New Roles for Pharmacists
Value-based pay creates opportunities

Inside

Diabetes Drug May Ease Nicotine Withdrawal
CVS Denies Medicare Lawsuit Claims
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.
NEW ROLES

The pharmacist’s role is expanding as the healthcare arena moves from fee-for-service to value-based payments.
NEW for the treatment of *Clostridium difficile*-associated diarrhea (CDAD)¹

**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**
- FIRVANQ™ must be given orally for treatment of *C. difficile*-associated diarrhea and staphylococcal enterocolitis. Orally administered vancomycin hydrochloride is not effective for treatment of other types of infections.
- 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 *C. 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.

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 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.

### CONTRAINDICATIONS

- Hypersensitivity to vancomycin

### WARNINGS AND PRECAUTIONS

- FIRVANQ™ must be given orally for treatment of C. difficile-associated diarrhea and staphylococcal enterocolitis. Orally administered 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 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 the 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.

- Ototoxicity 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 intracamerall 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 1: Common (≥5%) Adverse Reactions* for Vancomycin Hydrochloride Reported in Clinical In Clinical Trials for Treatment of C. difficile-Associated Diarrhea

<table>
<thead>
<tr>
<th>System/organ Class</th>
<th>Adverse Reaction</th>
<th>Vancomycin Hydrochloride (%) (N=260)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal disorders</td>
<td>Nausea</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Diarrhea</td>
<td>9</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>Infections 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.

### USE IN SPECIFIC POPULATIONS

- **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. Hemosfiltration 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 CutsisPharma, Inc. at 1-800-461-7449, EXT 103; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Initial U.S. Approval: 1964  Manufactured for Cutsis Pharma
841 Woburn St, Wilmington, MA 01887 USA
Rev. 2/2018
The delivery and financing of U.S. healthcare is changing rapidly. Pharmacists and other healthcare professionals have to reinvent themselves as healthcare becomes more of a retail business. With the threat of new competition, the pressure for pharmacists to add value in healthcare is mounting.

Ensuring the appropriate use and management of specialty pharmaceuticals is one area in which pharmacists can offer unique and necessary expertise. These medications will have a profound impact on the practice of pharmacy over the next ten years as they consume more of the healthcare dollar. They will affect all pharmacy practice settings—e.g., community, hospital, long-term care, etc.—accelerating the importance of medication management to ensure the appropriate use of these therapeutic agents.

Retail, mail-order, and specialty pharmacies account for the distribution of about 45% of specialty drugs that are covered under the pharmacy benefit. The majority of specialty pharmaceuticals are distributed and administered in the physician’s office, an outpatient setting, or as home infusion. All are covered under the medical benefit.

The role of the pharmacist in the physician’s office will emerge as a way to manage patients taking certain specialty medications. Currently, patients taking specialty pharmaceuticals represent only 1% of the patient population, yet, amazingly, they represent 30% of total drug spend.

As specialty pharmaceuticals costs escalate—some in excess of $50,000 annually (e.g., Solvaldi, Olysio)—it makes sense to place pharmacists closer to the patient. Even home visits will have direct pharmacist involvement for patients when using these medicines.

Some community pharmacists can fill this role where appropriate, if they can help patients improve drug use, minimize waste, and increase patient safety.

Systems will be developed to track patients across the healthcare system to ensure appropriate specialty medication use.

The most recent impact to the delivery of specialty drugs is “personalized medicine.” This term relates to the use of genetic testing—genomics—to guide the dispensing of the optimal type and dosage of a drug for a specified healthcare condition, through the identification of a patient’s individual cellular and genetic makeup. For example, genetic testing can provide information about patients’ liver enzymes and predict the rate they metabolize specific drugs. This information provides guidance to the prescribing physician in the medical management of a patient. This is an opportunity for the community pharmacist to work in collaboration with physicians.

Clearly, healthcare will need a different approach to the optimal dispensing of specialty pharmaceuticals. We have known this for years. The industry will need creativity and focus to demonstrate just how far specialty pharmaceuticals can take us.

The role of the pharmacist will be critical as specialty pharmaceuticals consume more of the healthcare dollar.

**MORE INSIDE**

**New Roles for Pharmacists**

The role of the pharmacist is expanding and more and more physicians are welcoming pharmacists into their practice.
CVS Health is denying allegations that its PBM, CVS Caremark, charged Medicare for higher prices than it was paying pharmacies.

“We believe this complaint is without merit and we intend to vigorously defend ourselves against these allegations,” Mike DeAngelis, senior director of corporate communications for CVS Health, tells Drug Topics. “CVS Health complies with all applicable laws and CMS regulations related to the Medicare Part D program, and the government filed a notice of declination with regard to this complaint.”

Aetna filed the lawsuit in U.S. District Court in 2014, but it was unsealed after the government declined to intervene in the case in early April.

In addition to the Medicare charges, Aetna claims that CVS Caremark “carefully managed the [maximum allowable cost] prices so as to hit the minimum aggregate discount it had guaranteed Aetna, but not to allow Aetna to get the benefit of any lower prices,” the complaint states.

DeAngelis says CVS Health is committed to helping patients and payers with solutions to lower their prescription drug costs. He added, in 2017, CVS kept drug price growth nearly flat for its PBM clients, despite manufacturer price inflation at near 10%.
Study: Smoking Cessation Drugs Don’t Increase Cardiovascular Risk

While concerns have been raised about the cardiovascular risks associated with smoking cessation drugs, a recent study found no evidence that varenicline (Chantix) and bupropion hydrochloride (Zyban, Wellbutrin) heighten the risk of serious cardiovascular adverse events.

Researchers conducted a double-blind randomized placebo- and active-controlled trial, along with a nontreatment extension trial, at 140 multinational centers. More than 8,000 smokers received either varenicline, bupropion hydrochloride, or nicotine replacement therapy.

The incidence of cardiovascular events during treatment and follow-up was low, at less than 0.5% for a major adverse cardiovascular event. “No significant treatment differences were observed in time to cardiovascular events, blood pressure, or heart rate. There was no significant difference in time to onset of [a major adverse cardiac event] for either varenicline or bupropion treatment versus placebo,” the researchers say.

The findings provide further evidence that “smoking cessation medications do not increase the risk of serious cardiovascular events in the general population of smokers,” the researchers add.

Psychiatric Pharmacy Needs to Show Value

Only when psychiatric pharmacy aligns performance and productivity metrics with the goals and priorities of patients and organizations will the profession be able to demonstrate its full value, psychiatric pharmacists concluded in a new editorial.

An American Journal of Health-System Pharmacy editorial, written by two psychiatric pharmacists and which accompanied a benchmarking report on state hospital pharmacies, notes an increase in pharmacist and technician full-time equivalents in state hospital psychiatric pharmacy departments, but also noted that staff:bed ratios remain “strikingly lower” than in non-psychiatric hospitals.

In addition, more than 30% of hospitals reported using no indicators to monitor pharmacy productivity, the report on 116 state hospitals reveals.

“The time has come to redefine pharmacy productivity metrics and align them with organizational goals and priorities to ensure sustainability and success in this new era of healthcare. Psychiatric pharmacy presents the opportunity to increase access to evidence-based care,” which should help ensure optimal outcomes for patients in acute and ambulatory care settings,” writes Tanya J. Fabian, PharmD, BCPP, associate professor of pharmacy and therapeutics and psychiatry at the University of Pittsburgh, and Jamie L. Montgomery, BSpPharm, BCPP, with pharmacy services at Western Psychiatric Institute and Clinic.

Government Targets Fentanyl, Heroin Ring

A recent government crackdown on illegal drugs removed thousands of pounds of fentanyl and heroin from the streets.

Operation Saigon Sunset, a joint effort between the U.S. Department of Justice and federal and state authorities, targeted 100 defendants for arrest who are part of a major multistate heroin and fentanyl distribution network, called the Peterson Drug Trafficking Organization.

The initiative “removed from our streets enough fentanyl to kill more than 250,000 people and massive amounts of other drugs that would have wreaked havoc and misery on our good citizens,” says U.S. Attorney Mike Stuart. “Best yet, today’s actions have resulted in the destruction of a supply network, the supplier of suppliers of illicit drugs. The peddlers of poisons like heroin and fentanyl are in the crosshairs of this Administration and law enforcement.”
ASHP Releases New Pediatric Pharmacy Guide

ASHP, in collaboration with the Pediatric Pharmacy Advocacy Group (PPAG), released updated national guidelines outlining best practices for pediatric pharmacy care in hospitals and health systems.

The ASHP-PPAG Guidelines for Providing Pediatric Pharmacy Services in Hospitals and Health Systems describe opportunities for pharmacists to contribute to the care of pediatric patients as part of a healthcare team and offers recommendations to address current and future challenges in pediatric pharmacy. For example: hospital and pharmacy department policies should encourage pharmacists with pediatric training to provide direct patient care, and, when possible, 24-hour pharmacy services should be provided to the pediatric population.

“Providing care to pediatric patients poses unique challenges for pharmacists, including limited data on the safety and efficacy of medications as well as operational demands and requirements that differ dramatically from those in a practice focused exclusively on adults,” says Vicki Basalyga, PharmD, BCPS, director of the Section of Clinical Specialists and Scientists at ASHP. “These guidelines will help ensure that pharmacy departments are equipped to address these issues and provide pediatric patients with care that is safe and effective.”

The guidelines include:

- Preparing
- Packaging and labeling medications
- Developing medication-use policies
- Addressing staffing and facility needs
- Strategies for managing drug shortages
- Selecting appropriate drug administration devices

Small Epi Injector Available

The first epinephrine autoinjector for infants and toddlers designed specifically to treat their allergic reactions, including anaphylaxis, became available in early May.

There was an estimated 130% increase between 2005 and 2014 in emergency room visits for anaphylaxis among children four years old and younger. It is estimated that nearly 39% of children with food allergies have a history of severe food-induced reactions.

FDA approved Kaleo’s AUVI-q (epinephrine injection, USP) 0.1 mg, for infants and toddlers weighing 16.5 to 33 pounds. AUVI-q has a shorter needle length and a lower dose of epinephrine than other FDA-approved epinephrine auto-injectors (EAIs), according to the manufacturer.

“Before the introduction of AUVI-q 0.1 mg, the youngest and most vulnerable population did not have a treatment for anaphylaxis designed for them,” says Eric S. Edwards, MD, PhD, vice president of innovation and research and development at Kaleo. “This day means a lot to me personally, as I suffer from life-threatening allergies and have a child who was diagnosed with life-threatening allergies as an infant.”

Before the introduction of AUVI-q 0.1 mg, the youngest and most vulnerable population did not have a treatment for anaphylaxis designed for them.”

ERIC S. EDWARDS, MD, PHD

Reference: Christine Blank is a contributing editor.
QS/1®'s SharpRx Pharmacy Management System is a completely new approach to pharmacy that works intuitively, so it’s easy to learn and use, allowing employees to be productive quickly.

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To learn more about QS/1’s new SharpRx Pharmacy Management System, visit www.qs1solutions.com/SharpRx, call 866.860.1332 or scan the code.

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The pharmacist’s role is expanding as the healthcare arena moves from fee-for-service to value-based payments.

“Physicians are warming to the idea of working alongside pharmacists in their practice settings. In fact, not only are they warming to it, many physicians are carving out a pharmaceutical piece of part of their risk-sharing agreements,” says Susan Cantrell, RPh, CEO of the Academy of Managed Care Pharmacy.

Medicare accountable care organizations (ACOs) do not directly include pharmacists and medications, but appropriate medication management is necessary to ensure success of value-based arrangement, Cantrell explains. “Therefore, we are seeing a trend where physicians are trying to integrate pharmacists and medication management to achieve good outcomes,” she says.

Medication therapy management (MTM) is one of the biggest areas in which physicians increasingly rely on pharmacists, says Lucinda Maine, PhD, RPh, executive vice president and CEO of the American Association of Col-

Kathleen Gannon Longo
In some cases, pharmacists embedded in practices or hospital pharmacists are meeting with patients prior to physician visits and conducting thorough medication reviews and assessments. “This relieves the physician of doing that part of the care plan,” she says. “Once physicians see the value of the pharmacist, they don’t want to practice any other way.”

Community pharmacists are also experiencing role changes, as they too are providing medication management across the continuum of care. Some community pharmacists are partnering with nearby hospitals to more thoroughly counsel patients regarding medication and adherence. The expanding role of pharmacy technicians and robotics should also liberate these pharmacists to take on more of these tasks, says Maine.

Here’s more on how the role of pharmacists is changing in various practice settings.

Community Pharmacy
Community pharmacy is the biggest area in which pharmacists can be better used because they have such frequent interactions with patients, says Marilyn Stebbins, PharmD, vice chair for clinical innovation, University of California San Francisco (UCSF) School of Pharmacy. “Most people visit a retail pharmacy more than 20 times a year; this is where the pharmacist’s impact is the greatest,” she says. Pharmacists are offering vaccinations, blood pressure screenings, and counseling on specific disease states such as diabetes. “In the retail setting, MTM, and not dispensing, should be the priority,” says Stebbins. “In this way, pharmacists can help improve outcomes and show their value.”

Community pharmacists are also experiencing a growing role as hospitals look to them as a resource to improve adherence and reduce readmissions, a key metric in many value-based payment arrangements.

One example is the “Meds to Beds” program at UCSF. Pharmacists from two retail pharmacies on the hospital campus meet with patients before they leave the hospital. The pharmacists explain the discharge medications and then follow up with patients to ensure they are compliant. The program has had good results, says Stebbins.

Pharmacists Recruited for Public Health Initiatives
In Ohio, 52 out of 88 counties are considered underserved, says Mehta. Ohio State University is offering a training program in public health to 125 pharmacists throughout the state. The course content includes public health resources, health information technology, and best practice models for federally-funded health centers and other free clinics.

“It’s important for patients in these areas to have access to pharmacists, as well as public health and other community resources,” says Mehta.

Specialty pharmacy is another model in which pharmacists are expanding their skills in both the retail and the hospital setting. Specialty pharmacies focus on high-risk patients who need intensive monitoring and intervention, explains Gary Matzke, PharmD, professor, Virginia Commonwealth University School of Pharmacy in Richmond. Walgreens, for example, has pharmacies dedicated to oncology and HIV, where pharmacists perform extensive medication reviews and work closely with the patient to ensure compliance. The specialty pharmacy “contracts with pharmaceutical companies to ensure the provision of product care,” Matzke adds.

Health-System Pharmacy
Pharmacists are now helping patients navigate the move from the health system to home or to another facility, an area covered by ambulatory care pharmacy. The Board of Pharmacy Specialties reports that 3,257 pharmacists are currently certified as ambulatory care specialists. The specialty ranks third in numbers, behind geriatric pharmacy (4,432) and pharmacotherapy (21,771).

Ambulatory care encompasses pharmacy practice in clinical settings that could include ambulatory care clinics, physicians’ offices, retail pharmacies, and pharmacies affiliated with long-term care facilities, says Ernest Wright, senior man...
The expanding role of pharmacy technicians and robotics should ‘liberate pharmacists’ in retail stores.”

—Lucinda Maine, PhD, RPh.

As new patient care models emerge, “we have to ensure that future pharmacists, as well as those pharmacists who have been in the workforce for 10 to 20 years, have the skill sets to move into these areas,” says Mehta. At OSU, “students have required interprofessional experiences and learn alongside medicine and other disciplines,” says Mehta. “As part of the curriculum, pharmacists learn about the different healthcare professions and how they can work collaboratively in team-based models.”

Internships in which students shadow pharmacists in different practice settings, as well as participating in independent research studies, are now emphasized early on to pharmacy students throughout the country, says AACP’s Bradley-Baker. Cantrell agrees that the training of pharmacists has changed dramatically. “As the profession moves forward, curriculums are focused on “the pharmacist as the medication expert … training the pharmacist to manage patients’ medication therapy.”

But Matzke warns that schools may not be able to provide experiential sites for all the students who need to receive on-site training within the new pharmacy models. While he feels students are being adequately educated/trained in the classroom, “until a student is actually responsible for the delivery of direct patient care, one does not know how they will perform.” He says more sites will open up, but it may take time.
More Industry Leaders Embrace Pharmacist Reimbursement

More than 100 healthcare executives were asked their thoughts on whether pharmacists should be reimbursed for their time conducting MTM and counseling patients. The executives were from large healthcare systems, benefit management organizations, health plans, long-term care organizations, group purchasing organizations, and more. They were asked:

Should pharmacists be compensated under Medicare Part B for prescribing medications and helping assess patient conditions?

**Yes** 76%

**No** 24%

Source: *Managed Healthcare Executive* Managed Care Pharmacy Survey 2018.

Pharmacists identified high-risk patients at hospital discharge, and from that point, coordinated among the clinic, the patient’s primary care physician, and the community pharmacist. High-risk patients were those with multiple disease states who were taking four or more long-term medications.

“We saw significant improvement in all clinical and utilization end points,” says Matzke. In looking at end points, blood pressure improved in participating patients, as well as cholesterol levels and A1c levels. “And many of the clinical results as well as the degree of hospital utilization were significantly better in the pharmacist group than in the retrospective control group that received usual care,” he adds.

Senior Care

Geriatrics is another area in which pharmacists are using their MTM skills to improve patient outcomes. “With the current demographics—with the baby boomers getting older and living longer—this generation is remaining a vital active member of the community,” explains Lynette Bradley-Baker, RPh, PhD, vice president for public affairs and engagement at AACP. “Subsequently, pharmacists are being asked to provide care in nursing homes and long-term care facilities.” In these settings, “MTM is critical to controlling chronic disease management,” she says.

A program at UCSF called “Care at Home” has the pharmacist addressing the needs of the older homebound patient...
via an e-visit. “It isn’t home healthcare, per se, but involves elderly, frail patients at higher risk who receive most of their healthcare in their home,” Stebbins explains. The program is a collaboration between the School of Pharmacy and the School of Nursing. “Through videoconferencing, the patient can receive a pharmacy consult at home,” she explains. “Additionally, the pharmacist may visit the home with the nurse practitioner, examine the patient’s medications and where they’re kept, and make recommendations.

**Managed Care**
In the managed care setting, more pharmacists are getting involved in utilization management programs for patients covered by Medicare Part D, says Cantrell. Ensuring proper usage can help curb costs, therefore helping organizations reach cost-based metrics in value-based arrangements.

Breaking it down further, pharmacists may be involved in population health management initiatives, in which healthcare organizations attempt to improve outcomes and reduce costs of care associated for groups of patients within specific disease states and demographics. “Pharmacists are involved in evaluating trends, evidence, and data to determine appropriate treatments, including medications, or preventative measures that will improve health among the patient population at a macro level to be implemented by individual clinicians, says Cantrell.”

In addition to offering these services in traditional managed care settings, such as ACOs, the managed care pharmacist is finding a new site in the in the physician’s office, says Cantrell. Placing these pharmacists in a doctor’s office, “allows them to be visible and lets the public see how they can improve patient care,” she says.

**Reimbursement**
As pharmacists move into new models of care and into new areas of employment, changes in how they are reimbursed must follow. Reimbursement for the provision of pharmacy services has long been a concern for the profession as a whole. “As the healthcare arena is moving toward paying for value, we’re seeing things move in the right direction for pharmacists,” Cantrell says.

Currently, pharmacists may bill for MTM services under Medicare Part D, but, says Stebbins, it is not automatic. “Not every Medicare Part D Plan allows pharmacists to bill; it is on a contractual basis.” In individual states, billing for services is contingent upon provider status, but Stebbins notes that while California is one of the most progressive states in recognizing the value of pharmacists, “pharmacists aren’t being paid, in most cases. The payment models need to be worked out.”

One innovative payment model in California was established by Inland Empire Health Plan, a Medicaid managed care plan. Inland Empire implemented a pharmacy network, designed to provide targeted care to patients with chronic illness and allows pharmacists to bill for MTM services. This pay-for-performance program evaluates pharmacies on a set of seven quality metrics and provides bonuses to high quality pharmacies.²

Pending federal legislation would allow pharmacists to bill for services under Medicare Part B. Once that is approved, pharmacists will be able to embrace their new roles, says Mehta. Some private insurers are also allowing pharmacists to bill, in some instances, says Matzke. But, he adds that adequate reimbursement doesn’t have to be dependent on billing for services. In a clinic, for example, “payment to the pharmacist is carved out of the payment that comes to the practice as a whole.” If the pharmacist is valued and can increase efficiency, Matzke says, the pharmacist will be appropriately compensated. Lack of provider status shouldn’t hold pharmacists back from stepping up to the plate and providing optimal patient care.

Kathleen Gannon Longo is a contributing editor.

**REFERENCES**
INTRODUCING A full line of over-the-counter products specifically formulated for people with diabetes

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**Cold & Flu**
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**Multi-Vitamins**
- Supports eye, metabolism, heart, and nerve health
- Sugar and gluten free

**Dry Eye Relief**
- Lubricant eye drops for irritated eyes
- Long lasting protection

**Foot Cream**
- Hydrates and helps restore severely dry skin
- Non-greasy

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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- H-E-B
- Meijer
About 3.8 billion prescriptions are written each year; but an estimated one in five are never filled, according to a 2017 Morbidity and Mortality Weekly Report from the CDC. In addition, approximately 50% of prescriptions are taken incorrectly based on timing, dosage, or frequency of duration recommendations.

Each year, nonadherence costs are estimated by the CDC to be between $100 and $300 billion in the United States.

Research shows that pharmacist counseling can improve patient adherence, but despite these studies, overall adherence rates have continued to remain low over several decades.

“We haven’t changed the way we talk to patients,” says Bruce Berger, PhD, president of Berger Consulting, a company that provides education and training on motivational interviewing techniques. “We’re stuck in an old paternalistic model of care, where we tell people what to do and assume if we educate them that’s enough.”

To enhance patient counseling skills, experts believe pharmacists need to move beyond reciting medical knowledge to a more collaborative and conversational approach—even when the time for each patient interaction is short.

Obstacles to Effective Patient Counseling
Jen Alexander, PharmD, pharmacy manager at NuCara Pharmacy in Pleasant Hill, IO, says that time is the biggest obstacle to effective counseling. In her role at a regional chain she’s given sufficient time to interact with each patient, but says she’s had jobs in the past where that wasn’t the case.

“They need to see your face, they need to know who you are, and need to know you are doing what is best for them even if they are in a hurry.” Jen Alexander, PharmD

“…”The other thing is patients who aren’t receptive, and that’s discouraging,” she says, adding that even in these cases she tries to highlight the most important information for a patient for a given medication. In a hospital setting, patients may not be receptive to counseling efforts because they may be overwhelmed by a new diagnosis or simply aren’t in a frame of mind where they can process the information, says Jacqueline L. Olin, PharmD, BCPS, FASHP, professor of pharmacy at Wingate University School of Pharmacy, Charlotte, NC.

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Brittany L. Melton, PhD, PharmD, assistant professor of pharmacy practice at the University of Kansas School of Pharmacy, and her colleague Zoe Lai, recently assessed pharmacy services

C O M M U N I C A T I O N S  S T R A T E G I E S

- Improve interpersonal relationships with patients
- Use the teach back method to ascertain what patients have learned

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“It’s those interpersonal skills, being able to relate with the patient and provide them information on their level that seemed to have a pretty significant impact.”

Alexander says pharmacists in her state, Iowa, are required to provide counseling for each new prescription. This helps pharmacists establish that interpersonal relationship with pharmacy

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customers. It’s an approach that pharmacists in other states, where this is not a requirement, might want to consider.

“It’s easy to hide behind the counter and check the prescription and make sure it’s all right, but they need to see your face, they need to know who you are, and need to know you are doing what is best for them even if they are in a hurry,” Alexander says.

2. **Adopt New Communication Strategies**

While most pharmacists don’t have a lot of time to establish this relationship, Berger believes they can use the time they do have more wisely by restructuring communication with patients.

“We’ve got to mine down to what’s causing this patient who has diabetes to not take their medication when their blood sugar is substantially elevated,” he says. “Is it because of side effects? Is it because they feel OK and don’t realize how serious this is? It is because of the cost of the medication?”

Berger offers an e-learning course through Purdue University and the NCPA bookstore on improving communication with patients using motivational interviewing. Berger says pharmacists should consider “sense making” when interacting with patients; the idea that patients’ behaviors and decisions about their care are primarily driven by how they make sense of their illness, their medications, or their perceptions of their healthcare professionals.

When people are ambivalent or resistant to change, he says, it is frequently caused by incomplete or incorrect knowledge. For example, a patient who has high blood pressure, may not understand why the medication is needed because he or she feels fine.

“A sense leads to a conclusion, which leads to a decision about a behavior. The sense is I feel fine, the conclusion is I am fine,” Berger says, adding that patients may then choose not to take the medication.

To combat incorrect knowledge, Berger recommends asking open-ended questions in a nonthreatening manner that reflect back the patient’s feelings, attitudes, or knowledge about a given medication. This positions the pharmacist to intervene and tailor his or her response to specifically address patient concerns in a conversational manner and invites the patient to reconsider their decision.

“We’ve got this idea in healthcare that we are driving the bus and the patient is the passenger. The reality is the patient is driving the bus and we’re trying to influence the routes,” Berger says.

Another strategy is to use what Norm Tomaka, BS Pharm, MS, FAPhA, a clinical consultant pharmacist, calls teach back: a strategy that asks patients to reflect back what they’ve learned. For example, a pharmacist may teach a patient how to properly use an inhaler and then have the patient demonstrate using it.

“The teach back method will unravel all these mysteries about a patient’s health literacy without having to directly say ‘Do you understand what I am saying?’” he says.

At her pharmacy, Alexander uses a summary wrap-up at the end of her counseling sessions that reiterates the most important aspects that the patient needs to remember. She also tries to sit down with a patient or have regular eye contact to make sure the patient is engaged in the conversation.

The goal with all three approaches is the same: to ensure patients walk away with the information they need. “If a patient comprehends their therapy and they buy into their therapy, they are much more likely to comply,” Tomaka says.

3. **Take a Team Approach**

The entire pharmacy team can play a role in promoting informational exchanges.

“We have clerks and we have pharmacy technicians and they all know how important it is that patient cannot leave until the pharmacist talks with them,” Alexander says.

Pharmacists can also hone their own communication skills by watching the language other pharmacists use during their patient counseling sessions and incorporating effective phrasing into their own scripts.

4. **Provide an Outlet for Future Communication**

Pharmacists can help foster a patient’s retention by providing resources, such as written instructions, calendars for complex dosing regimens, or links to videos that show a critical skill.

These supplemental tools can assist patients who may have additional questions once they leave the pharmacy or hospital, but these tools don’t take the place of a pharmacist.

An essential part of any patient counseling exchange should be letting the patient know how to get in touch with the pharmacist again if they have any questions or concerns.

“If there is a relationship between a pharmacist and a patient, a patient will feel comfortable in contacting that pharmacist for more information, but you have to build that trust,” Tomaka says.

Jill Sederstrom is a contributing editor.
Drug Makers Find New Ways to Slow Competition

Critics of “evergreening,” the tactics used by brand-name drug companies to extend a patent or regulatory monopoly, say that it is getting worse.

Chip Davis, president and CEO of the Association for Accessible Medicine (AAM), says the frequency of evergreening tactics has gone up, along with the creativity of delay strategies. “As patents on a product’s main ingredient and methods of use are getting close to expiring, what brand-name drug companies will do is make nominal changes. For example, they’ll change it from a tablet to a capsule or may say our dosing went from 20 mg to 30 mg and then secure a patent on the new dosing formula or formation.”

When the drug company receives the patent extension, it will use its sales force to get patients switched to the new formulation, says Davis. There are high-profile cases, he notes, such as renting the sovereign immunity of the Saint Regis Mohawk Tribe to block competition. In an effort to delay competition when one of Humira’s principal initial patents expired in 2016, manufacturer Abbvie filed more than 75 late-stage patents.

Davis says these tactics deny patients access to safe, effective, and affordable alternatives. “It’s negative to patients and their providers because more options are better than fewer.”

Davis says these tactics deny patients access to safe, effective, and affordable alternatives. “It’s negative to patients and their providers because more options are better than fewer. More options lead to the price coming down as opposed to a monopoly where the brand manufacturer has unbridled discretion to take 9.9% price increases once or twice a year, which is what’s going on, particularly in the specialty medicines area.”

An AAM paper published in February, Ensuring the Future of Accessible Medicines in the U.S., calls for ensuring that there are no “artificial barriers” to launching a new generic or biosimilar competitor.

Davis says that there’s no magic single solution to evergreening because the number of different systemic ways drug companies are using to prevent competition from coming to the market is growing. “So we have to have multiple proposed solutions to deal with them.”

AAM has an array of policy proposals including ensuring that generic companies can gain access to the number of samples needed for generic development and for filing applications with the FDA.

PHRMA DEFENDS PRACTICES

Nicole S. Longo, senior manager for public affairs at PhRMA, says many types of innovation are leading to valuable advances and improvements for patients. These include novel delivery mechanisms or new dosing schedules for previously approved medicines, which can result in increased patient adherence, improved health outcomes for patients, and fewer unnecessary hospitalizations, she says.

“Having additional competitors in different disease areas expands treatment options for patients and providers, can result in improved outcomes for patients, and spurs competition.”

Longo says it’s important to understand that added patents or exclusivities that cover new innovations relating to previously approved medicines do not extend patents or exclusivities on the earlier products or otherwise block FDA approval of generic copies of earlier versions.

“There is a misconception that innovation stops the minute a medicine is first approved by FDA. The reality is that research is ongoing long past the initial approval of a medicine. Each innovation has the potential to improve the lives of patients.”

That’s why biopharmaceutical researchers continue to work toward discovering advances such as expanded uses of medicines, new dosage forms, or alternative delivery systems, she says.
Observant Muslims fast from sunup to sundown during Ramadan, a practice that can be complicated if they must take medications. Pharmacists should know how to make adjustments in medication regimens that can help them and how to counsel their Muslim patients.

This year, Ramadan is between May 15 and June 14. Muslims who observe the fast will refrain from consuming anything by mouth between dawn and sunset, including food, water, and oral medications. Non-oral meds—injections, inhalers, suppositories, and eye or ear drops—are generally permissible.

“The general rule is if you can safely fast, then you do it,” explains Wasem Alsabbagh, PhD, a pharmacist and assistant professor at the School of Pharmacy at the University of Waterloo, Ontario, Canada. “The safety assessment usually falls on the shoulders of healthcare professionals who should approach the issue from a shared-decision point-of-view.”

The ban on oral medications can create a dilemma for patients who take part in the fast. Pharmacists can play an integral role by recommending medication adjustments and by counseling their patients on ways to avoid the potential hazards of fasting.

The Ramadan fast can be particularly challenging for people with diabetes due to the risk of hypoglycemia. The American Diabetes Association (ADA) recommends against prolonged fasting for patients with multiple diabetes complications. The ADA’s complete recommendations can be found at its website.

“Patients on insulin should measure glucose before, during, and after fasting,” advises Mohamed Jalloh, PharmD, assistant professor at Touro University in California. “I strongly encourage patients to know the hallmark signs and symptoms of low blood sugar.”

Any condition that requires medications taken several times a day or that is affected by food and drink intake (such as hypertension and thyroid disease) may require therapy adjustment. Alsabbagh says pharmacists can suggest adjustments to their medication regimens and to lifestyle to avoid any adverse effects of fasting.

Patients should be advised to consume enough water before and after fasting begins to prevent dehydration, he says. Patients should avoid too much activity and exposure to sun and high temperatures. If they become dehydrated, they should immediately break the fast and rehydrate, he says.

Jalloh says pharmacists can also adjust the times medications are taken. Once-daily formulations should be taken when patients break the fast or begin eating food after sunset, he notes.

Finally, Alsabbagh urges pharmacists to be proactive with their patients. “It is important for pharmacists to ask patients if they are considering fasting and engage in the conversation about safety and necessary adjustments, rather than restricting their intervention to patients who ask,” he concludes. Above all, pharmacists should be respectful of patients’ personal wishes and religious beliefs when offering counseling.

Beth Longware Duff is a freelance writer living in upstate New York.
“You know, children are not small adults,” a preceptor once told me during an early pharmacy practice rotation. Nearly 10 years later, I sometimes still hear her voice in my head. However, my patient population falls on the opposite end of the life spectrum: They are members of the geriatric community.

Like children, advanced members of our community require special considerations. Some disease states affect elderly patients differently than younger individuals. Liver function changes with age, resulting in altered drug metabolism. Physiological changes such as thinning of the skin and increased body fat can greatly alter drug metabolism, and affect how medications behave outside and inside the body. A prudent clinician may initiate therapy at a lower-than-normal starting dose and slowly titrate accordingly.

Pharmacy school alludes to some of the many differences seen in patients of advanced age. But providing a comprehensive overview of the circumstances that distinguish geriatric patients from younger patient populations is both arduous and impractical. Certification offers a solution.

One may have many motives for specializing in geriatrics—just as with any other therapeutic area. As with residencies and fellowships, many pharmacists choose to pursue board certification to deepen their clinical skills while gaining a leg up on the competition in the ever-tightening job market.

While these factors influenced my decision to become a board-certified geriatric pharmacist (BCGP), I ultimately chose geriatrics as a specialty because of my love for the elderly. I come from a culture in which its oldest members head the entire family, and caring for them is considered a community effort. I willingly forfeited sleeping late my senior year of high school to act as my grandfather’s morning chauffer, administer his medications, and take him to the barbershop every Saturday. I guess you could say the seed was planted early.

In my first role as a licensed pharmacist, I served a predominantly older population. Almost immediately, I recognized that successfully managing these patients required a higher skill set than pharmacy school offered. Providing medication therapy management consultations further highlighted what I felt were deficiencies in my skill set that additional experience alone could not address. It was during this time I first began considering certifying in geriatrics. However, with no residency under my belt, I needed several years of practical experience before sitting for the exam.

By the time I moved into managed care, I had become eligible to test. I was still consulting, but my patient population had become even more complex. I went from working with elderly populations in rural East Texas communities to serving a hybrid middle-aged/geriatric community that encompassed the gamut of cultural, racial, and ethnic diversity of New York City and surrounding areas. Special considerations required to manage this highly diverse demographic further amplified the need to upgrade my skill set.

My advice to pharmacists considering certifying in geriatrics: Don’t do it just to add extra letters to the alphabet soup of credentials after your name. Do it because you want to make a difference and build confidence in your ability to provide optimal patient experiences. In that lies the true reward.

Frieda Wiley, PharmD, BCGP, is a clinical pharmacist and a medical writer.
Arizona is poised to become the 24th state to adopt telepharmacy legislation. The legislation is expected to be signed into law this year with the first outlets scheduled to open in early 2019. Six other states have authorized pilot programs that could apply to telepharmacy and five states permit waivers of legislative or administrative requirements that could allow for telepharmacy, according to the Rural Policy Research Institute at the University of Iowa College of Public Health.

As more states allow telepharmacy, some pharmacists worry over what it could mean for patients and the pharmacist job outlook. To help address those concerns and others, the Arizona Pharmacy Association, which supported the legislation, negotiated a series of protections for pharmacists and patients.

“The big issue that came up from some of our members and other stakeholders is to ensure that this is a safe practice,” says association CEO Kelly Fine, RPh. “We are equipping and training both technicians and pharmacists, making sure that security and surveillance are sufficient, and requiring HIPPA-compliant high-definition video conferencing for face-to-face interaction with the remote pharmacist.”

Most telepharmacy locations will likely be in rural areas, at least to start, she says. But community health centers and hospitals have also expressed interest. “So have independent pharmacists who want to expand into pharmacy deserts, areas with few or no pharmacies and severely limited local access to pharmacy care.”

The potential for urban expansion has raised objections among some pharmacists. “This bill can and will likely be used to lay off hundreds of pharmacists and convert hundreds of ‘underperforming’ pharmacies in urban areas, effectively reducing pharmacist jobs by over 75%,” says P. Charles Zaffrey, RPh, pharmacist at Bashas’ United Drug, a supermarket chain pharmacy in Tempe, AZ, who opposed the legislation.

The Arizona Pharmacy Association insisted on including language in the legislation to help prevent such problems from occurring. It limits pharmacists to overseeing one remote location in addition to managing their own physical location. Pharmacists with no oversight responsibilities for a physical pharmacy will be allowed to oversee two remote locations.

Adam Chesler, PharmD, director of regulatory affairs for Cardinal Health, which is backing the legislation, says many providers who fear job loss due to telepharmacy may have misconceptions about state-level legislation.

“One of the lessons we have learned is the need for provider education,” he says. “Anything and everything a pharmacist has to do in a physical pharmacy today still has to be done in a telepharmacy.” Pharmacists still have oversight, counseling, and clinical responsibilities with telepharmacy and may have increasing clinical involvement by pharmacists because they are able to see more patients as telepharmacy expands access, he says.

Mark J. Hardy, PharmD, executive director of the North Dakota State Board of Pharmacy, says pharmacist employment hasn’t fallen since North Dakota became the first state to authorize telepharmacy in 2002. “If anything, telepharmacy has expanded the hiring of pharmacists across the state,” he says. “It has allowed them to focus on clinical duties and interact with more patients than ever before by expanding pharmacy access. If there have been job losses, they are attributable more to economics than to telepharmacy.”

Telepharmacy seems to be expanding steadily, if not quickly.

“Pharmacists are learning about it and state boards are taking deliberate approaches to be sure it will work in their state,” says Lisa Schwartz, PharmD, senior director of professional affairs for the NCPA.

Fred Gebhart is a contributing editor.
Ohio Regulators Rule for Drug Price Transparency

A new rule in Ohio will reveal drug prices to patients and allow pharmacists to tell their patients when not using their health insurance will save them money.

The Ohio Department of Insurance has told PBMs and health insurers that they have to disclose the lowest price for a prescription drug to patients and prohibits them from charging the full copay for prescription drugs that cost less than the copay. The department has also banned gagging pharmacists by contractually preventing them from telling patients they could pay less out of pocket for a drug than the insurance copay.

There had been many examples of egregious clawbacks in Ohio, says Antonio Ciaccia, using the term to describe the overcharging of the patient and the later collection of some of that overcharge by the PBM. Ciaccia is director of government and public affairs for the Ohio Pharmacists Association.

In testimony to a committee of the Ohio House of Representatives, Ciaccia gave an example: “For a medication used to treat severe vitamin deficiency, the pharmacy’s cash price was $92. The pharmacy processed the claim and was told to charge the patient $115.19. The PBM later performed a $55.47 clawback. So in the end, the patient was overcharged $23.19, the pharmacy lost $32.28, and the PBM pocketed it all. And again, while this was occurring, the pharmacist was prohibited in their contract from blowing the whistle on the charade, and helping the patient find a cheaper alternative method of payment.”

Preventing pharmacists from informing their patients about drug prices is a serious matter, Ciaccia told the committee. “Pharmacists should not be silent pawns in drug pricing shell games, and should be free to discuss all options for the patient at the pharmacy counter—including whether or not there are ways to save money on their needed medications.”

“Ultimately, the Ohio Department of Insurance acted once they learned how pervasive the problem of clawbacks was.”

The results of the ruling from the insurance department is an immediate lowering of drug copays, Ciaccia told Drug Topics. “Ultimately, the Ohio Department of Insurance acted once they learned how pervasive the problem of clawbacks was,” he says. The Ohio legislature had been making an effort to prohibit the practice of charging a higher copay than the actual price of a drug, which gave the insurance department the impetus to act, he adds.

Other states have enacted similar rules or are considering legislation to increase drug price transparency. “There seems to be a universal gag reflex by lawmakers who learn about co-pay clawbacks and mandated silence of pharmacists,” says Ciaccia. “The practices are so distasteful, that even the PBMs’ own association won’t stand up for them.”

Two large PBMs—Express Scripts and CVS Caremark—have told Reuters that their contracts include clauses that ensure that members receive the lowest drug price automatically.

On the federal level, two bills have been introduced in Congress that are aimed at making drug pricing transparent to consumers and preventing gag clauses.

The legality of such gag clauses has always been questionable, he adds, since they are the subject of several lawsuits across the country. “Theoretically, plans and PBMs could still penalize pharmacists for pushing back and blowing the whistle on noncompliance with the new rules, but ultimately, if PBMs ignore these new policies, they stand to be fined or having their licenses suspended by the Ohio Department of Insurance. Personally, I think the ODI edict . . . will end these shenanigans for good,” Ciaccia says.

Valerie DeBenedette is managing editor of Drug Topics.
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In 2000, HHS reported that a serious shortage of pharmacists was looming. But for the last few years, there has been talk that there are too many pharmacists for the number of available jobs.

The unweighted Pharmacist Demand Index (PDI), which reports perceptions of the demand for pharmacists, was 3.05 on a 1-to-5 scale, for the first quarter of 2018, the most recent data available. The population adjusted PDI is 2.98. A PDI of 5 means there is a critical demand for pharmacists, while 3 means that supply and demand are balanced. The PDI is higher in the West (3.55), and a bit lower in the Northeast and South (2.74 in both areas).

“My and the AACP’s position is that it doesn’t appear to be [a glut], and I realize that is not the universal position,” says Lucinda Maine, executive vice president and CEO of the American Association of Colleges of Pharmacy (AACP). But regionality, demographics, and economics may play roles in why a perception of too many pharmacists exists, she says.

Some regions of the country have greater need for pharmacists than other parts due to an older population with greater healthcare needs. Rural areas are more likely to have job openings than urban or suburban locales, she added.

In 2000, when HHS issued its report, the economy was booming. Pharmacists could work 20 hours a week and get full benefits from the pharmacy chains, Maine notes. “Clearly, many things have changed since then.”

Though the economy has picked up greatly since the recession hit, the explosive growth seen in the 1990s in pharmacy did not return, Maine says. “Some would say the economy is sizzling and the stock market is sizzling, but Walgreens isn’t opening a new store every 17 hours anymore,” she points out. Pharmacy chains now grow by buying existing pharmacies rather than opening new ones, which doesn’t add job openings, she notes.

“In 2000-ish, we had a very well defined national shortage, but we were graduating less than 8,000 pharmacists a year at that time,” Maine says. About 15,000 people graduate with a pharmacy degree annually now. “I ask our members pretty consistently, ‘How’s the job market for your graduating class?’ and the job market is by and large absorbing almost a doubling of the graduation cohorts,” she says. “The balance in supply and demand is likely best for the profession and the patients we serve.”

There may be an oversupply of pharmacists, but it might not be across the board for all of pharmacy, says David J. Fong, PharmD, a retail pharmacy consultant. “I think the simple answer is ‘to be determined,’” he says. “It is not clear today whether there is a glut.” Fong is a member of the Editorial Advisory Board of Drug Topics.

Maine notes that future job growth in pharmacy will likely be coming as pharmacists work more collaboratively with other healthcare professionals. “I just see a world of opportunities opening up for the profession. And I think one of the next ones that’s going to happen quickly is the integration of pharmacists into physician group practices.” (See Cover Story on page 14.)

Fong agrees. There are expanding roles with new types of jobs for pharmacists, and there is a need for pharmacists who are qualified for those new roles, he says. “We are trying to bring value to the healthcare supply chain and demonstrate what we do to make a difference.”

But not every pharmacist has pursued advanced qualifications, such as board certification in a specialty or in diabetes education. There is a need for individuals with specific qualifications, Fong says. Whether there are too many qualified people for such positions is unclear because the roles of pharmacists are continuing to evolve.

Valerie DeBenedette is managing editor of Drug Topics.
If you struggle to engage and motivate your pharmacy technicians, making some small changes can help. Here are some tips.

1. **Start a Mentoring Program.**

Shane P. Desselle, RPh, PhD, FAPhA, professor at Touro University California College of Pharmacy, Vallejo, CA, says it’s important for pharmacists to “provide an organizational climate that allows for technicians to mentor one another, in addition to the pharmacist mentoring them.”

Mentoring gives the senior technicians pride and accomplishment and the desire to remain with the organization, he says. At the same time, it allows a junior technician to learn aspects of the job like customer service, organization norms, and attitudes.

2. **Empower Them.**

Pharmacy technicians want more responsibility and one of the most important things a pharmacist can do is “delegate any and every responsibility procedures that they are legally accorded to do. I can’t overstate the importance of that,” Desselle says.

Tiffany Bartlett, CPhT, CSPT, agrees. She has been a certified pharmacy technician for more than 20 years and a specialty pharmacy technician at MD Anderson Cancer Center in Houston, for almost three years. Many responsibilities can be delegated to technicians, such as insurance specialist, educator, medication therapy management, and quality control. “With each new opportunity, each role should be evaluated and minimum guidelines should be established relating to educational requirements and work experience in order to choose the right candidate for the position,” says Bartlett. “Pharmacy technicians are anxious to break out of their traditional roles in retail and hospital and use their skills and knowledge to practice in exciting new opportunities.”

Kilee Yarosh, RPh, MBA, market pharmacy director, Turnbull Memorial Hospital, Northside Medical Center, Hillside Rehabilitation Hospital, and Steward Family Hospital in Ohio, notes that technicians can expand their roles. “As we continue to see the practice of pharmacy transform, it will be integral to our profession’s success that we work hand-in-hand with our technician workforce to ensure adequate training, credentialing, and support to provide the best care possible to our patients, regardless of practice setting,” Yarosh says.

3. **Use Them as a Resource.**

Bartlett creates continuing education content for about 180 pharmacy technicians at MD Anderson. She often seeks advice from clinical pharmacists on her team to troubleshoot problems within an online training module or receive feedback on the best way to present a real-life scenario to trainees.

The clinical pharmacists also seek advice from from her on how technicians work in the clean room. “They may ask questions regarding inpatient work flow improvement options, and gain insight from my work experience on preparing a patient-specific sterile compound,” Bartlett says.

4. **Have Difficult Conversations.**

Yarosh says that providing transparent feedback to technicians is one way to help them improve their job performance. Pharmacists should set clear expectations, have goal-setting discussions, and “provide projects that capitalize on their strengths but also push their comfort zone,” she says.

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**Pharmacy technicians are anxious to break out of their traditional roles in retail and hospital and use their skills and knowledge to practice in exciting new opportunities.”**

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Gail Kalinoski is a freelance writer in the Hudson Valley of New York.
In March, the FDA approved ibalizumab-uiyk (Trogarzo, TaiMed Biologics USA Corp.) for use in combination with other antiretroviral agents in adult patients with multi-drug-resistant HIV-1 who have received multiple antiretroviral therapies and who are on a regimen that is unable to suppress viral load. Ibalizumab-uiyk is a recombinant humanized monoclonal antibody. It binds to CD4 cells and interferes with post-attachment processes that allow entry of HIV-1 virus into a host cell. CD4-directed post-attachment HIV-1 inhibitors are a new class of antiretroviral drug therapy that offer a new option for patients with multi-drug-resistant infection.

Efficacy

Efficacy of ibalizumab-uiyk was established in a single-arm multicenter trial (TMB-301) of 40 participants. All participants had heavy treatment experience, a viral load greater than 1,000 copies/mL, and documented resistance to at least one antiretroviral drug from each of three classes: nucleoside reverse transcriptase inhibitors, nonnucleoside reverse transcriptase inhibitors, and protease inhibitors.

Trial participants had received therapy for at least 6 months and were currently failing therapy or had failed within the last 8 weeks. Throughout the trial, baseline antiretroviral therapy was continued. The first week of the trial served as a control period to establish baseline viral loads. On day 7, all participants received a 2,000-mg infusion of ibalizumab-uiyk and were monitored through day 13. This period was used to determine virologic activity of ibalizumab-uiyk.

A maintenance period from day 14 through week 25 assessed viral load changes. During the maintenance period, a participant’s background regimen was optimized to ensure viral susceptibility to at least one drug. Participants received 800 mg of ibalizumab-uiyk every two weeks from day 21 through week 25 of the trial. Within a week of initiating ibalizumab-uiyk therapy, 83% of participants demonstrated a significant decrease in viral load. At the conclusion of the study period, 43% of participants achieved HIV RNA suppression (HIV RNA <50 copies/mL). Studies have not demonstrated cross resistance between ibalizumab-uiyk and other antiretroviral therapies. A decrease in susceptibility to ibalizumab-uiyk therapy after multiple administrations of the drug has been observed. The development of cross-resistance to other classes of therapy has not been observed in cell culture studies.

Safety

Experience with ibalizumab-uiyk is limited: a total of 292 patients infected with HIV-1. The most common adverse reactions in TMB-301 were mild to moderate in severity and included: diarrhea (8%), dizziness (8%), nausea (5%), and rash (5%). Use of ibalizumab-uiyk can result in immune reconstitution inflammatory syndrome (IRIS), which occurred in one participant in the TMB-301 trial. Ibalizumab-uiyk can cross the placenta during pregnancy.

Dosage

Ibalizumab-uiyk therapy is administered intravenously every two weeks. Therapy is initiated with a 2,000 mg loading dose and maintained with 800-mg doses administered every two weeks. Dosing modifications due to renal, hepatic, or concomitant therapies were not studied. Modifications are not anticipated to be required for renal impairment or drug interactions. Ibalizumab-uiyk is administered intravenously over 15 to 30 minutes in a clinical setting. All patients must be monitored for one hour after the first dose is administered. If no reaction has occurred, the patient may be monitored for 15 minutes after administration of subsequent doses.

REFERENCE

Five Ways The New Merck Differs from the 1899 Edition

1. **It’s much larger.** The 20th edition of *The Merck Manual of Diagnosis and Therapy*, released in April, is divided into 24 sections and has more than 3,500 pages. It weighs 5 pounds, 15 ounces, and is just under 3 inches thick. The first edition, published in 1899, weighed 4.2 ounces and, at 4.25 inches wide, was made to fit in a coat pocket. The last edition that could conceivably fit into a large coat pocket was in the 1960s, says Robert S. Porter, MD, editor-in-chief for the Merck Manuals. “Other than a masochist, nobody since the 1950s would keep it in their coat.”

2. **Very few of the treatments listed in the 1899 version are of any real use today.** “A number years ago I went through and tried to pick out the things that were still done and things that worked, and I think I found a dozen things in there that are conceivably still done and another half dozen that might have worked. Everything else is useless,” Porter says.

   Some useless treatments listed in the 1899 manual are relatively harmless, like using olive oil to fade freckles, but others are can be extremely counter-productive. “There was a recommendation to give hot baths for sunstroke and heat exhaustion. That would probably just outright kill someone,” Porter says. Similarly, giving magnesium salts for diarrhea. “It’s a laxative. You get more diarrhea.” Another serious error? The manual recommends cocaine for angina. “It’s a coronary vasoconstrictor!” says Porter.

3. **There are some odd conditions listed in the first edition.** The first edition was named *Merck’s Manual of the Material Medica*, subtitled “A Ready-Reference Pocket Book for the Practicing Physician.” It was divided into three parts: The Materia Medica, Therapeutic Indications, and Classification of Medicaments. The medicaments were listed in alphabetical order and included many herbal tinctures and such curiosities as uranium nitrate. The therapeutic indications include common diseases or conditions such as diabetes, asthma, and inflammation, but also some more curious conditions such as gleet, sexual exhaustion, and hystero-epilepsy.

   The uranium nitrate? That was a treatment for diabetes.

4. **The latest edition makes use of current technology.** The printed edition is not the definitive edition of the new manual, according to Porter. The content of record for the manual is the material that is online at https://www.merckmanuals.com/professional, where it is always up to date. The digital edition also allows inclusion of more content than a book can hold and multimedia features. This differs, of course, from the 1899 edition, which had a nice leatherette cover.

   The 19th edition, published in 2011, was never even put on paper. It was only available online. For the 20th edition, the editors gave in to those who really prefer using a book and printed it, Porter says.

   The Merck is also available as free apps in both Android and iPhone formats, Porter notes. These apps return the Merck to being what it started out as: a pocket-sized resource for health professionals.

5. **Pharmacists are involved.** There are two pharmacists on the manual’s editorial board: Ina Caligaro, PharmD, and Eva M. Vivian, PharmD. The section on clinical pharmacology was written by Daphne E. Smith Marsh, PharmD; Shalini S. Lynch, PharmD; Abimbola Farinda, PhD, PharmD; and Jennifer Le, PharmD, MAS, BCPS-ID.

   No authors are listed for the 1899 edition, so it is not known if any pharmacists took part in its creation.

   So why should a pharmacist use the Merck? The manual is an excellent resource for pharmacists who might need to brush up on a medical condition, says Porter. It is the place to find information on any condition a pharmacist doesn’t deal with often.

   Despite all the changes between the two editions, one thing remains consistent: Pharmacists and health professionals in 1899 needed a convenient and thorough resource for looking up medical information. With medical knowledge now doubling every 18 months, this is truer than ever.

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Valerie DeBenedette is managing editor of Drug Topics.
Back in July, in a column about pharmacy technician staffing, I wrote: “In my 36 years on the bench I’ve found the difference between a great day and a challenging day isn’t the number of prescriptions, it is the level and quality of staffing.” Technicians in the pharmacy are indeed what keeps us pharmacists on task, so we can spend time helping the patients who seek our expertise, as well as verifying prescriptions.

The level of staffing unfortunately is left to those further up the food chain, usually district managers or someone sitting in a corporate office. For some reason they feel they have psychic powers that can determine the needs of a pharmacy they don’t ever see. Their formulas can’t possibly factor into account the health literacy of the population, which can require more “hands-on” work by the pharmacist and staff. Most of my patients can’t punch their prescriptions in on the interactive voice response (IVR). Instead, they dial our phone number and hit the “0” button to talk to a staff member. Writing down 12 prescription numbers takes us more time than processing 12 prescriptions directly off the IVR. Add to the mix drive-through windows, and staff can be spread mighty thin. In contrast, where my wife works in a university town, her patients are rather low maintenance, seldom calling for early refills, and always using the IVR.

Each chain has its own formula. One grocery chain uses the figure of 8.7 prescriptions per tech hour, which includes techs and cashiers on the pharmacy team. Fill 480 prescriptions in 12 hours, you get 55 hours to staff your pharmacy with cashiers and technicians. Another grocery chain allows 11 prescriptions per tech hour, not including the cashier who is up front. Fill 480 prescriptions at this pharmacy and you get 44 tech hours. Most chains just assign tech hours without any reasoning.

Dearth of Guidance

I find it amazing that state boards of pharmacy, APhA, NACDS, and NCPA have provided little if any guidance about the levels of staffing, which is the community pharmacist’s number one complaint. It might be a good way to increase their membership to take a stand on staffing and maybe the average community pharmacist might see value in joining the ranks of these associations. The only group that has taken a stand on pharmacy technician staffing is the Chicago City Council! It wants to pass legislation that requires mandatory pharmacist breaks as well as 10-technician hours for every 100 prescriptions filled. Those levels would need to be adjusted for flu vaccinations as well as other promotions that pull pharmacists away from prescription verification and counseling.

As far as the quality of technicians, that responsibility rests on the training programs. I have had amazing techs over the years, because I always take the time to train them, then allow them to develop their own skill set. The technician that keeps my store running like a well-oiled machine is Brad Wiegand. Brad came to us as a high school senior and worked as a stock boy. When he expressed interest in becoming a pharmacy tech, we taught him our pharmacy filling software program. As with any young kid, he excelled in operating the computer and is a dream technician.

As his senior year concluded, Brad was considering enrolling in a local pharmacy tech program. I promised I’d train him in store and save him around $11,000. He has rock star status, because everyone in the store gave him the opportunity to learn and excel.

If your technician is inadequate, I’ll bet it can be traced directly back to their training. We pharmacists are responsible for the training of our technicians. A well-trained technician is the difference between a great day and a challenging day. Just make sure you have enough of them!
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