PHARMACY ISSUE
SKYROCKETING PHARMACEUTICAL COSTS
MCOs FIGHT BACK

PLUS EXCLUSIVE MANAGED CARE PHARMACY SURVEY RESULTS
This year has already brought significant change and uncertainty regarding the future of U.S. healthcare. For our nation’s PBMs, however, current industry dynamics are painting a very clear picture as to the transformation necessary to thrive. Here are four of the most pressing areas of need:

1. **Enhance physician engagement**
   
   Future PBM programming must provide physicians with more enhanced and timely visibility into a patient’s overall care and opportunities for intervention. It is also critical that such strategies be incorporated directly into the provider’s daily workflow so as to decrease administrative burden for already-overwhelmed physician practices. With reimbursement models shifting toward pay-for-quality, providers should embrace such innovation in PBM programming as a way to improve their financial performance.

2. **Leverage touchpoints to drive engagement**
   
   Individuals utilize their pharmacy benefit more often than any other component of today’s healthcare system. Consequently, PBMs must devise strategies that can capitalize upon each of these touchpoints to better educate and engage patients in their healthcare. At a minimum, this should include providing all stakeholders who interact with patients on a routine basis with access to a continuously-updated, robust view into a patient’s full profile of care and areas of opportunity. Opportunities should include advice for the patient regarding lower cost treatment alternatives; insights into condition management and/or wellness resources; and the ability to immediately connect with a pharmacist or nurse to discuss drug-related gaps in care, interactions, dosing issues, and possible adherence challenges. Such tools must be complemented by IT advancements to connect today’s tech-savvy patients in ways much better aligned with their needs and today’s pace of living.

3. **Embrace the new age of alliance**
   
   PBMs must put aside “go-it-alone” approaches of the past and be more open to partnerships that can yield greater value to patients and providers. This will require greater connectivity with business partners; new and different contracting models; and bidirectional sharing of data and information with other key stakeholders such as medical carriers, behavioral health providers, pharmacies, lab vendors, care managers, and IT vendors. PBMs also need to find new ways to work with drug manufacturers to create improved pricing transparency, accountability, and aligned strategies that emphasize value over volume.

4. **Deliver multidimensional trend management solutions**
   
   While demands for transformation abound, PBMs must still hold true to their core competencies in delivering effective control of bottom-line pharmacy expenditures. This will require unprecedented vigilance in monitoring factors, both large and small, that can impact drug trends. Consequently, this will require investment in the development of a consistently expanded, yet flexible, suite of tools and services that can proactively, and aggressively, mitigate negative trends without compromising quality of care for patients.

Today’s more sophisticated purchaser of PBM services is demanding a much more transparent, progressive and holistically-focused set of services to effectively tackle the challenges of today’s healthcare system. Those with the foresight and resolve to embrace these changes and transform business models accordingly will emerge as leaders, while those that continue to stay the current course will likely fall by the wayside.

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Healthcare cost reduction realized through 12-month matched cohort study comparing claims and survey data between a study group and a historical control group. Enrolled members saw an average $687 PMPM cost reduction, including a 67% reduction in long-term care costs, a 32% reduction in acute hospitalizations and a 29% reduction in ED fees. Financial savings may vary by organization and are not guaranteed. Copyright ©2017 GreatCall, Inc.
Palliative care is not necessarily only for end-of-life situations but for patients at any point after diagnosis of a severe illness.

-LEE GOLDBERG, THE PEW CHARITABLE TRUSTS

The initiative has resulted in a 38% decrease in inpatient stays, 52% decrease in ED visits, 35% decrease in total cost of care, 46% fewer specialty care visits, and an ROI as much as 4:1, depending on the patient and timing of intervention, Gadbois says.

Priority partners with Aspire Health, which provides patient

Continued on page 10
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In-home counseling, provider training to engage patients and families in end-of-life care planning, and increased access to services.

The program tries to be inclusive, opening the door to anyone with a serious or complex illness without any designated time until end of life, says Bruce Smith, MD, executive medical director of the program. Services include:

- Nurse care management;
- Increased staffing and training with a focus on perinatal and pediatric patients;
- Emphasis on patient values, needs and desires;
- Caregiver and psychosocial support; and
- Provision of nonmedical needs, such as transportation and food.

Physicians, specialists, advanced practitioners, nurses, social workers, behavior health providers and clergy can submit claims for advance care planning. Members pay a standard copay for office visits without additional fees for home care.

As a result of the program, 67% of palliative care patients are in hospice when they die, indicating it successfully transitions patients from palliative care to hospice at the right time, says Smith.

**Blue Shield of California**

Blue Shield of California, Hills Physicians Medical Group (the largest independent physician association in Northern California), and Snowline Hospice (a community-based nonprofit hospice and palliative care provider), are collaborating to provide a home-based, palliative care program.

The program includes an interdisciplinary team—a physician, nurse, social worker, home health aide and chaplain—that delivers comprehensive care and support to seriously ill patients and their families.

Torrie Fields, senior program manager for palliative care, says that although Blue Shield of California doesn’t deliver care as an integrated healthcare system would, it can still make a contribution by:

- Supporting provider networks;
- Ensuring community members receive services throughout the state;
- Directly engaging members and partnering with employers about advance care planning and healthcare directives for employees;
- Educating PCPs; and
- Supporting state and federal policy initiatives as an advocate for access improvement.

Like Priority, Blue Shield provides its palliative care program to members as a standard benefit without a cost share.

The payer works closely with providers to identify which patients should have access to palliative care. “We want to ensure that our members receive services where and when they need them,” says Fields. “We don’t want younger people with illness to feel isolated. Palliative care is not just for older adults; anything can happen at any stage of life.”

**WHAT IS PALLIATIVE CARE?**

Palliative care is specialized medical care for people with serious illness. The goal is to improve quality of life for the patient, family and/or caregiver. Palliative care is provided by a team of doctors, nurses, and other specialists to provide an extra layer of support.

Source: Cambia Health Solutions, Regence BlueCross BlueShield of Oregon
“We wanted to move up the conversation and not wait until members became sicker and conditions exacerbated—make it a normal part of health maintenance.”

Susan Wang, MD, Southern California Permanente Medical Group

Kaiser Permanente

Southern California Permanente Medical Group, part of Kaiser Permanente, recognized a need to engage its members in advance care planning.

“We wanted to move up the conversation and not wait until members became sicker and conditions exacerbated—make it a normal part of health maintenance,” says Susan Wang, MD, vice president of the medical group and lead for life care planning. “A palliative care program falls right in step with Kaiser Permanente’s population health approach.”

Kaiser looked to the national Respecting Choices model, an advance care planning model that embraces person-centered care, for inspiration. Kaiser initially targeted members at high risk but more recently has developed multimodal techniques for identifying members who would benefit from advance care planning. For example, when a woman has just had a baby that might be the right time to discuss family planning and leverage support.

Wang says Kaiser identifies patients based on mortality risk—from members without a healthcare directive to those with chronic illness to those with advanced illnesses who are at risk of dying. It targets each member with an appropriate, sometimes scripted, conversation; and plans to train trainers to conduct and improve discussions.

Although Kaiser Permanente’s palliative care program doesn’t differ too much from other insurers, it embeds supportive services within standard care. Member copays cover home-based care. “Home-based care is the new frontier,” Wang says.

Sharp HealthCare

Sharp HealthCare, is an integrated regional healthcare delivery system in San Diego. A primary objective of its palliative care program is to prevent members from using the hospital as a tool for decompensation management of chronic illness, such as dementia, says Daniel Hoefer, MD, chief medical officer of Transitions, Sharp HealthCare’s outpatient palliative care program. “When these patients are recognized early, they won’t need those services,” he says.

Sharp created a program to teach providers how to identify these patients. “We also teach evidence-based prognostication and use it to justify keeping/putting people on the program.”

Program goals include reducing ED visits, completing advance care planning, and referring members to hospice on a timely basis.

Like Kaiser Permanente, Sharp puts a lot of stock in advance care planning, which Hoefer says improves quality of care, decreases hospital deaths, increases hospice use, and reduces ICU and ED visits and hospital lengths of stay.

Transitions also provides in-home patient and caregiver education about disease processes and medical, medication, and lifestyle change management.

“The program helps patients and their families understand what to expect—not if something is going to happen but when and how to prepare,” says Suzi Johnson, vice president, Sharp HospiceCare.

Reimbursement issues

Goldberg says it is difficult to get reimbursed in a fee-for-service system, requiring physicians to patch together different CPT codes. “Palliative care requires time-intensive services and needs highly specialized physicians to be with patients, making it hard to figure out how to cover costs,” he says.

Fields recommends a per-member per-month bundled payment for services, enabling providers to be more flexible in providing what patients need.

Wang suggests that providers could bill by time because of palliative care’s emphasis on labor rather than on service utilization. “We need meaningful metrics, such as how many days of the last six months were spent at home, admissions and readmissions, lengths of stay, and ICU use,” she says.

CMS adopted a ruling in October 2015—it began January 1, 2016—enabling providers to bill Medicare Part B for documented care goal conversations, discussions about advance care planning, and help with understanding advance directives.

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

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
Trulance™ is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.

Contraindications
• Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
• Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions
Risk of Serious Dehydration in Pediatric Patients
• Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
• Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

Diarrhea
• Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients.
• If severe diarrhea occurs, the healthcare provider should suspend dosing and rehydrate the patient.

Adverse Reactions
• In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence ≥2% and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
Diarrhea is not efficacy—it’s time to address the age-old tradeoff in CIC.1,2

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*Results over 12 weeks were statistically significant vs placebo, as shown in two Phase 3 clinical studies.4

Indication

• Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of chronic idiopathic constipation (CIC).


Please see Brief Summary of full Prescribing Information, including Box Warning, on the following page.
Trulance™ (plecanatide) tablets, for oral use

**Rx only**

**Brief Summary — Consult the package insert for complete prescribing information.**

**WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS**

- Trulance is contraindicated in patients less than 6 years of age; in non-clinical studies in young juvenile mice, administration of a single oral dose of plecanatide caused death due to dehydration [see Contraindications, Use in Specific Populations].

- Avoid use of Trulance in patients 6 years to less than 18 years of age [see Warnings and Precautions, Use in Specific Populations].

- The safety and effectiveness of Trulance have not been established in patients less than 18 years of age [see Use in Specific Populations].

**INDICATIONS AND USAGE:** Trulance is indicated in adults for the treatment of chronic idiopathic constipation (CIC).

**CONTRAINDICATIONS:** Trulance is contraindicated in:

- Patients less than 6 years of age due to the risk of serious dehydration [see Warnings and Precautions, Use in Specific Populations].

- Patients with known or suspected mechanical gastroduodenal obstruction.

**WARNINGS AND PRECAUTIONS:** Risk of Serious Dehydration in Pediatric Patients – Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid-secretion into the intestines as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.

Avoid the use of Trulance in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in younger mice and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of Trulance in patients 6 years to less than 18 years of age [see Contraindications, Warnings and Precautions, Use in Specific Populations].

**Diarrhea**

Diarrhea was the most common adverse reaction in the two placebo-controlled clinical trials. Severe diarrhea was reported in 0.6% of patients [see Adverse Reactions]. If severe diarrhea occurs, suspend dosing and rehydrate the patient.

**ADVERSE REACTIONS:** Clinical Trials Experience – Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described below reflect data from 1733 adult patients with CIC randomized in two double-blind, placebo-controlled clinical trials (Study 1 and Study 2) to receive placebo or 3 mg of Trulance once daily for 12 weeks. Demographic characteristics were comparable between the Trulance and placebo groups [see Clinical Studies in the full Prescribing Information].

**Most Common Adverse Reactions**

Table 1 provides the incidence of adverse reactions reported in at least 2% of CIC patients in the Trulance-treated group and at an incidence that was greater than in the placebo group.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Trulance (N = 863)</th>
<th>Placebo (N = 870)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>3 mg</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>5 mg</td>
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*reported in at least 2% of Trulance-treated patients and at an incidence greater than placebo

Diarrhea

The majority of reported cases of diarrhea occurred within 4 weeks of treatment initiation. Severe diarrhea was reported in 0.6% of Trulance-treated patients compared to 0.3% of placebo-treated patients. Severe diarrhea was reported to occur within the first 5 days of treatment [see Warnings and Precautions].

**Adverse Reactions Leading to Discontinuation**

Discontinuations due to adverse reactions occurred in 4% of Trulance-treated patients and 2% of placebo-treated patients. The most common adverse reaction leading to discontinuation was diarrhea: 2% of Trulance-treated patients and 0.5% of placebo-treated patients withdrew due to diarrhea.

**Less Common Adverse Reactions**

Adverse reactions reported in less than 2% of Trulance-treated patients and at an incidence greater than placebo were: sinusitis, upper abdominal pain, upper respiratory tract infection, abdominal distension, flatulence, abdominal tenderness, and increased liver biochemical tests (2 patients with alanine aminotransferase (ALT) greater than 5 to 15 times the upper limit of normal and 3 patients with aspartate aminotransferase (AST) greater than 5 times the upper limit of normal).

**USE IN SPECIFIC POPULATIONS:** Pregnancy – Risk Summary

Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration [see Clinical Pharmacology in the full Prescribing Information] and maternal use is not expected to result in fetal exposure to the drug.

The available data on Trulance use in pregnant women are not sufficient to inform any drug-associated risks for major birth defects and miscarriage. In animal developmental studies, no effects on embryo-fetal development were observed with oral administration of plecanatide in mice and rabbits during organogenesis at doses much higher than the recommended human dosage.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the United States general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

**Data**

**Animal Data**

Pregnant mice and rabbits were administered plecanatide during the period of organogenesis. There was no evidence of harm to embryo-fetal development at oral doses up to 800 mg/kg/day in mice and 250 mg/kg/day in rabbits. Oral administration of up to 600 mg/kg/day in mice during organogenesis through lactation produced no developmental abnormalities or effects on growth, learning and memory, or fertility in the offspring through maturation.

The maximum recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight. Limited systemic exposure to plecanatide was achieved in animals during organogenesis (area under the plasma aperatur-dose-time curve (AUC) = 449 mcg*min in rabbits given 250 mg/kg/day). Plecanatide and its active metabolite are not measurable in human plasma following administration of the recommended clinical dosage. Therefore, animal and human doses should not be compared directly for evaluating relative exposure.

**Lactation**

**Risk Summary**

There is no information regarding the presence of plecanatide in human milk, or its effects on milk production or the breastfed infant. No lactation studies in animals have been conducted. Plecanatide and its active metabolite are negligibly absorbed systemically following oral administration [see Clinical Pharmacology in the full Prescribing Information].

**It is unknown whether the negligible systemic absorption of plecanatide by adults will result in a clinically relevant exposure to breastfed infants. Exposure to plecanatide in breastfed infants has the potential for serious adverse effects [see Use in Special Populations]. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Trulance and any potential adverse effects on the breastfed infant from Trulance or from the underlying maternal condition.

**Pediatric Use**

Trulance is contraindicated in pediatric patients less than 6 years of age. Avoid use of Trulance in patients 6 years to less than 18 years of age [see Contraindications, Warnings and Precautions]. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established.

In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (human age equivalent of approximately 1 month to less than 2 years) following oral administration of plecanatide, as described below in Juvenile Animal Toxicity Data. Because of increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop diarrhea and its potentially serious consequences. Trulance is contraindicated in patients less than 6 years of age. Given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of Trulance in patients 6 years to less than 18 years of age.

**Juvenile Animal Toxicity Data**

Single oral doses of plecanatide at 0.5 mg/kg and 10 mg/kg caused mortality in young juvenile mice on postnatal days 7 and 14, respectively (human age equivalent of approximately 1 month to less than 2 years). Treatment-related increases in the weight of intestinal contents were observed in juvenile mice following single doses of plecanatide on postnatal day 14 (human age equivalent of approximately less than 2 years), consistent with increased fluid in the intestinal lumen. Although the recommended human dose is approximately 0.05 mg/kg/day, based on a 60-kg body weight, plecanatide and its active metabolite are not measurable in adult human plasma, whereas systemic absorption was demonstrated in the juvenile animal toxicity studies. Animal and human doses should not be compared directly for evaluating relative exposure.

**Geriatric Use**

Clinical studies of Trulance did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from patients 18 years to less than 65 years of age. Of 2601 subjects in clinical trials of Trulance, 273 (10%) were 65 years of age and over, and 47 (2%) were 75 years and over. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

**DOSEAGE AND ADMINISTRATION:** Recommended Dosage – The recommended adult dosage of Trulance is 3 mg taken orally once daily, with or without food. [See Preparation and Administration Instructions in the full Prescribing Information].

**Date of Issue:** 01/17

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s rising pharmaceutical costs continue to challenge healthcare leaders, Managed Healthcare Executive conducted its second annual managed care pharmacy survey during the first quarter of 2017. More than 200 executives at benefit management organizations, community/retail pharmacies, hospitals, health plans, specialty pharmacies, and more, weighed in.

Overall, survey respondents agreed that the top challenge facing managed care pharmacy is rising pharmaceutical costs, particularly when it comes to specialty drugs. However, they were split on what drives specialty drug costs, with 36% stating that the biggest driver is growing demand due to an aging or increased population; 21% saying it is manufacturer pricing for new products; 16% choosing new specialty drugs; 12% blaming broadened labeled indications and off-label use of existing products; and 11% citing inflation rates for specialty drugs already on market.

Kellie Rademacher, PharmD, senior director, specialty solutions, at Precision for Value, a pharmaceutical consulting firm, says growth rate is a huge factor indeed, as the number of specialty agents and demand for specialty drugs is projected to be 15% to 20% annually for years to come, according to the Alliance of Community Health Plans. In fact, the alliance
Specialty drugs will comprise 50% of all drug sales and reach approximately $402 billion in spend by 2020.

Source: Alliance of Community Health Plans

Skyrocketing pharmaceutical costs reports that specialty drugs have been projected to comprise 50% of all drug sales and reach approximately $402 billion in spend by 2020. Manufacturer pricing of new products is also a significant driver of specialty drug costs. For example, since 1990, the cost of newly approved oncology agents has risen tenfold.

Constance Wilkinson, of Epstein Becker & Green, a law firm with a focus on federal healthcare contracting, also believes that the survey’s responses reflect aspects of the current landscape, specifically the higher prices manufacturers typically assign to specialty products when launching them.

She agrees with survey respondents that a major factor in rising specialty drug costs is increased demand due to more people being at an age where they are likely to experience a condition requiring them. “This is the case for some treatments such as those for rheumatoid arthritis, but not necessarily for others such as oncology drugs or those for rare diseases,” Wilkinson says. For the latter drugs, the price may be driven more by a condition’s level of criticalness or the smaller population for which the drug is indicated (i.e., a more limited market).

Regardless of the reasons for rising costs, the current model is unsustainable. For patients to have access to the medications they need, MCOs must identify ways to address the rising costs.

Here are four more key findings from the managed care pharmacy survey that reveal how your peers believe this issue can be addressed.

FINDING #1

Collaboration is critical

In the survey, more than half of respondents, 54%, said increased collaboration to identify the most effective and cost-effective treatments is the most effective way to reduce pharmacy costs, for both specialty and non-specialty drugs.

Other responses included adopting more stringent, evidence-based clinical pathways (14%); more aggressive and expanded utilization management strategies (14%); and narrower and/or exclusionary formularies (7%).

“Collaboration could indeed have a positive effect on drug prices in both the near and long term,” says Will Hinde, managing director, West Monroe Partners, a business and technology consulting firm with a focus that includes healthcare. “Collaboration in the near term between the payer, provider, and patient would seem to offer hope for near-term price relief to consumers through better payer/provider coordination. However, significant barriers exist to this collaboration as each of these constituent groups jockey to ‘own’ patient and health data from various sources. Sharing all relevant data and information to truly identify cost and efficacy is a laborious and costly effort, and will take a long time.”

Opportunities for collaboration to reduce pharmacy costs include biomarker-based diagnostics and prior authorization standards, Hinde continues. These depend on laboratory results to identify whether a patient is an appropriate candidate for a specialty treatment, prior to authorization or reimbursement.

For example, providers, payers, and drug companies could collaborate to develop and validate genomics-based assays that identify patients with specific genetic and biomarker...
Regarding specialty pharmacy costs, 41% of respondents said performance-based (outcomes-based) pricing is the most effective strategy to reduce costs, while 22% said more aggressive and expansive utilization is key. Few respondents opted for exclusive specialty pharmacy contracting (15%); increased government regulation (10%); or formulary exclusions (5%).

While outcomes-based pricing is an attractive concept conceptually, there are many operational impediments to it, says Mark Ginestro, who works with life sciences clients as a principal at KPMG, an audit, tax, and advisory firm:

1. It is difficult to draw a definitive cause-and-effect link in many instances of healthcare where there are many variables and many treatments working in concert.
2. It requires sharing information and data—which has proven problematic for providers and payers with antiquated systems that often have challenges communicating within their own organizations.
3. It doesn’t always rein in costs. There have been instances where the value has been clear, but the resulting cost has been too high—so discussions have reverted to price and utilization.

Presently, outcomes-based pricing models are in their infancy and will develop and mature over time. Some models are being tested for specific drugs in which both sides have been willing to take some risk to see if it can work. Ultimately, Ginestro says, “Movement to outcomes-based models will not be a quick fix, but I think everyone involved is hopeful that solutions can be found.”

As far as the best coverage strategy for new, innovative therapeutics and biologics, more than half of respondents, 53%, again opted for value-based contracting or outcomes-based contracting with manufacturers. In addition, 22% said using manufacturer net pricing (wholesale acquisition) is best while 19% thought adjusting the premium costs across the broader pool is the way to go.

Value-based contracting is similar to performance-based contracting in that the financial risk is shared between the payer and the drug manufacturer. “As the entire healthcare system moves from volume to value, all stakeholders (i.e., providers, patients, payers, and manufacturers) will need to share in the risk,” Rademacher says.
Skyrocketing pharmaceutical costs

er says, “When all stakeholders have something to gain or lose, the system is more balanced.”

Wilkinson believes value-based contracting is most attractive to payers because it spreads some of the risk of the drug’s performance to the manufacturer. “If the outcomes selected for measurement are not achieved by patients taking the drug, the manufacturer provides price concessions to the payer or other healthcare therapies or services to the patient that effectively reduce the drug’s cost,” she says.

Specifically, Ginestro believes value-based contracting might work with certain therapies in which a new product is trying to gain inroads in a crowded drug category. “Pharma companies will want to take a product with a clear clinical benefit and try to use an alternative payment model that ties pricing or rebates to the performance of certain medications,” he says. “The difficulty is related to measuring patient outcomes and drawing the connection between the use of medications, because many patients may have other health factors that complicate matters.”

**FINDING #3**

Biosimilars could result in big changes

Among survey participants, 66% believe that biosimilars will reduce specialty drug costs over the next few years, leaving 34% as naysayers. One quarter of survey respondents foresee cost reductions due to biosimilars happening in 2018, 14% expect a reduction in 2019, 12% in 2020, and 15% after 2020.

Ginestro agrees with the majority, stating that when biosimilars hit the market, they will reduce specialty drug costs. “Generally, a competitive market will lead to lower specialty drug costs both in terms of switching to biosimilars and the originators reducing pricing to retain market share,” he explains. “But if the original product is still holding substantial market share, those changes may be slow. Health plans and pharmacy benefit managers may be big drivers in that adoption through plan design, but many physicians will opt to keep their patients on treatments that are showing benefit and will be reluctant to change them. Once interchangeability (a designation that a biosimilar is regarded as an equivalent to the original product) is established, payers will have many more options to negotiate prices and manage utilization.”

The biggest question, Ginestro says, is how quickly biosimilars can get to market and when and how fast interchangeability will be established. Biosimilars have taken a slow path to market in the United States due to patent litigation, and now biosimilar sponsors are seeking interchangeability as part of an initial approval. “Once on the market, there are many competitive dynamics between original products and biosimilars,” he says. The adoption of biosimilars in certain categories will dictate the speed and amount of savings; adoption and uptake will differ by therapeutic area. Without interchangeability, patients with chronic conditions may be reluctant to switch. Over time, new patients with the right incentives in place may be more willing to try them.”

Rademacher also believes that biosimilars will reduce drug costs in the long term. “Adoption of biosimilars in both the European market and the U.S. market has been modest initially, but it can be rapid when discounts are strong and incentives are aligned.”

—KELLIE RADERMACHER, PHARMD, PRECISION FOR VALUE
but it can be rapid when discounts are strong and incentives are aligned—as was seen in some Scandinavian and Eastern European countries,” she says. “High drug prices are an incentive for the market to speed adoption, however the lack of interchangeability is slowing uptake. As additional regulatory clarity is provided around interchangeability and both patients and providers become more experienced with biosimilars, their utilization will likely rapidly increase.”

But Lee Taurman, principal and national life sciences advisory leader for Grant Thornton LLP’s healthcare industry practice, says proceed cautiously. “Biosimilars will likely lower specialty drug costs, but not to the extent that some expect,” he says. “The generic market for traditional small molecule pharmaceutical products has led to more than a trillion dollars in savings for the American public over the last decade.”

Two key elements of the generic market that enable these savings are missing, at least to date, in the emerging biosimilar market, Taurman says:

1. Most generics are considered equivalent or interchangeable with their branded counterparts; therefore, a pharmacist can “substitute” a generic when filling the prescription. Biosimilars, by their name, are considered similar, but are not the same and are not substitutable in many states.

2. Generics do not carry proprietary names, but are referred to by their scientific names. All generic manufacturers use the same name for the same drug. Brands, on the other hand, are required to have proprietary names that are specific to the manufacturer. While the rules for biosimilars are still evolving, early entrants have launched with proprietary names. Without substitution and with brand names, the biosimilar market will function more like the existing branded market than the traditional generic market, limiting the potential savings.

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

FINDING #4

An integrated approach for rare disease treatment is key

According to survey respondents, the best long-term approaches to address the high cost of rare disease treatment are more integrated approaches by benefit managers (43%) and deploying more expansive strategies to access risk (21%). Lagging behind in the survey were using benefit incentives to drive consumer engagement and higher-value care (18%) and employing government guidelines or regulations (16%).

More drugs exist to treat orphan diseases than ever, Rademacher says. Agents that treat rare diseases have various routes of administration (e.g., self-injectable, oral, intravenous) and therefore are reimbursed by both medical and pharmacy benefits. “It is essential to integrate the pharmacy and medical benefit to more closely manage these costly diseases across benefits and reduce the total cost of care,” she says. “Management of rare disease drugs is common, but given the lack of competition in many of the rare disease categories, contracting strategies are not generally employed. Expanding the risk-sharing deployed in other specialty disease states by employing value or performance-based contracts could lower costs as seen in other disease states.”

With the most fragile patient populations, healthcare costs are significantly increased by issues with persistence and adherence due to the difficulty of the drug regimen and the other challenges a patient may face (e.g., scheduling, time, coordination of care), Wilkinson says.

“Stronger patient support regarding drugs and assistance with care coordination can improve outcomes,” she says. “Improved outcomes may make payers less likely to establish conditions of coverage that restrict access and lead to prescriptions that are written but never filled. This will enable manufacturers to consider basing pricing on effectiveness, because patient support will increase effectiveness and the market will become more stable.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
To identify the top managed care pharmacy challenges and what your peers are doing about them, *Managed Healthcare Executive* conducted its annual pharmacy survey during the first quarter of 2017.

The survey received more than 200 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.

**Money matters**

**Q:** What is the most effective way to reduce pharmaceutical costs (specialty and non-specialty)?

- **54.4%** Increased collaboration to identify the most effective and cost-effective treatments
- **13.6%** Adoption of more stringent, evidence-based clinical pathways
- **13.6%** More aggressive and expanded utilization management strategies (e.g., prior auth, step therapy, and limited initial refills)
- **7.3%** More narrow and/or exclusionary formularies
- **11.1%** Other (please specify)

Other responses included: More emphasis on generics, reduce drug development regulations, free/open competition, and Medicare price negotiations

*Continued on page 24*
Indication and Usage
AUSTEDO™ is indicated for the treatment of chorea associated with Huntington's disease.

Important Safety Information

WARNING: DEPRESSION AND SUICIDALITY
AUSTEDO™ can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of AUSTEDO™ must balance the risks of depression and suicidality with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. AUSTEDO™ is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression.

Please see Brief Summary of Full Prescribing Information, including Boxed Warning, on the following pages
AUSTEDO™ (deutetrabenazine) tablets

The management of NMS should include (1) immediate discontinuation of AUSTEDO; (2) intensive symptomatic treatment and medical monitoring; and (3) treatment of any concomitant serious medical problems for which treatment is indicated. There is no general agreement about specific pharmacological treatment regimens for NMS. Recurrence of NMS has been reported with resumption of drug therapy. If treatment with AUSTEDO is needed after recovery from NMS, patients should be monitored for signs of recurrence.

5.4 Akathisia, Agitation, and Restlessness

AUSTEDO may increase the risk of akathisia, agitation, and restlessness in patients with Huntington's disease. In a 12-week, double-blind, placebo-controlled trial, akathisia, agitation, or restlessness was reported by 4% of patients treated with AUSTEDO, compared to 2% of patients on placebo.

Patients receiving AUSTEDO should be monitored for signs and symptoms of restlessness and agitation, as these may be indicators of developing akathisia. If a patient develops akathisia during treatment with AUSTEDO, the AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

5.5 Parkinsonism

AUSTEDO may cause parkinsonism in patients with Huntington's disease. Because rigidity can develop as part of the underlying disease process in Huntington's disease, it may be difficult to distinguish between this potential drug-induced adverse reaction and progression of the underlying disease process. Drug-induced parkinsonism has the potential to cause more functional disability than untreated chorea in the patients with Huntington's disease. If a patient develops parkinsonism during treatment with AUSTEDO, the AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

5.6 Sedation and Somnolence

Sedation is a common dose-limiting adverse reaction of AUSTEDO. In a 12-week, double-blind, placebo-controlled trial, 11% of AUSTEDO-treated patients reported somnolence compared with 4% of patients on placebo and 9% of AUSTEDO-treated patients reported fatigue compared with 4% of placebo-treated patients. Patients should not perform activities requiring mental alertness to maintain the safety of themselves or others, such as operating a motor vehicle or operating hazardous machinery, until they are on a maintenance dose of AUSTEDO and know how the drug affects them.

5.7 QTc Prolongation

Tetrabenazine, a closely related VMAT2 inhibitor, causes an increase (about 8 msec) in the corrected QT (QTc) interval. QTc prolongation greater than 500 msec may occur in some patients treated with AUSTEDO who are CYP2D6 poor metabolizers or are co-administered a strong CYP2D6 inhibitor.

The use of AUSTEDO should be avoided in combination with other drugs that are known to prolong QTc (see Drug Interactions (7.6)).

5.8 Hyperprolactinemia

Serum prolactin levels were not evaluated in the AUSTEDO development program. Tetrabenazine, a closely related VMAT2 inhibitor, elevates serum prolactin concentrations in humans. Following administration of 25 mg of tetrabenazine to healthy volunteers, peak plasma prolactin levels increased 4- to 5-fold.

Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin-dependent. Although amenorrhea, galactorrhea, gynecomastia, and impotence can be caused by elevated serum prolactin concentrations, the clinical significance of elevated serum prolactin concentrations for most patients is unknown.

Chronic increase in serum prolactin levels (although not evaluated in the AUSTEDO or tetrabenazine development programs) has been associated with low levels of estrogen and increased risk of osteoporosis. If there is a clinical suspicion of symptomatic hyperprolactinemia, appropriate laboratory testing should be done and consideration should be given to discontinuation of AUSTEDO.

5.9 Tissue-Penetrating Containing Tissues

Since deuterabenazine or its metabolites bind to melanin-containing tissues, it could accumulate in these tissues over time. This raises the possibility that AUSTEDO may cause toxicity in these tissues after extended use. Neither ophthalmologic nor microscopic examination of the eye has been conducted in the chronic toxicity studies in a pigmented species such as dogs. Ophthalmologic monitoring in humans was inadequate to exclude the possibility of injury occurring after long-term exposure.

The clinical relevance of deutetrabenazine's binding to melanin-containing tissues is unknown. Although there are no specific recommendations for periodic ophthalmologic monitoring, prescribers should be aware of the possibility of long-term ophthalmologic effects.
6 ADVERSE REACTIONS
The following serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Depression and Suicidality [see Warnings and Precautions (5.2)]
- Neuroleptic Malignant Syndrome (NMS) [see Warnings and Precautions (5.3)]
- Akathisia, Agitation, and Restlessness [see Warnings and Precautions (5.4)]
- Parkinsonism [see Warnings and Precautions (5.5)]
- Sedation and Somnolence [see Warnings and Precautions (5.6)]
- QTc Prolongation [see Warnings and Precautions (5.7)]
- Hyperprolactinemia [see Warnings and Precautions (5.8)]
- Binding to Melanin-Containing Tissues [see Warnings and Precautions (5.9)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Study 1 was a randomized, 12-week, placebo-controlled study in patients with chorea associated with Huntington’s disease. A total of 45 patients received AUSTEDO, and 45 patients received placebo. Patients ranged in age between 23 and 74 years (mean 54 years); 56% were male, and 92% were Caucasian. The most common adverse reactions occurring in greater than 8% of AUSTEDO-treated patients were somnolence, diarrhea, dry mouth, and fatigue. Adverse reactions occurring in 4% or more of patients treated with AUSTEDO, and with a greater incidence than in patients on placebo, are summarized in Table 2.

Table 2. Adverse Reactions in Study 1 Experienced by at Least 4% of Patients on AUSTEDO and with a Greater Incidence than on Placebo

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>AUSTEDO (N=45)</th>
<th>Placebo (N=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Somnolence</td>
<td>11%</td>
<td>4%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>9%</td>
<td>0%</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>9%</td>
<td>7%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9%</td>
<td>4%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>7%</td>
<td>2%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Constipation</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Contusion</td>
<td>4%</td>
<td>2%</td>
</tr>
</tbody>
</table>

One or more adverse reactions resulted in a reduction in the dose of study medication in 7% of patients in Study 1. The most common adverse reaction resulting in dose reduction in patients receiving AUSTEDO was dizziness (4%). Agitation led to discontinuation in 2% of patients treated with AUSTEDO in Study 1.

7 DRUG INTERACTIONS
7.1 Strong CYP2D6 Inhibitors
A reduction in AUSTEDO dose may be necessary when adding a strong CYP2D6 inhibitor in patients maintained on a stable dose of AUSTEDO. Concomitant use of strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine, bupropion) has been shown to increase the systemic exposure to the active dyesuetabolites of deutetrabenazine by approximately 3-fold. The daily dose of AUSTEDO should not exceed 36 mg per day, and the maximum single dose of AUSTEDO should not exceed 18 mg in patients taking strong CYP2D6 inhibitors.

7.2 Reserpine
Reserpine binds irreversibly to VMAT2 and the duration of its effect is several days. Prescribers should wait for chorea to reemerge before administering AUSTEDO to help reduce the risk of oversedation and major depletion of serotonin and norepinephrine in the central nervous system. At least 20 days should elapse after stopping reserpine before starting AUSTEDO. AUSTEDO and reserpine should not be used concomitantly [see Contraindications (4)].

7.3 Monoamine Oxidase Inhibitors (MAOIs)
AUSTEDO is contraindicated in patients taking MAOIs. AUSTEDO should not be used in combination with an MAOI, or within 14 days of discontinuing therapy with an MAOI [see Contraindications (4)].

7.4 Neuroleptic Drugs
The risk for parkinsonism, NMS, and akathisia may be increased by concomitant use of AUSTEDO and dopamine antagonists or antipsychotics.

7.5 Alcohol or Other Sedating Drugs
Concomitant use of alcohol or other sedating drugs may have additive effects and worsen sedation and somnolence [see Warnings and Precautions (5.6)].

7.6 Drugs that Cause QTc Prolongation
Tetrahydrate, a closely related VMAT2 inhibitor, causes a small increase in the corrected QT (QTc) interval. Clinically relevant QT prolongation may also occur with AUSTEDO [see Warnings and Precautions (5.7)].

The use of AUSTEDO should be avoided in combination with other drugs that are known to prolong QTc, including antipsychotic medications (e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone), antidepressants (e.g., moclobemide, sleep sedatives, serotonergic medications, and any other medications known to prolong the QTc interval.

7.7 Tetrabenazine
AUSTEDO is contraindicated in patients currently taking tetrabenazine. AUSTEDO may be initiated the day following discontinuation of tetrabenazine.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Risk Summary
There are no adequate data on the developmental risk associated with the use of AUSTEDO in pregnant women. Administration of deutetrabenazine to rats during organogenesis produced no clear adverse effect on embryofetal development. However, administration of tetrabenazine to rats throughout pregnancy and lactation resulted in an increase in stillbirths and postnatal offspring mortality [see Data].

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Data
Animal Data
Oral administration of deutetrabenazine (5, 10, or 30 mg/kg/day) or tetrabenazine (30 mg/kg/day) to pregnant rats during organogenesis had no clear effect on embryofetal development. The highest dose tested was 6 times the maximum recommended human dose of 48 mg/day, on a body surface area (mg/m²) basis. The effects of deutetrabenazine when administered during organogenesis to rabbits or during pregnancy and lactation to rats have not been assessed.

Tetrabenazine had no effects on embryofetal development when administered to pregnant rabbits during the period of organogenesis at oral doses up to 60 mg/kg/day. When tetrabenazine was administered to female rats (doses of 5, 15, and 30 mg/kg/day) from the beginning of organogenesis through the lactation period, an increase in stillbirths and offspring postnatal mortality was observed at 15 and 30 mg/kg/day, and delayed pup maturation was observed at all doses.

8.2 Lactation
Risk Summary
There are no data on the presence of deutetrabenazine or its metabolites in human milk, the effects on the breastfed infant, or the effects of the drug on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for AUSTEDO and any potential adverse effects on the breastfed infant from AUSTEDO or from the underlying maternal condition.

8.3 Pediatric Use
There is no specific pediatric experience in pediatric patients; however, clinical studies of AUSTEDO did not include sufficient numbers of subjects aged 16 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of hepatic, renal, and cardiac dysfunction, and of concomitant disease or other drug therapy.

8.4 Geriatric Use
Clinical studies of AUSTEDO did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of hepatic, renal, and cardiac dysfunction, and of concomitant disease or other drug therapy.

8.5 Hepatic Impairment
The effect of hepatic impairment on the pharmacokinetics of deutetrabenazine and its primary metabolites has not been studied; however, in a clinical study conducted with tetrabenazine, a closely related VMAT2 inhibitor, there was a large increase in exposure to tetrabenazine and its active metabolites in patients with hepatic impairment. The clinical significance of this increased exposure has not been assessed, but because of concerns for a greater risk for serious adverse reactions, the use of AUSTEDO in patients with hepatic impairment is contraindicated [see Contraindications (4)].

8.7 Poor CYP2D6 Metabolizers
Although the pharmacokinetics of deutetrabenazine and its metabolites have not been systematically evaluated in patients who do not express the drug metabolizing enzyme, it is likely that the exposure to o-hydroxytetrabenazine and 6-hydroxytetrabenazine would be increased similarly to taking a strong CYP2D6 inhibitor (approximately 3-fold). In patients who are CYP2D6 poor metabolizers, the daily dose of AUSTEDO should not exceed 36 mg (maximum single dose of 18 mg).

Distributed by: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454
AUSTEDO™ is a trademark of Auspex Pharmaceuticals Inc., a member of the Teva Group. U.S. Patent No: 8,524,733

This Brief Summary is based on the Full Prescribing Information for AUSTEDO AUS-001.

AUS-40295 April 2017
Q: What is the best coverage strategy for new, innovative therapeutics and biologics?

- **53.4%** Value-based contracting with manufacturers
- **21.6%** Use manufacturer net pricing (wholesale acquisition cost plus discounts)
- **18.6%** Adjust the premium costs across the broader pool of members/employees
- **6.4%** Other

Q: How will performance-based pricing evolve over the next three to five years?

- **14.0%** Performance-based pricing will dominate
- **36.5%** Performance-based pricing will be used somewhat more than reference-based pricing
- **19.5%** Reference-based pricing will be used somewhat more than performance-based pricing
- **7.5%** Reference-based pricing will dominate
- **22.5%** Neither of these two models will dominate

Q: What is the best long-term approach to addressing the high cost of rare disease treatment?

- **42.6%** A more integrated approach by benefit managers around total cost of care across the healthcare continuum
- **20.6%** Deploying more expansive strategies to assess risk vs benefit with long-term use
- **18.1%** Use of benefit incentives to drive consumer engagement and higher-value care
- **16.2%** Government guidelines and/or regulations
- **2.5%** Other
**Specialty pharmaceuticals**

**Q:** What is the biggest opportunity to reduce specialty pharmaceutical costs?

- **15.1%** Exclusive specialty pharmacy contracting
- **4.9%** Formulary exclusions
- **41.0%** Performance-based (outcomes-based) pricing
- **21.5%** More aggressive and expansive utilization management strategies
- **9.8%** Increased government regulation
- **7.7%** Other

**Q:** What will be the biggest driver of specialty drug costs in 2017?

- **35.6%** Growing demand due to aging population/increased prevalence of chronic disease
- **16.1%** New specialty drugs
- **11.2%** Inflation rates for specialty drugs already on market
- **11.7%** Broadened labeled indications and off-label use of existing products
- **20.5%** Manufacturer pricing for new products
- **4.9%** Other

**Q:** Will biosimilars reduce specialty drug costs?

- **25.2%** Yes, starting in 2018
- **14.4%** Yes, starting in 2019
- **11.9%** Yes, starting in 2020
- **14.9%** Yes, post-2020
- **33.6%** No, they won’t
Q: Should pharmacists be compensated under Medicare Part B for prescribing medications and helping assess patient conditions?

- Yes: 76.2%
- No: 23.8%

Q: What is the most effective way to address the opioid epidemic?

- Increased use of lock-in programs: 6%
- Increased use and capabilities of prescription drug monitoring programs: 38.8%
- More enhanced efforts from health plans and PBMs to identify, flag, and intervene: 27.9%
- Increased availability and prescribing of opioid drug products with potential abuse-deterrent properties: 13.1%
- Other (please specify): 14.2%

Other responses included: Provider education and profiling, enhanced access to behavioral-based treatment programs, and more restrictive prescribing and quantity limits.

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

- Plans will focus more on medication therapy management: 31.1%
- Plans will collaborate more with retail pharmacies to improve ratings: 15.3%
- Plans will rework their preferred networks to include only high-performing pharmacies: 21.9%
- Plans with higher ratings will be able to charge higher premiums: 6%
- Plans will expand program offerings: 8.2%
- They will have little to no effect: 17.5%
Adherence. Outcomes. That’s what makes us specialty.

Patients that use Walgreens specialty pharmacies for MS medication are significantly more adherent, compared to other pharmacies¹

Walgreens provides the patient-focused specialty pharmacy access necessary to consistently deliver better outcomes. With over 250 specialty pharmacies, and access to specialty medication at every retail location, we’re improving adherence rates and changing how our partners think about specialty medicine.

To learn how Walgreens can make a difference for your members, please visit Walgreens.com/HealthSolutions

¹Staskon F, Fu C, Kirkham H. Multiple Sclerosis Medication Adherence within Walgreens Local Specialty Pharmacies is Significantly Higher Compared to Other Class of Trade Pharmacies. AMCP Managed Care & Specialty Pharmacy Annual Meeting. 27 Mar 2017.
How managed care organizations manage opioid utilization and some of the limitations to those strategies were hot topics at the AMCP Managed Care & Specialty Pharmacy Annual Meeting in Denver this spring.

Kimberly Lenz, PharmD, clinical pharmacy manager, University of Massachusetts Medical School (UMass Medical School), and Tyson Thompson, PharmD, clinical consultant pharmacist, UMass Medical School, also discussed recommendations from the AMCP Addiction Treatment Advisory Group (ATAG), in their talk, “Tackling the Opioid Epidemic and Addiction Treatment: A Managed Care Approach.”

Relatively common payer strategies to address opioid utilization include prior authorization on certain formulations/products, quantity limits, dose limits, controlled substance “lock-in” programs, and restrictions on the use of multiple short-acting or multiple long-acting opioids, Thompson told Managed Healthcare Executive (MHE). “If strategies are overly restrictive, access to appropriate pain management can be impeded,” he said.

Many management strategies used to promote safe opioid use can be skirted if the patient pays out of pocket, said Thompson. “There are also instances where a plan may try to manage a specific product that is popular for recreational use, and the utilization may simply shift to a different formulation or product, having minimal impact on reducing recreational use of that opioid,” he said.

Different approach
“What our program does [at UMass Medical School], that is fairly unique, is use our multidisciplinary team to collaborate with prescribers on appropriate opioid utilization,” said Thompson.

The program, the Opioid Therapeutic Class Management Workgroup (TCM Workgroup), is made up of the UMass Medical School medical director (a practicing internist), the clinical pharmacy manager for the UMass Medical School Medicaid client, a board-certified psychopharmacology pharmacist, an operations pharmacist, and two clinical consultant pharmacists.

“Our workgroup meets to discuss complex member cases that arise from our opioid prior-authorization process,” Thompson said. “The case discussions help develop individualized plans to address specific issues noted for each member discussed. The plans formulated often include prescriber outreach to establish a collaborative relationship to work toward more appropriate pain management strategies.”

The TCM Workgroup also drives appropriate pain management by identifying problematic use patterns that have potential to benefit from targeted outreach.

AMCP advisory group
The AMCP ATAG is comprised of behavioral health organizations, outpatient treatment centers, nonprofit advocacy groups, health plans, PBMs, manufacturers, and pharmacies with expertise in addiction treatment.

“Our objectives are to identify areas with the greatest potential to significantly improve patient outcomes, develop recommendations to remove barriers, improve processes and modify systems that allow for improved outcomes, and serve as advocates in adopting our recommendations,” Lenz, an ATAG member, told MHE. Healthcare executives should compare ATAG guidance to that within their own organization, she said.

“Tracey Walker is content manager for Managed Healthcare Executive.”
Creating a ‘robust’ specialty pharmacy network

by TRACEY WALKER

Approaches health plans take when thinking about creating specialty pharmacy networks, and how to improve upon those endeavors, are key issues for healthcare executives.

At the AMCP meeting, Christine Strahl, PharmD, MBA, BPCS, senior manager, specialty pharmacy programs at HealthPartners, shared challenges to managing specialty pharmacies, and discussed the importance of creating a “robust” specialty pharmacy, during the presentation, “Creating a Robust Specialty Pharmacy Network—The Payer Approach.” She co-presented with Sheila Arquette, executive director for the National Association of Specialty Pharmacy, and pharmacy special projects advisor at Independent Health.

Robust pharmacy
Specialty medications cost about $5,000 a month and account for about one-third of pharmacy benefit costs, yet fewer than 1% of members with a pharmacy benefit use them, Strahl said.

“This means that a limited number of drugs and claims are really driving the cost of insurance for drugs today and we need to be prudent in the management of these costs,” she said. “Additionally, the pipeline of drugs in development is primarily focused on these types of drugs—driving estimates that a majority of pharmacy benefit spend will be in specialty drugs in the next several years. There are many specialty pharmacies and many other existing pharmacies that are also very interested in dispensing specialty medications.”

Health plans must consider external and internal factors when determining what pharmacies to include in network, said Strahl. This includes “any-willing-provider” laws, which may require plans to allow all pharmacies to dispense specialty drugs, she said.

“Additionally, a health plan may not want to narrow its network if its competitors don’t,” Strahl said. “Internal factors include the desire to maintain relationships with local pharmacies and concern about negative perceptions from a narrow network.” She added that plans may want to dispense specialty drugs internally through their own pharmacy/pharmacies.

“Specialty pharmacies provide expertise in the management of these less-widely used drugs,” Strahl said. “There are several commodity services that specialty pharmacies provide including benefit investigations and copay assistance support, 24/7 pharmacist availability, delivery to home, and monthly calls to set up the next refill.”

The differentiating services—clinical programs, waste management programs, delivery to retail locations, access to the care team or electronic health record, willingness to share risk and outcome reporting—may drive a health plan to select one specialty pharmacy over another, she said.

Challenges
The challenges of managing a specialty pharmacy network vary based on the pharmacies in the network. “If you own your own pharmacy, that presents an entirely different suite of internal challenges,” Strahl said. “If you manage a network, and have more more pharmacy partners, the more internal resources may be needed. This includes informatics for reporting, account management, and contracting resources. Employ a good PBM partner who is willing to facilitate your pharmacy claim system programming. Clear communications for members and providers are also helpful.”

HealthPartners, and its marketplace, adopted the concept of using an exclusive specialty pharmacy over 10 years ago, said Strahl. “We felt this was the prudent step given the cost of the medications and the need for additional management for these high-cost drugs.”

Critical questions
Strahl said payers should ask themselves the following when creating a specialty pharmacy network:

1. Should we build a specialty pharmacy or dispense them through existing pharmacies?
2. Do we think there is value in and is there a will to restrict dispensing to one or just a handful of pharmacies?
3. How do we ensure access to limited distribution drugs that network pharmacy partners can’t dispense?

Tracey Walker is content manager for Managed Healthcare Executive.
Drugs to treat inflammatory conditions, diabetes, and oncology were the top three most expensive therapy classes in 2016, according to Express Scripts.

But there are some positive changes on the horizon.

“Managed care executives should be hopeful that new drugs pending approval in 2017 could increase competition within these classes. We are also keeping an eye on the pipeline of drugs to treat Alzheimer’s,” says Aimee Tharaldson, PharmD, senior clinical consultant, Emerging Therapeutics, Express Scripts.

Although the drug pipeline for Alzheimer’s disease has not been as rich as patients and experts would have hoped, there could be some form of a drug to combat this debilitating condition by 2025, CNN recently reported. With more than 20 candidates in phase 3 trials and many more in earlier stages of development, researchers are hopeful that this goal will be realized.

Here’s more on these drug classes, and what you can anticipate in the year ahead.

**Autoimmune diseases**

There are two key autoimmune pipeline developments to watch in 2017, according to Tharaldson. They are investigational baricitinib, a once-daily oral medication for the treatment of moderate-to-severe rheumatoid arthritis (RA), and guselkumab, an anti-interleukin-23 (IL-23) monoclonal antibody for moderate-to-severe plaque psoriasis.

In April, the FDA delayed approval of baricitinib, an oral Janus kinase (JAK) inhibitor. The FDA said that more clinical data is needed because of safety concerns across treatment arms. Baricitinib is also being studied in phase 2 trials for atopic dermatitis and systemic lupus erythematosus, and a phase 3 trial for patients with psoriatic arthritis is expected to be initiated in 2017.

IL-23 is a protein which has been shown to play a key role in the development of immune-mediated inflammatory diseases. Guselkumab is a subcutaneously administered IL-23 inhibitor in phase 3 development to treat moderate-to-severe plaque psoriasis. At press time, a phase 2 study evaluating the drug for the treatment of moderately to severely active psoriatic arthritis was ongoing.

“Watch for more competition in this space due to an increasing number of therapeutic options,” Tharaldson says. “Biosimilars may also help to increase competition. Although biosimilars for Humira and Enbrel have been approved by the FDA, several biosimilar-related patent disputes have prevented their launch.”

Patrick Gleason, PharmD, FCCP, FAMCP, BCPS, senior director, health outcomes, Prime Therapeutics, says it has identified Dupixent (dupilumab) as a new potential blockbuster drug for the treatment of atopic dermatitis. Dupixent is a self-administered subcutaneous injection, approved by the FDA in March. It is the first biologic to treat atop dermatitis, a condition typically treated with topical moisturizers, corticosteroids, and calcineurin inhibitors. Dupixent works by inhibiting interleukin-4 and interleukin-13, two key cytokines required for certain immune responses.

Over the past four years, Prime has seen the autoimmune drug class spend increase 25% each year. Gleason expects this trend to continue due to price inflation and more patients using these specialty drugs more quickly when diagnosed.

**Diabetes**

There are new diabetes medications to watch, according to Farrah Wong, PharmD, director, pipeline and drug surveillance, OptumRx. They include semaglutide, sotagliflozin, and insulin tregopil.

Semaglutide is a GLP-1 agonist in development for glycemic
control in patients with type 2 diabetes. At press time, it was being developed as both subcutaneous (Novo Nordisk) and oral (Novartis) formulations. The subcutaneous formulation is under FDA review first and may be approved in December 2017. Oral semaglutide may become the first oral GLP-1 receptor agonist on the market, with the potential advantage of easier and less-invasive administration.

Sotagliflozin is a sodium-dependent glucose transporter (SGLT-1 and SGLT-2) inhibitor in development for both type 1 and type 2 diabetes at press time. If approved (anticipated in the second half of 2018), it would be the first oral drug approved for type 1 diabetes, a disease that typically has been managed by lifestyle modifications and insulins, according to Wong.

New insulin products may also be approved soon. Insulin tregopil is an oral insulin in phase 2 development for both type 1 and type 2 diabetes and has the potential to be the first oral insulin on the market, with anticipated approval to be in 2020. Basalog, an insulin glargine product, was in phase 3 development at press time. It is unknown whether manufacturer Mylan/Biocon will seek approval as a competing brand insulin or as a generic to Sanofi’s Lantus.

Also in the diabetes management armamentarium is Medtronic’s hybrid closed-loop system for patients with type 1 diabetes. The MiniMed 670G System, which was FDA approved in September 2016, features an advanced algorithm that automates and personalizes the delivery of basal insulin 24 hours a day to maintain glucose levels.

“The hybrid closed loop system requires minimal input, with patients only needing to enter mealtime carbohydrates, accept bolus correction recommendations, and periodically calibrate the sensor,” says Mike Hill, vice president of Global Marketing, Intensive Insulin Management, Medtronic. “With a fully automated closed loop system, Medtronic is working toward decreasing this interaction to further simplify diabetes management for patients with type 1 diabetes.”

Oncology

“Oncology continues to be a key area of focus for pharmaceutical manufacturers given the significant need for effective treatment options across a host of different types of cancer,” says Nadina Rosier, health and group benefits practice leader, pharmacy, Willis Towers Watson. “This year we are expecting at least 10 agents to be FDA approved for cancer indications, four of which are for breast cancer.”

These agents are all oral drugs and could cost at least $120,000 per patient per year, “placing significant pressure on healthcare executives to more aggressively manage the specialty pharmacy aspect of their medical and pharmacy benefit programs more tightly,” says Rosier.

Pipeline breast cancer therapies include abemaciclib, entinostat, and neratinib.

Lilly is seeking FDA approval for abemaciclib, a cyclin-dependent kinase-4 and cyclin-dependent kinase-6 inhibitor for refractory patients with hormone-receptor positive, human epidermal growth factor 2-negative (HER2) metastatic breast cancer. Approval is expected in the second half of 2017.

Abemaciclib is also being studied in non-small cell lung cancer (NSCLC).

Entinostat, an oral, small molecule histone deacetylase (HDAC) inhibitor, has direct effects on both cancer cells and immune regulatory cells, potentially enhancing the body’s immune response to tumors. Approval is anticipated this year with the proposed indication of treatment of postmenopausal women with advanced estrogen receptor-positive (ER+) breast cancer who have progressed on a non-steroidal aromatase inhibitor. If approved, it would be given orally once weekly in combination with exemestane. Entinostat is also in phase 2 development for

Knowledge bite

- Medications to treat inflammatory conditions and diabetes were the two most expensive therapy classes ranked by per-member-per-year spend in 2016.
- One of every $5 spent on prescription drugs was for a diabetes or specialty inflammatory conditions drug.
- Oncology was the third most expensive class last year, and trend for this class is expected to increase more than 20% in the next three years.

Source: Express Scripts 2016 Drug Trend Report

—Prepared by Aimee Tharaldson, PharmD, Express Scripts.
Drugs In The Pipeline

NSCLC, non-Hodgkin's lymphoma and ovarian cancer.

Neratinib is an oral, irreversible pan-ErbB receptor tyrosine kinase inhibitor in phase 3 development for the treatment of advanced breast cancer (including HER2+), as a monotherapy and in combination with chemotherapy. At press time, approval of neratinib was expected in July 2017 for advanced breast cancer (including HER2+).

Unique approaches to overcoming tumor resistance is also being explored in the oncology space. “Certain cancers have been shown to accumulate high levels of hyaluronan [HA], a naturally occurring sugar in the body,” according to Helen Torley, president and CEO of biotechnology company Halozyme. “This accumulation creates a unique microenvironment that can foster the growth of tumor cells and create a barrier to drug delivery, inhibiting the potential effectiveness of many anti-cancer agents.”

Halozyme is seeking to target the tumor microenvironment with PEGPH20, its lead investigational drug currently being evaluated in multiple tumor types that accumulate high levels of HA, Torley says.

Earlier this year, Halozyme announced positive data from its phase 2 study, HALO-202, which evaluated PEGPH20 in combination with nab-paclitaxel and gemcitabine in patients with advanced pancreatic cancer. Halozyme is partnering with other pharmaceutical companies to evaluate the pan tumor potential of PEGPH20 in combination with other therapies for the treatment of pancreatic, gastric and metastatic breast cancers.

Alzheimer’s

More than half of drugs in current late-stage trials for Alzheimer’s disease target beta-amyloid proteins, which stick together to form plaques between nerve cells in the brain of Alzheimer’s patients. These plaques destroy surrounding cells and impair cognition.

Biogen recently announced that its antibody-based therapy, aducanumab, saw a statistically significant reduction in these plaques, as well as a slowing of mental decline at the 12-month mark.

Another group of drugs in the Alzheimer’s pipeline to watch are the beta secretase cleaving enzyme (BACE) inhibitors, which block the production of beta-secretase, an enzyme needed for production of beta-amyloid proteins. By blocking production of the proteins rather than destroying them once they’re formed, it’s hoped these drugs may have a bigger impact.

In August 2016, AZD3293 (Lilly and AstraZeneca), an oral BACE inhibitor, received fast-track designation for the development program in Alzheimer’s disease. A pivotal Phase II/III clinical trial of AZD3293 started in late 2014 and is planned to recruit 1,500 patients and end in May 2019. In April 2016 the company announced it would advance to phase 3 without modification. According to the manufacturer, AZD3293 has been shown in studies to reduce levels of amyloid beta in the cerebro-spinal fluid of people with Alzheimer’s and healthy volunteers.

Another potential target in the treatment of Alzheimer’s are tau proteins, which form tangles inside brain cells. TauRx Pharmaceuticals’ LMTX, a second-generation tau aggregation inhibitor, acts by reducing levels of aggregated or misfolded tau proteins, which are associated with the progressive neurodegeneration which is the hallmark of Alzheimer’s disease, according to the company. At press time, TauRx had completed two large phase 3 clinical trials of LMTX in Alzheimer’s disease.

Flortaucipir (Lilly), a molecular imaging agent under investigation for detecting the presence of amyloid plaque in the brain, has been submitted to the FDA for approval.

According to the Alzheimer’s Association, plaques form when protein pieces called beta-amyloid clump together. Beta-amyloid comes from a larger protein found in the fatty membrane surrounding nerve cells.

“[Alzheimer’s disease] is unique due to the process of diagnosis, which is based on memory impairment, thinking skills, functional abilities and behavioral changes,” says Andrew Lyle, director of business development, Curexa Pharmacy. “Furthermore, the true physical tests that can be completed will only rule out other diagnoses; you can test for amyloid plaques and swelling of the brain but at that point the disease has already taken its toll.”

—NADINA ROSIER, WILLIS TOWERS WATSON

This year we are expecting at least 10 agents to be FDA approved for cancer indications, four of which are for breast cancer.”

Erin Bastick, PharmD, RPh, is a staff pharmacist at Southwest General Health Center in Middleburg Heights, Ohio.
Three ways tech is improving pharmacy

Benefits include improved access, safety

by DONNA MARBURY

When Walmart announced in March 2017 that it would allow patients to fill prescriptions via its mobile app and it would provide express pickup for medications, the conversation around technology in pharmacies made headline news. The message was clear: Patients have retail expectations when it comes to engaging with pharmacies.

In fact, several recent technology advances in the pharmacy field have been driven by consumer demand for improved pharmacy access, safety, and service. Here are three of the biggest ways technology is improving pharmacy:

1 **Access improvements**

Endexx Corporation, an inventory management and tech company, plans to use AutoSpense automated inventory and vending technology in retail pharmacies to give patients access to prescription will-call and other pharmacy support. The technology, which was approved in March, aims to reduce transaction time for customers, giving pharmacies the ability to serve more patients daily.

“We believe our technology empowers customers and increases efficiency among the retail markets to improve patient care and give them better access to their medical care,” said Todd Davis, CEO of Endexx, in a statement. “The major trend that is shifting in the business of retail pharmacies is on expanding the services offered, and we believe our technology will serve both customers and our retail clients to improve front-end sales and overall revenues and profits.”

2 **Safety improvements**

Robotic devices and other machines that fill, dispense, and measure medications for vials, bottles, and blister packs, are another area of technology growth in pharmacies. The pharmacy automation market is expected to reach $4.1 billion in 2018, according to a study by Transparency Market Research released in September 2016. An effort to cut medication errors resulting in patient death or illness is a top reason why automation is in high demand, the study found.

“We have an ingrained belief in healthcare that manual processes are good enough and we don’t take to heart the errors from other organizations.”

—CRAIG BOYCE, RPh, ARXiUM

Another example is a partnership between Publix Pharmacy, a retail pharmacy with hundreds of locations in the Southern U.S., and BayCare health system, which includes 14 hospitals in Tampa Bay and central Florida. The companies will use telehealth in pharmacies and in hospitals in four Florida counties.

BayCare will place branded telehealth sites in Publix locations and in Publix pharmacies in five hospitals. The companies hope to have all locations using the technology by the end of this year. Patients using the telehealth technology in pharmacies will be able to speak to doctors through video conferencing and utilize diagnostic tools, such as blood pressure cuffs and stethoscopes. The doctors participating in video conference can write prescriptions so that patients can pick them up on site.
Robotics, which has been used in other automation industries for decades, has been slower to gain traction in the pharmacy space. “When you look at efficiency, other industries have known and acknowledged for years that humans make mistakes. To rely on visual inspection, you can often miss many errors that cannot be caught by the human eye,” Boyce says.

In general, safety risks to patients include wrong dosage or medication contamination, which can occur in 0.7% to up to 14% of prescriptions, Boyce says. “We have an ingrained belief in healthcare that manual processes are good enough and we don’t take to heart the errors from other organizations. But mistakes do happen,” Boyce says.

The company introduced a new version of an automated IV compounding system in November 2016, which prepares syringes and IV bags in a safe and sterile environment. The robotic device checks medications through various stages of the preparation process, including precise labeling, and aims to eliminate errors and make prescription filling more efficient. Though a version of the device has been on the market since 2008 and has filled more than 6.3 million doses globally, the latest version has features that maximize efficiency and increase productivity.

Automation in the pharmacy field has yet to see widespread adoption, but Boyce says that as technology companies make devices more user friendly, pharmacy fulfillment could be just as automated as Amazon.

“We are wasting a huge amount of pharmacy resources. With this technology, we can start offloading repetitive tasks, and allow humans to focus on specialty, high-value work,” Boyce says.
Top five healthcare leadership problems

Biggest pitfalls industry leaders say you should avoid

by AUBREY WESTGATE

1. Valuing loyalty over competence
   “Loyalty and tenure are important. It takes time to understand an organization, its various layers of leadership and administration, and the personalities involved. Having an in-depth understanding of these is required to organize highly effective teams and to be truly effective in one's role. However, loyalty and tenure are not a complete substitute for competence and the ability to creatively problem solve, effectively implement programs, and drive change. Rewarding loyalty and tenure alone with advancement in the organization all too often leads to the reality of 'The Peter Principle,' where managers have risen to the level of their incompetence.”
   —Alan R. Ertle, MD, MPH, MBA, chief medical officer, Mercy Medical Group, Inc.

2. Failing to acquire necessary skills
   “One top leadership problem is lack of population health management experience for business and clinical people in healthcare companies.”
   —Perry Cohen, PharmD, chief executive officer, The Pharmacy Group, Managed Healthcare Executive editorial advisor

3. Refusing to break down barriers
   “Though this area has improved, there's still a far from successful effort on behalf of leaders throughout the industry to break down walls and silos within which our healthcare system operates, and deliver a much more connected, well-coordinated model of care that will inevitably drive down costs yet preserve access and quality of care.”
   —David Calabrese, vice president and chief pharmacy officer, OptumRx, managed Healthcare Executive editorial advisor

4. Ignoring real problems
   “I believe the biggest problem confronting healthcare leaders is their inability to identify the root causes of issues and then find remediation steps. For example, the current dialogue in Washington, D.C., centers on health plan premiums and affordability—when in my opinion, the real root causes of our issues are the underlying cost of care and their rate of growth plus the relatively lower effectiveness of care relative to other developed countries.”
   —David Schmidt, president of the TPG International Health Academy, Managed Healthcare Executive editorial advisor

5. Lacking innovative, independent thinking
   “Healthcare has historically been a very conservative industry and generally resistant to change. Ideally, I think we need more risk-takers in this era of reform and leaders who are prepared to truly lead (vs. follow) should be rewarded for their efforts.”
   —Douglas L. Chaet, FACHE, founder and chairman emeritus of the American Association of Integrated Healthcare Delivery Systems and a managed care thought leader, Managed Healthcare Executive editorial advisor
Few consumers trust health organizations

Report has troubling findings

Consumer trust in health plans, health systems, and the pharmaceutical industry is waning. That’s according to a Harris Poll study released in January, based on a June 2016 poll of 1,018 U.S. adults. Here are four of the key findings.

1. Consumers believe companies value profits over patients.

Only 9% of U.S. consumers believe pharmaceutical and biotechnology companies put patients over profits, while only 16% believe health insurance companies do. Meanwhile, 36% of U.S. adults believe healthcare providers (such as doctors and nurses) put patients over profits, compared to hospitals (23%).

Michael Colarusso, managing director, NFP, an insurance brokerage and consulting firm, doesn’t find the results surprising, as both the pharma and health insurance industries continue to struggle with a lack of transparency around costs and services. Compounding the issue, companies continue to publicize rising profits while consumers struggle to find ways to pay for these services, he says.

2. Hospitals and providers have better reputations than pharma.

While most consumers feel neutral about healthcare companies, more consumers rate health insurance (24%) and pharmaceutical and biotechnology companies (20%) with low reputations, compared to hospitals (6%) and doctors and nurses (5%).

Gil Bashe, APR, managing partner, Global Health, Finn Partners, notes that health professionals have a personal connection to patients. In comparison, payers and biopharma companies are faceless. “Patients have little transparency into how health insurance plan formularies are created and even less exposure to how medicines are priced,” he says. “High mystery leads to low reputation; payers and pharma companies should take heed of ever-dropping reputation statistics.”

3. Consumers say providers know best how to solve industry problems.

When asked where solutions to healthcare industry challenges will come from, more than half of U.S. consumers (55%) say providers. Nearly half (47%) see patients and consumers solving healthcare challenges, while 38% cite the government.

Says Colarusso, “Consumers have a more personal relationship with doctors and nurses that is founded on trust.”

Wendy Salomon, vice president, reputation management and public affairs at Nielsen, says consumers yearn to have their voices heard. “If a company wants to be seen as a problem-solver, it’s fundamental that patient input is part of their process,” she says.

4. Ethics is the most important attribute for organizations, say consumers.

In order to be part of the solution in addressing U.S. healthcare needs, consumers say it is most important for organizations to demonstrate ethics (62%), quality (57%), and transparency (57%). Other critical factors include efficiency (49%), collaboration (47%), flexibility (47%), and transparency (47%).

“These behavioral attributes must be harnessed to get sector-to-sector leaders talking and collaborating around new ways to achieve economic objectives while remembering when patient needs are the priority, and societal value is achieved, the possibility for profit is welcomed,” Bashe says.

### Q: Does the industry put patients over profits?

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Source: Harris Poll of consumers

ABOUT THE AUTHOR
Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Value-based contracting shifts risk to manufacturers

by MARI EDLIN

The whole idea of value-based contracting is to pay for value—something basic in any other industry, says Michael Sherman, MD, chief medical officer, Harvard Pilgrim Health Care, Wellesley, Massachusetts. “We are getting closer, however, with pay-for-performance programs for providers.”

While these contracts do not yet dominate the kinds of agreements between manufacturers and payers, they have existed since 2009, when Cigna and Merck penned a deal for Januvia (sitagliptin) and Janumet (sitagliptin and metformin HCl) for type 2 diabetes.

Merck provided a discount on the two drugs if plan members on any oral anti-diabetic drug lowered their blood sugar levels after a year and additional rebates if members on the two drugs took their medications according to physicians’ instructions. In return, Cigna put the drugs on a low copayment tier to induce adherence.

How they work
Typically, value-based contracts are built around guaranteed performance by a drug based on specific outcomes from clinical trials, and if a drug fails to meet benchmarks, a manufacturer offers a lower price and/or rebates, Donovan says. She adds that it’s only in the past three years that these contracts have taken off.

While it might seem that manufacturers would hesitate to take on one-sided risk, Donovan says it indicates they stand behind their products—a powerful thing. These contracts also are a vehicle for expanding patient access to a drug in a competitive class and enable manufacturers to get their drugs on formulary as a preferred product, she says.

For insurers, value-based contracts could help reduce the cost of drugs and improve ratings for various metrics under HEDIS or the Medicare Shared Savings Program.

And for both manufacturers and insurers, these contracts help predict costs.

Donovan also is seeing two-sided risk agreements. For example, a manufacturer and health plan might establish a contract based on several behavioral indications, including drug adherence, specific dose regimens, or other pharmaceutical, claims-based metrics.

At the end of an agreed measurement period (typically 12 months), if members on average in a health plan exceed contract...
parameters, this would be deemed a success. In this case, the health plan would transfer funds to a manufacturer as a result of meeting the performance guarantee. If members on average fail to meet contract parameters, the situation would be reversed—with funds going from a manufacturer to an insurer.

The transfer of funds, Donovan says, could take on many forms, such as an additional rebate or funds set aside at the beginning of a measurement period to cover payments in either direction.

Donovan predicts that follow-on phases of value-based contracting could include more creative contracting parameters, such as the introduction of overall healthcare (medical and pharmaceutical) costs, performance measured against peer benchmarks, or performance targets adjusted on an annual basis.

**When they make sense**

For value-based contracting to work, there must be measurable outcomes for the population being treated and no generic treatments available, according to “Value-Based Pricing in Pharmaceuticals,” an October 2016 KPMG report. If generics are on the market, a drug is competing on cost, not outcomes. The report outlines three other criteria that make a value-based contract appropriate:

1. When the effectiveness and appropriateness of a drug is questioned by payers/clinicians.
2. If a drug is highly competitive.
3. When the potential for actual sales volume is significant.

**Real-world example**

In 2015, Harvard Pilgrim contracted with Amgen for the drug Repatha (evolocumab), a PCSK9 inhibitor. The insurer receives a lower price for the drug by making it a preferred agent on its formulary, while also earning rebates if Repatha doesn’t lower LDL cholesterol to the levels observed during clinical trials. Harvard Pilgrim’s contract is for two years, based on 12-month results.

“Value contracts can limit member liability and ensure affordability because we are paying for what works,” Sherman says. “We are spending our dollars wisely.”

Bill Woodward, senior director, contract services pharmacy for Vizient, a network of community-owned healthcare systems, agrees with Sherman. “We shouldn’t pay for products that don’t work, and this is another avenue to explore as we strive to find the best way to treat patients and deliver the best outcomes at the lowest cost.”

Harvard Pilgrim also signed contracts with Amgen for its RA drug Enbrel (etanercept); and with Eli Lilly for Forteo (teriparatide [rDNA origin] injection), an osteoporosis drug; and for Trulicity (dulaglutide), for type 2 diabetes.

Enbrel is tied to six criteria including patient compliance, dose escalation and switching or adding drugs. The Eli Lilly contract will measure patient adherence to Forteo and reduce costs if there are meaningful improvements. Harvard Pilgrim has made Trulicity a preferred drug in exchange for a discount if the drug indicates better performance than competing medications. “Traditional agreements simply trade off price against volume and formulary placement, but adding outcomes offers an additional dimension on which the two sides can negotiate,” Sherman says.

Harvard Pilgrim is not the only insurer that has bought into value-based contracts. Aetna and Cigna have developed ones with Novartis for its heart failure therapy, Entresto (sacubitril/valsartan). Aetna’s agreement is based on results that replicate those found in clinical trials, while Cigna’s rests on improvements in patient health, including decreasing heart failure related hospitalizations. In return, Novartis provides both an outcomes incentive and an outcomes incentive in which rebates increase or decrease depending on whether Entresto reaches its potential.

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

Four things to know

Karen Appold

THE SECOND phase of a Zika vaccine trial is underway. The investigational vaccine was developed by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). Here are four things MCOs should know about the trial:

Key objectives

The phase 2 trial consists of parts A and B. Part A, which began in late March, is building on ongoing phase 1 trials and will continue to evaluate the vaccine’s safety and ability to stimulate an immune response. It will also help to determine the optimal dosage and ideal injection sites. Part B, which was set to begin in May or June at press time, aims to determine if the vaccine can effectively protect against Zika-related disease when someone is exposed.

What the trial will entail

Part A will enroll 90 healthy men and nonpregnant women between the ages of 18 and 35. Participants will randomly receive either a standard dose or a high dose of the investigational vaccine, and will be followed for about 32 weeks.

Part B will enroll at least 2,400 healthy men and nonpregnant women between the ages of 18 and 35. Participants will randomly receive either the investigational vaccine or a placebo. They will be followed for almost two years.

Investigators will compare the rates of confirmed cases of Zika in the groups to determine if the vaccine protects against Zika infection.

Current findings

After extensive testing in animals, early-stage human testing began in 2016. Initial findings indicated that the vaccine is safe and able to induce a neutralizing antibody response against Zika virus.

What’s next

“Completion of the trial depends on the intensity of Zika virus transmission and efficacy of the vaccine candidate,” said Anthony S. Fauci, MD, director of NIAID, during a press conference on March 31. “Initial results could be available as early as the end of 2017.” The study is expected to conclude in 2019.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Multiple myeloma is a rare cancer, representing about 1.8% of all cancers combined, according to the National Cancer Institute. About 30,000 new cases are expected in the U.S. in 2017. It is more common in men than women, among individuals of African-American descent, and those aged 65 years and older. The SEER Cancer Statistics Review, a report of the most recent cancer incidence, mortality, survival, prevalence, and lifetime risk statistics published annually by the Surveillance Research Program of the National Cancer Institute, notes that the five-year survival rate of myeloma is 49.6%.

It has been an exciting time at the Myeloma Institute at the University of Arkansas for Medical Sciences (UAMS), in Little Rock, Arkansas, on all fronts, namely, embarking on research that could play an important role in the development of preventative and curative strategies for multiple myeloma in the future.

“We continue to see a large number of patients with multiple myeloma and other plasma cell disorders from across the U.S. and the world,” says Gareth Morgan, MD, a physician and director of the Myeloma Institute. “Our research investigations have led to some exciting discoveries in the biology of myeloma based on the genetic variations within the human genome. With our colleagues in Europe, we have identified eight new genetic variations that could be linked to an increased risk of developing myeloma.”

UAMS is focused on developing a molecular classification of patient subgroups with distinct pathogenesis and clinical behavior. It partnered with Celgene and the Dana–Farber Cancer Institute in establishing a global collaboration called the Myeloma Genome Project.

“The goal of this project is to compile and analyze the largest set of genomic and clinical data to design a molecular classification system to improve the diagnosis, prognosis and treatment of myeloma,” Morgan says. “This initiative could really lead the way in developing targeted treatments for patients in the future.”

“… We have identified eight new genetic variations that could be linked to an increased risk of developing myeloma.”

Morgan recently spoke with Managed Healthcare Executive (MHE) about other promising developments regarding multiple myeloma, as well as the challenges and ways to overcome them.

Q: MHE: What are healthcare executives’ major challenges in the area of multiple myeloma?

Morgan: Uncertainty about the future of healthcare policy and payer coverage is clearly one of the biggest challenges faced by leaders across the industry. We know that patients diagnosed with a complex cancer like myeloma fare better when they are treated by a specialist at an experienced facility like the UAMS Myeloma Institute, when compared to oncologists in community-practice settings for whom myeloma may only represent a small portion of their patient population. Unfortunately, some patients don’t have access to specialized myeloma...
programs because of insurance or other financial restrictions. This is something we see every day.

The personal and economic burden of a cancer diagnosis like myeloma really heightens the urgency for more research, but decreases in federal and state funding have made it more difficult.

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**Q:** MHE: How can these challenges be met or avoided?

**Morgan:** Maintaining the quality of clinical care and sustaining our research program are our highest priorities. We are not implementing cost reduction strategies but rather are discovering more effective ways to improve outcomes by addressing variations in practice and optimizing resources through a service-line approach. We are also expanding our collaborations with university and industry partners to develop new clinical trials to answer strategic questions related to high-risk disease. We are also working on improving the myeloma clinical guidelines through the International Myeloma Working Group.

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**Q:** MHE: What are promising developments in multiple myeloma?

**Morgan:** The increased understanding of the genetics and epigenetics involved in the initiation and development of myeloma cells has really powered the concept of precision medicine, such as the development of targeted therapies directed at specific mutations at the molecular level.

Immunotherapy represents another promising treatment approach for patients. Addressing relapsed disease via resistant clones has led to the development of new immune-based strategies, some which are already approved and providing results and others which are in development.

An exciting advancement on the horizon is the development of a peripheral blood biopsy as an alternative to bone marrow aspirate and biopsy, which not only would be more comfortable and convenient for patients, but may also offer a more comprehensive profile of myeloma cells, which could be of particular use in the earlier stages of the disease, such as in monoclonal gammopathy of undetermined significance and smoldering myeloma.

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Tracey Walker is content manager for Managed Healthcare Executive.

**New scientific advances at the genetic and protein levels**

Major advances have occurred over the past two decades in treating multiple myeloma, and these advances are progressing rapidly today, says Gerry Messerschmidt, MD, FACP, chief medical officer of Precision Oncology. Many innovative strategies and combinations of approved and experimental therapies have a high likelihood of gaining approval and becoming standard use. “This means more therapy, more often, and thus, potential financial ramifications for payers of myeloma treatment,” Messerschmidt said.

As a clinical oncologist and an executive with a leading oncology development provider specializing in clinical trial execution, biomarker services, and analytics, Messerschmidt is tuned into the changes in the myeloma landscape. Managed Healthcare Executive (MHE) recently spoke with Messerschmidt about new therapies on the radar, and how they could impact treatment. To found out what he said, visit bit.ly/Myeloma-innovations

**Spotlight: Medical College of Wisconsin’s Multiple Myeloma Program**

At the Medical College of Wisconsin (MCW), providers see about 300 new multiple myeloma patients each year, and perform approximately 120 to 150 stem cell transplant-based treatments annually for myeloma alone. In 2016, providers saw a total of 928 individual multiple myeloma patients.

MCW multiple myeloma experts, Parameswaran Hari, MD, interim chief, professor of medicine, hematology and oncology, and Binod Dhakal, MD, MS, assistant professor of medicine, division of hematology/oncology, spoke with Managed Healthcare Executive (MHE) about opportunities and challenges in this area. To find out what they said, visit bit.ly/Myeloma-MCW