Pharmacy Issue

TRENDS TO WATCH

Experts sound off regarding the managed care pharmacy survey findings

Roundtable
Rising cost of specialty pharmaceuticals

Plus
FULL SURVEY RESULTS
Okay, we’re not claiming she literally said it. But as a public figure and policy maker who believed in access to healthcare as a fundamental human right, she’s the kind of visionary who would have not only pointed out the ways healthcare is broken today — she’d have devoted her life to unbreaking it. athenahealth.com
Opinion

from DAVID CALABRESE, RPH, MHP

We all need to take responsibility for the opioid epidemic

Five ways to do your part

It is rare these days to scan the healthcare newswire on any given day and not find a story focused upon the prescription opioid abuse epidemic that is plaguing our country. So dramatic is this problem that in 2014, drug overdose overtook automobile accidents as the leading cause of accidental death in the U.S., with 47,055 lethal drug overdoses, according to the CDC. The death toll however tells only half the story. According to the national data, an additional 4.5 million Americans are estimated as being addicted to opioid prescription pain relievers, according to a study published in Annual Review of Public Health.

Unlike other conditions, prescription opioid addiction is unique for several reasons. Foremost, it does not discriminate by race, ethnicity, gender, age or socioeconomic status. The victims are our sons, daughters, brothers and sisters, moms and dads, friends and coworkers. Secondly, it is a condition with a prevalence rate that is growing at an alarming pace and a cure rate that remains woefully low. Lastly, and most tragically, it is considered to be a condition largely brought upon by the healthcare system itself and our failure to protect individuals from the dangers of indiscriminate prescribing and consumption of these drugs.

How did we get here?

Physicians trained in the 1960s and 1970s were taught to reserve opioids for the most severe forms of pain, such as cancer or end-of-life care. In the late 1990s however, opioid prescribing policies changed. Patient advocacy groups and pain specialists began to argue that doctors were undertreating common forms of pain that could benefit from opioids, such as backaches and joint pain. Around this same time the American Pain Society introduced the “Pain as the 5th Vital Sign” campaign. This effort garnered impressive institutional support, and not surprisingly, was further amplified by multimillion-dollar, physician-directed promotional campaigns, largely funded by the pharmaceutical industry. According to the organization Shatterproof—a national organization committed to preventing substance use disorder and facilitating access to evidence-based treatments without shame or stigma for those afflicted—new, long-acting drugs like OxyContin were promoted as less addictive.

This promotional campaign has since been considered one of the biggest mistakes in modern medicine. Between 1999 and 2014, sales of prescription opioids in the U.S. increased by over 400%. During this same time, a strong, linear relationship was established between opioid sales volume and the steady growth in U.S. morbidity and mortality rates associated with these products, according to the CDC. Whatever advantages gained in alleviating pain in subsets of the population were vastly overwhelmed by the subsequent epidemic of addiction and overdose.

New guidelines

In March of this year, the CDC published the “Guideline for Prescribing Opioids for Chronic Pain,” which is aimed at improving patient care and safety and preventing opioid overdose. In general, the new guidelines promote the avoidance of opioids as first-line treatment of patients with chronic pain; remind clinicians of the significant risks versus limited benefits of therapy based upon available clinical evidence; set limits on dosing; and establish rules for monitoring patients who are taking opioids. And while the new CDC guidelines are welcome, they are only a first step toward a more comprehensive and effective solution.
What can MCOs and PBMs do to help?

There are multiple ways that healthcare organizations can help drive us to solutions that can truly impact the opioid epidemic. I see these broken into five primary domains, which I have personally coined “Five-For-Life.”

1. **Upfront education and prevention**
   This should include strategies to increase public awareness of the issues; to better educate providers regarding safe and appropriate prescribing of these agents and how to best manage patients with possible and/or documented abuse issues; and to educate patients, particularly young adults, on the dangers of these agents and how to appropriately use, store and dispose of them when they are prescribed for legitimate purposes.

2. **First-fill exposure limits**
   The dangers of opioid use begin with the first prescription. Here, PBMs and MCOs are in a unique position to create disruptive, yet highly warranted limitations on which patients should receive which opioid drugs, in what doses, for what purpose and duration, prescribed by which physicians, and dispensed by which pharmacies. By far, if universally adopted, I see such strategies as the most effective means of impacting the prevalence trends.

3. **‘High-risk’ patient identification and intervention**
   Here, a more forensic approach is encouraged to uncover patterns of patient-specific drug utilization that may be indicative of misuse, abuse or diversion. Such strategies should involve the integration of medical and pharmacy claims data and the application of well-designed, evidence-based algorithms to identify issues early on and allow for proper intervention with the patient and prescriber as needed.

4. **Vigilant prescriber and pharmacy surveillance**
   While most organizations employ programs today to monitor fraud, waste and abuse, many of these programs may be outdated or vastly limited in depth and scope. Here, organizations are urged to revisit, and amplify where appropriate, existing efforts to identify and shut down the disproportionate and potentially abusive opioid prescribing by physicians, and dispensing by pharmacies, that is contributing to this nationwide crisis.

5. **Appropriate support and management of the afflicted**
   Patients with documented opioid abuse disorder require comprehensive, well-coordinated care and support to overcome their addiction. Here, organizations must ensure appropriate access to the right resources for these individuals including properly accredited treatment centers; behavioral health services; medication-assisted treatment programs; post-discharge monitoring, coaching and counseling services; and prescriber and pharmacy “lock-in” strategies where appropriate.

**Shared accountability needed**

It is well-evident that the opioid crisis in the U.S. is a multi-dimensional problem requiring a multi-stakeholder solution. As members of the healthcare community, we all to a certain degree share accountability for this crisis, and as such we each have the same (if not greater) responsibility in delivering a solution. The time is now for us to step up with the courage to develop and deploy market-disruptive strategies that will drive positive change and ultimately save lives.

**ABOUT THE AUTHOR**

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Mission Managed Healthcare Executive provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.

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**Mark Boxer, PhD**, is executive vice president and global chief information officer for Cigna, where he is responsible for driving the company’s worldwide technology strategy.

**Joel V. Britt, MD**, is the chief medical officer for Predictive Health, LLC, which partners with stakeholders to improve coverage of value-driven care that optimizes health for people.

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Introducing the Affirm™ Prone Breast Biopsy System. In a survey of early patients, 98% agree that the procedure was faster, more comfortable, and less painful than expected.† Is your facility ready for a better biopsy experience?

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*Compared to the MultiCare® Platinum system.
†Based on a survey of 57 patients post procedure on the Affirm™ Prone Breast Biopsy System (8 clinicians, 2 sites).

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Rising drug costs are a big problem at St. Louis, Missouri-based Ascension, the largest nonprofit health system in the United States. Despite efforts to monitor the drugs used by the health system, the cost of many older generics has increased by as much as 10.5% in the last year, says Roy Guharoy, PharmD, vice president and chief pharmacy officer for The Resource Group at Ascension. This increase, which only includes older generics, cost the health system as much as $70 million between May 2015 and May 2016.

These and other drug price increases are untenable, especially in the midst of the transition to value-based care, Guharoy says. And it’s particularly challenging, given that Ascension is a faith-based healthcare organization that provided approximately $1.8 billion in charity care in 2015.

**New role for physicians**

Ascension monitors price changes in as close to real time as possible so that leadership can take immediate action, such as switching to generic drugs or another drug at a better price, says Guharoy. Integral to this process is having physician leaders and specialists review the literature to look at the efficacy of certain drugs to determine their appropriate usage. Once a drug is approved for use across the health system, physicians have 90 days to implement the medication change. Ascension then tracks the implementation at each hospital.

One of the drugs the health system applied such changes to is a cardiac drug that increased in price by 1,000%, says Guharoy. The health system eliminated the drug from crash carts. When the drug must be used, clinicians minimize waste by getting multiple doses from each vial. As a result of these and other changes, the health system saved approximately $1.5 million dollars, says Guharoy.

He says it’s relatively easy to convince doctors of a medication change when you present them with the evidence to back up the change and the reality that the health system can’t continue to provide charity care at current levels if it doesn’t monitor the cost of drugs and make changes accordingly.

The science is there to support these prescribing decisions, it’s just a new way of practicing medicine, he says. “These decisions should be based on science and on delivering the most effective, high-quality and cost-effective care.”

**Smarter drug protocols**

“It’s very difficult to manage drug costs when you’re seeing double-digit price increases on a monthly basis,” says Bill Forslev, PharmD, system vice president of pharmacy services at Advocate Health Care, the largest health system in Illinois. “It puts a burden on our healthcare system, our patients, and our payers.”

To hold back the tide of rising drug prices, the faith-based, nonprofit health system has focused on a collaborative approach similar to Ascension’s, where physicians across the system contribute to a systemwide interdisciplinary committee to develop and implement evidence-based decisions about the drugs used to treat patients.

Feedback from physicians ensures drug choices are based on evidence and outcomes, says Rishi Sikka, MD, senior vice president of clinical operations at Advocate Health Care. An additional benefit of including the voices of physicians is the initiative doesn’t have the feel of a “top-down approach,” he adds.

Successful implementation of the interdisciplinary team’s efforts hinges on having information on appropriate medication use “hard-wired” into the electronic health record (EHR),
Hospitals & Providers

says Forslev. “It’s really apparent to physicians and pharmacists and everybody that this is the new protocol that we’re going to use, and we have found that to be very valuable in directing us toward the most appropriate drugs for our health system and our patients.”

If a drug is taken out of the health system’s protocols, it won’t automatically show up as an option when the physician is in the EHR, says Forslev, who notes that physicians can still order non-protocol drugs. The word “restricted” is noted within the EHR for drugs that are outside protocol, and pop-ups illustrate the appropriate criteria for usage of that drug.

The health system’s collaborative approach is key to compliance with the drug protocols in the long- and short-term, says Sikka, and the rationale behind these decisions is communicated to physicians across the system.

“That’s really important because if all you see in the EHR is [that a drug isn’t available], that may engender compliance in the short term, but it certainly won’t engender partnership and compliance in the long term,” he says.

Real-time knowledge of the availability of drugs also helps support Advocate Health Care’s work on countering rising drug prices, since it can translate to better volume discounts. The health system uses a central repository to house all of its prescription drugs; and it has smaller versions of this central repository at each of its more than 400 sites of care, including 12 acute care hospitals.

**New partnerships**

Salt Lake City-based Intermountain Healthcare saw an 11% increase in drug costs in 2014 and a 14% increase in costs in 2015, says Nannette Berensen, assistant vice president of pharmacy services, who notes that prescription medications are the single fastest growing expense at the health system. Specialty drugs, in particular, are increasing at a rate of 20% each year. While specialty drugs are used by fewer than 2% of patients, they account for about one-third of the dollars spent on prescription medications, she adds.

With the skyrocketing cost of medications, Intermountain Healthcare has focused on working closely with SelectHealth, its insurance entity, to align and share best practices with respect to utilization.

Berensen also calls out work with the health system’s supply chain team on sourcing and contracting initiatives, adherence to evidence-based best practices, a disciplined approach to formulary management, a focus on waste elimination, and exploration of different payment models with pharmaceutical manufacturers as key to addressing drug affordability.

Berensen’s advice for other organizations is to focus squarely on patients. “Everything that can be done to ensure that patients understand why they are taking medications and how to take them as the prescriber intended should be done,” she says.

Healthcare leaders should also keep in mind that when patient cost sharing goes up, medication adherence goes down and that can lead to poorer health outcomes, she says. Thus, she recommends that healthcare leaders take a robust approach to patient financial assistance.

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**DRUGS PRICES—2005 VS. 2013**

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Source: AARP’s Public Policy Institute
Technology leads to pharma improvements

Benefits include safety, efficiency gains

by MARI EDLIN

Technology in pharmacy is nothing new, with e-prescribing coming on board more than a decade ago. In November 2005, CMS published the first set of adopted standards that applied to e-prescribing under Part D of the Medicare Modernization Act.

Between December 2008 and April 2014, the percent of doctors e-prescribing using an electronic health record (EHR) increased from 7% to 70%, according to the Office of the National Coordinator for Health Information Technology. But that was just a start for the industry, which now embraces information exchange via EHRs, drug barcoding, computerized physician order entry, robotic dispensers, automated medication identification, prior authorization, and drug verification.

Nicholas Galeota, director of pharmacy, SUNY Downstate Medical Center in Brooklyn, New York, says EHRs, e-prescribing and barcoding help ensure safety, such as avoiding overdosing, prescription errors and contraindicated drugs.

"The human eye can’t pick up every error or issue; you need a computer with certain criteria embedded," he says. He points to “smart” infusion pumps, which have software that allows organizations to create a library of medications to help providers program and calculate dose and delivery rates, preventing errors and patient injury.

**Safety gains**

While technology is improving safety on the patient-provider side, retail pharmacies are also recognizing the benefits of technology. Tiffany Natural Pharmacy, Westfield, New York, has adopted the use of barcoded drug labels, based on the National Drug Code, to ensure accountability. The information in a barcode enables a comparison of a medication being administered with what was ordered for a patient so that patients receive the right drugs at the right time.

Brian Pinto, pharmacist-in-charge and owner of the five-store pharmacy that dispenses 2,200 prescriptions per week, says the business is deploying other technology to ensure safety and accountability.

A counting device called the Eyecon, integrated with the pharmacy software system, reads a barcode and displays pertinent information related to a prescription, such as quantity, patient name and drug name. Either a technician or pharmacist scans the barcodes on a prescription label and on a stock bottle to ensure they match.

The individual then places the medication on a tray that counts the quantity, and once it reaches the right amount, a screen displays a green light, allowing the pills to be dispensed after the Eyecon takes a photo of the tray. These

**CONSUMER-ORIENTED TECH**

Searching for low-cost drugs and convenient pharmacies can be a consumer nemesis, but new apps are helping change that. One is FamilyWize, which offers a prescription savings card and price locator app.

For example, consumers using the Walgreens Transfer and Walgreens Refill features in the FamilyWize app can request that Walgreens transfer their prescriptions from the pharmacy where the script was originally filled to another pharmacy, if prices are lower at that other pharmacy.

The FamilyWize program is available to the insured, uninsured and underinsured, with no eligibility requirements. It encourages loyalty to one pharmacy to make it easier to track patient use and to ensure appropriate utilization, says Joseph Sanginiti, president and chief operating officer.
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Technology

Continued from page 8

pictures are readily available from the pharmacy software system.

Pinto says the next frontier is medication delivery to homebound patients, with patient signatures recorded with an iPad.

While Pinto says he is not sure if technology has really saved him money, he knows he has reduced prescription errors and waste by ensuring the right drugs and doses are prescribed. “We are trying to stay on par with chains while still offering one-on-one, personal service,” he says.

**Streamlined processes**

Each year, approximately 186 million prescriptions in the United States require prior authorization (PA). Of those, 40% are abandoned, resulting in the patient not receiving a medication due to the complex process associated with the PA process, according to CoverMyMeds. To help address this issue, the company offers an electronic prior authorization (ePA) process and completes requests through an integrated clinical system or online Web portal.

Pharmacists typically access ePA functionality through their pharmacy system, while prescribers can initiate or complete a PA request at the point of prescribing through their EHR systems or a free website.

Matt Scantland, CEO/founder of CoverMyMeds, says ePA reduces administrative waste and long-term healthcare costs, while improving care provided by pharmacists and doctors. He says ePA can reduce a health plan’s operational costs for processing a PA from $40 per request to less than $20.

Michael Bukach, vice president, pharmacy chain accounts for the company, says ePA provides “one stop shopping” so that pharmacists and physicians can use a standardized, single electronic process rather than navigating dozens of proprietary health plan systems. CoverMyMeds is working with pharmacy customers on decision support to automate more of the ePA work flow; with its provider and EHR partners to expose the ePA process in the prescribing work flow; and with payers to apply their coverage rules in real-time so they become a new kind of decision support at the point of prescribing.

**Fewer errors**

Phoenix Children’s Hospital, a 465-licensed bed, freestanding children’s hospital, rolled out a dose-range checking system in 2011 specifically for pediatric patients.

“There was no dose information for patients over 18 years old so we needed to tailor a system to the prescription habits of our patients and doctors,” says Vanessa Holton, PharmD, specialty leader, inpatient pharmacy, Phoenix Children’s Hospital.

The new system coupled these data with drug dosage reference information and input from pharmacists and physicians, and defined thresholds for “very high” and “dangerously high” doses.

Holton’s colleague Rhonda Kurz, PharmD, specialty leader, explains how a wide range in weight among patients at the children’s hospital and lack of a frame of reference for doses outside normal parameters makes it difficult to maintain a dose range checking system. Errors, she says, could just be a matter of a hundredth of a decimal point.

The hospital created a two-tiered alert system within the EHR system that notifies prescribers at the time of order entry about dosing. When a prescribed dose exceeds a “very high” range, the system generates a soft stop alert requiring a provider to double check the order, amend as needed or note why he/she is prescribing the dose. If a prescription exceeds a “dangerous” dose, a hard stop alert fires, preventing physicians from proceeding with the order without first consulting directly with a pharmacist.

Since the program’s inception, there has not been a single prescription overdose error, says Holton.

Mari Edlin, a frequent contributor to Managed Healthcare Executive, is based in Sonoma, California.
The List

MY MOST TRUSTED ADVISOR

INDUSTRY LEADERS SHARE WHO THEY CALL WHEN THEY NEED ADVICE

by AUBREY WESTGATE

MY BOARD MEMBER

“I have a board member who has a long history with CareSource. This person understands the evolution of the company, has been a trusted ally and allows me to incubate innovative ideas. I can count on an unbiased opinion and I benefit from the experience and advice.”

—Pamela Morris, president and CEO, CareSource

MY BUSINESS PARTNER

“My business partner and I have worked together for nearly 25 years and she is unabashed in her advice and criticism. She’s helped me take a hard look at my management style and how to reach objectives.”

—Don Hall, principal, DeltaSigma LLC, Managed Healthcare Executive editorial advisor

PATIENTS’ FAMILIES

“It’s critical we stay in touch with the families we serve. They provide the feedback we need to ensure our focus and decisions do not stray from what is most important.”

—Chad Johnson, senior vice president, Phoenix Children’s Care Network

MY WIFE

“When faced with a difficult issue, she brings a fresh, consumer, non-business, non-healthcare perspective to the discussion. She helps me to step back and take a look at the question from the global, not just the narrow perspective of the issue at hand. She reminds me to consider, ‘How do you do the right thing, and how do you do it right?’”

—Joel Brill, MD, chief medical officer, Predictive Health, LLC, Managed Healthcare Executive editorial advisor

PREVIOUS LEADERSHIP

“I’ve never been someone to rely only on one adviser. I’ve always been open to advice from a range of perspectives—from inside and outside healthcare. I get tremendous support from the Institute for Healthcare Improvement (IHI) Board. They have such a richness of perspective and diversity of experience. I am also hugely fortunate to get advice from my two predecessors at the IHI, Don Berwick and Maureen Bisognano—both senior fellows. I believe it’s rare for a CEO to continue to work closely with the previous leaders of the organization. For me, it’s the best of both worlds. I get access to two of the most thoughtful and influential leaders in healthcare when I need advice and, at the same time, they encourage me to find my own path.”

—Derek Feeley, president and CEO, Institute for Healthcare Improvement

MY WIFE

“She’s my biggest supporter and after 25 years, hasn’t steered me wrong as of yet.”

—David Calabrese, vice president and chief pharmacy officer, OptumRx, Managed Healthcare Executive editorial advisor

MY FRIEND, ZACH GERGER

“Zach is someone I met in pharmacy school in 1974 and has gone on to become a physician and a pain management specialist. He is my best friend.”

—Perry Cohen, PharmD, chief executive officer, The Pharmacy Group, Managed Healthcare Executive editorial advisor
PHARMACY TRENDS TO WATCH

Experts sound off regarding our managed care pharmacy survey findings

By KAREN APPOLD
THE PHARMACEUTICAL INDUSTRY IS COMPLEX—it’s ever changing and growing. That’s why Managed Healthcare Executive (MHE) conducted its first-ever managed care pharmacy survey to better identify top industry trends and challenges. To conduct the survey, which was performed during the second quarter of 2016 and received nearly 230 responses, MHE partnered with Access Market Intelligence and the National Institute of Collaborative Healthcare. Here’s a look at some of the key trends reflected by the survey findings, and analysis from experts. The full survey findings appear on Page 22.

TREND #1: SEVERAL FACTORS ARE DRIVING UP SPECIALTY DRUG COSTS

According to survey participants, the biggest drivers of specialty drug costs in 2017 will be a growing demand because of an aging population and increased prevalence of chronic disease (this answer received 38.1% of responses), followed by the introduction of new specialty drugs to market (26.5% of responses) and manufacturer pricing for new products (14.2% of responses). Inflation rates for specialty drugs already on market as well as broadened labeled indications and off-label use of existing products were both in the single digits, with 9.3% of responses and 8% of responses, respectively.

“The results show that a diverse set of factors is causing expenditures on specialty drugs to grow,” says Dan Mendelson, CEO, Avalere Health, Washington, D.C. “Because it’s not just one factor playing a role, rising spend on specialty drugs is a complex issue.”

Mark Ginestro, principal, KPMG LLP, an audit, tax, and advisory firm headquartered in New York, agrees with survey takers that both an aging population and increased prevalence of chronic disease will be significant drivers. He points to cancer as one disease with a big impact, because cancer patients are among the biggest users of specialty drugs. Furthermore, he says, oncology drugs are some of the most expensive treatments available. He believes that due to some remarkable innovations now on the market, such as targeted therapies, access to these drugs is improving and therefore demand is increasing. As the pharmaceutical industry is complex—it’s ever changing and growing. That’s why Managed Healthcare Executive (MHE) conducted its first-ever managed care pharmacy survey to better identify top industry trends and challenges. To conduct the survey, which was performed during the second quarter of 2016 and received nearly 230 responses, MHE partnered with Access Market Intelligence and the National Institute of Collaborative Healthcare. Here’s a look at some of the key trends reflected by the survey findings, and analysis from experts. The full survey findings appear on Page 22.

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Q: What do you predict will be the biggest driver of specialty costs in 2017?

Growing demand for specialty drugs due to an aging population and increased prevalence of chronic disease. 38.1%

Introduction of new specialty drugs to the market. 26.5%

Manufacturer pricing for new products. 14.2%

Inflation rates for specialty drugs already on market. 9.3%

Broadened labeled indications and off-label use of existing products. 8.0%

Other. 3.9%

“Patients expect to be able to get the benefit of medical improvement under their insurance products—whether it’s a cure for hepatitis C or psoriasis therapy.”

— DAN MENDELSON, AVALERE HEALTH
population ages, demand for oncology therapies will only continue to rise, he says.

Other chronic diseases that will drive increased specialty drug spend include HIV and hepatitis C, driven by drug addiction and the sharing of hypodermic needles, says Ginestro. “The comorbidities are challenging to manage and will continue to be a problem in 2017, thereby driving the cost of specialty drugs,” he says.

Mendelson adds that patients’ expectations about their healthcare are changing, which is also leading to higher specialty drug spend. “Patients expect to be able to get the benefit of medical improvement under their insurance products—whether it’s a cure for hepatitis C or psoriasis therapy,” he says. “Awareness has also grown as specialty drugs have been prominently in the news.”

Ginestro says much of the recent cost increases have come from new drugs that have either been curative or have targeted specific populations where they have strong efficacy. “In both cases, there is a strong arguable value and incentive for patients to take them,” he says. “Value drives cost and incentives drive utilization. Our current system is not structured to absorb curative treatments.”

**TREND #2: UPTAKE OF BIOSIMILARS WILL INCREASE—SLOWLY**

Biosimilars hold great promise in reducing the drug trend for specialty drugs, say experts. So how soon could they have this effect? Only 8.5% of survey respondents foresee this happening in 2017. But 21.4% of respondents expect a reduction in 2018, 13.4% in 2019, and 25% in 2020.

“I think the results sound about right,” says Spencer Borden IV, MD, MBA, principal, Integrity Consulting, LLC, Concord, Massachusetts. “Biosimilars will disrupt the market, but their effects will be much slower than pill-based generic medications due to their lower rate of production, slower rate of adoption, and concern about equivalency of clinical outcomes. The cost differential between biosimilars and branded biologics will be smaller than generic discounts because of the high costs of protein manufacturing. The uptake will be slower as the approval process gets more standardized and well known.”

Ginestro agrees that the results reflect a realistic, staggered view of the impact of biosimilars. “We are seeing a more gradual introduction of biosimilars into the market than many were expecting,” he says. “Patents, a key indicator of timing, are and will be expiring. But many other factors are involved as well, including the cost to develop and get a biosimilar approved. As a result, the biosimilar market will not be a flood of low-cost competitors. Rather, it will be a staggering of one to several key players entering the market. In this regard, it will function more as a competitive branded market where a new entrant will bring down the price of the incum-
bent to a certain extent, but not to the extent that the incumbent leaves the market.”

Borden thinks the biosimilar market will take between three and seven years to grow and peak. “The full impact will occur when the approval process becomes routine and there are several biosimilar competitors in each drug category,” he says. “Then, I expect price competition to occur between biosimilar competitors. Those with a large and existing market share will have to offer discounts in order to fend off new entrants in their category. New entrants will find it challenging to take market share away from well-known biosimilar standards.”

Another reason it will take several or more years for biosimilars to reduce the drug trend for specialty drugs is that biosimilars will need to prove that their clinical outcomes are not different than the branded biologics, says Borden. “By definition, their chemical structure is different from branded biologic products,” he says. “Proof of clinical equivalence will require time-consuming clinical trials and subsequent publications. Failure to prove equivalent clinical outcomes will cause biologics to be slow to replace branded biologics, or even fail in a certain drug category.”

Notably, the survey also revealed that 31.7% of respondents don’t think biosimilars will reduce the drug trend for specialty drugs. Gineestro surmises that these respondents probably expect one of two things to happen, which will cause overall specialty spend to continue to increase:

1. Demographics will continue to shift toward an aging population, which will continue to increase demand.

2. Next-generation products will debut that may mitigate the demand for biosimilars, which will offset savings.

Borden reasons that some respondents think that biosimilars won’t reduce the drug trend for specialty drugs because the uptake will be slow compared to generic pills. “The discounts will be smaller and new entrants will be slower to manufacture and appear in the marketplace as manufacturing challenges remain stiff,” he says.

Finally, an additional hurdle will be for manufacturers to work with professional associations to get biosimilars included in current clinical guidelines as best practices in specific disease treatments, Borden says.

TREND #3: EXECUTIVES AGREE THAT NEW PRICING MODELS MUST BE EXPLORED

When participants were asked about the best strategy to allow for coverage of new innovative therapeutics and biologics, using value-based contracting where manufacturers are willing to go at risk for the therapeutic performance received the highest number of responses at 44.7%. In second place, 30.5% of participants pointed to excluding the most-costly products from the formulary—unless there is a proven benefit. Using manufacturer net pricing (wholesale acquisition costs plus discounts) ranked third, with 14.2% of responses; and adjusting the premium costs across the broader pool of members/employees was last, with 5.3%.

Randy Vogenberg, PhD, RPh, partner, Access Market Intelligence and the National Institute of Collaborative Healthcare, Greenville, South Carolina, agrees with most survey respondents that to confront this issue of ensuring coverage for new products, new pricing models must be explored. “As part of the sea of change that is swamping the post-ACA healthcare market, value-based contracting is a moderate to significant change in the way business is done by healthcare stakeholders,” he says. “For biologic and specialty therapeutic agents, old rules and methods don’t apply like traditional drugs. New methods and payment strategies need to emerge.”
What do you think would be the best strategy to allow for coverage of new innovative therapeutics and biologics?

Use value-based contracting where manufacturers are willing to go at risk for the therapeutic performance.  

44.7%

Exclude the most costly products from the formulary unless there is proven benefit (survival, quality of life, fewer side effects) vs. the standard of care.  

30.5%

Use the manufacturer net pricing (wholesale acquisition costs plus discounts) which places the product at a competitive advantage to others used for the same indication(s).  

14.2%

Adjust the premium costs across the broader pool or members/employees.  

5.3%

Other.  

5.3%

From a payer standpoint, Ashraf Shehata, principal and member of the Global Healthcare Center of Excellence, KPMG LLP, Cincinnati, Ohio, says value-based contracts are seen as a means to control unit costs for medications. “However, there needs to be consistency in the standards and outcomes being measured, and there needs to be trust between health plans/pharmacy benefit managers, providers, and payers that the outcomes are being presented fairly,” he says. “With many new drugs, manufacturers often find themselves providing significant details to the payer community in order to spell out a drug’s benefits so they can get it included in formularies.”

Shehata says value-based contracting also must be approached in the right manner to ensure patient care is not jeopardized. “Globally, some national health programs remove that decision about covering certain treatments from the hands of doctors and patients by excluding drugs that do little to extend survival or improve the quality of life,” he says. “That is taking the stringency around formulary design to an extreme. Value-based contracting or step therapy is acceptable in drug categories where there are other alternative treatments, but there needs to be a case made about the use of a specialty drug.”

Vogenberg says many value-based strategies are being used to allow for the coverage of new innovative therapeutics and biologics. Different forms of value-based pricing include: economic or cost focus only, such as value-based purchasing; middle-ground with some balance of cost and quality metrics related to value that employers are interested in; and quality or outcomes centric models that tend to be more holistic and moderate and focus away from just cost.

“Most have had some short-term success, but none have been universally proven to be the most successful for all stakeholders,” he says. “Medicare and commercial markets operate somewhat differently, so differentiation of market segments and stakeholders in each segment is necessary to determine the best strategy for each segment. What may work in CMS-based reimbursement does not necessarily work for commercial markets and vice versa.”

Vogenberg did not find the survey findings regarding value-based contracting as a solution to ensuring coverage of new therapeutics and biologics surprising. “It’s a typical view of market options and thought processes around contracting, where value is never clearly defined or interpreted,” he says. “This is an important area for research and innovation in more optimally addressing acquisition costs with appropriate reimbursement.”  

Continued on page 21

“Most have had some short-term success, but none have been universally proven to be the most successful for all stakeholders,” he says. “Medicare and commercial markets operate somewhat differently, so differentiation of market segments and stakeholders in each segment is necessary to determine the best strategy for each segment. What may work in CMS-based reimbursement does not necessarily work for commercial markets and vice versa.”

— RANDY VOGENBERG, ACCESS MARKET INTELLIGENCE AND THE NATIONAL INSTITUTE OF COLLABORATIVE HEALTHCARE
How do you think the trend toward performance-based pricing for pharmaceuticals, vs. reference-based pricing, will evolve over the next three to five years?

**Q:** Performance-based pricing will be the dominant agreement. 19.9%
Performance-based pricing will be used somewhat more than the reference-based pricing. 42.5%
Reference-based pricing will be used somewhat more than the performance-based pricing. 23.1%
Reference-based pricing will be the dominant agreement. 14.5%

**TREND #4:**
**PERFORMANCE-BASED CONTRACTING IS ALREADY GAINING TRACTION**

Also in the survey, participants were asked: “How do you think the trend toward performance-based pricing for pharmaceuticals vs. reference-based pricing will evolve over the next three to five years?” The majority of respondents (62.4%) predicted that performance-based pricing will be used more often than reference-based pricing.

“The findings are not that surprising, given the push toward finding value in healthcare,” says Shehata. “Payers are looking for greater value and are pressuring drugmakers to prove their outcomes, especially in cases in which drug categories are largely comprised of generic treatments. A new drug has to make a case for why it should replace a drug that only costs a few dollars a month.”

Shehata expects performance-based pricing to be used somewhat more than reference pricing because some drug categories lack alternatives, especially in cases of rare diseases or some specialty drugs. “In those instances, the drug manufacturer has an upper hand,” he says. “If drugmakers find new ways to tweak drug formulas or delivery systems to improve medication adherence or patient outcomes, the negotiation between payer and the manufacturer becomes less about price and more about lowering the overall cost of care.”

Robert Taketomo, PharmD, MBA, president/CEO, Ventegra, Inc., a California benefit corporation in Glendale, anticipates pricing to continue to evolve beyond traditional practices, but such evolution will be dictated to some degree by market segment (i.e., Medicare, Medicaid, commercial, classes of trade, and distribution channels).

Vogenberg agrees that commercial versus public sector differences will vary from the traditional practices today, but differs on the future role for reference-based pricing. He says there is greater value from a risk basis incorporating today’s reference-based pricing that actuaries and underwriters prefer versus the vagaries of only performance-based pricing.

Shehata says the biggest pricing battles will be regarding specialty drugs competing against existing specialty drugs; cases in which biosimilars will be launched; or cases in which the brand name drug has to prove clear superiority in a category with mostly low-cost generics. “We are seeing this play out with Amgen’s launch of Repatha [evolocumab] to lower cholesterol and Novartis’ Entresto [sacubitril/valsartan] to treat heart failure,” he says. “Both manufacturers are taking on pricing risk to prove that their drugs work.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.

“A new drug has to make a case for why it should replace a drug that only costs a few dollars a month.”

— ASHRAF SHEHATA, KPMG LLP
To identify the top managed care pharmacy challenges and what your peers are doing about them, *Managed Healthcare Executive*, in partnership with Access Market Intelligence and the National Institute of Collaborative Healthcare, conducted its first-ever pharmacy survey during the second quarter of 2016.

The survey received a total of 228 responses from executives at medical practices, hospitals, large healthcare systems, benefit management organizations, health plans, long-term care organizations, group purchasing organizations, consulting firms, and more. Here are some of the key findings (additional findings appear in the cover story on Page 12).

Q: What do you think is the single biggest opportunity in managing pharmaceutical costs that really makes a difference to the purchaser of healthcare (government program, employer or consumer)?

- **47.1%** increased collaboration to identify the most effective and cost-effective treatments.
- **14.7%** adoption and enforcement of more stringent, evidence-based clinical pathways.
- **12.4%** prior authorization, step therapy, and limited initial refills.
- **10.7%** more disciplined contracting/purchasing.
- **6.2%** more narrow and/or exclusionary formularies.
- **8.9%** other.
Q: In your opinion, what is the single most effective way to manage specialty drug costs?

36.1% Performance-based (outcomes-based) pricing for pharmaceuticals. Pharmaceutical companies should share risk, such as through upfront discounts and bonus payments later if drugs live up to the promise of fewer hospitalizations and lower costs.

22.9% Increased price transparency. The more physicians and patients understand what medications cost, the more willing and able they will be to identify low-cost alternatives.

16.7% Increased government regulation. The government needs to step in and work with pharmaceutical companies to rein in these costs.

15.4% Increased action by health plans. Health plans can better ensure these drugs are used properly by those who will benefit the most, such as through prior authorizations, limited initial refills, formulary exclusions, and mandated use of specialty pharmacy.

2.6% Referenced-based pricing. Drug plans reimburse the cost of the reference drug or drugs in an entire class.

6.3% Other.

Q: On average, to what degree do you feel pharmacy benefit plans are integrated with medical coverage?

43.5% Partially complementary (delays in getting information, not full picture, resulting in information gaps).

27.8% Limited complementary (access by disease state or practice).

14.3% Fully complementary (access to complete pharmacy and claims to view clinical and economic patient outcomes).

14.4% Not at all complementary (not able to view or retrieve clinical and economic patient information).

Q: In your opinion, how will new specialty drug blockbuster categories impact overall spending for your medical or pharmacy benefit?

32.9% They will have a huge impact. There’s little that plans will be able to do to curb costs.

59.1% They will have a somewhat high impact. Programs such as prior authorization and step therapy will help curb the impact.

5.3% They will have very little impact. The adoption of these drugs will be limited.

2.7% They will have no impact.
Q. What might be the best long-term approach for addressing the high cost of rare disease treatment?

- 39.7% A more integrated approach by benefit managers around access for these agents.
- 30.4% Use of benefit incentives to drive consumer engagement and drive higher value care.
- 22.8% Government guidelines and/or regulations.
- 7.1% Other.

Q. Do you believe that pharmacists should be able to initiate, adjust and discontinue medications and participate in the evaluation and management of health conditions in collaboration with other providers?

- Yes 82.7%
- No 17.3%

Q. Do you believe that pharmacists should be compensated under Medicare Part B for prescribing medications and working with other healthcare team members to assess patient conditions?

- Yes 87.6%
- No 12.4%

Continued on page 26
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Q: What do you think is the most effective way to address opioid abuse/misuse/diversion?

- 27.0% Increased use of lock-in programs that identify potential abusers and limit them to a single pharmacy or prescriber.
- 26.1% Increased use and capabilities of prescription drug monitoring programs.
- 26.1% More enhanced efforts from health plans and PBMs to identify, flag, and intervene in cases where there appears to be abuse/misuse/diversion.
- 8.1% Increased availability and prescribing of opioid drug products with potential abuse deterrent properties.
- 6.2% Government intervention to limit opioid prescribing and dispensing practices.
- 6.5% Other.

Q: How do you think quality ratings will most impact prescription drug plans?

- 37.0% Plans will focus more aggressively on Medication Therapy Management.
- 19.0% More plans will collaborate with retail pharmacies to improve ratings.
- 15.6% Plans will rework their preferred networks to include only high-performing pharmacies.
- 11.4% They will have little to no effect.
- 8.5% Plans with higher ratings will be able to charge higher premiums.
- 8.5% Plans will expand program offerings.

Q: Who do you believe will be affected most by quality ratings, such as through the Star Rating program, over the next two to three years?

- 41.2% Health plans (using preferred networks, collaborating more with pharmacies, and more robust program offerings).
- 37.9% Providers (engaging with consumers around prescribing, use of drugs).
- 13.3% Consumers (using higher-quality providers).
- 7.6% Self-funded plans (using preferred networks, collaborating more with pharmacies, and more robust program offerings).
As health plans work to develop and price products for the 2017 open-enrollment cycle—beginning November 1, 2016—it looks like some premiums are set to rise substantially.

Reports show that some premiums could rise more than 60% in Texas, Tennessee, and Arizona, as well as other states.

Simply put, John Barkett, senior director of policy affairs, Willis Towers Watson, Washington, D.C., says payers are hiking premiums to make their individual lines of business profitable in 2017.

“They’ve been unprofitable to date for a myriad of reasons: cutthroat competition caused some insurers to underprice the market; governmental risk mitigation programs promised a financial backstop that never materialized; and some customers used special enrollment periods to obtain insurance only after they became sick,” he says.

Federal government programs that didn’t work as expected are also to blame, says Jim Whisler, principal, Deloitte, Minneapolis, Minnesota. He points to the risk corridors program as an example. “Given the uncertainty in pricing plans for the exchange population, it was supposed to provide insurers with protection for underpriced plans,” he says. “If an exchange plan’s loss ratio—that is the amount of claims relative to premiums—was above a certain percentage, then the government would pay the insurer a proportion of the excess. In 2014, only 12.6% of the dollars owed through the program were actually paid because of funding issues.”

In addition, the government’s reinsurance program will no longer be in effect in 2017, says Whisler. This program protected plans that had a disproportionate share of people with significant health needs, by covering a percentage of the costs in excess of the attachment point for up to $250,000 for each plan member. This program paid out more than was initially anticipated. “So plans’ rates for 2017 need to reflect the fact that they will no longer get funding through this program,” he says.

Another contributor to rising premiums is the fact that initial projections indicated a much higher exchange membership by this point. The lower-than-expected enrollment has resulted in a mix of members who are sicker than a typical insured population. “When health plans initially priced their products, they assumed that this population would have a more balanced mix of insureds as it relates to health status,” Whisler says.

Antoinette Kraus, director, Pennsylvania Health Access Network, Philadelphia, says that pent-up demand for access to treatment is another driver of rate increases. “For many years, people who lacked health coverage delayed care or paid for limited care based on their ability to pay for it,” she says. Furthermore, she believes that certain companies, in an effort to attract volume, underpriced their products initially and were then overwhelmed by demand.

Kraus cites other forces at work as well. “Flawed modeling that relied on data from the previously existing commercial market could have been corrected by relying more heavily on data from the Medicaid managed care companies,” Kraus says. “We believe that important policy tools like an all-payer claims database would have provided better resources and information on which plans could rely.”

Clare Krusing, press secretary, America’s Health Insurance Plans, Washington, D.C., says premiums are also expected to increase because medical costs and the underlying costs of providing care are increasing.

**Comparing 2016 to 2017**

In 2016, weighted average premiums increased by 12% compared to 2015. For 2017, weighted average requested premium increases will be around 21%, according to Charles Gaba, who compiles requested increases for the model he...
Policy Outlook

State variation in exchange premiums


Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.

runs at ACASignups.net, Barkett says. However, final premiums will be lower than requested, on average, and will likely be around 15%.” But that number assumes no one changes plans,” says Barkett. “Once enrollees do change plans, the weighted average increase will likely be down to around 10%.”

Whisler says a number of health plans with high exchange membership have been significantly under-priced as demonstrated by their losses, and as a result will need rate increases well above medical trend to reflect this historical underpricing. In other cases, plans are pulling out of exchange markets in certain states, such as UnitedHealthcare. “Those staying in will need to get to a stable point with their premiums rates,” he says. “Some will bite the bullet and implement a large increase in 2017, even though they tried to ride it out in the past as they hoped that the number of healthier members would increase.”

Addressing the problem

Whisler believes that plans with broad networks, such as those with PPOs in which members can seek care wherever they want, will be among those with the highest increases. A good strategy to avoid having to implement high rate increases is to have a more narrowed network that can forge close relationships with specific care systems, Whisler says. “The sickest people tend to seek out plans where they have the most choices in seeking care.”

Value-based care is a way for plans to get providers involved in sharing some of the risk. “This has been done successfully in California, for instance, which may be one of the reasons rates haven’t increased as much there,” Whisler says. “Care systems have much more stake in medical expenses when they have some risk incentive. Furthermore, value-based care arrangements are frequently paired with having narrower networks.”

For Whisler, the ultimate success of the exchanges is dependent upon getting a better mix of members enrolled in the exchanges, instead of having primarily sick members. “Having such a disproportionate share of sick people enrolled increases premium rates and keeps healthier people out of exchanges,” he says. “Healthier people don’t enroll because they don’t think they will use the insurance and that it’s not a good deal for them relative to the penalty. Health plans can get more healthy people to enroll by creating narrow networks and closely managing patients. The federal government should do more as well, such as not allowing as many people to avoid paying the penalty, and marketing the importance of insurance to typically healthy segments of the population.”

Are exchange plans failing?

So far, the exchange component of Obamacare has been pretty rocky. But Whisler thinks the jury is still out on the success of exchanges. “If more people don’t enroll in the exchanges, you won’t have a market as it was originally anticipated,” he says. “However, if enrollment can be increased through health plan and government actions, then the exchange markets can be stabilized.” But it doesn’t look like 2017 will be a good year for exchanges; action will be required to improve the outlook for 2018.

Barkett isn’t ready to call the exchanges a failure, either. “The market is going through growing pains. Premium spikes should become rarer over time as the market stabilizes,” he maintains.

Kraus believes that as more people gain access to coverage, they can seek medical treatment that should ultimately improve their health outcomes and lower costs. “In the interim, companies need to find the appropriate rate to ensure solvency,” she says. “It will take several years to strike the appropriate balance.”

Krusing adds, “Premium increases show that there is still more work to be done to bring underlying costs under control. We need to look at the factors that drive premium increases, such as the prices being charged for medical services.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Depression is one of the most common mental disorders in the United States, affecting approximately 6.7% of adults each year, according to the Anxiety and Depression Association of America.

Depression also takes a heavy economic toll. In 2010, the estimated economic burden of depression, including workplace costs, direct costs, and suicide-related costs, was $210.5 billion, according to a report published by the Journal of Clinical Psychiatry. Of that $210.5 billion, only 38% of the total costs were due to major depressive disorder (MDD) itself as opposed to comorbid conditions.

“Depression is often a comorbidity with other chronic illnesses, such as heart conditions or cancer, and often is an impediment to managing other chronic illnesses,” says Cynthia Ambres, MD, a partner at KPMG Strategy and a member of the firm’s Global Healthcare Center of Excellence.

Current treatments
Antidepressants are a popular treatment choice. Although they may not cure depression, they can reduce symptoms, such as low mood, anxiety, and decreased energy.

According to Farrah Wong, PharmD, director of pipeline and drug surveillance at OptumRx, about one in every 10 Americans, aged 12 years and older, takes an antidepressant medication. Of those individuals, more than 60% have been taking it for longer than two years, and 14% take more than one antidepressant.

The main medications used to treat depression include selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, bupropion, mirtazapine, and adjunctive therapies such as atypical antipsychotics.

“Despite a large armamentarium of pharmacotherapy used to treat depression, only 60% to 70% of patients with depression respond to antidepressant therapy,” says Wong. “Of those who do not respond, 10% to 30% exhibit treatment-resistant symptoms coupled with difficulties in social and occupational function, decline of physical health, suicidal thoughts, and increased healthcare utilization.”

Patients diagnosed with MDD are defined as having treatment-resistant depression if their depression has failed two or more antidepressant therapies. These patients pose a major therapeutic challenge to mental health experts as they require specialized treatment-resistant management.

The global anxiety disorder and depression treatment market stood at $22.5 billion in 2013 and is expected to decrease to $18.2 billion by 2020, according to a report published by Transparency Market Research. Wong believes that this anticipated slow decline in spend is because of a weak pipeline of novel drugs and an increasing number of generic entries to the market.

Although the market is experiencing diminished spending in antidepressant drugs, insurance coverage is improving. According to Ambres, mental health parity laws have changed how behavioral conditions are covered. The share of total mental health treatment expenditures financed by private insurance, Medicare, and Medicaid increased from 44% in 1986 to 68% in 2014, according to a study in Health Affairs.

In the pipeline
Pharmaceutical Research and Manufacturers of America
(PhRMA) lists several antidepressants undergoing phase 3 trials for the treatment of depression. Some of these drugs are already on the market and seeking additional indications for depression. For example, cariprazine (Vraylar, Allergan and Gedeon Richter Plc) was approved by FDA in 2015 for the treatment of schizophrenia and mania associated with bipolar disorder. The manufacturers are seeking an indication as an adjunctive treatment for MDD, according to PhRMA.

“As many blockbuster antidepressants have gone generic in the last decade—for example, Prozac, Zoloft and Cymbalta—the late-stage antidepressant pipeline has been rather sparse,” says Wong. “However, we are seeing drugs in development for treatment-resistant depression, including esketamine, and dextromethorphan bupropion [AXS-05].”

Esketamine (Janssen Pharmaceuticals) is a chemical variant of ketamine that acts as an N-Methyl-D-aspartate (NMDA) receptor antagonist to ameliorate depressive symptoms. Esketamine has been granted fast-track designation by FDA for MDD. Researchers are currently recruiting participants for a safety and efficacy study of intranasal esketamine for use in treatment-resistant depression.

AXS-05, an oral combination of dextromethorphan and bupropion developed by Axsome Therapeutics, is also in late-stage testing for treatment-resistant depression and other central nervous system (CNS) disorders. Both drugs have CNS activity, and when used together, bupropion is thought to increase the bioavailability of dextromethorphan.

Another pipeline treatment currently being evaluated for its use in MDD is rapastinel (formerly known as GLYX-13, Allergan), an investigational intravenous formulation of a novel NMDA receptor partial agonist. Rapastinel will be manufactured as a pre-filled intravenous syringe that can be administered in under one minute. Rapastinel received breakthrough therapy designation from FDA for adjunctive treatment of MDD. This follows the fast-track designation for rapastinel granted by the FDA in 2014. Because rapastinel is administered intravenously, it will likely be covered as a medical benefit drug and may incur additional costs, such as facility fees and administration fees, says Wong.

“Many of the SSRI and SNRI drugs have generic options that have diminished spending in the area of antidepressants,” says Ambres. “Introduction of new drugs could boost some of the spending again for treating depression on the margins, since there are so many antidepressants available.”

Future challenges
Treatment-resistant depression continues to challenge mental healthcare providers, and Wong believes that drugs being studied for this use may provide promising clinical benefits and additional therapeutic options.

According to Andrew Lyle, director of business development at Curexa Pharmacy, the future for this category is going to include biologic injectables and repurposing older drug classes to treat depression. For example, onabotulinumtoxinA (Botox, Allergan) is currently in phase 2 for treatment of depression.

“With the increase in drug prices, sprawling indications, and an increase in biologic injectables, specialty pharmacies will have to begin to play a major role in the dispensing of these drugs,” says Lyle. “The biggest threat to the patient and insurers is non-adherence. Specialty pharmacies that are URAC-accredited and Accreditation Commission for Health Care accredited are required to do patient training, clinical follow-up and proactive refills. This will in turn help the patient stay adherent to their medication. That is a win-win for payers and patients.”

Another trend that Lyle predicts is finding new indications for existing depression treatments. One example is flibanserin (Addyi, Sprout Pharmaceuticals), indicated for hypoactive sexual desire disorder (HSDD).

“In reality, this drug at its core is very similar to an SSRI, such as Prozac,” says Lyle. “While standard SSRI’s raise the levels of the neurotransmitter serotonin, Addyi blocks certain receptors from responding to the increased levels of serotonin. Because Addyi is so similar to an SSRI, it is already positioned to be used in other ‘mental health’-type conditions such as postpartum depression.”

Mental health is still relatively undertreated, despite benefit parity laws, Ambres says. “As a society, we need to remove some of the stigmas associated with mental health to guide people to seek treatment,” she says. “A holistic approach to patient care can assist those patients whose depression is interfering with the treatment of other illnesses. Antidepressants paired with psychotherapy can help patients overcome barriers in managing chronic illnesses.”

Erin Bastick, PharmD, RPh, is a graduate intern at University Hospitals Elyria Medical Center in Elyria, Ohio.
Over the past year, the healthcare industry made little progress in managing the high cost of specialty drugs. According to UnitedHealth Group, growth in specialty pharmacy spending could quadruple by 2020, reaching $400 billion or 9.1% of national healthcare spending in the United States.

Industry experts have predicted that specialty drugs will represent 45% of pharmaceutical manufacturer sales by 2017. And, Artemetrx expects specialty drug spend to surpass traditional drug spend for most plan sponsors due to double-digit growth in specialty that will continue for the foreseeable future across both the pharmacy and medical benefit.

Managed Healthcare Executive recently invited a panel of experts representing different sectors of the industry to explore these challenges and identify potential solutions.

The following experts served on the panel, which was moderated by Perry Cohen, CEO of The Pharmacy Group:

Ken Schaecher, MD, medical director, SelectHealth
David Calabrese, RPh, MHP, chief pharmacy officer, OptumRx
Bobby Dubois, MD, PhD, chief science officer, National Pharmaceutical Council
Cheryl Larson, vice president, Midwest Business Group on Health

Q: How can stakeholders most effectively manage specialty drug costs and patient outcomes?

As medical director of an HMO and an integrated delivery network, Schaecher said he didn’t presume to represent every managed care plan around the country but that collaborative communication and quality care initiatives—pay-for-value activities—seem to be solutions. “I think everyone recognizes the cost of healthcare in the United States is excessive and as a consequence, we have to work together to find solutions, such as oncology pathways, formulary design and step edits—that make sense for everyone, and that no one solution is necessarily going to work,” he said.

OptumRx, a pharmacy benefits manager (PBM), is attempting to tap into the vast resources that it has at its disposal via its larger Optum enterprise system, bringing many different stakeholders to the table, Calabrese said. The PBM owns a specialty pharmacy distribution service; has home infusion capabilities; and provides data integration and analysis, behavioral health services, health and wellness capabilities, a case management component, etc., that can deliver a much more integrated and holistic solution to support this patient population, he said.
“On the pharma side, we’re working close to the pharmaceutical manufacturers around things such as innovative outcomes and value-based contracting, price protection and other things that are critical in the specialty area,” said Calabrese.

He explained that OptumRx is also collaborating with external organizations that have expertise in value-based contracting, such as the Institute for Clinical and Economic Review (ICER), to leverage their capabilities and understanding of cost effectiveness of specialty therapies. These efforts should help the PBM better position products going forward and manage them based on their inherent value supported by available evidence, he said.

“In addition, we are working aggressively on site-of-care channel management to try and ensure that drugs—especially infusibles—are being dispensed and administered in the sites of care that make the most amount of sense from both patient access and cost perspectives,” said Calabrese.

We’re working close to the pharmaceutical manufacturers around things such as innovative outcomes and value-based contracting, price protection and other things that are critical in the specialty area.”

—DAVID CALABRESE, OPTUMRX

In approaching the value and utilization of specialty drugs, Dubois divided activities into three types—unilateral, bilateral and multilateral. On the unilateral front, he said, there is a lot of attention being paid to the development and use of value framework, each developed by individual organizations—especially in the oncology area—by the American Society of Clinical Oncology; the National Comprehensive Cancer Network (NCCN); Sloan Kettering’s Drug Abacus, an interactive drug price comparison tool based on value; and ICER.

Examples of bilateral approaches include manufacturer-payer risk-sharing relationships, such as the one between Harvard Pilgrim Health Care and Amgen in the use of its PCSK9 drug Repatha; and Aetna’s and Cigna’s pay-for-performance arrangement with Novartis for its heart drug Entresto, said Dubois. In an ideal world, we would not have unilateral or bilateral approaches, but multilateral ones where payers, providers, and patients engage in both the dialogue and exploration of solutions, he said. “There needs to be a forum and focal point where this can occur.”

Larson said that employers, in particular, are usually considered an afterthought in involvement in initiatives that impact providers and the drug industry. She is optimistic, however, that the scenario is changing.

“The reality is that self-insured employers represent a little over half of all healthcare spending in this country, which means we’re paying the lion’s share of biologic and specialty drug costs,” Larson said. “In fact, in my world, employers are the real purchasers and payers of healthcare, while health plans and PBMs serve as the middlemen. As purchasers, we care about the health and productivity of our employees and family members and seek to put the right benefits packages together to do that. Specialty drug and treatment costs, however, are making it more difficult to do that, especially for the small and mid-sized employer.”

Larson coleads an employer-led, national research project, the “National Employer Initiative on Biologics and Specialty Drugs,” that focuses on educating employers about the specialty benefits marketplace; researches and pilots new strategic approaches; and brings stakeholders together to discuss value and address the main issues that are driving care and cost increases.

She acknowledged that her organization cannot control drug costs, but it can, she said, do something about the stakeholders who are adding to these costs by not sharing rebates with employers or by purchasing drugs from a manufacturer and hiking up the cost of the drug—all at the expense of the employer who keeps paying more each year.

Q: Have specialty drugs, such as new high-cost hepatitis C drugs, indicated sufficient value to merit their high costs?

Schaecher said it depends on the stakeholder. “Value is a judgment, and there are
a lot of judgments out there. I think on the whole, there’s grave concerns about the cost of specialty drugs. When you’re seeing 15% to 20% to 25% annual increases in the cost of specialty drugs added to some of the limitations put on us by ACA [Affordable Care Act] legislation, such as having to use community ratings instead of individually rated plans, it’s really a struggle,” he said.

Calabrese agreed that value is in the eye of the beholder. “Certainly, taken as a whole, specialty drugs have enhanced our ability to manage a number of key conditions that in the past were not well-managed or where we had few if any treatment options,” he said. “They have brought value to the table not only in terms of their efficacy, but also in areas such as quality of life and daily functioning. Whether the cost justifies the added value, particularly the annual increases in cost we continue to see, remains a largely unanswered question.”

As a result, he sees organizations, such as ICER and NCCN in the oncology space, building tools and resources into their support services that will help to answer some of those questions when new drugs are being introduced to the market.

Most health plans, Schaecher said, believe the value of specialty drugs does not justify their costs, that they are overvalued and overpriced for their clinical results. He said that clinical studies are often conducted to bring drugs to market that meet regulatory requirements without concern for whether plans will receive adequate clinical value.

“If a drug improves any patient’s health—even by a little—providers consider that it has value,” Schaecher said. “But when we’re asked to make population-based decisions and those population costs result in potentially the inability to provide other benefits that may be of greater value, it’s a real challenge. For example, for some patients, the new high-cost drugs for hepatitis C are cost-effective and for others, they aren’t.”

Calabrese said the value of specialty drugs year over year is not commensurate with price increases that are being charged. He blames it on inflation. “While we are seeing these types of inflation rates, we’re not seeing additional data coming to the table that says the clinical value has increased 15% to 25% a year,” Calabrese said, noting that this forces PBMs to take a much more aggressive stance, as illustrated by the evolution of exclusionary formularies and more aggressive utilization management programs.

“So there’s a lot of work to be done here and the onus is on the manufacturer,” he continued. “They establish this initial pricing and annualized price increases. They have to be the ones to invest in the type of sound comparative pharmacoeconomic analyses that will justify such increases.”

Dubois said it is important to separate the cost of drugs for an individual patient from the cost for a population. For an individual patient, a drug may provide real benefit and be cost effective. However, if there are many patients who might benefit from the therapy, that can lead to substantial budget impact. It is a payment challenge but not a value one, he said. He also raised the point that what are deemed costly branded agents today will become generic drugs in the future.

“We found if you look at every brand to generic conversion over the last 20 years and you average the drug’s price over the lifecycle of those products, you end up with costs that are about half of what people think,” he said. “It is important to examine drug costs longitudinally as you think about the cost per patient. One of the challenges relates to the coming availability of high-cost, curative interventions like gene therapy, where the insurer paying the bill for a patient might not be the insurer that receives the economic benefits.”

Schaecher said it is important to consider the repercussions on small and mid-sized employer groups who must compensate for the high cost of drugs by raising premiums or eliminating coverage, thus increasing the number of uninsured. While the ACA was implemented to prevent that, he said, many plans have pulled out of the exchanges because they have proved to be unprofitable. In addition, he pointed out that utilization of specialty drugs is higher among exchange members.

It is important to examine drug costs longitudinally as you think about the cost per patient.”

—BOBBY DUBOIS, MD, PHD, NATIONAL PHARMACEUTICAL COUNCIL
How can cancer drugs be adequately managed as the pipeline fills and demand increases?

Schaecher said that drug management doesn’t depend too much on the pipeline but rather on a societal point of view and the willingness of providers, patients and society to look at cancer differently and realize that not all conditions can be cured.

“There is a lot of cancer therapy administered that has zero effect or perhaps even a negative effect on health outcomes or quality near the end of life. And I think that’s where we need to focus our efforts to try to reduce the unnecessary therapies that don’t improve health outcomes,” Schaecher said.

He also noted that as cancer becomes a chronic disease, short-term spend on drugs has changed into a long-term, annualized process, while prices keep rising with the reiteration and development of drugs.

What can be done to effectively manage specialty drug costs while not taking advantage of payers?

From the PBM perspective, Calabrese said OptumRx is offering a greater level of transparency in its processes by meeting with clients and providing information about how the company factors in rebates. The PBM also is aggressively negotiating with manufacturers to build in price protection to ensure that if the cost of drugs increases, a client receives appropriate reimbursement.
OptumRx, Calabrese said, is also helping to manage drugs that typically fall outside the pharmacy benefit—especially infused products that land in the medical benefit and represent more than 50% of specialty spend—and coordinating both sides of benefits to deliver the most value clinically and financially for a client.

He added that the PBM’s National Pharmacy & Therapeutics Committee operates in a fully transparent fashion, allowing clients the opportunity to observe firsthand the clinical deliberations that drive formulary and utilization management programs. The organization also deploys a highly proactive approach to major pipeline drugs, advising clients before drugs come to market in the evaluation of drugs’ clinical merits based on published evidence and on how these new drugs might best be used, and conducting critical clinical appraisal of these drugs via P&T prior to FDA approval.

Schaecher puts his money on collaboration between specialty pharmacies, PBMs and health plans working with providers to ensure drugs are being used appropriately and responsibly. "It comes down to getting the right drug to the right patient in the right amount at the right time for the right duration ... recognizing that each drug may have some unique aspects to it that don’t allow you to just take a singular, cookie-cutter approach,” Schaecher said.

Larson agreed that to ensure healthcare delivery is optimized and customized, stakeholders need to address the whole process and use of specialty drugs.

“Some employers, such as manufacturing firms, focus heavily on productivity so the right drug at the right time is very important,” she said. “Others are only focused on costs and shifting more cost to the consumer, which is resulting in people not filling their drug prescriptions or getting needed treatment. This doesn’t help anyone except vendors that make money on the drug.”

“Strategies that align with all stakeholders through collaboration are critical, and we still don’t see much of that happening,” Larson continued. “In the end, stakeholders may need to make a little less money so that employers can stay in the benefits game. If employers choose to walk away from offering healthcare benefits because they can no longer afford them, we are talking about a major tipping point for us all.”

She said that employers need to be educated about avoiding financial risk in the system, such as by eliminating vendor drug cost waste caused by overcharging, non-transparent contracts, and iron-clad PBM contracts that only benefit the PBM.

“Employer education is key; taking action is key; stakeholder collaboration for effective cost management is key,” Larson said. “For the employer plan sponsor, doing nothing is no longer an option.”

Mari Edlin, a frequent contributor to Managed Healthcare Executive, is based in Sonoma, California.

ONLINE EXCLUSIVE

Q: How can multidisciplinary care teams—pharmacists, doctors, nurses, and home health aides—best treat patients with complex medical conditions?

Ken Schaecher, MD, medical director, SelectHealth, said that multidisciplinary team management has become a well-accepted model for most health plans. “I believe it’s been woven into the fabric of education of a new generation of providers and that healthcare systems throughout the country are looking at this as the solution instead of siloing care,” he said. “They’re trying to manage it from cradle to grave in a multidisciplinary environment, recognizing the connections to improve the health, wellness and outcomes for patients, while at the same time, recognizing you are reducing redundancy, waste and costs.”

Visit bit.ly/pharma-teams to find out what other roundtable participants said.
Up for debate: Hospital star ratings

CMS moves forward despite concerns

Tracey Walker

Despite some pressure from hospital groups and other stakeholders to delay the release of the star ratings system for hospitals, CMS recently moved forward with releasing the Overall Hospital Quality Star Ratings.

The American Hospital Association said it was “disappointed” that CMS released the ratings, while others are calling for greater transparency of hospital quality.

“This is a first attempt and more an indication of the shape of things to come, rather than the definitive stars rating program,” says Nilesh Chandra, healthcare expert, PA Consulting Group. “CMS might have wanted to get the ball rolling on this before the election.”

The Overall Hospital Quality Star Ratings combine 64 measures that fall into seven groups, including mortality, safety, readmission, and patient experience. Star ratings will be updated each quarter. Currently, 102 hospitals have five stars, 934 have four stars, 1,770 have three stars, 723 have two stars and 133 have one star.

Criticisms and Concerns

“One question is whether the current ratings scheme unfairly penalizes teaching hospitals and those serving higher numbers of the poor,” says Managed Healthcare Executive editorial advisor Joel V. Brill, MD, chief medical officer, Predictive Health. “The overall goal should be to improve the ratings, so that they are helpful and useful to both patients and the hospitals that treat them.”

The complaints made by teaching hospitals and hospitals serving predominantly low-income populations have some legitimacy, says Kev Coleman, head of research and data, HealthPocket.

“Both hospital categories have factors that can negatively affect key quality metrics such as hospital readmissions. Teaching hospitals can attract more unusual and complicated patients due to their specialties, and low-income hospitals serve populations with environmental and behavioral trends that can negatively affect health status,” Coleman says. “However, the lobbying to delay the release of the hospital rating data would have unnecessarily interfered with the positive contribution that the data will make presently to the public and researchers alike. With the genie out of the bottle, teaching hospitals and low-income hospitals will now need to lobby for data collection and analysis adjustments that can accurately reflect the quality of care they deliver.”

Tracey Walker is content manager for Managed Healthcare Executive.
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