from the manufacturing world, where when a safety issue is identified, anyone can stop the assembly line.

“Applying this concept to the pharmacy setting, think of near-miss safety risks and drug-drug interactions,” he says. “Anyone who catches one should be empowered to speak up, regardless of how a difficult colleague feels.”

**Strive for service quality.** Working relationships aren’t just about maintaining a pleasant environment. They are also vital to business success.

“If a coworker is inconsiderate or gives patients a hard time, you should step in, whether that involves immediate service recovery or bringing it up to management,” Lee says. “These days, customers have many choices and they don’t want to jump through hoops.” He points to the old adage: One happy customer tells 10 people, one unhappy customer tells 100.

**Look inward.** A reasonable amount of self-analysis is always advisable, according to Mars.

“It’s important to recognize that the problem might be us,” she says. “Sometimes it may seem that our coworkers are difficult, but the problem is really how we interact with them.” She notes, for example, that in times of personal stress, anyone can find themselves being short with colleagues. If relationships with others become strained, pausing to analyze one’s own behavior is never a bad idea.

“Some things we can modify, some things we can’t,” Mars says. “But it always helps when people see us trying to do our best.”

**Consider more than the workplace.** Everyone should leave their personal problems at home, but that doesn’t always reflect reality.

“So often a person can be difficult at work for reasons that have nothing to do with work,” Mars says. “Family issues, money stress, or love lives can put even the best employee in a bad mood.”

This may be especially likely if a coworker’s challenging behavior has not been a long-term pattern, if the colleague is suddenly acting difficult. In such instances, one approach is to point out the problem and ask if there is something going on (work-related or not) that could be affecting work performance.

“Good coworkers will handle these interactions respectfully and admit there is a problem,” Mars says. “They may even open up and ask for advice or ways to improve the situation.”

**Pick your battles.** “Some people will continue to be difficult regardless of your efforts,” Lee says. “Learn to distinguish when to take a stand and when it may not be worth it.”

Before confronting a coworker, pause to ask yourself if the issue at hand is important enough to warrant a frank discussion. Is it a real problem, or just a different approach than what you would prefer?

“Although you may not like the way someone does something or would rather it’s done your way, this does not always mean it needs changing,” Jones says. “If the job is getting done and in a reasonable timeframe, then don’t fight it.” In fact if you’re too quick to criticize, you yourself could be seen as a difficult colleague.

“You don’t have to be friends with everyone you work with,” Jones adds. “But you do have to work with them, so don’t make everything an issue.”

**Know your colleagues.** Perhaps the most important strategy of all is taking the time to know your colleagues well enough to understand their outlooks toward daily work routines.

“Take the time to build deep relationships with team members to better understand them and their perspective,” Patel says.

This doesn’t mean trying to become everyone’s best friend, or being overly accommodating to each person’s pet preferences. But even the most difficult colleagues may seem less challenging if you can gain a glimpse of their point of view.

“Remember that different personality types play a part in how we react to situations,” Jones says. “Understanding each member of the team better can help resolve conflicts by adapting your style.”

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**More Resources for Working with Difficult People**

- **Bad Apples: How to Manage Difficult Employees, Encourage Good Ones to Stay, and Boost Productivity,** by Brette Sember.
- **The One Thing You Need to Know,** by Marcus Buckingham.
- **The One Minute Manager,** by Kenneth Blanchard and Spencer Johnson.
As pharmacists struggle to practice at the top of their licenses and become a recognized and integral part of a care team, these goals are coming to fruition in patient-centered medical homes (PCMHs).

The Agency for Healthcare Research and Quality’s definition of a PCMH emphasizes a care team that includes pharmacists, physicians, advanced practice nurses, physician assistants, nurses, nutritionists, social workers, educators, and care coordinators as key elements. The team provides comprehensive and coordinated care centered around the patient.

The American College of Clinical Pharmacy (ACCP) believes that clinical pharmacists should enhance the care provided by collaborating professionals by sharing their pharmacotherapeutic expertise—rather than serving as a substitute or extender.

Daniel Aistrope, PharmD, BCACP, director of clinical practice advancement for ACCP, considers comprehensive medication management (CMM)—a clinical service that includes an individualized care plan to achieve the intended goals of therapy with appropriate follow-up to determine actual patient outcomes—to be the primary responsibility of a pharmacist in a PCMH.

Aistrope provides support and consultation to members across the country seeking to develop and advance clinical pharmacy services integrated into team-based medical practices, including the implementation of CMM.

According to the ACCP, patients who could benefit from CMM include those who:

- Have not reached or are not maintaining their intended therapy goal.
- Are experiencing adverse effects from their medications.
- Have difficulty understanding or following a medication regimen.
- Need preventive therapy.
- Are often readmitted to the hospital.

“It’s one thing to put therapy problems on paper, but another to bring solutions to reality through team-based care,” Aistrope says. “Optimizing medication therapy is a primary goal in a medical home.”

Pharmacists in PCMHs

Five clinical pharmacists who practice in PCMHs shared their experience with Drug Topics. They have many of the same responsibilities, benefit from many of the same advantages of the setting, and face similar challenges.

In general, their duties include reviewing patients’ medical profiles, reconciling medications, evaluating lab results, assessing the appropriateness of drugs, finding drug-related problems, educating patients, developing a care plan, and following up.

Many PCMHs rely on population management tools to resolve pharmacy-related problems, including registries that:

- Highlight how well patients as a whole and as individuals are achieving certain quality measures and reaching medication goals.
- Find possible pitfalls, such as patients not on appropriate effective medications or who are nonadherent to a drug regimen.
- Identify patients with certain chronic diseases to uncover medication intolerance, side effects, and trouble with polypharmacy.

“These tools help with adherence and indicate if medications need adjustment,” says Liza W. Claus, PharmD, assistant professor and clinical pharmacist at the University of Colorado Anschutz Campus in Aurora.
Kelly Cochran, PharmD, clinical associate professor at the University of Missouri-Kansas City School of Pharmacy and a clinical pharmacist at the University of Missouri General Internal Medicine Clinic in Columbia, serves in a consulting role as part of a collaborative team of primary care physicians, behavioral health professionals, nurse care coordinators, and a dietitian.

The interpersonal and interdisciplinary approach enhances the level of care, Cochran says, and enables the team to better understand patient problems—including social determinants of health—and help solve them. Her team lacks a social worker, which Cochran believes would be a valuable resource, along with additional providers.

Similar to clinical pharmacists in other medical homes, Cochran has access to EHRs, lab data, and patient medical histories, which most community pharmacists do not. She says the information enables her to make ongoing changes in medication therapy.

She and other clinical pharmacists in her practice are part of a collaborative practice agreement with one or more physicians that allows them to assume professional responsibility for performing patient assessments; order medication-related laboratory tests; select, initiate, and monitor medications; and adjust medication regimens.

A PCMH’s Heart

At the heart of a PCMH is integration and coordination, says Daniel Rehrauer, PharmD, senior manager of medication therapy management (MTM) for HealthPartners in Minneapolis. “Working in a medical home, you have access to medical records and work side by side with other members of a care team. If I am working with a patient on a medication issue and discover the real problem is diet related, I can walk down the hall and talk to the dietician or just send a referral. That is much more difficult to do in a community pharmacy setting. With that being said, there are opportunities for community pharmacists to make inroads and form partnerships with local providers,” he says.

“The medical home, however, is what will allow organizations to have success in these new payment models and to spend more time on providing care than on figuring out payment,” he says.

Liza W. Claus, PharmD, of the University of Colorado Anschutz Campus in Aurora, draws some similarities between her role in a medical home with that of a pharmacy. “Both are concerned with medication safety and appropriateness and counsel patients using a medication for the first time or having trouble with a particular drug,” she says.

“One key difference is the location” Claus says. A clinic with close proximity to other providers “creates a physically integrated team giving pharmacists the ability to manage therapy under collaborative protocols.”

Kyle Turner, PharmD, of University of Utah Health, says community pharmacists optimize medications for patients, but their emphasis is on how to take drugs to boost adherence, while in his role in a PCMH, he also manages a patient’s entire drug regimen. “For us, medication therapy management is a marathon, not a sprint,” he says.

One big difference, says Allyson Schlichte, PharmD, of Fairview Uptown Clinic in Minneapolis, is her ability to form relationships with prescribers, which was missing when she served as a community pharmacist. On the other hand, she believes that community pharmacists touch patients more than she does in the clinic and that they are able to reinforce how to take certain medications appropriately.

Rehrauer says that access to patient medical records, documentation from other providers, and shared care plans enables pharmacists to understand when it makes sense to get involved. “This coordination makes it easier to make changes because the system is built to support those decisions,” he says.

On the other hand, Rehrauer faces a challenge recognized by his peers—being able to tell other health professionals of how pharmacists can add value and how it is worth it for medical homes to invest in adding pharmacists to the staff. He says he has successfully accomplished that at HealthPartners.
PCMH Pharmacists as Consultants

Like her counterparts, Claus serves in a pharmacotherapy consulting position aligned with primary care physicians and other team members, including a behavioral healthcare professional, social worker, case managers, a podiatrist, sports medical specialists, telepsychiatry, and a physician assistant. Serving 16,400 people, there are 46 providers (or the equivalent of 12 full-time people) in the PCMH, which also serves as a training site for both pharmacy and medical residents.

Claus also has a part-time practice partner and works with three PGY-2 ambulatory care pharmacy residents, one of whom is with her on a daily basis.

She applies her pharmacy expertise to about 50% of patients who come to the clinic. Most of the patients who receive CMM suffer from chronic diseases such as diabetes and hypertension and are taking multiple drugs. Claus reviews patients’ drug and medical histories to ensure all disease states are being treated safely and effectively and are linked to the right indication, and to avoid drug interactions and side effects.

Serving as Providers

Fairview Health Services has provided MTM services in its clinics—24 primary care and 10 specialty—since 1998. Its MTM pharmacists have cared for 10,901 patients with about double the number of visits in 2018, and have identified more than 130,000 drug therapy problems since the program’s inception.

Allyson Schlichte, PharmD, MTM operations lead and MTM provider at Fairview Uptown Clinic in Minneapolis, says she saw 253 patients with 533 encounters in 2018, to initiate, stop, or change drug regimens. Like her peers, she has a collaborative practice agreement with physicians in her clinic.

In addition to eight physicians, her team includes a social worker, care coordinator, eight medical assistants, four triage nurses, and a PGY-1 pharmacy resident, with access to specialists and a diabetes educator.

“I am looking at the same outcomes as physicians, while also fine-tuning drugs to fit patients’ lifestyles,” she says. “I use layperson’s terms to ensure patients understand why they are taking their drugs and how to take them, while tackling personal and clinical issues to achieve goals.”

In her role at Fairview, Schlichte addresses chronic conditions, including diabetes, depression, hypertension, and asthma for patients discharged from a hospital or referred by her team members.

She focuses her attention on:
1. Indication—whether a drug aligns with a clinical problem.
2. Effectiveness.
3. Safety—interactions and side effects.
4. Convenience—which leads to better adherence when patients know how to take their drugs appropriately.

Schlichte reaps the same advantages as her counterparts at other medical homes but says her access to medical histories is somewhat limited to information found only in an EHR, which she doesn’t believe is 100% trustworthy. She values the data she acquires from pharmacists outside the clinic, as well as information from patients.

Social Determinants of Health

The majority of the clients in Kyle Turner’s PCMH are low income or have a high-deductible plan, which is one reason he pays particular attention to affordability for the 300+ patients he sees as a clinical pharmacist at University of Utah Health. Turner, a PharmD, also spends half of his time as an assistant professor at the University of Utah College of Pharmacy.

He manages medications along with a case manager, who is able to highlight social determinants of health such as income; a social worker; nurses; nine physicians; and a medical assistant. “We serve as a medication resource,” he says.

Turner works with a technician to review claims for coverage and cost to determine affordability and appropriateness from the start, he says.

He schedules meetings with patients with chronic disease to optimize their drug regimens—whether that is choosing the most appropriate and effective drug for the right condition, affordability, or ease of use.

For example, he might weigh the benefits of an older less expensive but equally effective drug against a newer more expensive one. “We rely on evidence-based medicine to ensure effectiveness and fewer side effects,” he says.

While Turner applauds the collaborative teamwork with its multiple disciplines in a medical home, he also is aware of the importance of ensuring the group has synergy above the level of care found in an individual office setting. “You have to make sure you get the right people involved before handing off a patient,” he adds.
Harnessing Technology to Enhance Diabetes Adherence

Matching the technology to the patient

By Tzipora R. Lieder, RPh, contributing writer

Chances are that one in ten people who crossed your path today has diabetes. The CDC’s 2017 National Diabetes Statistics Report estimates that 30.3 million people in the United States (9.4% of the population, and 12.2% of adults) have diabetes, of whom only 23.1 million are diagnosed. Attaining glycemic control so that the macrovascular and microvascular complications of this disease can be avoided involves changes to diet and physical activity as well as drug therapy.

Today there are more tools than ever available to help patients adhere to their medication regimens and manage their diabetes, but education is still key to maximizing the benefits.

The Role of Diabetes Technology

In light of the increasingly important role that technology plays in diabetes management, the 2019 edition of the American Diabetes Association’s (ADA’s) annual Standards of Medical Care for Diabetes has consolidated information that had been spread throughout the standards. It is now in one dedicated section on diabetes technology, says Joshua J. Neumiller, PharmD, CDE, FASCP, chair of the professional practice committee of the ADA, which develops these standards. The section now focuses on use of insulin syringes versus pens,
continuous glucose monitors (CGMs), and insulin pumps, but Neumiller anticipates it will evolve to include other things like apps and other technologies.

According to Jennifer Trujillo, PharmD, CDE, BC-ADM, ambulatory care pharmacist at the University of Colorado Center for Adult Diabetes Care and Research, CGMs, which measure glucose taken from interstitial fluid at five-minute intervals, have been a huge game changer for patients, particularly those with type 1 diabetes (5% of people with diabetes, according to the CDC), helping them with their decision-making about bolus insulin doses.

Real-time CGMs show glucose trends over the last eight hours, display trend arrows that show patients how quickly glucose levels are increasing or decreasing, and alert patients when their blood glucose is falling, which can be a lifesaving feature, says Trujillo.

The Dexcom G6 is a big advancement over older devices, as it can be worn for 10 days, does not require calibration using glucometers, and can interface with smart devices, sharing data with up to five devices, she says. “Parents can look at their phone and know what their child’s blood sugar is and how it’s trending.”

Intermittently scanning or flash CGMs such as the Freestyle Libre, which are less costly than real-time CGMs, require a device to be waved over them to display data from the last eight hours, Trujillo says. Because they do not provide alerts about dropping blood glucose, Trujillo says, flash CGMs may be more appropriate for patients with type 2 diabetes. “Data is power,” she explains. The CGMs “can tell patients what their glucose level is doing all the time, instead of just a couple of independent moments throughout the day.” This enables patients to see how their glucose is impacted by food, exercise, or skipping an insulin dose, she says.

Regardless of which device is used to monitor blood glucose, it is crucial that patients be taught how to use the information they get, says Candis M. Morello, PharmD, CDE, FASHP, director of the Diabetes Intense Medical Management Clinic at the Veterans Affairs San Diego Health System. “We teach them how to use them appropriately so they can learn what their numbers mean and then what to do about them,” she says, “and that always helps adherence.”

Another huge area where technology can aid diabetes management is the plethora of apps that help with carb counting, insulin dosing calculation, healthy eating, setting and meeting fitness goals, maintaining glucose logs, tracking lab data, and more, reports Trujillo. The challenging part is keeping track of new apps since this changes so fast, Neumiller says.

**Table 1: FDA Diabetes Device Approvals 2018**

<table>
<thead>
<tr>
<th>Name</th>
<th>Manufacturer</th>
<th>Device type</th>
<th>Approval date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>MiniMed 670G</td>
<td>Medtronic MiniMed, Inc.</td>
<td>Hybrid closed-loop system</td>
<td>6/21/18</td>
<td>Now approved for ages 7-14 in addition to 14+</td>
</tr>
<tr>
<td>MiniMed 630G with SmartGuard</td>
<td>Medtronic MiniMed, Inc.</td>
<td>Hybrid closed-loop system</td>
<td>2/13/18 (initial approval 6/2/17)</td>
<td>New indication to insert the sensor into the patient’s upper arm.</td>
</tr>
<tr>
<td>Guardian Connect</td>
<td>Medtronic MiniMed, Inc.</td>
<td>CGM</td>
<td>3/8/18</td>
<td>Wirelessly sends glucose levels to Guardian Connect app</td>
</tr>
<tr>
<td>Eversense CGM</td>
<td>Senseonics, Inc.</td>
<td>CGM</td>
<td>6/21/18</td>
<td>90-day implantable subcutaneous sensor</td>
</tr>
<tr>
<td>t:slim X2 Insulin Pump with Basal-IQ Technology</td>
<td>Tandem Diabetes Care</td>
<td>CGM and insulin pump with threshold suspend</td>
<td>6/21/18</td>
<td>Use with Dexcom G5 Mobile CGM</td>
</tr>
<tr>
<td>Freestyle Libre 14 Day Flash Glucose Monitoring System</td>
<td>Abbott Diabetes Care</td>
<td>CGM</td>
<td>7/23/18</td>
<td></td>
</tr>
</tbody>
</table>

Source: FDA
University of Pennsylvania Health System, “but one of those barriers tends to be remembering to inject themselves and making sure they have the supplies that they need at the time, so insulin pumps and continuous delivery devices can definitely help improve adherence, which therefore improves glycemic control overall.”

There are several continuous subcutaneous insulin injection devices or insulin pumps on the market, which deliver basal insulin throughout the day and boluses as instructed by the user. “No one pump is better for everybody,” Neumiller says. Choosing the right pump for each patient involves looking at the options and deciding which is most appropriate. An important safety feature of some pumps is that, when used in conjunction with a CGM, there is a threshold suspend feature so the pump stops insulin delivery if blood glucose levels drop below a predetermined level, Neumiller explains.

Another option for type 2 diabetes patients, according to Morello, is a wearable insulin delivery system (V-go) that is worn as a patch for 24 hours and delivers continuous preset basal insulin and on-demand bolus dosing by pushing a button at mealtimes. “We’ve found that patients using the V-go have had better A1c control and sometimes even with less insulin,” Morello reports. She has also found inhaled insulin (Afrezza) for prandial use to be helpful for adherence, especially in patients who would be frustrated carrying insulin injection supplies.

Afrezza is approved for both type 1 and type 2 diabetes, but is only useful for patients who need lower doses of insulin at mealtimes, she says. For patients using multiple daily injections of insulin there are now vials and insulin pens that keep track of when and how much people are injecting, which can be invaluable in assessing adherence, Neumiller says.

The next level of CGM and insulin pump connectivity is an artificial pancreas. In a hybrid closed-loop system, the insulin pump communicates with the CGM and adjusts the patient’s basal insulin infusion rate based on the CGM data. The first and only available hybrid closed-loop system, Medtronic’s Minimed 670G, has an automatic mode in which it adjusts the basal insulin dose every 5 minutes based on CGM values, suspends insulin up to 30 minutes before glucose levels reach a preset low, and restarts insulin once glucose levels recover. Patients must still initiate bolus insulin doses at mealtimes.

Many manufacturers are working on similar devices, Neumiller says. “We’re moving closer and closer all the time to a fully automated artificial pancreas,” he says.

Changing Recommendations for Type 2 Diabetes

The landscape of type 2 diabetes treatment has been transformed by two new major drug classes: sodium-glucose cotransporter type 2 inhibitors (SGLT2 inhibitors) and glucagon-like peptide-1 receptor agonists (GLP-1 RA), Morello says. SGLT2 inhibitors are oral drugs that work by reabsorption of glucose via the kidneys so that excess glucose is excreted through the urine, while GLP-1 receptor agonists are injectable drugs that help the body release insulin.

“Their overall profiles are very positive,” reports Trujillo. “They lower glucose, they reduce weight, they do not cause hypoglycemia, and they have shown positive results in cardiovascular (CV) outcomes trials, so they reduce the risk of heart attacks, strokes,
and CV-related mortality in patients who have established CV disease."

Both drug classes also slow the progression of chronic kidney disease and the SGLT2 inhibitors also reduce heart failure (HF) exacerbations, Trujillo says.

In light of all this, the ADA’s standards now recommend that patients who fail to meet glycemic goals on metformin monotherapy and have comorbid atherosclerotic CV disease, HF, or kidney disease be treated next with an appropriate drug in the SGLT2 inhibitor or GLP-1 RA classes, Neumiller says.

Additionally, patients that fail combination oral therapy are now advised to consider a GLP-1 RA as the first injectable, he says, as it has some advantages over insulin, including weight loss potential and lower hypoglycemia risk.

In addition to side effect profiles that guide drug choice, a major difference between these two drug classes is their route of administration. Some patients prefer once-a-day oral SGLT2 inhibitors because they are fearful of injectables, reports Smith, but the fact that some of the GLP-1 RA are once weekly injections can sometimes win them over. Morello agrees. “If I can convert them to something that they’re taking four days a month, that’s exceptional at improving the quality of life, they feel happier, and their diabetes control is able to be achieved.”

On the other hand, Neumiller notes, some patients do better with the routine of a daily medication rather than remembering to take a once-a-week drug. He also points out the importance of making sure patients are capable of preparing any injectable drug they are prescribed.

The Pharmacist’s Role
With so many drugs and devices available, why are so many patients still suffering the sequelae of poor glycemic control? There are many barriers. Pharmacists play an important role in helping patients overcome them.

Factors like a patient’s belief about medications and financial problems are huge influences on adherence, says Smith. “A lot of patients are resistant to take meds due to side effects, not understanding how they work, not understanding how they impact the disease states,” she says, “but I think because we have more knowledge of those medications we can definitely help alleviate a lot of their concerns.”

Trujillo’s clinic has a new initiative to identify patients who are struggling with medication costs. “Once you’ve identified those patients you can go down the path of helping them come up with treatment options that are not as expensive,” she says. “Pharmacists really have to step up and be able to navigate that world of insurance coverage, cost savings cards, issues with Medicare and the doughnut hole, Medicare Part D, all of those issues that really impact patients in terms of cost.”

Pharmacists are the frontline healthcare providers, says Trujillo, who are easily accessible to patients. “They can help patients a lot just by listening to what their problems are and helping patients troubleshoot them, which could mean really being a jack-of-all-trades and being well-versed in a lot of different areas related to diabetes.”

The question pharmacists can help patients answer, says Morello, is “How can I manage diabetes and make it fit in my life so that diabetes is not managing me, I’m managing the diabetes?”

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SGLT2 Inhibitors</strong></td>
<td></td>
</tr>
<tr>
<td>Empagliflozin* (Jardiance)</td>
<td>Once daily in AM</td>
</tr>
<tr>
<td>Canagliflozin* (Invokana)</td>
<td>Once daily</td>
</tr>
<tr>
<td>Dapagliflozin (Farxiga)</td>
<td>Once daily in AM</td>
</tr>
<tr>
<td>Ertugliflozin (Steglatro)</td>
<td>Once daily in AM</td>
</tr>
<tr>
<td><strong>GLP-1 receptor agonists</strong></td>
<td></td>
</tr>
<tr>
<td>Dulaglutide (Trulicity)</td>
<td>Once weekly injection</td>
</tr>
<tr>
<td>Liraglutide* (Victoza)</td>
<td>Once daily injection</td>
</tr>
<tr>
<td>Semaglutide* (Ozempic)</td>
<td>Once weekly injection</td>
</tr>
<tr>
<td>Exenatide* (Bydureon)</td>
<td>Once weekly injection</td>
</tr>
<tr>
<td>Exenatide (Byetta)</td>
<td>Twice daily injection</td>
</tr>
<tr>
<td>Lixisenatide (Adlyxin)</td>
<td>Once daily injection</td>
</tr>
</tbody>
</table>

* Has demonstrated benefit on cardiovascular and renal outcomes in published trials (source: Joshua Neumiller, PharmD)

LISTS OF DIABETES APPS:
- Diabetes Forecast: https://bit.ly/2HiwkA

Resources for More Information
- Comparison of insulin pumps: https://bit.ly/2um7jre
- Comparison of CGMs: https://bit.ly/2JBETnY

TABLE 2 New Drug Classes for Type 2 Diabetes
Remedichain Will Connect Patients With Costly Meds

The new program uses Blockchain technology to legally dispense meds to underserved and poor populations

By Drew Boxler, associate editor

As with many other areas of healthcare, blockchain is expected to change how the pharmacy industry works. Blockchain is defined as an open record of transactions, or a ledger, that can be made and distributed to several stakeholders instead of being maintained in one location. Because the integrity of the data is distributed across several blocks, data tampering is more difficult, and transactions are easier to trace.

The platform has given rise to Bitcoin and other cryptocurrencies, and now it is working its way into pharmacy on a few levels.

Ultimately, Blockchain technology will saturate the pharmacy supply chain, and will challenge fraud and waste amid the ongoing opioid epidemic. But the technology may also provide another use—connecting underserved populations with necessary medications.

Philip Baker, PharmD, is the founder of both Good Shepherd Health Pharmacy (GSP) in Memphis, TN, and Remedichain, a new platform using blockchain technology and partnering with major cancer centers around the nation. Building off of one of the pharmacy’s founding principles, Baker hopes to use blockchain to connect unused prescription medications with populations that are most in need of them.

DT: How did Remedichain evolve from GSP?

Baker: GSP opened in September of 2015. We are a nonprofit 501(c)(3) charity pharmacy. We opened with a supply of meds that we got through manufacturer donations that were for low-income uninsured people.

That was great. But it wasn’t nearly enough. Drugs that we couldn’t get through donation, we started buying and selling at cost.

I knew that I was never going to contract with PBMs. We are not registered with Medicare or Medicaid. We don’t want to play with any third parties—we would always be a direct-to-consumer business. Donated medications allowed us to get started buying drugs and selling them at cost.

I worked six years as a pharmacy manager in retail. I saw people leaving their medications at the counter because they couldn’t afford them. It was just criminal, to be quite honest. “Clawbacks” are well documented now, but 10 years ago I was seeing that.

We believe that the value a pharmacist provides is completely independent of the cost of the medication. Whether it’s a $1 or $100 pill, the value that we bring to the table remains the same.

The education, the medication review, counseling the patient. It doesn’t matter what the cost of the pill is.

We set up a membership pharmacy, three-years running now. Our members pay a fixed monthly membership fee. If we can get their medications for free through donations and [the members] qualify, then we dispense those for free. If we can’t, then we order the meds and sell them at cost.

We’re honest about the costs, and we actually lose money when it’s all said and done.

In the state of Tennessee, [medication reclamation] was illegal. Back in 2016, I started to get the law changed. I researched every reclamation program in the country, looked at the laws in every state, and found that a lot of states had...
Q&A

laws that would allow programs.

I knew if we started a program, we had to figure out how to make it financially self-sustainable.

The longest and most successful program in the country is SafeNet in Iowa. They’ve been reclaiming medicine and redispensing for seven or eight years for several million dollars, but they’re completely dependent upon money from the state. If their funding were to get cut, they would go out of business. I didn’t want to go down that road.

And that was pretty much the genesis of Remedichain.

Last February, I started learning about Blockchain. There are several movers in the pharmacy space and blockchain because it is such a good use case. I was surprised to find out how early on we are.

[My presentation at the FedEx Institute of Technology last year] opened the door. I’ve learned more about Blockchain as a workaround with PBMs, to just work directly with the customer and a new infrastructure that could allow you to build the “claims.”

For example, I can work with an employer and fill prescriptions for his employees and just bill him directly, without having to run [the bill] through the PBM and have the pharmacy’s money tied up for six weeks waiting to be reimbursed.

Q: How does this program work?

Baker: Any individual donor will go to our website, register the donation, and mail the donation to us at their own expense or take it to one of our local partner donation cancer center sites. (The website will capture all of the HIPAA-related stuff.)

Oncology clinics can partner with us and it doesn’t cost them anything. The clinics don’t have to maintain any sort of paperwork, just have a box to accept donations.

When we get two or three donations, we’ll come and pick it up. We’ve tried to make it as easy as possible with no extra work for the cancer clinics and no liability.

Q: How do you plan to expand Remedichain’s services and scope?

Baker: What I don’t want to do is build a megapharmacy in Memphis. My goal is to redefine what community pharmacy is and to give local independent pharmacists tools to keep their doors open.

The system we’re building is twofold. It allows the independent pharmacist to contract and create an infrastructure outside of PBMs. The same system will be used to scale our nonprofit pharmacies, which [distribute] the donated meds.

It’s a new way to do claims that doesn’t take a huge cut out of the pharmacy’s pockets. It makes drugs cheaper, and the profit margins higher—it’s a win-win.

Remedichain is focused on oncology meds. Oncology clinics can partner with us and it doesn’t cost them anything. That’s intentional, but not all we plan to do.

We want to reclaim and reuse anything of value. To that end, we have connections in Tennessee and Iowa. There are 14 other states where we have partners. It’s definitely a national program in scope.
Prucalopride Approved for Idiopathic Constipation

By Kathryn Wheeler, PharmD, BCPS

In December, prucalopride (Motegrity, Shire) received FDA approval for treatment of chronic idiopathic constipation. It is a prokinetic agent that stimulates selective serotonin type 4 receptors, which results in increased peristalsis and gastrointestinal motility. It is approved for use in adult patients.

Efficacy
Prucalopride was approved based on the results of six randomized, double-blind placebo-controlled multicenter clinical trials that included 2,484 adult participants. Treatment lasted 12 weeks in five of the studies and 24 weeks in one study.

Eligible participants had a history of chronic constipation (defined as fewer than three spontaneous bowel movements per week that provided a feeling of complete evacuation) and at least one of the following for at least 25% of bowel movements over the previous three months: hard stools, straining at defecation, or a feeling of incomplete evacuation. Patients were not eligible for the studies if constipation could be contributed to another medical condition or medications. All participants less than 65 years of age received 2 mg of prucalopride daily. In five studies, participants older than 65 years were initiated on 1 mg of prucalopride daily. The dose was increased within two to four weeks based on effect.

Across these studies, 81% of geriatric patients initiated on 1 mg later received the higher dose. During the trials, participants were defined as responders if, over the course of 12 weeks, she or he reported an average of three or more complete spontaneous bowel movements (CSBM) weekly. Overall, more responders across the studies had been given prucalopride than placebo.

This primary endpoint was achieved with statistical significance in five of the six studies. Participants taking prucalopride could experience improvement of symptoms as early as the first week of therapy and maintained the benefits through week 12.

Safety
Prucalopride is contraindicated in patients with intestinal obstruction or perforation. The manufacturer includes a warning to immediately discontinue prucalopride if depression worsens or suicidal ideation or behavior occurs. Patients should be counseled to discontinue prucalopride and call their prescriber if these conditions occur.

The most common adverse effects occurring in study participants included: headache, abdominal pain, nausea, abdominal distension, dizziness, vomiting, flatulence, and fatigue. These adverse effects occurred in both participant groups, but each occurred with greater frequency among participants administered prucalopride. Collectively in the six studies, 5% of participants who were given prucalopride discontinued therapy compared to 3% of participants receiving placebo. The most common adverse reactions leading to discontinuation of therapy were nausea, headache, diarrhea, and abdominal pain. There is insufficient data on use of prucalopride in pregnancy or lactation.

Prucalopride is found in breast milk. Its effects on milk production and the child are not known.

Dosing
Prucalopride is available as 1-mg and 2-mg tablets that can be taken with or without food. It is approved for use in adult patients as a once daily 2-mg dose. Patients with severe renal impairment (CrCl<30 mL/min) should take a reduced dose of 1 mg daily. Prucalopride is a substrate of CYP 3A4.

Studies to date have not identified clinically significant interactions with coadministration of other drugs.
LEGAL MATTERS

By Natalia Mazina, JD

Copays Required

Government and PBMs can pursue penalties for noncompliance

Do you remember the old practice of simply waiving copays if a patient could not afford them? If you do, forget it completely because waiving copays presents the following legal issues:

Contractual violations. All PBMs’ manuals and third-party payer contracts require that participating pharmacies collect deductibles, copays, or coinsurance amounts. If during a PBM audit, the pharmacy cannot present evidence it collected copays or made a fair attempt to collect, the PBM usually initiates a recoupment of all reimbursements paid to the pharmacy for medications on which the pharmacy failed to collect copays. Then, PBMs usually terminate the pharmacy out of their network.

Violations of state and federal laws. Under federal laws and most state laws, routinely waiving copays raises potential Federal Anti-Kickback Statute, Federal False Claims Act, and state law liabilities.

Insurance fraud. Waiving copays often constitutes health insurance fraud because the pharmacy misrepresents the correct charge for dispensing medications. Let’s say a patient has a $5 copay. The PBM will reimburse the pharmacy $45 for a $50 drug. If the pharmacy waived the copay, the actual cost of the drug is not $50 but $45. Waiving the copay in this scenario would affect the pharmacy’s usual and customary drug price.

If a PBM discovers the pharmacy was routinely waiving copays, it usually raises all of the above legal issues.

I have represented pharmacies where PBMs claimed millions of dollars for overpaying the pharmacies. Not only did these pharmacies face significant recoupments and contractual terminations, they also faced criminal investigations.

PBMs are obligated to report any suspected healthcare fraud to the U.S. Department of Justice and state departments of justice for Medicaid.

In a recent case, Express Scripts (ESI) terminated HM Compounding Pharmacy from its pharmacy provider network for misrepresenting during a recredentialing process, claiming that it never waived or discounted member copays. HM sued ESI asserting various statutory and common law claims against ESI.

The evidence established that HM breached ESI’s agreement by failing to collect copays, and therefore submitted manipulated usual and customary cash prices for reimbursement. After four years of litigation, HM pharmacy lost the case and had to pay $20 million to Express Scripts.

There are only two scenarios when a pharmacy may waive copays:

1. Financial Hardship. If a patient presents evidence of financial distress, the pharmacy must document such evidence with a financial hardship form and make copies of all information presented by the patient in support of waiving the copay, such as Medicaid cards, pay stubs, tax forms, etc. This practice should never be advertised and should be applied to all patients. In other words, if you allow Medicare patients to submit financial hardship forms, you should do the same for all patients.

2. Inability to collect copays. This usually applies for delivered or mailed medications. Pharmacies must pursue debt collection against patients and record all conversations with patients regarding financial responsibilities. During an audit, the pharmacy should be able to provide evidence that a good faith effort was made to comply with the law and healthcare contracts.

A typical procedure under this scenario is to send an invoice to the patient, follow up, send another letter notifying of collection efforts, and write off the amount as uncollectable copay.

Collecting copays will continue to be a focus of government enforcement and PBM audits. Many PBMs require that pharmacies have policies and procedures describing its collection practice and circumstances under which copays may be waived. If you have such policies and procedure, review them, educate your staff, and enforce them regularly. If you do not have such policies in place, it is time to draft them.

“There are only two scenarios when a pharmacy may waive copays: financial hardship and inability to collect.”

Natalia Mazina, JD, is the founder of Mazina Law, a healthcare law firm in San Anselmo, CA, focusing on pharmacy law and legal issues that pharmacists face in their day-to-day operations. Natalia represents pharmacies and pharmacists in regulatory compliance, PBM audits, government investigations, and business formation.

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