EXCLUSIVE

PHARMACY SURVEY

Cost reduction strategies

Evolving PBM landscape

Most anticipated drugs

June 2019 VOL. 29 NO. 6

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Managed Care Pharmacy Survey 2019

The top managed care pharmacy challenges—and how healthcare executives are solving those problems  PAGE 8

ESSENTIALS
4 Hospital Pharmacist Role Expands in Patient Care
14 Seven Pharmacy Regulations Health Execs Must Watch
16 Eight Ways to Help Patients Navigate Healthcare Costs
22 Featured Exec Joan Budden: President and CEO at Priority Health
24 The Latest Vaccine News
27 Conference Insider
30 Cut Through the Cloud Clutter

COMMENTARY
3 Seven Pharmacy Questions to Consider for 2020 and Beyond from Perry Cohen

DEPARTMENTS
2 Editorial Advisors
33 The Bottom Line
Mission: Managed Healthcare Executive provides healthcare executives at health plans and provider organizations with analysis, insights, and strategies to pursue value-driven solutions.
Seven Pharmacy Questions to Consider for 2020 and Beyond

As the cost and use of pharmaceuticals is now on the front page of newspapers, some people think that this is a new phenomenon, but drug costs have been discussed and analyzed for decades. As you plan for 2020 and beyond, here are some key questions to consider:

1. **Who is the customer?**
The customer is changing from a physician-centric to a patient-centric world.

2. **What are appropriate pricing strategies?**
Employers are questioning the value of new drug treatments and their price. As patients pay more of the cost of these expensive therapies, drug companies are trying to develop value-based contracting ties to outcomes to address the cost problem.

Drug companies are also launching more “specialty drugs” that are covered under the medical benefit, so these drugs cannot be managed.

The current conversation around the future of rebates is interesting, but drug companies will always discount their products or purchases that can drive market share.

3. **What is the role of the pharmacists?**
As prescription dispensing is increasingly handled by automation and pharmacy technicians, pharmacists will need to manage a patient’s drug therapy and be connected to others on the healthcare team. Using information technology can enable timely communication.

4. **Is there a better model?**
Yes. As companies like Amazon impact the drug distribution model for pharmacy and reshape the consumer experience in buying prescription drugs, pharmacy needs to invent care models to remain relevant.

5. **What is the value of PBM companies?**
PBMs have amassed large databases of pharmacy claims data to analyze drug utilization and track financial performance. They used this role to “manage” the cost of the pharmacy benefit while simultaneously creating new ways to create profits. PBMs are currently selling commodity services (e.g., pharmacy claims processing, pharmacy network contracting, and drug rebates) to employers and health plans. As the focus for drug cost management moves to the drugs covered under the medical benefit, PBMs will try to position themselves to manage these medications.

6. **How will technology impact pharmacy?**
Two technologies are emerging that ensure every patient is receiving the right medication in the prescribed dosages: (1) using digital imaging makes it much easier and faster for the to verify the prescription and (2) improvements in machines specifically engineered to count dosages ensures that the pill count is correct.

Technology such as telemedicine extends pharmacy services to the internet.

Pharmacies will increasingly use analytics like EHR systems to gain a better picture of the overall health of the patient and in turn provide better services to its customers. In addition, pharmacies will use business analytics to identify customer choices and take action to improve its brand.

Consumers will embrace technologies that give them greater access to relevant information, such as technologies that provide consumer awareness of drug pricing disparities between pharmacies will impact their decision on where to get the prescription filled.

7. **What is a healthcare executive to do?**
A forward-thinking healthcare executive should have a process to scan the industry for innovative applications for consumer-centered healthcare and be willing to make incremental strategic investments that can benefit their members.

For example, you need to focus on lowering drug costs by having a “state of the art” fraud, waste, and abuse program.

**Perry Cohen** is an editorial advisor for Managed Healthcare Executive and is Chief Executive Officer, The Pharmacy Group.

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*OPINION FROM PERRY COHEN*
Hospital pharmacists are not unlike pharmacists in other practice settings. Their primary objective is to ensure that patients experience safe medication use. Beyond that purpose, however, the role of hospital pharmacists (also known as health-system or clinical pharmacists) encompasses a broad range of duties with the ultimate goal of providing quality care during an inpatient stay, ensuring a seamless transition of care, and reducing the number of medication errors.

Hospital pharmacists consult on diagnosis, examine patient charts, conduct patient evaluations to recommend a course of treatment, and choose the appropriate dosing of medications and evaluate their effectiveness.

“In health systems, pharmacists are more involved with direct patient care than ever before. There’s an incredible opportunity for pharmacists to improve patient outcomes.”

—NORMAN TOMAKA, CRPH

American Society of Health-System Pharmacists (ASHP). “They’re part of an interprofessional team that may cut across different settings of care. Some of this is driven by a move to value-based care, such as CMS’ quality measures and readmission targets.”

Proactive steps
The suggested pharmacist-to-patient ratio for optimal care is about 1-to-30 (1-to-20 in the intensive care unit), notes Kimberly A. Boothe, PharmD, MHA, system director, pharmacy services for St. Elizabeth Healthcare in Fort Thomas, Kentucky. (The traditional pharmacist-to-patient ratio is in the 1-to-50 to 1-to-100 range).

With fewer patients to treat, hospital pharmacists can examine patients more holistically for both acute and chronic conditions.

Acutely, a patient is admitted with signs and symptoms of emerging sepsis, although the lab work initially seems fine. Hospital pharmacists are knowledgeable about those signs and symptoms. They can identify a drug that may be harmful if not adjusted.
to compensate for acute changes in kidney function because of emerging sepsis.

“A hospital pharmacist can take steps to communicate with the nursing and physician team about a dose adjustment or preemptively recommend discontinuing a medication,” Maroyka stresses. “They can make proactive changes based on evidence instead of reactive changes later that will unnecessarily extend a patient’s hospital stay.”

For patients with chronic conditions, hospital pharmacists can collaborate with physicians to manage disease states such as hypertension and chronic obstructive pulmonary disease, mainly through patient education and counseling, drug safety management, medication review, monitoring and reconciliation, detection and control of specific risk factors, and outcomes.

These examples of interactions show the value of the hospital pharmacist participating in rounds as part of the care team.

“Many times, the body stresses when someone is in the hospital,” says Brook DesRivieres, PharmD, MS, a member-spokeswoman for the American Pharmacists Association (APhA).

“What works at home may not work in the hospital. Hospital pharmacists can make sure prescriptions and doses are clinically appropriate,” DesRivieres says. DesRivieres describes the hospital pharmacist as a watchdog. “We’re the safety net,” she stresses. “A provider may order a drug therapy, but it may not be administered until the pharmacist does a safety check. That’s the biggest contribution pharmacists make in the inpatient setting.”

“Transition of care
Medication management has many gaps that, if not closed, could result in an adverse event for patients. Those gaps become more noticeable—and potentially more life threatening—during a transition of care from the hospital to home, a rehab or skilled nursing facility, or other care setting. Hospital pharmacists coordinate post-discharge care to prevent adverse events.

At discharge, pharmacists ensure there is an accurate and updated medication list communicated with patients and their providers. In certain cases, pharmacists will check to see whether patients have access to the pharmacy and a way to pay for the medications. Care coordination may be done with the servicing outpatient pharmacy.

“The pharmacist can deter-

“Training Hospital Pharmacists
Upon receiving a pharmacy degree, pharmacists whose goal is to work in a hospital or health-system setting can pursue further training as a resident. Similar to medical residency program, there is intense competition among students to secure a spot in a hospital pharmacy residency program.

Residency training is divided into two postgraduate years. Postgraduate year one (PGY-1) offers a general pharmacy residency, which provides experience in a variety of clinical situations. Postgraduate year two (PGY-2) emphasizes a specific area of interest, such as pediatric oncology or infectious diseases.

After completing residency training, many hospital pharmacists become board-certified, mostly in pharmacotherapy, although some choose certification in a specialty.

Most hospital pharmacists serve at least one year of residency training, which is equal to three to five years of work experience.

“More hospital pharmacists are doing more training,” says Vicki Basalyga, PharmD, BCPS, director of the Clinical Specialists and Scientist section for ASHP. “They receive a skill set and advanced knowledge, so they can be integrated into patient care.”
mine whether there is a reason that a medication is no longer indicated and be discontinued,” notes Erika Thomas, MBA, BS Pharm, director of the Inpatient Care Practitioners section for ASHP.

“If the patient is elderly and at risk for falls, the risk and benefits of certain medications must be evaluated,” Thomas says.

Transition of care is important for the health of the patient and because of the changeover from fee for service to value-based payments.

More than 2,500 hospitals nationwide will receive reduced reimbursement because of high patient readmission rates during fiscal year 2019 (ending September 30), according to CMS.

“Readmissions will impact the bottom line,” Tomaka maintains. “Reimbursements are lower due to readmissions. Hospital pharmacists can collaborate with community practitioners, including primary care physicians, nursing home agency, and home healthcare, so there is a medication management plan carried out when patients leave the hospital to prevent readmissions.”

Fewer medication errors
Numerous studies show hospital pharmacists substantially contribute to safer medication use by collaborating with other providers, and they improve the quality (reduced medication discrepancies) of admission and discharge reconciliation by exercising oversight.

Further studies document that pharmacists identify a significantly higher number of medications taken per patient, including more over-the-counter and herbal medications, compared with nurses, and they contact patients’ outpatient pharmacies significantly more often than nurses.

“There has been lots of research that documents the important role of hospital pharmacists,” Boothe stresses.

Data at St. Elizabeth Healthcare show a reduction of errors from 2.8 discrepancies per patient to 0.5 discrepancies per patient with a pharmacy-assisted medication reconciliation process with the addition of medication history technicians and a pharmacist reconciliation review.

Hospital care is complex, and there are multiple opportunities for miscommunication—both in the hospital and post discharge. Hospital pharmacists are trained to circumvent miscommunication. By doing so, they help ensure a quality patient experience.

“Hospital pharmacists must move beyond dispensing and into more clinical areas,” says Melanie R. Smith, PharmD, BCACP, DPLA, director of the Ambulatory Care Practitioners section for ASHP.

“This increases patient access to care, while also expanding the role of the pharmacist on a healthcare team. All of which helps to improve the patient care experience.”

Ken Krizner is a freelance writer based in Cleveland, Ohio.

“We’re the safety net. A provider may order a drug therapy, but it may not be administered until the pharmacist does a safety check. That’s the biggest contribution pharmacists make in the inpatient setting.” — BROOK DESRIVERES, PHARMD, MS, APhA
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MANAGED CARE PHARMACY SURVEY 2019

To identify some of the top managed care pharmacy challenges—and how healthcare executives are solving those problems—Managed Healthcare Executive polled over 200 executives in medical practices, hospitals, large health systems, pharmacy benefit management organizations, consulting firms, and more.

The annual poll, conducted in the first quarter of 2019, covers fears about cost and access to pharmaceuticals, the changing roles of pharmacy benefit managers, evolving payment models, and more.

Coupled with the results of the survey are insights from experts from around the field, from executives at pharmacy benefit managers to pharmacy consultants, helping to break down the data and give other healthcare executives a path forward to 2020 and beyond.
**Q: What is the most effective way to reduce pharmaceutical costs (specialty and non-specialty)?**

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>34%</td>
<td>Enhanced point-of-prescribing tools to assist prescribers in identification and encourage use of the most cost-effective treatments</td>
</tr>
<tr>
<td>19%</td>
<td>Adoption and enforced deployment of evidence-based clinical pathways</td>
</tr>
<tr>
<td>12%</td>
<td>Revised benefit design models to further incentivize patient use of lower cost options</td>
</tr>
<tr>
<td>5%</td>
<td>Narrower and/or more exclusionary formularies</td>
</tr>
<tr>
<td>3%</td>
<td>More aggressive and expanded utilization management strategies (e.g., Prior auth, step therapy, and limited initial refills)</td>
</tr>
<tr>
<td>27%</td>
<td>Other*</td>
</tr>
</tbody>
</table>

*Other responses included: Get rid of PBMs, no direct patient advertising, expand 340B, medications must be cheaper, no direct patient advertising, price negotiation

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

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>27%</td>
<td>Performance-based (outcomes-based) contracting with drug manufacturers</td>
</tr>
<tr>
<td>23%</td>
<td>Governmental pricing regulation</td>
</tr>
<tr>
<td>14%</td>
<td>Aggressive promotion of biosimilars</td>
</tr>
<tr>
<td>12%</td>
<td>More aggressive and expansive utilization management strategies</td>
</tr>
<tr>
<td>5%</td>
<td>Expanded exclusion of specialty drugs from formulary</td>
</tr>
<tr>
<td>5%</td>
<td>ICER-based formulary limits</td>
</tr>
<tr>
<td>3%</td>
<td>Exclusive contracting with a single specialty pharmacy</td>
</tr>
<tr>
<td>11%</td>
<td>Other*</td>
</tr>
</tbody>
</table>

*Other responses included: Allow interchangeability of biosimilars, government negotiations with the industry, restore free enterprise competition, patient-specific care, price transparency

“As our current era of digital and technologic advancement further evolves, it is well-evident from these results that our nation’s key healthcare stakeholders recognize the critical value, and unmet need, related to enhancing communication with the prescribing community at the point of patient care. Unlike other industries, our industry continues to lag behind in the adoption and deployment of more progressive communications mechanisms that can improve the timing, efficiency and quality of service provided to the end-user...in this case the patient. Providing greater transparency for providers into comparative drug prices, utilization management programs, and patient-specific clinical intervention opportunities at point of prescribing not only offers the potential to reduce pharmacy costs, but also increases the likelihood for longer-term improvement in patient outcomes and total cost of care.

— David Calabrese, RPh, MHP, senior vice president and chief pharmacy officer of OptumRx, a pharmacy benefits firm that provides pharmacy care services for than 65 million lives. He also is an editorial advisor for Managed Healthcare Executive.
What will be the biggest driver of specialty drug costs in 2019?

- 36%: Growing demand/uptake due to aging population; increased prevalence of chronic disease
- 20%: Shift from traditional (non-specialty) to specialty drugs in high-prevalence disease states
- 16%: FDA-approval of new high-cost specialty drugs
- 11%: Inflation rates for specialty drugs already on market
- 6%: Broadened labeled indications and off-label use of existing products
- 11%: Other*

*Other responses included: A more complex pharma supply chain, direct marketing, lack of physician education in prescribing, lack of patient self-care

What is the best long-term approach to addressing the high cost of rare disease (e.g., orphan drug) treatment?

- 28%: A more integrated approach by benefit managers around total cost of care across the healthcare continuum
- 22%: NICE-like or ICER-based limitations around access to such therapies based upon some measure of cost-benefit (e.g., cost/QALY)
- 20%: Deploying more aggressive UM strategies to more routinely (e.g., every 3 or 6 months) assess risk vs. benefit of such therapies and promote discontinuation where possible
- 17%: Use of benefit incentives to drive consumer engagement and higher-value care
- 13%: Other*

*Other responses included: A federal program to develop these drugs and license several manufacturers at a time to produce and market the drugs, decrease the orphan drug loophole, government-funded research development, special re-insured risk pools

“There are many factors that drive specialty drugs costs:
• The high cost of new specialty drugs that are replacing lower-cost therapies.
• New specialty drugs that treat diseases that were untreatable before.
• Price increase of existing specialty drugs.
• Sales and marketing activities to physicians and patients to drive demand for specialty drugs.
• Lack of systems and processes in place to manage drugs covered under the medical benefit.
• Ineffective programs by health plans and PBMs to improve the utilization of these drugs.
• Slow introduction of biosimilars.

“Each patient population (e.g., commercial, Medicare, and Medicaid) will feel the rising drug costs differently.”

—Perry Cohen, PharmD, chief executive officer of The Pharmacy Group and the TPG family of companies, which provides services to associations, healthcare and information technology organizations, payers, and pharmaceutical companies. He also is an editorial advisor for Managed Healthcare Executive.
“I am surprised that almost half of the survey’s respondents feel that the current drug manufacturer rebate contracts to payers and PBMs will be replaced by value-based contracts. Healthcare executives and plan sponsors do not tend to move that quickly, and health benefits are traditionally very slow in terms of adapting to innovation. It’s one thing to say you’re going to adopt value-based contracts, but it’s another thing to actually make that shift, as some organizations are very resistant to change. This also brings up a much bigger question around total compensation; if you start changing how healthcare benefits are structured, members can be very averse to that, and that can be difficult for large-scale organizations to navigate. Value-based contracts are definitely the most progressive approach and seem to be where we’re headed. It’s really a matter of how and when this will become the rule rather than the exception.”

— David Henka, president and CEO, ActiveRADAR, a company specializing in pharmacy cost reduction programs for employers, trust funds, and health plans.

“The business model for today’s PBMs will stay the same for many customers (e.g., small employers and small health plans). The large PBMs will discount their services to retain customers. There will be new competitors to PBMs that will provide lower drug costs and better service with creative use of new technology-enabled services. New pharmacy care models will emerge to impact the traditional drug dispensing model. This will impact the role of the current PBMs.”

— Cohen

“We’re seeing renewed scrutiny of the PBMs on a large scale, and I think that’s probably why more people predicted that a performance-based, shared savings model will take flight. The overall opacity of the current PBM system is at the root of most of the concerns that purchasers have today. The idea of a true pass-through model is becoming less and less realistic, as there are often contracting provisions buried deep within the documents, charging for things you wouldn’t normally be charged for. This makes it difficult for benefits professionals to see the subtle differences regarding where and how costs are being incurred. Even as PBMs claim to bring more transparency to their purchasing, rebates, contracting, and formularies, they will always find a way to make their margins.”

— Henka
**Q:** What do you believe will transpire at the drug manufacturer level as it relates to drug pricing in the next 3 years?

- **37%** We will see a short-period of decrease in annual inflation rates, followed by a return to higher rates.
- **30%** Inflation rates on existing products will continue to grow as they have for the last 5-10 years.
- **19%** We will see a prolonged decrease in annual inflation rates due to increased scrutiny.
- **14%** We will see substantially greater numbers of manufacturers actually decreasing their current list price of their medications.

**Q:** What do you believe is the most effective strategy to increase patient engagement and adherence to key maintenance therapies?

- **34%** Newer benefit designs that reward patients for high-level engagement/adherence.
- **31%** Advancement in digital tools and other technologies to support patient adherence/engagement.
- **14%** Greater outreach, education, and counseling by PBMs/MCOs.
- **12%** Enhanced alerts to providers when their patients fall out of appropriate adherence.
- **9%** Newer benefit designs that penalize patients for poor levels of engagement/adherence.

**Q:** Do you believe that payers should adopt tools like ICER cost-effectiveness analyses to determine whether high-cost medications should or should not be covered?

- **62%** Yes
- **38%** No

“While ICER cost-effectiveness analyses have been underappreciated in this space, the findings suggest that payers are really starting to understand the value of this organization and its tremendous work. ICER-like tools are the gold standard and what payers should be looking to in order to identify cost-effective pharmaceutical therapies. The next step is to determine how to best integrate these kinds of tools into a benefits package or a purchasing program for a plan sponsor.”

—Henka
**Q:** What new pharmaceuticals approved over the past 12 months are you most excited about?

- **27%** Epidiolex (first-in-class cannabinoid-based product for treatment of rare, severe forms of epilepsy disorder in children 2 years and older)
- **26%** Erleada (once-daily oral treatment option for patients with non-metastatic, castration-resistant prostate cancer)
- **23%** Aimovig (first-in-class CGRP antagonist introduction for migraine prevention)
- **15%** Biktarvy (complete regimen for the treatment of HIV-1 infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed)
- **9%** Other

*Other responses included: Zulresso (brexanolone) for postpartum depression, Spravato (esketamine) for depression, Aristada Initio (aripiprazole lauroxil extended-release injectable suspension) for schizophrenia

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**Q:** What pharmaceuticals in the pipeline—specialty, new, generic, or other—are you most excited about over the next 24 months (choose all that apply)?

- **63%** Crenezumab: monoclonal antibody that binds to amyloid-beta proteins to prevent and break up their aggregation in plaques with Alzheimer’s disease
- **17%** Bempedoic: first-in-class, non-statin oral therapy that significantly reduces elevated LDL-C levels in patients with hypercholesterolemia
- **12%** AVXS-101 (approved May 24, 2019 as Zolgensma): gene replacement therapy that treats root cause of spinal muscular atrophy
- **9%** Uburogapt: first oral CGRP receptor antagonist for the acute treatment of migraine
- **8%** Obeticholic acid: potentially the first FDA-approved therapy for treatment of nonalcoholic steatohepatitis (NASH)
- **7%** Other

*Other responses included: Genetic effectiveness-based ADHD medications

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“Responses here clearly reflect the strong desire amongst our healthcare colleagues for manufacturers to focus their R&D efforts in bringing about new products that represent true innovation in patient care versus small, incremental clinical advancements and/or more ‘me-too’ type therapies.”

—Calabrese

“The overwhelming response here in favor of crenezumab is not surprising. For decades, we have struggled as an industry in identifying and bringing forth meaningful advancements in the treatment of Alzheimer’s in a time of growing disease prevalence. Unfortunately, with crenezumab, those struggles continue as the manufacturer (Roche) in early February announced that it would discontinue its phase 3 clinical trials as an interim analysis found the drug was unlikely to reach its primary clinical end point. Not long thereafter, on March 21, manufacturer Biogen announced that it, as well, was halting two late-stage studies of a similar anti-amyloid compound, aducanumab, after an interim analysis showed that it as well was unlikely to work. Meanwhile, hope continues as other nonamyloid approaches are also making their way through clinical testing, including drugs that target the protein tau that builds up inside neurons of the brain.”

—Calabrese
Health system executives are finding it difficult to stay ahead of the multiple trends culminating at once—reimbursement pressures, rising drug costs, regulatory complexity (340B), and the central role of pharmacy in value-based care.

Ed Francis, a senior director of life sciences at West Monroe Partners, says changes in drug pricing represents a particularly important issue that health executives will need to watch out for in the coming year, starting with optimizing the drug rebate system.

“Congress and the executive branch have discussed everything from eliminating the system entirely to writing laws that increase pricing transparency,” he says. “Even without government intervention there has been movement with some new PBMs that offer rebates as 100% pass-through to consumer. Other companies have emerged that are offering online drug price comparisons in a local area. All of this will help to solve the problem.”

Here are five other policies to keep an eye on in the year ahead.

1/ **USP 800**
Pharmacy expert Ernie Gates, president of Gates Healthcare Associates, believes that compliance with USP 800—the new workplace safety standard for pharmacy—will bedevil many healthcare organizations and the cost of non-compliance could be staggering.

“Many pharmacies, including those inside of institutions such as hospitals, are not prepared to comply with USP 800, which goes into effect later this year.”

—ERNIE GATES, GATES HEALTHCARE ASSOCIATES

USP 800 is about protecting the healthcare worker, patient, and environment from accidental exposure to hazardous drugs and requires changes to standard operating procedures across an organization, beginning with receipt of a hazardous drug and ending with disposal.

“Many pharmacies, including those inside of institutions such as hospitals, are not prepared to comply with USP 800, which goes into effect later this year,” he says. “This could be problematic for any healthcare organization that is dependent upon pharmacies, including health plans that operate or simply reimburse pharmacies.”

2/ **Drug Supply Chain Security Act (DSCSA)**
The DSCSA was designed so an electronic system could track and trace certain prescription drugs in the United States. Katrina Harper, senior clinical manager, pharmacy for Vizient, says what’s important with DSCSA is compliance with current regulations to ensure the integrity of the pharmaceutical within the supply chain.

“We are now starting to see enforcement actions in the form of fines,” she says. “One large wholesale distributor was the FDA’s first ever warning letter for non-compliance. They also need to be preparing to comply with the new aspects of this regulation that take effect in 2020.”

By 2020, all Rx products covered under DSCSA must be serialized, and all transactions can only involve serialized product.

3/ **The Lowest Price Act**
This act was signed into law on October 10, 2018, and will become
“The good news is that there will be improved alignment to DEA requirements for disposal and the change in requirements may impact an organization’s waste generation classification which could result in lower costs,” says Joyce Thomas, associate principle, pharmacy advisory services for Vizient.

4/ EPA update of the Resource Conservation and Recovery Act (RCRA) standards

These regulations were published in early 2019 to clarify an organization’s responsibility related to the disposal of hazardous and controlled substance pharmaceuticals in the waste stream.

“The good news is that there will be improved alignment to DEA requirements for disposal and the change in requirements may impact an organization’s waste generation classification which could result in lower costs,” says Joyce Thomas, associate principle, pharmacy advisory services for Vizient.

5/ CMS Hospital Outpatient Prospective Payment Proposed Rule CY 2019 (OPPS)

Romig explains this proposed rule further expands cuts to the 340B Drug Pricing program made in 2018 and institutes a site-neutrality payment policy for hospital outpatient departments by cutting reimbursement by 40% for the most commonly reimbursed G-codes in order to match payment under the Physician Fee Schedule.

“The proposed rule also includes a request for information related to a potential Competitive Acquisition Program for Part B drugs and biologics, which would run through the Center for Medicare and Medicaid Innovation,” he says.

6/ Provider status changes

Expanding the scope of practice for pharmacists is being considered in state legislatures and in Congress. This is particularly true in states with large underserved areas.

“In Congress, a main consideration is whether Medicare should cover payments to pharmacists in these underserved areas,” Romig says. “More than half of the 100 total members in the U.S. Senate have signed on to support the Pharmacy and Medically Underserved Areas Enhancement Act [S 109]. The bill has surpassed the number of votes necessary to pass this legislation in the Senate. The same bill is HR 592 in the House of Representatives.”

The bill would provide for Medicare coverage and payment for certain pharmacist services that are furnished by a pharmacist in a health-professional shortage area, and that would otherwise be covered under Medicare if furnished by a physician. On the state level, many are considering allowing pharmacists to prescribe oral contraceptives, while others would allow them to prescribe treatments for flu or strep throat. Virginia is considering allowing pharmacists to perform opioid abuse counseling. Pennsylvania is discussing allowing pharmacists to counsel for tobacco cessation.

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.
Eight Ways to Help Patients Navigate Healthcare Costs

Lack of transparency still plagues healthcare

BY KAREN APPOLD

While employees’ wages have remained mostly stagnant, family insurance premiums for employer health plans have increased 20% since 2011. Furthermore, more than 50% of individuals have a plan with a deductible of $1,000 or higher per year, says Joan Budden, MPA, president and chief executive officer, Priority Health, a health insurer based in Grand Rapids, Michigan. Consequently, four in 10 insured adults say they struggle to afford their deductible.

Historically, the cost of health services has been hidden behind a cloak of secrecy. In some cases, people avoid getting necessary care because they don’t think they can afford it, Budden says. Other times, they pay more than necessary because they weren’t aware that lower cost options were available.

The first step in helping consumers navigate the cost of care is to provide them with a basic understanding of what healthcare services actually cost.

“A lack of transparency is a huge problem that the healthcare industry needs to address,” Budden says. “Members deserve to have this information.”

Here are eight ways that health insurers can help patients navigate care.

1 PROVIDE MEMBERS WITH COST ESTIMATES FOR SELECT MEDICAL SERVICES

The healthcare industry sits on a mountain of data in electronic health records, but the industry has yet to fully tap into the data’s potential. “Payers and providers can leverage technology to automate analysis of historical claims data and provide patients with cost estimates before treatment or the final bill,” says Matt Hawkins, MBA, CEO, and board member of Waystar, a company focused on simplifying and unifying healthcare payments. “Based on similar claims that have been approved or denied by a patient’s provider, predictive analytics can give the patient a confident estimate of what they will ultimately pay for a procedure.” Price estimation technology can empower a patient with information so they understand a procedure’s cost ahead of time, check insurance eligibility, and determine their ability to pay.

Priority Health provides members with easy-to-use, digital tools to help them understand their healthcare costs. In 2015 it launched the Cost Estimator tool with the goal of providing members with estimates of their out-of-pocket costs on services and procedures. The tool provides members with pricing that is specific to their own health plan and includes their deductible and copays. “Our effort moves beyond the traditional approach of offering historical averages and instead focuses on information tailored...
to a specific individual,” Budden says. Priority Health pre-processes claims, providing an accurate estimate of the member’s cost for services they’re considering. The insurer has reported millions in shared healthcare savings as a result of the Cost Estimator.

**2 Educate Consumers**

Health insurers can educate consumers on their coverage options and out-of-pocket costs in several ways. They can partner with employers to provide health benefits education at the start of employment or each year during benefits enrollment, says Mark Spinner, president and CEO, AccessOne, which provides patient financing solutions. Such education can be provided virtually, telephonically, or in person in a large-group setting. Some payers work with employers to ensure employees gain points for participating in online education around health benefits. These points can be applied to the employee’s wellness incentive where wellness programs exist.

**3 Simplify the User Experience**

To help consumers understand exactly what their benefits entail, human resource departments should revisit benefits-related documents, such as Summary Plan Descriptions (SPDs). SPDs present an opportunity to enhance and simplify benefits communications. While these documents are traditionally dense and difficult to understand, human resource departments can add charts, callout boxes, and icons to make documents more appealing and digestible. Some employers are beginning to convert their SPDs into digital, interactive documents that employees can access anywhere and anytime. “The move to digital allows human resources to track which sections employees visit most, which terms are most often searched on, and how many employees view the document to enhance benefit communications,” says Bridget Lipezker, MBA, senior vice president and general manager, Advocacy and Transparency, DirectPath, LLC, which provides personalized benefits education.

Employers must also leverage multi-channel engagement strategies to keep consumers informed year-round. “With today’s workforce spanning five generations, employers must rethink how they communicate benefits offerings and information to ensure that consumers are getting the right information at the right time,” Lipezker says. Traditional forms of communication such as flyers and booklets can be reinforced and supplemented with newer methods such as webcasts, on-demand videos, and targeted texts and emails to reach both broad groups of employees and specific individuals.

**4 Incentivize Health Providers and Consumers to Work Together in Navigating Health Insurance Options**

Steady shifting of healthcare costs from payers to individuals not only intensifies pressure on members’ pocketbooks, but also changes their attitude toward insurance coverage and payment, Spinner says. A growing number of members who find they can’t afford the out-of-pocket expenses associated with their insurance plan have opted out of insurance altogether.

Meanwhile, the more members owe pro-

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**The Other Side of the Equation: Prescription Medication Costs**

- **48%** The share of Americans who say their prescriptions cost more than their grocery bills
- **66%** of Americans are willing to use generic medications to reduce costs
- **$200** The amount of money Americans spend on drugs (beyond their own medications) for friends and family
- **1 in 10** Americans managed prescription costs for their parents
- **54%** of Americans use their mobile device to research drugs to save on costs

Source: RetailMeNot RxSaver

Continued on page 20
Innovative Solutions Help Patients Successfully Transition to Post-Acute Infusion

Matthew Deans, Senior Vice President, Business Development, Option Care Enterprises, Inc.

Today’s value-based reimbursement programs require hospitals and health systems to shorten the length of time patients are hospitalized, reduce readmissions and improve quality of care. When post-acute infusion therapy is required, these challenges can be heightened, but are readily achievable for individuals who are relatively healthy, stable and financially secure. However, the risk of poor outcomes increases significantly for those who: are sicker and have comorbidities; have limited caregiver support; lack transportation options; or have Medicare without a Medigap plan, a high-deductible commercial plan or are uninsured or underinsured.

Ensuring all patients can be successfully transitioned to post-acute care as soon as possible requires a forward-thinking infusion provider that can offer comprehensive solutions for all patient types. Option Care’s highly trained and experienced multi-disciplinary teams of Clinical Care Transition Specialists, infusion nurses, pharmacists, dietitians, patient registration and reimbursement professionals ensure any patient that is able to go home, can go home by offering the following support:

**Comprehensive clinical support.** Option Care’s clinical care, including 24/7 access to a pharmacist or nurse, is built around a personalized treatment plan developed with providers and patients, including:

- **Extensive preparation.** Prior to discharge, a Care Transition Specialist meets with the patient and/or caregiver to assess social, psychological and financial readiness for post-acute care. Once an assessment has been made, a nurse provides extensive education and instruction to the patient and/or caregiver to ensure they are prepared to implement care at home and understand the importance of taking medication as directed.

- **Ongoing monitoring.** Option Care clinical staff closely monitor patients to confirm timely interventions and reduce complications. An Option Care study of 116 people with short bowel syndrome discharged on parenteral nutrition (PN) found clinical interventions provided by a dietitian-led nutrition support team prevented hospital readmissions due to dehydration.\(^1\) Researchers estimated 189 hospital days were prevented (based on an average three-day stay for the indication) saving $378,000.\(^2\),\(^3\)

**Transportation services.** Not all patients are well-suited for at-home care and need to receive post-acute care at an Option Care Ambulatory Infusion Suite. The staff can help facilitate transportation for patients lacking these resources to make sure they get the treatment they need.

An Option Care team recently worked with a veteran who was not a good candidate for home infusion therapy due to a history of drug abuse and was living in a shelter for men and women with addictions. The patient did not have access to transportation, but Option Care’s partnership with a third-party transportation service made it possible for him to get to the Ambulatory Infusion Suite for all of his treatments.

**Financial assistance.** Option Care has dedicated financial counselors to work with patients who are uninsured or underinsured to ensure financial vulnerability doesn’t impact access to treatment. They offer payment options as well as work to identify and coordinate access to patient assistance programs which help minimize out-of-pocket expenses. Option Care also partners with hospitals to extend services to uninsured patients at home through their Charity Care programs.
For example, Option Care worked with the family of one patient who needed therapy for complex medical issues, but ran out of hospital days covered by his insurance plan and couldn’t afford the copay for post-acute care. Rather than face thousands of dollars in out-of-pocket costs, Option Care helped arrange financial assistance allowing him to be discharged from the hospital and get his medicine at home.

Option Care also supports hospitals and health systems as a valued post-acute infusion partner with extensive payer coverage, demonstrated quality results and access to a wide range of limited distribution specialty infusion drugs that can be delivered in a more affordable setting.

Many patients require infusion treatment upon discharge from the hospital. Partnering with a quality infusion provider ensures effective care transitions for all individuals, mitigating the risk for hospitals and health systems and ensuring patients have access to the treatment they need.

References
Relationship between business office satisfaction and bill payment

![Bar chart showing the relationship between business office satisfaction and bill payment.](image)

Source: Waystar

Likely to ask a friend or expert for help understanding a bill

![Bar chart showing the likelihood of asking for help understanding a bill.](image)

Source: Waystar

Preferred approach to pay a bill

![Bar chart showing preferred approaches to pay a bill.](image)

Source: Waystar

Continued from page 17

...viders, the less likely they are to return for care. One recent study found just 54% of primary care patients return for care when they owe their physicians $100 to $200. Just 42% seek care when their balance is more than $200.

"Given these statistics, health providers and payers have an economic stake in working together to help members navigate health insurance options," Spinner says. These types of partnerships will become even more critical as members shoulder a greater portion of the costs of care.

5 Offer cash-back rewards when members select a lower-cost service or procedure

Some employers are offering rewards for employees who choose lower-cost options for medical services or procedures. This incentivizes employees to shop around for healthcare treatments and procedures. Through the process, it helps them understand price variations between services even when they’re in the same network and geographic area, says Lipezker. Rewards programs work...
best when the employer communicates the program well and makes it part of the overall benefit program.

Spinner has seen examples of employers and health plans offering incentives for use of lower-cost, high-quality sites for care. For example, Anthem Blue Cross and Blue Shield in Ohio and its affiliated health plans partner with the Cleveland Clinic Cardiac Concierge Program to provide employees from a national grocery store chain with access to cardiac surgery performed at Cleveland Clinic. The grocery store chain pays 100% of travel costs for members and one companion. Anthem helps coordinate the travel through a medical tourism facilitator.

Spinner is also seeing cash-back rewards programs for members who choose lower-cost care. In Massachusetts, a SmartShopper program offered through Anthem enables members to receive an incentive check each time they choose lower-cost options for care. Under this program, members can earn incentives monthly. Such tools also can have an impact on member care by encouraging providers to find ways to lower costs of care delivery.

6 PROVIDE FINANCIAL COUNSELING SERVICES

As consumers take on more of the financial responsibility of paying for healthcare, the industry is still opaque—offering no financial guidance for patients and leading to more surprise medical bills and unpaid claims, says Hawkins. A counterparty can work with patients to evaluate financial decisions as they move through the care process, and ensure that they’re putting their money in the right services and procedures at the right time.

A professional analysis of the quality and value of care available to a patient can enable smarter spending and better outcomes. It is estimated that $200 billion is wasted annually on unnecessary medical tests and treatment, and with healthcare spending projected to grow at a faster rate than the national gross domestic product over the coming decade, it’s important for patients to have access to an advisor to guide them through the process of evaluating care from a financial perspective, Hawkins says.

Employers can provide enrollment services that help educate employees on how to select the right health plan based on individual situations, as well as year-round access to benefits experts who can help them choose the best options for healthcare delivery (e.g., should they go to a retail clinic, urgent care, the emergency room, or just wait it out). “By demonstrating the range of costs associated with the plans themselves and with the point of service, consumers can begin to budget for paying out-of-pocket expenses more carefully,” Lipezker says. As a result, the costs to both the employee and employer decrease.

7 PROVIDE PATIENT ADVOCATES

Some employers are beginning to offer patient advocacy services. These services are designed to help make sure that insurance is working the way it’s meant to and that consumers are engaged. “Access to knowledgeable and experienced advocates who can help employees shop for their healthcare, answer benefit questions, locate in-network providers, and resolve claims issues helps employees make better decisions about their care and enables employers to reduce administrative and healthcare costs,” Lipezker says.

As healthcare costs continue to climb, advocacy services empower employees to be smart consumers, particularly when it comes to understanding medical bills. Advocates can help employees understand each cost included on a medical bill to ensure there aren’t any unnecessary or overpriced charges, Lipezker says. If there are errors, these advocates can work to ensure consumers only pay for what they received. Health plan designers can include references to advocacy services, so that consumers have the information on hand.

8 OFFER SIMPLE, PER-VISIT COPAYMENTS INSTEAD OF COMPLEX DEDUCTIBLE AND COINSURANCE PLANS

A 2018 analysis shows that balances rose to $781 in 2018 for patients with commercial health insurance coverage—a $314 increase over 2012 figures. “For members to successfully navigate their healthcare costs, they must have a clear understanding of their health benefits under commercial and government health plans as well as their out-of-pocket costs of care,” Spinner says. “This requires health plans to focus on ways to make it easier for members to navigate health plan choices and benefits, with simple, easy-to-understand approaches to deductibles and copays.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Priority Health is a $4 billion Michigan-based health plan that is nationally recognized for improving the health and lives of the people it serves—and leading the efforts is Joan Budden, its president and CEO.

“I really see my responsibilities as being threefold. First, it’s dealing with the current real-world healthcare issues and figuring out how to provide affordable care product and services that our members need to get healthy, be healthy, and stay healthy,” she says. “Second, it’s developing strategies for the future to understand what will be needed and anticipating how the industry will continue to evolve to make sure that Priority Health is well-positioned to take on the challenges of tomorrow.”

And the third, which Budden has done to a tee, is to be a leader and champion of culture and talent within the organization.

“Underlying all of that, my most important responsibility is truly to our members, figuring out how we can provide value to the people and communities we serve,” she says.

Under Budden’s leadership, Priority Health has reported growth across all business lines for the past five years and is now the second-largest health insurer in Michigan, impacting nearly 1 million lives across the state each year. Priority Health was also the only insurer in Michigan to reduce rates on the individual market for 2019.

The road to Priority Health

With over 30 years of healthcare experience, Budden came to the health plan in 2009 looking for a change.

“After many years of experience in a standalone insurance company, I was interested in exploring the complexities and advantages of a fully integrated health system that included a health plan, a medical group, and a hospital,” Budden says. “The opportunity to address complex healthcare issues from multiple perspectives and collaboratively debate the challenges and develop solutions was something that fascinated me.”

Today, she is a fierce advocate for Priority Health members and is committed to ensuring that they...
have the tools and resources they need to help them play an active role in managing their own health.

Under her leadership, Priority Health has designed affordable health plans that meet the needs of individuals across Michigan, which has resulted in a 35% increase in the number of people being covered.

“Many integrated delivery systems often have the heart of the member through the provider ties, but may lack some of the expertise from an insurance perspective to really soar,” she says. “We’ve always been known for being member focused, but recently we’ve also focused on strengthening our financial discipline and expertise to make sure we had a solid foundation from a business perspective. In addition, we have also made a commitment to really understand our members and their needs across all of our key market segments.”

For instance, she notes the needs of a 67-year-old Medicare member are significantly different from that of a 28-year-old shopping for insurance on the ACA exchange. So, by customizing the approach and focusing on the unique needs of each segment of membership, Priority Health was able to design plans and services that met the specific needs of every member.

**Innovative thinking**

Over the years, Budden has spearheaded numerous programs that reflect her commitment to transparency and member engagement.

“When trying to lift the cloak of secrecy surrounding cost of care, many people have resorted to price-shaming providers,” she says. “We took a very different approach. We recognize that it’s not about passing the buck or blaming others, it’s about giving consumers the information they need to be proactive and make an informed decision about their care.”

Priority Health’s Cost Estimator provides members instant access to cost information for hundreds of health care procedures in a way that’s personalized to their individual health plan—specific to their location, prescription, and benefits—to help them make truly informed decisions.

Hundreds of procedures are available in the tool, and earlier this year, more than 6,000 prescriptions were also added.

“We also enhanced our Cost Estimator with a provider view to allow doctors and other healthcare providers to work together with their patients to find the best value when seeking care,” she says.

Launched late last year, the Priority Health Wellbeing Hub offers a personalized online health and well-being experience. The Wellbeing Hub is intended to help members get and stay healthy by providing content and tools tailored to their specific health and well-being needs.

“I’m also proud of new care model programs like Home-Based Primary Care that allows us to meet members where they are, and provide personalized care—which improves outcomes and reduces costs,” Budden says.

**A strong leader**

Budden likes to think of herself as an inclusive leader and hopes her team agrees with that assessment.

“I’ve always tried to encourage a culture of collaboration and innovation, and I think one of the best ways to do that is to try and provide as many opportunities as possible for every employee to feel like they have a voice,” she says. “Over the past year, I held 17 listening tours across Priority Health’s multiple campuses throughout the state to receive feedback from all employees, personally.”

In the meetings, there are open discussions about what is going well and what needs improvement.

She also encouraged employees to share their ideas about how Priority Health might be able to better execute on the company’s vision.

“My philosophy on innovation has always been ‘think big, start small, adjust fast, grow to scale,’” Budden says, “and that’s the approach I’ve tried to instill in my team.”

“My philosophy on innovation has always been ‘think big, start small, adjust fast, grow to scale’ and that’s the approach I’ve tried to instill in my team.”

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**Life away from work**

When not at her job, Budden likes to spend as much time with family and friends as possible. An empty nester at home with her husband Doug, with their children Megan and Mitchell off working on their own education and careers, the couple likes to golf, hike, and enjoy all types of outdoor activity.

“One of the things that I really enjoy is mentoring. I personally benefitted from having a couple of wonderful mentors over the course of my career, so I try and work with young women each year—offering advice and support, hoping to provide them with some guidance to help them along in their careers,” she says. “One of the pieces of advice that I share from my own experience is that sometimes you have to be bold and take a chance.”

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.
The drug approval process is infamous for its complexity and the length of time to develop. But as complicated as standard drugs are to develop, biologics—such as vaccines—are more complicated. On average, vaccines take about 10 to 15 years to develop, compared to the average six to seven years for a standard drug. In addition to the longer development period, vaccines also have a lower success rate—Fewer than 10% of vaccine candidates ever reach the market, compared to about a 12% success rate for drug candidates overall.

That long lead time and high failure rate means that a large number of needed vaccines are still missing from healthcare’s armamentarium.

One study from the Duke Global Health Institute’s Center for Policy Impact in Global Health forecasts a bleak future for vaccines. Analyzing over 500 vaccine candidates for 35 neglected diseases in the pipeline, the study found the chances of efficacious vaccines gaining approval over the next five years is “unlikely.” The study concluded that there is a significant gap in funding.

However, not all of the pipeline news is as bleak. From improved flu vaccines to the first C. diff (Clostridioides difficile)—what was until recently called Clostridium difficile) vaccines, there are many exciting recent and upcoming developments in vaccines.

**C. diff**

C. diff infects close to half a million Americans every year, according to the CDC. A large reason for the spread of C. diff is inappropriate antibiotic prescribing. According to the CDC, about 30% of antibiotic prescriptions are unnecessary—and while measures have been made to reduce overprescribing, C. diff still directly leads to around 15,000 deaths annually. The CDC concludes that C. diff is still a “major health threat.”

Beyond reducing overuse, part of the fight against those infections are vaccines in the pipeline. The C. diff vaccine pipeline took a hit when Sanofi ended trials of its promising C. difficile vaccine in late 2017. However, there are still two good candidates in the pipeline.

The current frontrunner is Pfizer’s PF-06425090. After favorable phase 2 trials, Pfizer is hopeful that phase 3 trials, set to conclude late next year, will allow the vaccine to be the first C. diff drug to grant long-term protection.

VLA84, from Valneva, is another candidate that ran into money problems. While the company says its vaccine is ready for phase 3 trials, it has put those trials on hold due to lack of a partner to help shoulder the cost of trials. Valneva says that they will only continue trials if there is another vaccine approved and it can perform a head-to-head trial against it. That gamble could pay off though—Valneva says the market potential for prophylactic C. diff products could exceed $1 billion annually.

**Influenza**

Every year, according to an article published last year in *Vaccine*, influenza results in $32 billion in direct costs, along with $8 billion in indirect costs. The last flu season resulted in 959,000 hospitalizations and 79,400 deaths, according to the CDC.

Despite this, flu vaccination rates remain low—the CDC estimates that only 37.1% of eligible adults received a flu vaccine over the 2017-2018 flu season. While initial reports those numbers may be slightly higher over this most recent flu season (full data won’t be available until September this year), those numbers are much lower than the CDC would like.

While the general population gives a wide variety of reasons for not getting a vaccine—including unfounded fears of getting flu from the vaccine or not having access—many people (particularly younger people) cite the fact that the flu vaccine doesn’t work. This notion isn’t without weight: The 2017-2018 flu vaccines had such a low efficacy rate (36%) that former FDA Commissioner Scott Gottlieb, MD, made multiple announcements on why the vaccine was not effective and what the FDA was doing to increase that effectiveness.

But recently approved and as-yet-unapproved products could...
make that dream of a more effective vaccine a reality.

Flucelvax, from Seqirus, is the only cell culture-based flu vaccine available in the United States, first approved in 2016. This formulation, based on preliminary studies, appears to perform much more favorably than traditional egg-based flu vaccines.

What’s most exciting about cell culture-based vaccines though, according to the FDA, is their ability to be quickly manufactured—making them an ideal candidate for dealing with possible pandemics.

Another exciting prospect in the pipeline also relies on something other than an egg base. Medicago’s VLP quadrivalent plant-based flu vaccine, currently in phase 3 efficacy trials in seven countries including the United States, could present another option for faster-produced, more effective vaccines.

Medicago says that it’s plant-based process requires only five to six weeks to produce a clinical-grade vaccine, compared to the five to six months it generally takes for egg-based vaccines. This speed, the company says, could allow for it to more easily keep up with the constantly-mutating flu virus.

This is due to the fact that egg-based vaccines are susceptible to changes. Because viruses only grow in living cells, viruses for vaccines must be propagated in cells. For flu vaccines, this is often done in chicken eggs. This process

While early and preclinical trials are generally poor indicators of what will actually come to market, they still provide an interesting look at what might be possible. These are some of the interesting vaccines in very early stages.

**Heroin vaccine**

Several companies are currently developing a vaccine for heroin that would prevent users from getting high and addicted to the drug. Still in very early stages (human clinical trials have yet to begin, though researchers say they are close), the vaccine could be a much-needed solution to a serious problem—heroin led to 15,482 deaths in 2017, in part driven by the ongoing opioid epidemic.

**HIV vaccine**

An HIV vaccine has remained elusive for pharmaceutical manufacturers. Currently, the best chance of success is with the study HVTN 702, a South African phase 3 trial set to complete in 2021. That trial is using a modified version of a vaccine first tested in Thailand—that study delivered results in 2009 that showed that it prevented the virus, but the results were modest. The South African study is being cofunded by the National Institutes of Health.

**Respiratory Syncytial Virus (RSV) infection**

RSV hospitalizes over 57,000 children each year, along with 177,000 older adults. About 14,000 of those older adults die from the infection each year, according to the CDC. No vaccine exists, the current treatment is palivizumab, which can provide some protection—but requires a monthly shot and isn’t always effective.

While Novavax’s ResVax seemed promising, it recently announced that it failed its primary objective of prevention. According to Datamonitor Healthcare, Novavax has sent its drug back to phase 2 trials with a different formulation so it could launch for the 2021-2022 season. Two other drugs, Johnson & Johnson’s Ad26.RSV.preF and Bavarian Nordic’s MVA-BN RSV could both launch in the coming years for use in the elderly population.
can lead to egg-adapted changes in viruses, which create viruses that are different than those found in the wild. While some research suggests that these egg-adapted changes are not always responsible for poor-performing flu vaccines, it may be a factor that if eliminated could result in much more effective vaccines.

Another pipeline candidate is Seqirus’ Fluad QIV, an upgraded, quadrivalent formulation of its already-approved trivalent Fluad. If approved, Fluad QIV would be the first adjuvanted quadrivalent flu vaccine. According to Datamonitor Healthcare, it performs better than other traditional inactivated flu vaccines, meaning that in its expected launch for the 2020-2021 flu season it could capture a large part of the elderly population.

While perhaps more tenuous, new so-called universal flu vaccines are designed to cover all strains for several seasons. They could help increase protection over multiple years and avoid problems with shifting virus strains—if they receive approval and demonstrate those claims. Datamonitor Healthcare says that if approved, these vaccines could hold great promise, as they could boost confidence in vaccination and increase coverage rates.

One of the best candidates, BiondVax’s M-001 is currently only in phase 2 in the United States. However, it has been a part of multiple successful Phase 2 studies in Europe and Israel, and is currently in Phase 3 in Europe. FLU-v from IVIVO is another phase 2 universal vaccine candidate, and it too is set to begin phase 3 trials in Europe.

One potential problem for universal vaccines, according to Datamonitor Healthcare, is that payers are looking for low-cost vaccines—indicating that these could be priced higher than traditional vaccines.

**Pneumococcal disease**

According to the CDC, around 900,000 Americans get pneumococcal pneumonia (the most common form of pneumococcal disease in adults) every year—resulting in over 400,000 hospitalizations. While vaccines exist, the CDC says that about 80% of adults with conditions that put them at increased risk and 40% of adult aged 65 or older are unvaccinated.

Currently, the best-selling vaccine is Pfizer’s Prevnar 13, with about $3.5 billion in U.S. sales forecasted for 2019. The pneumococcal vaccine is the 2010 update to the previously-approved Prevnar 7. First approved in 2000, Prevnar 7 was the first pneumococcal conjugate vaccine. The update added an additional five serotypes to the original, due to the possibility of shifting strains of the disease (known as serotype drift). The CDC recommended in 2014 that all adults over the age of 65 receive Prevnar 13, leading to its massive spike in sales.

However, other pneumococcal vaccines with additional serotypes could threaten Pfizer’s market dominance.

Merck currently has a 15-serotype vaccine—V114—in phase 3 trials. According to Datamonitor Healthcare, it could replace Prevnar 13 on its expected approval in 2022—if it proves superior to Pfizer’s drug and if serotype drift occurs. GlaxoSmithKline also has a drug in phase 2 trials that, while only a 10-serotype version, is formulated in such a way that it could provide more coverage than Prevnar 13.

One of the biggest threats to Prevnar 13 could be an upgrade to Prevnar—Pfizer is currently working on a 20-serotype vaccine. That vaccine just began its Phase 3 trials earlier this year, so it likely won’t see a release for years.

**Meningococcal disease**

Current meningococcal vaccine schedules can be confusing for patients and physicians alike. All preteens and teens should receive the meningococcal conjugate vaccine, with a booster given at 16, while only some are recommended the serogroup B meningococcal vaccine. That schedule can be affected by a host of other risk factors, potentially adding to the confusion.

GSK’s MenABCW-135Y is trying to clear up that confusion. According to Datamonitor Healthcare, it could achieve this due to its broad serotype coverage—it would be the first vaccine cover serotypes A, B, C, W, and Y, which could allow it to cover a wide range of patient populations. It would then replace GSK’s current Bexsero and Menveo vaccines. This would have the added benefit of reducing the number of physician visits required for vaccination. If approved, it is expected on the market in late 2021.

Another possible ripple in the meningococcal market is Sanofi’s MenQuad TT, a likely replacement to the well-established Menactra. According to Datamonitor Healthcare, it could then charge a premium price if it shows superior immunogenicity to Menactra and Menveo.

However, that premium price may be short lived. While its expected launch date is a full year ahead of MenABCW-135Y (Q1 2020), GSK’s vaccine is likely to overtake it. This would give the vaccine a short window of use.

Nicholas Hamm is an editor with Managed Healthcare Executive.
The Forces Driving Specialty Drug Spending

by TRACEY WALKER

Healthcare executives should continue to monitor specialty medical pharmacy claim information and trends, according to Eric McKinley, PharmD, director, specialty clinical solutions at Magellan Rx Management.

“The five-year trend for specialty drugs on the medical benefit is 68% and 22% respectively for commercial and Medicare lines of business, yet visibility into this spend generally has been limited for a variety of reasons, including complex benefits, numerous places of service, varied payment models, bundled claims, and complicated data,” said McKinley in his presentation, "Strategies for Staying Ahead of Specialty Drug Trends: Focus on the Medical Pharmacy Benefit" at the Academy of Managed Care & Specialty Pharmacy Annual Meeting 2019 in San Diego.

“This fast increase, as well as the payer concerns, emphasizes the importance of developing strategies to stay ahead of the trend and pipeline,” he said.

Spend for drugs on the medical benefit has been identified as allowed amounts of $29.97 per-member-per-month (PMPM) for commercial members and Medicare PMPM allowed amounts of $52.19 which has increased 18% and 12%, respectively over the last year; driven by inflation, utilization, drug mix, and shifts in site of service, according to McKinley.

In 2018, the FDA approved 25 specialty medications that would be billed under the medical benefit, according to McKinley. “This, along with the increase of independent physicians moving into employment under health systems, has led to more patients having their medical pharmacy medications billed under the hospital outpatient setting, which is a more expensive setting than alternatives such as independent provider offices or home infusion,” he said.

“All five medications have an approved FDA biosimilar,” McKinley said. “Hopefully, in the next few months, all of the biosimilars will be available on the market.”

McKinley’s presentation was presented in two sections. The first section of the presentation covered the medical pharmacy trend data from the recent "Medical Pharmacy Trend Report," from Magellan Rx Management.

“The last 12 months saw significant changes to many provider-administered specialty medications,” he said. “Novel oncology therapies and immunotherapies continue to drive the highest increases in medical specialty drug spend. Along with the high increases in medical pharmacy trends, we saw that costs for the same specialty medical pharmacy medications varied greatly by the site of where the medication was administered. Specialty medical pharmacy claims administered through the hospital outpatient site of service were consistently two times higher than claims for the same medication.

Continued on page 28
The Promises and Challenges of Gene Therapy

Gene therapy offers great hope for patients, but comes with a bevy of challenges for patients and payers alike  

by NICHOLAS HAMM

Gene therapies—infamous for their high prices, as well as their great potential for patients—are slowly becoming a larger part of the healthcare landscape.

As more of these therapies come to market, payers have been searching for a way to deal with the high up-front costs. Compared with traditional medicines, gene therapies largely frontload their costs—rather than a series of payments over the course of months or years, many gene therapies require fewer doses overall, or are a one-time treatment.

““For gene therapies to be sustainable, the healthcare system needs to adapt the reimbursement and valuation of these products.””

—KELLIE RADEMACHER PHARMD, PRECISION FOR VALUE

At the Academy of Managed Care & Specialty Pharmacy Annual Meeting 2019, Kellie Rademacher PharmD, vice president, access experience team for Precision for Value, outlined some of the pros and cons of gene therapy in her talk, “Managing Access for Gene Therapy: Learnings from an International Perspective.”

Overall, Rademacher said, gene therapies have been accessible to patients, but payers are still adapting and attempting to find the best models.

“There is a significant need in the United States to develop payment models that support potentially curable therapies that come with substantial price tags,” she said. “For gene therapies to be sustainable, the healthcare system needs to adapt the reimbursement and valuation of these products.”

As more of these high-cost therapies enter the market, Rademacher explained, it will be up to managed care organizations to evaluate them, decide on their place in a formulary, consider access problems, and also to provide reimbursement.

“With only a couple of agents on the market, established techniques in managed care have been sufficient: however, as multiple gene therapies enter the market and competition within a category increases, managed care needs a more dynamic way to provide access, manage affordability, and support the sustainability of new therapies,” said Rademacher.

But how can organizations meet those challenges? The answer, according to Rademacher, is not a one-size-fits-all solution. Rather, it is “more likely that managed care organizations will need to be nimble enough to have multiple modalities for payment based on the archetype of the population (e.g., orphan diseases without other options, orphan diseases with a current standard of care, populations with larger incidence and prevalence).”

Overall, Rademacher said, scientific innovation is moving faster than the healthcare system, and it’s time for healthcare to “adapt and catch up” with what is an undeniably “innovative scientific advancement with large-scale applications.”

“Both the government and private sector will need to collaborate across stakeholders to face these challenges,” concluded Radmacher. “As the market shifts, adaptation and reimbursement innovation needs to be rapid and fluid.”

Nicholas Hamm is an editor with Managed Healthcare Executive.

Continued from page 27

through the physician or home administration setting”

The second section of the presentation was in collaboration with Carly Rodriguez, PharmD, pharmacy director, clinical innovation at Moda Health, who presented Moda Health’s approach to management strategies for specialty medications processed through the medical pharmacy benefit. The health plan implemented a mandatory site of service program in 2017, with an average successful shift rate of 86%.

“The health plan was able to obtain significant savings from the program over a 12-month period,” Rodriguez said. “This savings was achieved even with the health plan being able to treat 30% more patients on these medications. The average allowed drug cost per patient decreased from $19,985 (pre-implementation) to $13,346 in the last quarter of the program review period.”

Tracey Walker is content manager for Managed Healthcare Executive.
Whether healthcare executives like it or not, rebates as currently administered may soon be a thing of the past.

This is according to Ross Margulies, JD, MPH, an attorney at the law firm Foley Hoag LLP, in his presentation “The Current Status of Safe Harbor Protection for Rebates: Is the End Near?” at the Academy of Managed Care & Specialty Pharmacy Annual Meeting 2019 in San Diego.

“The current practice of retrospective rebating—in which manufacturers, plans, and PBMs negotiate discounts in exchange for formulary placement, market share, and volume commitments—is widespread and the predominant method by which payers negotiate discounts off of the list price of a drug,” said Margulies.

“This trend is only increasing. In recent years, rebates as a percentage of total gross drug spending have increased. On the one hand, rebates are largely credited with keeping net drug prices relatively stable. On the other hand, the Trump administration has identified the current rebating system as potentially problematic due to the impacts of rebates on manufacturer prices and beneficiary cost sharing.

In February, the HHS’ Office of Inspector General (HHS-OIG) issued a Proposed Rule that, if adopted, would upend the current rebate system as potentially problematic due to the federal Anti-Kickback Statute (AKS). The federal AKS makes it a crime to pay or receive anything of value as an incentive or an inducement to use a healthcare service that is reimbursable by a federal healthcare program, according to Margulies.

“However, if HHS-OIG finalizes its rule as proposed, it would eliminate this protection and subject these arrangements to significant legal risk,” Margulies said. “A rebate paid to encourage a Part D plan or a Medicaid managed care plan to favor a particular drug would be, on its face, a violation of the AKS—with evidence of the requisite intent. However, a regulatory ‘safe harbor’—called the ‘discount safe harbor’—currently protects most rebating arrangements. It is this safe harbor the HHS-OIG proposed to amend.”

A significant cause
“According to HHS-OIG, the current rebate system is a significant cause of high drug prices,” said Margulies. “The major focus of the Proposed Rule is disrupting the existing manufacturer rebate system under which drug manufacturers negotiate rebates with plan sponsors—and their contracted PBMs—in exchange for formulary placement, development of a pharmacy network, and favorable coverage policies. The Proposed Rule, if adopted, would result in an elimination or restriction of rebates in favor of upfront discounts or fixed prices for brand drugs.”

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“The time is now to begin thinking about how to address the significant challenges that will flow from a world without rebates—including what future manufacturer negotiations look like.”

—ROSS MARGULIES, JD, MPH, FOLEY HOAG LLP

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Are Drug Rebates Going Away?

A new HHS proposal could do away with—or at least forever change—PBM drug rebates by TRACEY WALKER

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Tracey Walker is content manager for Managed Healthcare Executive.
Cut Through the Cloud Clutter

How to vet cloud computing vendors  by RACHAEL ZIMLICH, RN, BSN

Today’s healthcare consumers want a seamless digital experience, one that allows them to be an active participant in their healthcare. The problem is keeping up with the rapid changes that technology offers and making sure the capabilities you are offering to customers aren’t obsolete before they are up and running.

The question is, how do you stay ahead of the game? While it’s nearly impossible to predict what new technologies are coming up, cloud technology offers a flexible and agile solution. The key is knowing what your customers want and what kind of model your organization will be comfortable with.

A recent report from the Harvard Business Review Analytic Services shows that 53% of healthcare businesses take many months to a year to integrate technology changes into their existing systems. That’s because 62% of them report using between two and 10 different customer-facing software systems. Roughly one-quarter of healthcare leaders responding to the Harvard Business Review Analytic Services survey weren’t even sure how many software systems they utilized.

For these reasons and many more, healthcare companies are looking to simplify their digital solutions and create a better experience for consumers, and one that can change more swiftly with the rapidly-changing technology landscape.

The report goes on to note that 58% of companies in the survey planned to consolidate technology platforms for simplicity, 49% were looking to improve agility, and 43% were looking to migrate to cloud-based applications to achieve these goals.

With so many cloud-based services to choose from, the question then becomes, how does one choose the right fit and stay ahead of the game?

What is cloud technology and why do I need it?

Cloud technology is used in many customer-facing systems across industries and is a way for a company or service provider to interface with consumers using web-based tools and applications, rather than through an in-house server. Building and maintaining in-house technology can be expensive and time-consuming—not to mention the fact that it can quickly become obsolete.

Kevin Riley, senior vice president and general manager at Vlocity, a developer of industry-specific cloud and mobile software in San Francisco, says cloud technology is the key to digital transformation.

“You’re going to have to adopt a technology, and that technology should be cloud,” Riley says. “Regardless of what problem you’re solving for, if you’re not buying cloud technology, you’re buying an expensive problem.”

Cloud technology takes away the burden of maintaining an in-house system by letting someone else with probably more expertise build and host the system not to mention deal with security.

Digital transformation is being driven by several factors, Riley explains, and all of these set the stage for the healthcare industry to adopt cloud technology. The first is customer experience. Bad customer experiences have put the health insurance industry in particular at the bottom of the customer experience scale, Riley says. That doesn’t mean, however, that the healthcare industry should rush into creating a lot of technical debt to improve their customer service experience.

“Modern day vendors already have customer experience people on staff,” Riley says. “Work with vendors that are telling you they can change your customer experience.”

The second driver of digital transformation is product innovation. It’s important to be able to stand out in the products you offer, and to have the technology to bring those new products to market quickly, Riley says. Top startups use lean technology to bring new products to market and test distribution channels without high overhead costs, Riley says. Utilize vendors who have these systems in place rather than recreating the wheel.
Another key to digital transformation is making sure that you are using a vendor who offers straightforward automation or processing, Riley says.

“Can the vendor help prevent partner fatigue? Is the process tedious or attractive? Is it end-to-end and does it look unified?” are key questions to ask when reviewing a vendor’s process, Riley says.

Finally, companies should seek out cloud vendors that provide application consolidation, Riley says. Some health plans have hundreds of apps to manage, and a good cloud vendor will be able to help with that.

**Identify your organization’s needs**

Each cloud vendor offers similar services, yet each have their niche as well. Some might have stronger customer service elements, while others might excel in healthcare-specific services.

Riley says it’s important when seeking out a cloud vendor to find one that has customers with similar service lines to yours. The ideal vendor will have worked with other companies within your industry and be well-established and well-funded enough that you can be sure they will stay in business and aren’t a fly-by-night startup.

It’s also important to find out how willing and able that vendor is to create new products and services to meet your unique needs. For this reason, Riley says leaders should always question accessibility when choosing a cloud vendor.

“How much access do you have to the people that think about and create the product, and can you drive product design?” Riley says. “People are building software now using agile technologies. The software never stops being developed. The only way to judge that is to see whether you have access to influence the people who control what gets built.”

**Know what you want and what is being offered**

Graham Hughes, MD, chief executive of Sutherland Healthcare, an international process transformation company, says there is a lot of confusion around cloud-based services in the healthcare industry. The first step to knowing what you need is to really understand first what you want to achieve, and second what level of service is offered by a vendor. Hughes says he often shares with his customers an analogy about pizza.

“If you want pizza, you’ve got choices. You can make it from scratch with flexibility and control, but not with scale. You have to pick a kind and stick with it,” Hughes explains. “That model is like an on-premise model where you have everything in-house to manage technology and infrastructure.”

The next option, Hughes says, is to buy your pizza from a store. “Frozen pizza has everything you need, but you still have to cook it,” he says. “That is more like infrastructure as a service. It’s the most basic way, where you just use technology for storage and computing.”

The next service level is delivery pizza. With that model, someone else does all the work and delivers it to you, but you still have to arrange for cleanup. That is more like a platform-based service, he explains, where you use a vendor’s infrastructure to do more than the basic functions.

Finally, there is going to a restaurant for pizza. “You have your choice and it’s full service,” Hughes says.

The key is knowing how much you need, how much control of flexibility you want, and how involved you want to be.

“There’s so many different flavors of cloud that you can adopt, and we encourage customers we work with to think through what they are trying to do and which of these models they want.”

**Vetting vendors is key**

Ken Cahill, chief executive officer of SilverCloud Health, a global health technology company, says regardless of the vendor you choose, it’s important that they be vetted, and that you take care in how you are selecting that vendor.

“There’s something to be learned from the old adage, “You can’t be fired for buying IBM,” Cahill says. “The fundamentals of business have and haven’t changed.”

Whatever vendor you choose, you must be conscious about who is leading that organization, how it is being led, what colleagues are saying about that vendor’s services, and make sure that the product will hold the same level of regard as whatever it is replacing, Cahill says.

“We’ve seen a number of vendors who can come into a marketplace and look slick and shiny, but we have to see what’s behind that,” Cahill says. Ask for case studies and testimonials, he suggests.

Some newer vendors might not be able to compete with the sheer scale that vendors like Google or Microsoft have, but maybe they have had contracts with larger healthcare systems or government entities, he adds. Then again, those
bigger vendors have proven track records when it comes to things like security. It can be tempting to jump into transitioning to cloud services, and to jump into the next big thing. But Cahill warns that first or fastest isn’t always best. “The caution I would raise is to move at pace, but make sure you’re doing the right things in terms of due diligence and vetting,” Cahill says, adding you have to be able to show your board the steps and processes you went through in making your vendor selection. “Fast has to be at pace, but it can’t be at a reckless one.”

Technology is getting too complex to have all the talent needs in-house, whether it’s infrastructure services, cloud service, platform, or software.”

— GRAHAM HUGHES, MD, SUTHERLAND HEALTHCARE

Don’t rush, make a plan
There are so many options when it comes to cloud vendors and services. This is a good thing—and it’s not. “You have to plan it, understand what you are trying to accomplish, and what roles you need, and that culminates in a three-year transformation blueprint,” Hughes says of the way cloud transitions work through Sutherland.

Anticipate surprises and be prepared to have lots of questions about your organization’s needs, he says. “No one should start knowing the journey they are on,” Hughes says. “Think, what do I need the cloud to do for me? Understand the customers’ needs, what the clinicians need, and design it. Think about the end-to-end journey and what it means to users.”

Leadership may also want to review what other applications they are using in the planning phase of a cloud transition, and plan for restructuring in a measured pace. “The big bang approach is typically not a great recipe for success,” he says. The move to cloud services and any related restructuring should be done in phases, with considerations about what to do with data and how to phase out old tech, Hughes says.

Keep in mind, Hughes says, that cloud isn’t necessarily the cheapest option—depending on which options you choose, cloud could be costly. “It will probably give you the best total cost of ownership over a three- to five-year period as capabilities evolve,” Hughes says. “The thing that you get with cloud services is instead of every individual hospital trying to keep up with and maintain the latest technologies and security measures, you can just push all of that to people who are managing it for tens of thousands of other organizations.”

Consider a hybrid
The nice thing about cloud, Hughes adds, is that there is a fit for every need. From basic storage to computing, you pay for how much you use—and that might mean using more than one vendor.

Cloud vendors are also working to distinguish themselves from one another, developing specific capabilities tailored to healthcare. Each vendor may have their own specialty, such as algorithms for managing diabetes patients, and many healthcare companies may look to hybrid models to best meet their needs, Hughes says.

“The whole world is likely to evolve over the next five to 10 years in a hybrid cloud model,” Hughes says. “That’s where the idea of plan it and design it comes in, so you can keep your flexibility.”

Using multiple vendors allows an organization to keep their options open with the ability to be more flexible, Hughes says. Larger organizations may be able to manage using multiple vendors in a hybrid model, where smaller organizations may want to pick one vendor with the best fit and stick with them.

“You’ve really got to think about the size of your organization and the skillset you’ve got,” Hughes says. “Technology is getting too complex to have all the talent needs in-house, whether it’s infrastructure services, cloud service, platform, or software.”

“Organizations just absolutely are going to have to leverage more and more of these services or they won’t be able to keep up with the rate of change. Our customers are looking for someone to make it easy.”

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Comparing senior health factors: 2017 vs 2002

- Excessive drinking: 42%
- Obesity: 36%
- Diabetes: 36%
- Death: 16%
- Reporting very good or excellent health: 11%

Source: United Health Foundation

Most Common Prescription Drugs Used by Age Group: 2015-2016

- 0-11: bronchodilators
- 12-19: nervous system stimulants
- 20-59: antidepressants
- >60: lipid-lowering drugs

Source: CDC

$4.6 billion: The annual cost of physician burnout

Source: Annals of Internal Medicine

Specialty Medication Troubles

- 40% of providers say it takes 1 to 2 weeks to get patients on specialty meds
- 3 hours: The amount of time providers spend weekly on paperwork for specialty meds
- 67% of providers change or reroute order when encountering prescribing barriers
- <33% of providers are extremely or very satisfied with their organization’s specialty med efficiency

Source: Surescripts

2017 Drug Spending in the U.S.

- 14% of drug spending out-of-pocket
- $4.9 billion for Humira for large employers
- $4.4 billion for Harvoni for Part D

Source: KFF

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