6 CHALLENGES Facing Execs in 2020

Oncology
Adapting to new models

Drug Pipeline
Top picks for 2020

Pharmacy/Formulary
Pharmacogenetic testing benefits

Population Health
Top SDoH programs

Technology
Personalizing approaches
WHAT IS HPV?

Human papillomavirus, or HPV, is a virus with potentially serious consequences that can affect both males and females.¹

For most people, HPV clears on its own. But, for those who don’t clear the virus, it could cause certain cancers and diseases.¹ There is no way to know which patients who have HPV will develop cancer or other health problems.²

About 50% of all HPV-related cervical cancers are estimated to be attributable to HPV infections acquired after the age of ~20³,a

There are about 14 MILLION new HPV infections each year in the United States¹

Only 17.5% of girls and women were exposed to 2 or more types of HPV⁴,b

¹In the absence of primary (ie, HPV vaccination) or secondary (ie, screening) prevention.
²Based on an estimated modeling of NHANES data from 2005-2006, among women ages 14-59 (n=2603), before the introduction of HPV vaccination. Data among HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
NHANES=National Health and Nutrition Examination Survey.

HPV CAN LEAD TO CERTAIN HPV-RELATED CANCERS IN MALES AND FEMALES¹

PREVENTION STARTS WITH EDUCATION, INCLUDING CDC-RECOMMENDED VACCINATION

• Both the American Cancer Society (ACS) and the Centers for Disease Control and Prevention (CDC) recommend routine HPV vaccination at 11 or 12 years of age.⁵,⁶
• Catch-up HPV vaccination is recommended for appropriate persons through age 26 years who are not adequately vaccinated.⁶

EDUCATE YOUR ELIGIBLE HEALTH PLAN MEMBERS TO SPEAK TO THEIR DOCTOR ABOUT HPV.

Understanding and knowing the critical issues facing the industry in 2020 will help you plan, prepare, and strategize. Managed Healthcare Executive®’s cover story (page 6) will help identify the challenges ahead and steps to take to help you cope with another year of uncertainty in the healthcare marketplace.

- Focus your efforts where needed. The ACA likely will remain—but there are other regulatory changes on the horizon. Be prepared.
- Be ready for transparency laws and hire experts to help you explain costs to your patients/members.
- Keep focused on value-based care, it will remain a key foundation for quality measurement and reimbursement.
- Don’t wait for legislative changes or new CMS edicts. Look into the issues affecting your population and proactively develop the programs that target their needs.

The cover also reveals:
- How to use big data and gain meaningful insights that make the data actionable and contextual.
- How to implement cybersecurity measures.
- How to continue efforts to be a part of the solution of the rising cost of healthcare.

In addition, other great content in this issue will help you map out 2020. You’ll learn about the most valuable drugs in the pipeline for 2020; how to define success; pharmacogenetic testing; using data analytics to improve hospital care; and the changes impacting a variety of therapeutic areas.

Mike Hennessy, Sr.
Chairman and Founder of MJH Life Sciences
Top 6 Challenges Healthcare Executives Will Face in 2020

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Managed Healthcare Executive is published monthly by MultiMedia Healthcare LLC, 230 W Superior ST, STE 400, Duluth MN 55802. Subscription rates: 1 year $99.00, 2 years $145.00 in the United States & Possessions; 1 year $122.00, 2 years $173.25 in Canada and Mexico; 1 year $192.00, 2 years $295.00 in all other countries. For air-expedited service, include an additional $87.00 per order annually. Single copies (prepaid only) $9.00 in the United States, $22.00 all other countries. Back issues, if available, $35.00 in the U.S., $70.00 all other countries. Include $15.00 per order plus $3 per additional copy for U.S. postage and handling. If shipping outside the U.S., include an additional $50 per order plus $15 per additional copy. Periodical postage paid at Duluth MN 55802 and additional mailing offices. POSTMASTER: Please send address changes to Managed Healthcare Executive®, PO Box 457, Cranbury, NJ 08512-0457. Canadian GST number: R-124213133RT001.

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

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As providers of medicine, our primary focus is—and always should be—the care and comfort of our patients. But it can’t be our only focus. From affordability issues to the caregiver burnout epidemic, many of the challenges that face our industry in 2020 and beyond will require us to rethink the way we engage with our various stakeholders, taking a more holistic view of the entire healthcare system. These include:

**IMPROVING THE WORKPLACE ENVIRONMENT**

Of course, we want to create the best possible experience for our patients and customers. But to do that, we also have to create healthier workplaces for our employees, particularly on the provider side.

Medicine is a demanding field, and some clinical settings are inherently more stressful than others. We continuously ask a lot of our employees.

Which is why we need to have their backs, particularly when it comes to creating a culture of wellness. There’s a growing body of evidence suggesting a direct correlation between employee engagement and well-being, patient experience, and quality of care. Improving the overall workplace culture often improves patient outcomes.

In other words, it’s all interrelated—and if our employees aren’t at their best, our patients can’t be, either.

There are a lot of complex pieces to this puzzle.

It means doing more to secure the safety of our caregivers, protecting nurses and aides from the violence that occasionally visits the emergen-

**CONTROLLING COSTS AND DELIVERING VALUE**

These are separate concepts, but from the perspective of the patient and the consumer, they go hand-in-hand.

Why? Because patients, while they may not understand the full complexity of our industry, understand at a basic level that healthcare simply costs too much. According to CMS, nearly one in five dollars in this country is spent on healthcare services or prescription medicine. And as high-deductible health plans continue to surge—about half of the pre-Medicare commercial market now has a high-deductible health plan—our patients are exposed to more and more out-of-pocket costs.

Bending the cost curve will require more preventive medicine, reducing overutilized testing and procedures, and delivering lower-acuity care in less-expensive settings.

It also requires a greater commitment to value-based care. As an industry, we’ve been predicting this shift for a while, but it’s happening slowly. At some point, we’ll have to jump in feet first.

**INVESTING IN THE FUTURE OF HEALTHCARE**

On one hand, our national goal is to provide better care for lower cost. On the other hand, in order to achieve that goal, we know that we have to invest in the future—artificial intelligence, robotics, virtual health systems, and more modern care facilities. Over the coming decade, medicine will be virtualized and access will be democratized. All of this will come at a cost.

How do we bear the cost together, while minimizing financial impact to our customers? It will require increasing collaboration—and in some cases, full-scale integration—between payers, providers, and ancillary stakeholders.

Traditional boundaries between payer and provider, between pharmacy and supplier, have been blurring for years, and for good reason: Without clear sightlines among stakeholders, it’s hard for providers and insurers to align on the future state of healthcare.

Integration promotes that alignment and understanding. It also provides a shared platform to address current and future cost burdens, to streamline patient billing, to create value from big data, and to simplify the overall navigation of the healthcare industry for our patients.

Vertical integration won’t solve all of the industry challenges, but it can allow a more unified approach toward advancing the goals of improved health, greater affordability, and better experiences for employees and patients.

Cynthia Hundorfean is president and CEO of Allegheny Health Network (AHN), an integrated healthcare delivery system that serves Western Pennsylvania. AHN is part of the Highmark Health family of companies.
Drugs In The Pipeline

The Most Valuable Pipeline Drugs For 2020

The top drugs expected to be approved this year and their financial impact

by JENNIFER GERSHMAN, PHARMD, CPH

According to the FDA, 38 drugs have been approved in 2019 as of November 15, 2019, bringing more treatment options to the market for patients. Vizient, a healthcare performance improvement company, released its 2019 Drug Price Forecast for health systems, with an expected 4.57% increase for pharmaceutical purchases made from January 1, 2020 to December 31, 2020.

Here are pipeline drugs expected to be approved in 2020 and their financial impact.

Pipeline drugs for 2020
It can sometimes be difficult to predict which medications will be approved, as there can be drug safety issues that the FDA needs more clarification on and further studies may be warranted, says Erin Fox, PharmD, BCPS, FASHP, senior director, Drug Information and Support Services, University of Utah Health, Salt Lake City. Fox provides budget forecasting in her clinical practice setting and discussed that the budget is generally set after drugs receive FDA approval.

The FDA approved Eli Lilly’s Reyvow (lasmiditan) for acute treatment of migraine with or without aura, and it is expected to be available in January 2020.

Adakveo (crizanlizumab-tmca) received FDA approval November 15, 2019, which is two months ahead of schedule. Adakveo is manufactured by Novartis and is the first targeted therapy to treat patients with sickle cell pain. Alder Biopharmaceuticals submitted the Biologics License Application for eptinezumab for migraine prevention, and the expected approval date is February 21, 2020.

Seattle Genetics and Astellas received accelerated approval December 18, 2019, for Padcev (enfortumab vedotin-ejfv) for advanced or metastatic bladder cancer.

Merck received FDA approval December 19, 2019 for Ervebo, the first FDA approved vaccine for the prevention of Ebola virus disease. Biohaven Pharmaceuticals is studying rimegepant for acute treatment and prevention of migraine. Rimegepant is a CGRP receptor antagonist with a long half-life and good oral bioavailability, and the New Drug Application (NDA) has been submitted to the FDA with an expected approval of early 2020. Data presented at the International Headache Conference demonstrated that rimegepant decreased disability by about 41% and reduced lost productivity time by approximately 50% over a one-year treatment period. Alnylam’s Givlaari (givosiran) was approved November 20, 2019, earlier than the expected date of February 4, 2020, for the treatment of acute hepatic porphyria, a rare genetic disease that can resemble other conditions and affect quality of life. Givlaari is the first drug approved for this rare disease, and it comes with a high wholesale price of $575,000. Alnylam plans to offer patient assistance and work with insurance companies to help provide coverage. Epizyme’s tazemetostat was granted priority review for patients with epithelioid sarcoma who cannot receive curative surgery, and approval is expected January 2020. Intercept has submitted an NDA for obeticholic acid for patients with fibrosis due to non-alcoholic steatohepatitis (NASH), a type of liver disease. Approval is expected in 2020 based on positive results from the REGENERATE phase 3 study showing obeticholic acid improved liver fibrosis without worsening NASH at 18 months.

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Managed Healthcare Executive.com
As a new decade begins, healthcare executives will continue to grapple with challenges of the past as well as new issues that emerge. We asked healthcare leaders to cite their top challenges, as well as coping strategies. It was no surprise, particularly with 2020 being a presidential election year, that dealing with an ever-changing landscape of government regulations topped the list. Here’s a closer look at what they said.
**CHALLENGE 1: COMPLYING WITH NEW GOVERNMENT REQUIREMENTS AND MANDATES**

Efforts to repeal the ACA seem unlikely in the near term. “Nonetheless, healthcare executives always need to proactively stay on top of regulatory developments so they can position their organizations for the opportunities and challenges that may emerge as a result of changes,” says Kim Bell, senior vice president of health services, NFP, an insurance broker and consulting firm in Austin, Texas.

New mandates, both at the state and federal level, add a layer of complexity to running a business. Healthcare remains one of the most highly regulated industries, since approximately half of all of the industry’s spending comes from government sources (e.g., Medicare, Medicaid, Veterans Affairs, and government employee benefits), says Ashraf Shehata, MBA, MHA, national sector leader for healthcare and life sciences, KPMG LLP, an audit, tax, and advisory firm. “They update their rules with great regularity, so it’s important for healthcare organizations to stay current with the latest regulatory developments,” he says.

In particular, CMS’ push toward price transparency has resulted in many questions from payers and providers. “In 2020, we will see the price transparency mandate continue to play out and likely encounter more uncertainties,” says Tara Bradley, chief operating officer, Vitalware, a mid-cycle revenue software-as-a-service solutions provider, in Yakima, Washington. “Specifically, hospitals have been tasked with the complicated duty of posting their chargemasters online. This process is not only difficult, but the information presented in a chargemaster is confusing and does little to further transparency or education.”

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“Instead of waiting for CMS directives, hospitals should feel empowered to initiate processes and programs to educate patients and make pricing less complicated.”

— TARA BRADLEY, VITALWARE

**CHALLENGE 2: SHIFTING TO VALUE-BASED PAYMENT MODELS**

The shift from fee-for-service reimbursement to value-based payment models will continue in 2020, including the trend for healthcare providers and third-party vendors operating in the healthcare space to assume some of the financial risk along with the health insurer. “While these relationships are appealing, there is the risk that they will be unprofitable if not structured properly,” says Layna Cook Rush, JD, shareholder, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, a law firm with offices in the Southeastern United States and Washington, D.C.

Along these lines, Matt Gagalis, head of payer market development, CarePort Health, a care coordination software company, says that...
as value-based care continues to take hold and the number of stakeholders responsible for improving patient outcomes increases, the fragmentation within the healthcare industry has become increasingly apparent. There will be a critical need for alignment and coordination across the continuum.

**Challenge 3: Using Big Data**

To gain meaningful data insights, payers must adopt technology that makes the data actionable and contextual—using it to inform clinical decision-making and improve care management, Gagalis says. Health plans should seek solutions that not only provide data from disparate sources, but that can also display data in a way that is meaningful and actionable.

For example, the recently enacted California Consumer Privacy Act requires businesses to inform consumers about the personal information they collect and how it will be used; consumers’ personal information cannot be used for any purpose that wasn’t disclosed at collection, Cook Rush says.

**Dealing with this Challenge**

“With multiple stakeholders trying to manage a patient’s care, there is immense opportunity for enhanced stakeholder interoperability to reduce disparate systems of care and align a network on one centralized platform,” Gagalis says. To share existing data, synchronize work flows and streamline processes between various stakeholders; payers, and providers should use care coordination technology that collects, analyzes, and shares information across the continuum.

Because payments in these models are contingent, at least in part, on the provider meeting certain metrics, it is imperative that those metrics are within the provider’s control, Cook Rush says. Also, it’s important from both parties’ perspectives that the metrics and data being measured are an actual assessment of improved health that will result in cost savings. “When entering into an outcome- or value-based contract, healthcare executives need to analyze historical data to ensure that the metrics are an attainable and appropriate measurement of health improvement,” she says.

Furthermore, as parties enter into these types of agreements and providers take on additional responsibilities and financial risk, it is important to assess whether the relationship will be subject to regulation under state insurance or managed care regulations, Cook Rush says.

**Challenge 4: Implementing Cybersecurity Measures**

Healthcare entities are continuing to see a rise in the number of cyberattacks. Attackers are getting smarter and more persistent. Employees are getting more comfortable working with electronic information (which sometimes makes them more relaxed and susceptible to oversights). Records maintained within the healthcare industry are valuable due to the vast amount of information contained therein, and providers typically maintain several electronic systems containing patient information (e.g., electronic medical records, billing, practice management, email), all of which are susceptible to attack, Fleming says.

**Dealing with this Challenge**

Since many recent threats to security arise from phishing scams and ransomware attacks, it is imperative that companies not only have policies and procedures in place, but that they also create a culture of "cyber hygiene."
employees must be trained on, and continually reminded of, how to detect and respond to a potential phishing email, Cook Rush says. And, sanctions for continued violators should be implemented. Given the prevalence of ransomware attacks, companies should routinely back up critical data and have an incident response plan that addresses swift access to back-up data to ensure that operations and services can continue with minimal interruption. Incident response plans should be reviewed and tested routinely.

Furthermore, entities should implement plans for stopping an attack and mitigating harm, as well as notifying those who have been affected, Fleming says. Regarding notification, providers must not only be familiar with the laws in their state but also the states in which their patients reside. This is because a number of state data privacy and security laws are attempting to impose obligations on entities located outside of the state that maintain information on residents living within the state.

**CHALLENGE 5: RISING COST OF HEALTHCARE**

According to Kaiser Family Foundation research, the annual cost of a family health insurance plan has now surpassed $20,000. Some of the primary reasons include escalating drug prices, particularly in specialty drugs; high-cost therapies coming to market; and industry consolidation, Bell says.

Employers have traditionally shifted higher costs to employees. But as costs continue to rise, employers are discovering a number of ways to mitigate the impact of rising costs, such as narrowing networks, promoting medical tourism through centers of excellence, creating reference-based pricing structures, and offering bundled pricing, direct primary care access, and expert opinions, Bell says.

**DEALING WITH THIS CHALLENGE**

Payers and providers should continue their efforts to be a part of the solution, working to partner with employer coalitions and work groups to help solve the problems that contribute to the high cost of healthcare. In addition, they should increase their focus on innovative solutions to the problem. “Consider what can be done differently to enhance efficiency and effectiveness, both in terms of improving what is working and fixing what’s not,” Bell says.

**CHALLENGE 6: RISING COST OF SPECIALTY DRUGS**

Plan sponsors recognize the value that specialty medications have in treating complex and rare diseases; the trend is up by 9.4%. But specialty drugs cost 50 times more than traditional drugs. In most cases, price increases directly affect Americans who, in some cases, can no longer afford medications they so desperately need, Bell says.

**DEALING WITH THIS CHALLENGE**

In May 2018, the Trump administration issued a strategy blueprint, “American Patients First,” designed to tackle U.S. drug pricing and healthcare costs. According to Bell, a few of the key components related to reducing drug pricing are:

- Promoting the use of biosimilars and reducing utilization barriers;
- Preventing branded drug manufacturers from gaming FDA risk management strategies and 180-day generic launch rules to forestall generic competition;
- Requiring drug rebates negotiated by pharmacy benefit managers to be passed directly to patients;
- Requiring drug companies to disclose list prices for their drugs in television ads, just as they do for side effects and other drug risks.

While many components have not yet been addressed, areas such as providing avenues to bring more generics to market have.

On October 16, 2019, HHS Secretary Alex Azar announced that in fiscal year 2019, the FDA approved a total of 1,171 generic drugs, an all-time record, following a record 971 approvals in fiscal year 2018 and a record 937 approvals in fiscal year 2017.

In addition, Azar said that legislation, such as HR-3’s Title I of The Lower Drug Cost Act of 2019, is proposing that HHS be allowed to negotiate drug prices based on international standards. “We have also seen significant moves toward bringing more transparency to consumers, through removal of gag orders on pharmacists not to mention lower cost drugs and requirements that drug ads disclose the cost of the drug being advertised,” Azar said.

Diligently monitoring and understanding these changes is critical, as is making sure they are aligned with the best industry solutions in the space, Bell says. Also consider their effect on programs such as value-based care and established clinical pathways.

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
With intense legislative pressure on drug pricing and healthcare transparency as well as broad public support for changes to the healthcare model, managed healthcare executives will need to focus on several areas in 2020 including better transparency, stable or lower healthcare costs, and reinforcing the value managed healthcare organizations provide in the healthcare market of the United States.

"Success in these measures will be defined by stakeholders including patients, providers, and employers having a better understanding and view of their healthcare costs; stable or reduced costs of healthcare that patients and employers actually feel through premiums and cost share; and improvement in the perception of health plans and PBMs by the public," says Jeremy Schafer, PharmD, senior vice president of New York-based Precision for Value, a group of consultants providing payer insights. "Achieving these objectives will be critical..."
to reduce the risk of seismic changes to healthcare after the 2020 election.”

Here are some other thoughts on what will define success in 2020.

Chris Wing, CEO of SCAN Health Plan, a not-for-profit, Medicare Advantage, health maintenance organization based in Long Beach, California, says there is no shortage of challenges and opportunities ahead.

“In 2020, I expect to see increased competition within the Medicare Advantage market,” he says. “As the population ages and more seniors seek the resources and services needed to age independently, plans must offer flexible benefits that will align with a variety of needs. Along with more entrants into the market, we believe the curve for CMS star ratings will become steeper as a result.”

He adds that the company will continue to measure success by such standard metrics as enrollment growth and operating margin.

“SCAN also measures how well we are meeting the needs of the older adults in our communities,” he says. “For example, we will continue to monitor the impact of our investments in digital technology, as well as our progress toward addressing social determinants of health.”

Pat A. Basu MD, president & CEO of Boca Raton, Florida-based Cancer Treatment Centers of America, a group of five cancer research centers, notes success is always about the patient so his measure of success includes being in the top 1% nationally in cancer survival rates, patient satisfaction, patient accessibility and affordability, and clinical trial enrollment and access for underserved patients.

“We also believe that to defeat cancer we must combine forces instead of being siloed,” Basu says. “I’d like to expand our partnerships with other providers, payers, employers, and pharma by 100%.”

Christopher Maiona, MD, CMO of Newton, Massachusetts-based PatientKeeper, Inc., develops physician healthcare information systems, says that for many of the company’s hospital clients, a key goal in 2020 is to improve physician satisfaction.

“The physician burnout problem is real, and well-managed healthcare provider organizations are extremely sensitive to the causes of it,” he says. “Cumbersome, intrusive technology—particularly EHRs—is one, which is why so many organizations are evaluating and implementing EHR optimization solutions to improve physician workflow and clinicians’ user experience. Successfully improving physician satisfaction will be measured in various ways, including higher patient satisfaction scores, improved quality of care, and reduced medical staff turnover.”

Todd Latz, CEO of GoHealth Urgent Care, a national group of walk-in clinics, believes success in 2020 should be defined by significantly greater consumer self-advocacy.

“We live in an age when there has never been more information available—on quality, on price, on provider reputation. Yet, it is still very difficult for the average healthcare consumer to sort through everything, to understand their benefits, to decide how to best access care, and—perhaps most important— to discern how to assess true ‘value,’” he says. “Self-advocacy can and should be measured by how well all of us, as providers, payers, and other participants across the healthcare continuum, help educate consumers on how and what to value in the care they receive.”

When it comes to transparency, Schafer notes the implementation of systems that provide understandable information to patients, providers, and employers on the cost of different healthcare services as well as the cost of alternative services or drugs that may help patients or employers save money will be the measure of success.

Terry Rovinski, president & CEO of Milwaukee-based Health Payment Systems, Inc., a healthcare tech and services solution company, says his company is focusing on the social contract between providers of healthcare services, employers, and employees to provide for and then appropriate use of healthcare insurance products.

“Our healthcare provider network is accessed by partially self-funded employer groups that wish to have a differentiated approach of procuring, measuring, and rationalizing healthcare expense,” he says. “We wish to support their employers’ desires by providing additional resources to the enrolled employees and their families to understand their medical spend and help them pay for their medical expenses thereby fulfilling this social contract.”

Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years.
The year 2020 holds many exciting changes in the ever-evolving world of managed care. Experts say that organizations can expect to see the launch of new therapies and the payer-related nuances—a direct reflection of the continued push toward personalized medicine.

“We are living through an era of exponential change,” observes Ross Hoffman, MD, chief medical officer at Envelope Pharmacy Solutions.

These changes will impact several areas across a variety of therapeutic areas while driving formulary changes and new payment considerations.

**SPECIALTY DRUGS AND DRUGS FOR RARE DISEASES ABOUND**

New specialty drugs emerging from the pipeline will enter the market at an accelerating pace. According to Melissa Duke, PharmD, executive director of population health pharmacy solutions at Banner Health in Phoenix, Arizona, this forthcoming trend will have a significant impact on the managed care industry while altering the patient experience.

“Payers who support these industries are experiencing unprecedented growth—especially with rare diseases and orphan drugs,” Duke observes. “These new drugs for rare diseases are life extending and improve quality of life in patients who previously didn’t have a therapy available to them.”

More specifically, therapeutic categories with new products on the horizon include gene replacement therapy, gene editing, cell therapy, and cancer immunotherapy—significant industry disruptors that Hoffman says will only help enhance the industry-wide progression to more individualized therapy.

However, the benefits do not come risk free. Many of these drugs are first-in-class with never-before-seen mechanisms of action, unique drug development processes, and special supply chain considerations. And the novel breakthroughs often come at a steep price, with the cost of some of these drugs exceeding $1 million per dose.
Additionally, Sheila Arquette, RPh, executive director at the National Association of Specialty Pharmacy, points out that patients will continue to face challenges accessing specialty drugs, a direct consequence of health plans and payers continuing to limit access to participation in certain networks. Pharmacy carve-outs and channels, or carve-ins, only add to this problem.

The result leaves patients dealing with the fallout—many of whom find the degree of autonomy in selecting pharmacies increasingly more limited. Hoffman believes the price points associated with specialty therapies carry transformative potential while leaving some controversy surrounding unanswered questions regarding the long-term value of these novel drugs.

“We’re seeing accelerated FDA approvals of breakthrough status agents, with only partial evidence of long-term treatment efficacy or durability,” he notes.

CURATIVE THERAPIES POTENTIALLY DISRUPTIVE THERAPEUTICALLY AND FINANCIALLY

Duke cites Zolgensma—the drug that famously, or infamously—broke records as the world’s most expensive drug at the cost of more than $2 million—as a game-changer. And its impact exceeds its hefty price tag.

While the drug’s high cost is disruptive in itself, the potential for curative therapy it offers enhances its impact in the healthcare world.

"Previously, kids who had spinal muscular atrophy didn’t live beyond 2 to 6 years old,” Duke says. "Now, they have a normal life expectancy."

The new year will also include the launch of several novel therapies for hemophilia, a therapy which Hoffman says now holds the promise to cure a subset of the affected population. Like their predecessor Zolgensma, the curative potential of these drugs promises to transform the patient experience as well as the lives of their families. The emergence of such therapies could potentially disrupt industry providers associated with hemophilia support products and factor replacement therapies.

Despite having received FDA approval in early 2019, Novo Nordisk’s Esperoct (turoctocog alfa pegol, N8-GP) for the treatment of hemophilia A in children and adults will not make its market debut until 2020. BioMarin has its sights set on gaining approval for valoctogene roxaparvovec (BMN 270) for hemophilia in 2020.

FORMULARY AND PAYER CHANGES CREATE HURDLES AS WELL AS SOLUTIONS

To help address the costs of higher-end drugs, such as Zolgensma and other gene therapies, organizations might want to consider cost modeling. Zolgensma manufacturer Novartis reportedly engaged in a payment plan with the hospital for the first recipient who received the drug in the summer of 2019—an arrangement Duke says is a new payment model. In such cases, the agreement is made between the hospital administering the drug and the manufacturer.

As for formulary changes, both Duke and Arquette agree that biosimilars will receive the greatest focus, as their price point typically falls lower than the reference drug. Payers have an opportunity to negotiate a lower price point.

In fact, nearly 70% of specialty drugs currently in the pipeline share an association with an identified biomarker. Identifying a biomarker serves two important purposes: (1) it plays an important role in helping providers select and customize the most appropriate therapy for the patients—especially when combined with pharmacogenomics—and (2) it also offers manufacturers positive reassurance regarding the value of their products. The combination of these two features helps to ensure superior outcomes for patients, notes Arquette.

In an effort to contain costs, step therapy will also become more of a trend. According to Duke, this phenomenon will follow suit behind 2019 initiatives by CMS that encourage step therapy. The organization expanded step therapy to include Medicare Part B. The rule requires that Part D sponsors expand their formularies to include all drugs listed as protected classes of psychoactive drugs such as anticonvulsants, antidepressants, antipsychotics, antineoplastics, antiretrovirals, and immunosuppressants for transplant rejection treatment. The rule offers Part D sponsors the option of requiring prior au-

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Authorization and step therapy requirements for new patients.

There will also be an uptick in enhanced efforts to implement value-based contracting—a feature Arquette says will reach an unprecedented level of interest.

“While managing the cost of specialty products has focused mainly on drug prices in the past, value-based contracting seeks to link the price of a drug to clinical or economic performance,” she says.

These demands illustrate the benefit of specialty pharmacies, which make significant contributions to the patient care paradigm through the provision of what Arquette defines as “high-touch patient care” and coordination of care with other healthcare providers, resulting in enhanced healthcare outcomes.

Despite the apparent benefits, Arquette cautions that implementing value-based contracting is no small undertaking. Instead, this type of contracting demands tremendous efforts on behalf of healthcare providers in the form of collaboration and coordination among healthcare providers while requiring organizations to assume some degree of financial risk.

DRUG PRICING REFORM, IMPROVING ADHERENCE MAY HELP EASE ECONOMIC BURDEN

Legislative and regulatory activity aimed at addressing the high cost of prescription drugs, including specialty drugs, is underway. The federal government is currently mulling over policies that would directly reduce drug costs at the point of sale—regardless of whether the transaction occurs at the pharmacy counter or during the provision of care.

In the world of specialty pharmacy, Arquette says a form of payment overhaul known as “pharmacy direct and indirect remuneration (DIR) reform” would bring these patients immediate financial relief, and senior citizens would enjoy copay reductions on expensive therapies for which no generic alternatives exist.

“Pharmacy DIR reform ensures all pharmacy price concessions are used by a plan to reduce a Medicare patient’s upfront cost,” Arquette explains. “This reform also would support services needed to improve patient outcomes through drug management.”

Another critical element in easing the financial burden is addressing medication adherence. Optimizing patient adherence amplifies the patient outcomes and utilization of the healthcare system by optimizing therapeutic value, reducing waste, and improving cost containment. Implementing quantity limits (30-day fill) can be helpful, but Arquette says partial fills can also prove beneficial when ascertaining a patient’s tolerance for a medication. Additional cost management strategies include prior authorization and utilization management edits, such as step therapy.

LOOKING TO 2020 AND BEYOND

In addition to new drugs that will help mitigate chronic conditions such as hemophilia A, hemophilia B, and beta thalassemia, patients who have sickle cell anemia also have new hope.

The approval of Endari (L-glutamine) for sickle cell anemia in 2017 marked the first approval of a new drug for sickle cell anemia in nearly 20 years. In 2020 there will be two new drugs for the condition on the market—both of which gained approval in late 2019. The FDA approved Advakveo (cizanlizumab) in November 2019, and Oxbryta (voxelotor) gained accelerated approval several days later.

Cancer will continue to remain a hot therapeutic area experiencing tremendous growth, according to Hoffman, who says more than 400 immunotherapies are in development.

While generic options for specialty medications have been minimal, the future may paint a different picture.

“Substantial investments in the development of generic specialty medications are being made, and it is expected within the next five years that alternatives to significant specialty drugs will be available soon,” Arquette says.

With numerous biosimilars in the pipeline, she projects 2020 may see a few blockbuster drugs. Given the high cost of the biological reference drug after which these drugs are patterned to emulate in effect, the prospect of more biosimilars on the horizon could have a tremendous impact on patient access as well as healthcare spending. 

Frieda Wiley, PharmD, RPh, is a contract writer and consultant pharmacist.
The Benefits of Pharmacogenetic Testing

by FRIEDA WILEY, PHARMD, RPH

Pharmacogenetics presents clinicians an attractive option to optimize drug therapy, minimize harmful effects, and contain costs; but, payers may not be maximizing cost-saving potential by choosing only to cover the costs associated with single-gene interrogation.

Sources vary, but a single pharmacogenetics test ranges from $100 to $500. An entire panel is a similar price.

Despite the cost savings, payers are reluctant to cover the cost of running a full panel of tests. Experts differ in their speculations as to why many payer organizations do not pay for running an entire test panel.

“Many payers lack the total body of knowledge,” says Ruben Bonilla-Guerrero, MD, FACMG, FAACC, MB(ASCP), CGMBS, medical director of medical affairs at Admera Health, a leader in personalized med-icine and non-invasive cancer testing in South Plainfield, New Jersey. “To them, running an entire test panel is experimental—even more than 200 drug labels mention pharmacogenetics testing.”

Pharmacogenetic testing offers important advantages by facilitating the prescriber’s ability to select, initiate, and adjust a medications much more precisely than conventional dose titration. Pre-emptive testing also helps prevent adverse drug events that occur as a result of overdosing medications.

However, to truly optimize outcomes, organizations must evaluate costs and benefits.

“Payers want to reimburse for tests run for a specific indication and that have evidence-based, actionable treatments based on the results,” says Erin Lopata, PharmD, MPH, senior director of the Access Experience Team at Precision for Value, part of Precision Value & Health, a corporation that performs value and access consulting services for entities.

Additionally, some provider habits may inadvertently contribute to payer pushback. For instance, providers may order tests on certain populations, medications, genes, and gene–drug pairs or add their own tests. Sometimes, they base their decisions on misleading information purported by the mainstream media that is devoid of clinical application—or patient value. In these cases, ordering extra tests would be impractical.

To avoid unnecessary testing, Bonilla-Guerrero believes it is imperative to educate payers on the circumstances under which interrogating a gene panel would prove most beneficial for the patient.

“It’s about having a conversation about what’s actionable, the available sources, and the clinical utility,” says Bonilla-Guerrero.

Lopata points out that organizations should exercise prudence when ordering panels; failing to do so could promote negative stigmas associated with testing and result in ineffective medication use.

For example, “fishing expeditions” occur when prescribers run large panels to diagnose or identify a treat-ment for a condition. Engaging in such practices can promote off-label prescribing for specific mutations when sufficient evidence is lacking. Off-label medication use is relatively common in the oncology world—a therapeutic area in which Lopata says research evolves quickly and exhausting treatment options is common.

Yet, having sufficient evidence does not always guarantee therapeutic success. The evidence derived from pharmacogenetic testing may translate to poorer outcomes when presented to some patients. A study published in Pharmacogenomics Journal in 2013 found that pharmacogenetic testing can create patient doubt when the drug he or she prefers is found to be less effective or safe.

As a result, the anxiety and distrust patients feel may negatively impact perceptions and adherence.

Looking forward, Lopata anticipates payers will shift their focus on containing costs in oncology. She believes the evidence will continue to play an essential role across all therapeutic areas.

“Evidence generation to determine the best timing and test to use (panel vs. single-mutation) will support better payer coverage and patient access to these tests,” she says.

Frieda Wiley, PharmD, RPh, is a contract writer and consultant pharmacist.
Pharmacists have an important responsibility not only to keep up with new drug approvals but also to stay abreast of the latest pharmacy regulations affecting the profession. The Oath of a Pharmacist states: "I will accept the lifelong obligation to improve my professional knowledge and competence." Pharmacists can stay up to date by participating in continuing education (CE) programs, through various resources, such as professional organizations, and registering for email alerts with the Drug Enforcement Administration (DEA) and FDA.

Here are the new and proposed federal regulations, as well as state laws, that are trending across the United States.

**Proposed Laws Aimed to Reduce Opioid Abuse**

The DEA recently announced proposed regulations to further limit excess quantities of opioids amid the epidemic. According to the National Institute on Drug Abuse, more than 130 people in the United States die daily from an opioid overdose. Additionally, opioid abuse results in an U.S. economic burden of $78.5 billion a year, which includes healthcare costs, loss of productivity, addiction treatment, and criminal justice involvement. The DEA has issued a proposal to reduce the amounts of five Schedule II opioid-controlled substances manufactured in 2020 compared with 2019. The proposal includes reducing the production by these drugs by the following amounts: fentanyl (31%), hydrocodone (19%), hydromorphone (25%), oxycodone (9%), and oxy-morphone (55%). This is expected to result in a quota that would be a 53% decrease in the amount of allowable production of these opioids since 2016. Comments were due by October 10, 2019 and will be reviewed by the DEA.

"Reducing the amount of opioids of these Schedule II drugs that have the highest potential for abuse will hopefully help to combat the opioid epidemic," says Fred Weissman, PharmD, JD, associate professor, clinical pharmacy, USC School of Pharmacy, Los Angeles. Weissman has also authored the book "A Guide to California Community Pharmacy Law" and discussed the importance of laws that are aimed to curb prescription drug abuse. Controlled substance prescriptions must be issued for a legitimate medical purpose by a practitioner. However, pharmacists have a corresponding responsibility when filling and dispensing the prescription and must use their professional judgment.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery Treatment for Patients and Communities Act (SUPPORT Act) became law in 2018 and helped to establish more treatment programs for opioid abuse as well as strengthen monitoring of controlled substance prescriptions.

The DEA also announced additional proposed regulations for monitoring quotas for Schedule II controlled substances to help prevent prescription drug abuse as part of the SUPPORT Act. The SUPPORT Act requires that appropriate quota reductions be made after estimating potential for diversion and would help to ensure that there are sufficient quantities of the medications for the medical, scientific, research,
and industrial needs of patients in the United States. The notice of the proposed regulation was published in the Federal Register, and the comment period ends December 23, 2019.

Most states and the District of Columbia have passed laws that allow pharmacists to dispense the emergency opioid overdose reversal treatment, naloxone, under a standing order, which takes the place of an individual prescription. Additionally, some states have given pharmacists direct authority to prescribe and sell naloxone to consumers. Weissman discussed that pharmacists can play an important role in dispensing naloxone to help prevent opioid overdoses. However, naloxone access can be limited in some communities. The FDA is currently working to ensure that this lifesaving drug is accessible, and one of the efforts is making it easier for companies to develop it as an over-the-counter (OTC) product. The FDA has designed, tested, and validated the key labeling requirements to approve an OTC naloxone product by developing a model Drug Facts Label (DFL) with pictogram instructions so that anyone with access to the drug can better understand how to administer it. Additionally, this is the first time that the FDA has proactively established and tested a DFL to assist with creating an OTC product. There are likely to be more laws and regulations in 2020 to reflect the expanded naloxone access and possible OTC availability.

**Drug Supply Chain Security Act (DSCSA)**

Certain aspects of the DSCSA will be implemented in 2020, which affects pharmacies. It was first enacted in 2013 and sets out serialization and track and trace requirements for the U.S. drug supply chain from the manufacturer to dispensers. “Every drug product should come from a legitimate source,” says Weissman. The DSCSA will enhance the FDA’s ability to help protect consumers from exposure to counterfeit, stolen, or contaminated drugs. Weissman discussed the importance of pharmacists understanding their responsibilities for protecting patients under the DSCSA, as many of the requirements affecting dispensers occur in 2020.

Pharmacists should check the following: registration of manufacturers and repackagers; licensing of wholesaler distributors and third-party logistics providers; and licensing of pharmacies through the state. Pharmacies should only accept prescription drugs that have the following three product tracing documentation: transaction information, transaction history, and transaction statement. The product tracing documentation must be stored in paper or electronic format for 6 years. Pharmacies must also ensure that they have a process in place to investigate and handle prescription medications that they believe are illegitimate, which include counterfeit, diverted, stolen, intentionally adulterated, or unfit for dispensing. Pharmacists must work with the manufacturers to ensure that appropriate measures are taken so that patients do not receive these illegitimate products, and the FDA, as well as trading partners they purchased the drug from and sold the medication to, must be notified immediately. Pharmacists should also check out the FDA’s free CE program that explains the DSCSA requirements.

**Pharmacists and Hormonal Contraception Prescribing**

The American College of Obstetricians and Gynecologists recently issued recommendations that hormonal contraception should be available OTC to expand access to patients without age restrictions. Evidence suggests that women want easier access to hormonal contraception. As of April 2019, 13 states and the District of Columbia allow pharmacists to prescribe certain types of hormonal contraceptives, which is now a growing trend across the country. Weissman discussed that each of the states have different training requirements for pharmacists, which is implemented by their respective board of pharmacy. In order to switch from prescription to OTC status, drug manufacturers can submit a New Drug Application to the FDA. The FDA considers the following for a switch: consumer labeling; analysis of whether patients can adequately self-screen based on the label; and evaluation of actual-use to simulate how the products would be used by consumers. Additionally, the FDA must ensure that the label and package inserts are written so that important information is understood by the layperson. Pharmacists can help to play an important role in women’s health as access to hormonal contraception continues to expand in 2020.

Jennifer Gershman, PharmD, CPh is a pharmacist and medical writer residing in South Florida.

**Pharmacy Best Practices**

Pharmacy/Formulary Development
Providing Personalized Healthcare via New Technologies

See how these tools improve health, well-being, and increase value

by DONNA MARBURY

Personalized services are already a huge part of retail and financial sectors. Being able to reach patients with direct services using technology is even more critical as the need for chronic care continues to grow.

"Personalized approaches are so important because each individual’s health and well-being is highly complex," says Yoona Kim, CEO and co-founder, Arine, a healthcare technology company located in San Francisco, that combines data science with clinical expertise via artificial intelligence (AI).

Many healthcare organizations are using technology as a way to add value to services. "We want our technology experiences to enhance human connection, not replace it," says Nikki Caputo, senior director of experience and innovation, UCHealth.

**Voice-enabled assistants**
For UCHealth, a nonprofit network of 12 acute care hospitals and more than 150 clinics throughout Colorado, Wyoming, and Nebraska, using voice-enabled technology started with a comprehensive AI strategy.

"Two years ago, we began to operationalize our conversational AI strategy. Voice has always been a piece of that. More importantly, it’s about giving people choices to access information," Caputo says.

In summer 2019, UCHealth began utilizing the Livi skill on Amazon Alexa smart speakers, as a virtual assistant for patients and their caregivers. Users are able to ask questions about health conditions and location information for practitioners or specific doctors.

“You can ask Livi to find the nearest urgent care and she’ll tell you the closest location and..."
“One of the biggest things we learned was that patients don’t respond to generic interventions or engagement techniques, even if these are aimed at improving their well-being at no additional out-of-pocket cost to them.”
— YODA KIM, ARINE

follow up with a text message that includes contact information and driving directions,” Caputo says. Caputo says that there are several use cases for voice-activated technology and that the organization is cognizant of possible challenges.

“If Alexa can’t understand the customer’s voice when asking for a doctor’s phone number, that’s an issue,” Caputo says. “We want to use conversational AI to deliver more personalized experiences to build stronger relationships with our customers. To do that we need to make sure our integrations are fully secure.”

**Telehealth**

Telehealth is growing faster than any other healthcare option, according to a national study of insurance claims from 2016 to 2017 by Fair Health. The study found that telehealth claims increased by 53%, while claims to urgent care centers increased by 14% and retail clinics by 7%.

Retailers are investing in telehealth to increase engagement by offering more convenient options to patients. Walgreens announced plans to close 160 clinics and increase the reach of its telehealth platform, Walgreens Find Care, focusing on diabetes, chronic obstructive pulmonary disease, and asthma patients.

“We believe that by integrating connected care devices, digital therapeutics and the pharmacy experience, we’ll help individuals better manage their chronic conditions while also lowering the overall cost of care,” said Giovanni Monti, vice president and director of healthcare innovation, Walgreens Boots Alliance, Inc.

“Though telehealth options continue to grow, a 2019 survey conducted by J.D. Power found that only 10% of healthcare consumers have used it.

“Once providers and payers refine the formula for awareness and adoption, telehealth will change the landscape of how affordable and quality care is delivered,” says Greg Truex, managing director of health intelligence, J.D. Power.

“We want to use conversational AI to deliver more personalized experiences to build stronger relationships with our customers. To do that we need to make sure our integrations are fully secure.”
— NIKKI CAPUTO, UCHEALTH

**AI for chronic care patients**

At the Oklahoma Health Care Authority, a pilot using AI to engage patients who need user-friendly medication monitoring has expanded across the health system of more than 800,000 patients.

“The program utilizes AI technology from Arine’s Virtual Pharmacist platform to continuously monitor patients’ conditions and recommend changes to care plans and medications. During the pilot, 92% of care plan adjustments were implemented by physicians and the health system saw a 40% reduction in hospitalizations.

“Our platform makes use of a sophisticated feedback loop where our data-driven clinical interventions can be continuously improved upon to achieve specific treatment goals for an individual, driving clinical and economic outcomes,” Kim says, adding that a combination of hands-on care from practitioners informed by AI’s personalization will give patients the maximum benefit.

“One of the biggest things we learned was that patients don’t respond to generic interventions or engagement techniques, even if these are aimed at improving their well-being at no additional out-of-pocket cost,” Kim says. “AI can help healthcare organizations understand how and when to best intervene on a patient given their unique circumstances.”

Donna Marbury is a writer in Columbus, Ohio.

Managed Healthcare Executive.com
There’s a reason that healthcare systems address social determinants of health (SDoH): Studies show that when patients have stable housing, nutritious food, and transportation to medical visits, their health improves and their use of the most expensive medical services, like visits to the emergency department (ED), decreases. SDoH are conditions that affect a person’s health, like where they live, their educational and socioeconomic status, and their social support networks. Healthcare systems around the country address various aspects of SDoH, whether in new, small pilot programs, or larger well-established ones.

Some of the most innovative programs are run through Medicaid plans. The Kaiser Family Foundation conducted a 2017 national survey of Medicaid managed care organizations, showing that more than 90% of plans run at least one SDoH program. “If we, as providers, struggle with that, you can imagine the burdens that our community members have accessing them,” says Michele Horan, the director of operations for the Healthy Together platform. Instead of providers calling, faxing, and emailing community-based organizations (CBOs) for referrals, they can now go through a web-based platform tying them all together. Healthy Together is the Alliance’s branded name for the Unite Us platform, integrating health and social care. Providers can now send and track referrals in a closed loop, documenting patient situations once so they don’t have to repeat their stories to every new agency.

“All the partners can communicate with one another (in Healthy Together) to ensure that someone doesn’t fall through the cracks,” says Keshana Owens-Cody, Alliance’s senior director of partner success. Social service providers enroll in the network for free. Healthy Together currently has 20 service categories, 132 subcategories, and 75 enrolled organizations with 275 programs included. It actively recruits organizations to join the network and help onboard them. Given the relatively short time frame it’s been live, Healthy Together has not yet parsed the data to look at outcomes, but anecdotally it is thrilled with its connectivity, transparency, and ease of use.

Here are four programs making a difference.

1. **HEALTHY TOGETHER**

   Until April 2018, when Alliance for Better Health IPA practices in upstate New York wanted to make a referral to a social services organization, they consulted a resource guide. The problem? The resource guide was out of date even before it was published, as new programs popped up frequently.

   “If we, as providers, struggle with that, you can imagine the burdens that our community members have accessing them,” says Michele Horan, the director of operations for the Healthy Together platform. Instead of providers calling, faxing, and emailing community-based organizations (CBOs) for referrals, they can now go through a web-based platform tying them all together. Healthy Together is the Alliance’s branded name for the Unite Us platform, integrating health and social care. Providers can now send and track referrals in a closed loop, documenting patient situations once so they don’t have to repeat their stories to every new agency.

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2. **WELLNESS ON WHEELS**

   Since starting its Wellness on Wheels mobile primary care clinic three afternoons a week in January 2017, OhioHealth decreased inappropriate ED visits by 50%. The healthcare system started its Hilltop neighborhood clinic in the YMCA parking lot in an impove-
ished and medically underserved neighborhood not far from one of its hospitals. Community health workers in the hospital setting encouraged patients to establish care at the mobile clinic, as many don’t have primary care physicians.

The Hilltop clinic is an expansion of the OhioHealth women’s health clinic, with a 26-year history. The 54-foot mobile unit has two exam rooms, housing clinicians and a social worker who screens for SDOH and make referrals in both settings, says Shannon Ginther, OhioHealth senior director of community health partnerships.

The clinic also just began offering the mobile unit and medical care for 225 Holocaust survivors in Central Ohio, partnering with Jewish Family Services (JFS) who provides wraparound services. About 225 survivors live in the area and “have an understandable mistrust and fear of healthcare providers,” Ginther says. Bringing the unit to the JFS parking lot and having JFS refer patients provides that trust. Most of the survivors live below the poverty level and have other social needs, with which JFS assists.

The programs are partly supported by outside philanthropic funding, and partly by OhioHealth itself. The clinic accepts insurance, if the patient has it.

3 ASTHMA TO PRIMARY CARE

The Sinai Urban Health Institute (SUHI), located in Chicago, started multiple SDOH programs over the years, based on where it sees community needs. That includes programs focused on diseases like diabetes, breast health, and asthma. They reduced asthma-related ED visits by 73% and hospitalizations by 75% during the program’s first year, sending community health workers into patient homes for one-on-one education and assistance.

SUHI recently did two large door-to-door surveys in different Chicago communities to pinpoint current needs and analyzed Chicago Department of Public Health data as well. As a result, the latest program is also using community health workers, often starting in the ED. SUHI trains them in core skills for motivational interviewing, home visits, and cultural competence.

“Utilizing healthcare workers can be a cost-effective way to reduce utilization,” says Stacy Ignoffo, SUHI’s director of community health innovations. “Our own research shows if we do some interventions, they can decrease healthcare utilization in expensive hospital and emergency room usage,” while increasing the less expensive outpatient care.

Like the OhioHealth Hilltop program, SUHI community health workers identify patients in the ED without primary care physicians, screening them for SDoH. After identifying needs, they provide referrals and follow up with patients in the home setting if possible, to ensure they’re connecting with the agencies, as well as with primary care providers. “We’re finding that primary care and food insecurity are up there in needs, as well as housing,” she says.

4 CULTIVATING HEALTH FOR SUCCESS

Housing is an important issue in Pittsburgh as well, and Medicaid plan UPMC for You took this issue on for some of its patients in the Cultivating Health for Success (CHFS) program.

“When looking into how to make an impact up to a decade ago, housing was number one,” says Dan LaValle, director of government programs, UPMC Health Plans. Until recently, the program targeted those who met the strict U.S. Department of Housing and Urban Development (HUD) definition of homelessness, with a goal of finding and placing up to 25 individuals in housing that year. Some stay with the housing program permanently, some move on, and UPMC is fine with either—it doesn’t place conditions on the patients.

Using a team and partnership model, UPMC community health workers, clinicians, and its partner, the local HUD vendor Community Human Services, work together to ensure the patients in the program get needed housing, medical care, transportation, food, and any other needs met. “The vast majority of individuals we serve have a significant number of chronic conditions and co-occurring behavioral health diagnoses,” LaValle says.

UPMC found it took 10 months of consecutive stable housing to get to the changes it wanted to see: better primary care trends and less ED utilization. “We now know that if we can get someone housed for 10 months, that will change their trajectory,” he says. With the program, those enrolled saved about $6,000 per member per year on expenses, which UPMC put back into the program.

It is starting to expand the program to those who don’t meet the HUD definition of homelessness but qualify for Section 8 housing vouchers. This population also has high needs, is not getting recommended medical screenings, and goes to the ED frequently. UPMC is using the same agency and model for partnership and case management, with some funding differences. One change is incentivizing providers with shared savings in a pay-for-performance model.

While 72% of hospitals are not investing in SDOH programs, according to a 2017 Deloitte Center for Health Solutions survey of 300 hospitals and health system, most that do limit their investments to a targeted small patient population, which may include high healthcare utilizers, or those who may be frequent ED visitors. Healthcare organizations don’t have to do it all by themselves, as UPMC showed. Partnering with other organizations can make a big difference.

Deborah Abrams Kaplan covers medical and practice management topics.
Hurricane Katrina hit the New Orleans area on August 29, 2005, with such ferocity that half the city’s residents were displaced. The storm’s more than 100 mile-per-hour winds damaged or destroyed homes and businesses. But New Orleans’ residents are resilient, and city leaders were committed to rebuilding the city.

Warner Thomas, CEO and president of New Orleans-based Ochsner Health System, Louisiana’s largest nonprofit, academic health system, had a healthcare leadership skills honed in midst of disaster.

by AINE CRYTS

Warner Thomas, President and CEO at Ochsner Health System

- Earned a BS in accounting from Southern New Hampshire University and an MBA (healthcare) from Boston University; he’s also a certified public accountant.
- Held a variety of leadership roles at Southern New Hampshire Health.
- Served as a senior auditor at Ernst & Young.
- Received the 2019 Ernst & Young Entrepreneur of the Year Award in the Gulf Coast Area (Healthcare and Related Services Category).
- Received the Anti-Defamation League 2018 A.I. Botnick Torch of Liberty Award.
- Received a Glassdoor Employees’ Choice Award honoring the top CEOs in 2018.
- Named the 2017 CEO of the Year by Biz New Orleans magazine.
organization to run. Pre-Hurricane Katrina, his strategy to keep the health system operational involved creating a Team A and a Team B.

When the hurricane hit, Team A would be on scene to run the health system during the storm, and Team B would take over health system operations post-Hurricane Katrina.

**Timely, regular communication is key**

To keep in sync with his leadership team during and after the hurricane, Thomas had scheduled check-ins every morning, late afternoon, and evening. The goal? Get all hands on deck and focus on the work of keeping the health systems’ doors open, while treating patients and supporting staff members.

Post-Hurricane Katrina, many of Ochsner Health System’s staff members didn’t have homes to return to at the end of the workday. The storm had damaged 70% of the city’s occupied housing units, according to CNN. In addition, other hospitals in the area had sustained damage in the storm. Ochsner Health System ultimately acquired three hospitals from Tenant Healthcare Corporation after Hurricane Katrina hit New Orleans.

Lisa Goldstein, associate managing director at Moody’s Investor Service and a nonprofit hospital analyst, told CNBC, “It was a market that...went from over 2,000 hospital beds, to—shortly after Katrina—just 500.”

In the best of times, hospital mergers are difficult. The three hospitals Ochsner Health System acquired from Tenant Healthcare had different systems and cultures—that’s typical with hospital mergers. But this was the worst of times: Medical records had been destroyed, in addition to physical structures—and the staff at the new hospitals were also struggling with housing and uncertain about the future of the city and the surrounding area.

Thomas acknowledges that recovery efforts after Hurricane Katrina—in addition to the hospital mergers—were challenging. Clear and ongoing communication among his leadership team and throughout the health system was pivotal to Ochsner Health System’s success.

**Solving New Orleans’ toughest challenges**

Thomas continues to apply the hard-earned lessons he learned during Hurricane Katrina and the city’s recovery. He kicks off each workday with a 15-minute check-in call with the 12 members of his leadership team. It’s an opportunity to focus on the most pressing challenges of the day, which can range from a public relations issue to a drug shortage, he says.

Ochsner Health System grapples with many of the same challenges facing any multi-hospital health system. For example, 13%—or more than 521,000 of the state’s residents—have diabetes, according to the American Diabetes Association. More than a million people in the state have prediabetes, which means their blood glucose levels are higher than normal but not yet high enough to be diagnosed as diabetes.

In addition, rates of heart disease and stroke were 25% higher in Louisiana than the U.S. average in 2017, and the percentage of adults who are obese increased from 35.5% in 2016 to 36.2% in 2017, according to the Louisiana Department of Health’s Office of Public Health.

To support community members in tackling these chronic conditions, in 2014, Ochsner Health System launched the O Bar, retail locations where patients and non-patients can purchase items such as activity monitors, wireless blood pressure monitors, and weighing scales. Technology specialists staff the O Bar locations, which means shoppers have help choosing the right digital health app and troubleshooting technical and support issues.

Aimee Quirk, CEO of innovationOchsner, an innovation lab and accelerator founded by the health system, says, “This is a really powerful way to help address some of the access issues and disparities we see.”

She acknowledged that the acute care model is changing—and that’s due in large part to payment incentives ushered in by value-based care. Today, there are seven O Bar locations at health system facilities, and a mobile O Bar travels to locations around the state.

Encouraging staff members to maintain their focus on both the digital and “bricks and mortar” aspects of healthcare isn’t easy, Thomas admits. Supporting team members to work “outside their ‘silos’” helps, he says.

Thomas stresses that it’s about motivating all team members to embrace a “both/and” philosophy. For Ochsner Health System, that requires a commitment to delivering clinical care in its hos-
pitals and physician practices, in addition to providing the expertise patients need when they call an O Bar expert to learn about a new digital health device.

**Mapping his journey to New Orleans**

Thomas, a Vermont native, started his career as an auditor at consulting firm Ernst & Young. Many of his clients were in the healthcare ecosystem, including community and tertiary hospitals, physician groups, and healthcare systems throughout New England. That’s what drove his decision to work at Nashua-based Southern New Hampshire Health, where he rose through the leadership ranks as controller/director of finance; interim chief financial officer; president of Foundation Medical Partners, Inc, a medical group practice that’s part of Southern New Hampshire Health; and vice president of managed care and network development.

One of his successes at Southern New Hampshire Health was the expansion of a multi-specialty physician group to nearly 100 providers in six years; the physician group included 20 locations, 200 staff employees, and more than $30 million in net revenue.

In fact, Thomas hadn’t visited the Bayou State until he interviewed for a job at Ochsner Health System. An ongoing thread in his career—and one that carries through his current role as a health system president and CEO—is his belief that healthcare is about helping people improve their lives.

In his capacity as Ochsner Health System’s president and CEO, Thomas is responsible for strategy, operations, and growth. Due to his efforts, the health system has expanded across Louisiana and the Gulf South. He’ll continue to have his work cut out for him; patient-centered technology will be pivotal to bringing advanced care closer to patients’ homes, which is important in a state where 750,000 residents live in rural areas.

What helps keep him focused during the inevitably stressful days of running a health system? Daily exercise, such as swimming. “Exercise is a critical part of my routine. It helps me stay sharp and is a great stress reliever,” says Thomas, who has participated in triathlons and Ironman competitions. “To keep an active mind, you have to keep an active body.”

Aine Cryts is a writer based in Boston.
Thanks to advances in medical innovation, survival rates for cancer patients have increased substantially in the past 30 years. However, such clinical improvements have come at a cost. Analysis from the National Institutes of Health indicates cancer spending increased 27% over 10 years, estimated to reach $158 billion in 2020. Much of the rise is attributed to the surge in newer and more costly drug therapies. For example, the median annual list prices of new cancer drugs coming on the market doubled between 2013 and 2017. Meanwhile, payers and the 1.7 million patients who will be diagnosed with cancer this year are often left with difficult financial propositions.

It’s this combination of high prevalence and high treatment costs that’s driving a fundamental shift toward value-based reimbursement models in oncology. Both Medicare and commercial payers are seeking strategies that optimize care while reducing spending. “Five years ago, there was a lot of resistance to value-based care, clinical pathways and making physicians responsible for outcomes,” says Andrew Hertler, MD, FACP, chief medical officer for New Century Health, an oncology specialty management company. “But over the last two years, there’s been a willingness to embrace these alternative payment models.”

**Medicare model**
Medicare is now three years into its Oncology Care Model (OCM), a pilot involving 175 practices and about a dozen commercial payers. OCM includes real-time monthly payments of $160 to reimburse providers for enhanced services, in addition to usual fee-for-service payments and retrospective quality bonuses. Currently, OCM providers have taken only upside risk, but CMS intends to transition providers to two-sided risk.

Rhonda Henschel, director of value-based commercial programs for McKesson, says CMS is leading the way in alternative payment, and commercial insurers are looking to gain insights from Medicare’s experience. “Commercial payers want to be operating in value-based models, but there are barriers with legacy claim systems and their ability to execute the models,” Henschel says. “Claim systems are designed on fee-for-service. So it’s challenging for payers and providers to operate on a bundled case rate or episodic payment structure.” She says payer and provider must come to the table to create a partnership, working out the logistics collaboratively because each participant will likely be at a different point of relative readiness for a value-based arrangement. “The key is to be deliberate with your strategy,” Henschel says.

Success hinges on oncologists being incentivized and enabled to deliver high-quality care alongside measurable cost savings. Experts say there are some emerging opportunities that stakeholders must examine in order to realize value in today’s oncology reimbursement models.

**Optimize drug therapy**
Treating cancer is much different now than in years past. In many cases, it’s become a chronic disease that can be managed with drug therapy over many years, and payment structures must reflect that, says Hertler, who is an oncologist. Innovative treatments include immunobiologics and agents that target cancer cells based on their genetic mutations. “How do we create value-based care in a world in which we have the ability to keep cancer controlled, with patients living quite normal lives as long as they take very expensive drugs? The key is going to be using these new tools,” Hertler says.

*Top Ways to Find Value in Oncology* by JULIE MILLER

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For example, in lung cancer, there are several known genetic mutations. With genetic analysis, oncologists can choose the drug therapy most likely to be effective for the patient’s specific type of lung cancer, rather than using a trial-and-error approach. In the past, trial and error was the only treatment strategy, Hertler says, and it caused a lot of waste in the form of ineffective drug treatment.

He believes the upfront costs of genetic tests are offset by the value of choosing the right drug treatment from the outset. For example, a lung cancer liquid biopsy might cost $6,000, but he says it makes sense when drug therapies cost $20,000.

"We need to change the financial alignment with providers, and we need to pay for the care that they deliver.”
— ANDREW HERTLER, MD, FACP, NEW CENTURY HEALTH

Avoid ED use and hospitalizations
Value-based models in general seek to reduce emergency department (ED) use and hospitalizations by favoring outpatient and preventive care. For oncology, symptom management presents an opportunity to save by shifting care to a less-costly setting when appropriate.

Hertler says the large majority of hospitalizations related to cancer are attributed to complications from therapy, and as many as half of those hospitalizations are avoidable. Changing therapies, addressing nutrition and hydration issues, prescribing preventive antibiotics, and even adding home care services can help.

"When we’re globally managing a patient, the biggest cost of care is drugs, and the other is hospital admissions and emergency room visits,” says Ray D. Page, DO, PhD, FACOI, an oncologist and hematologist. "If we can identify and manage patients to keep them out of the ED and out of the hospital, that’s to our practice’s advantage.

Page says symptom management and triage pathways have been proven to reduce ED visits and hospitalizations for cancer patients. Pathways are essentially care protocols based on evidence. Value-based programs are beginning to integrate pathways into quality metrics.

In one study presented in the Journal of Oncology Practice in December 2018, Page and colleagues found that two practices were able to create $3.85 million in annualized cost savings by avoiding 222 ED incidents with associated hospitalizations. Nurses triaged the incidents—which included symptoms such as nausea and vomiting—via phone and followed symptom pathways to direct patients to physicians’ offices for assessment rather than the hospital.

“We did a lot of practice transformation around the triage system to show we can better manage those patients at risk of emergency room or hospitalizations, and by keeping them out, we save money for the payers,” he says.

Page, who is immediate past chair of the American Society of Clinical Oncology’s (ASCO) Clinical Practice Committee, says clinical pathways started gaining traction about three years ago as a means to increase value. They help care teams avoid ED and hospitalizations while also increasing efficiency and treatment effectiveness. ASCO estimates 60 U.S. health insurance plans are now using oncology pathways.

"I would guess that 20% to 25% of oncology practices across the U.S. are under a treatment pathway model or in the process of implementing it," he says. "We have a ways to go.”

Align provider payment without full risk
Oncology has historically relied on a misaligned financial model. In the future, value-based oncology strategies will shift payment structures toward more rational reimbursement that accounts for the actual cost of care.

“We need to change the financial alignment with providers, and we need to pay for the care that they deliver,” Hertler says. “I’m not advocating that they be paid less. I’m advocating that they be paid differently.”

For most practices, the majority of the provider’s profits traditionally have come from the markup on chemotherapy drugs, he says. And that extra 20% or more in markup drove the organization’s finances, compensating for other unreimbursed services.

Some of the unreimbursed services include case management...
provided by nurse practitioners or physician assistants who can’t bill directly. Cancer patients often need nutritional counseling—another activity that isn’t reimbursed under fee-for-service. And many practices in the past have defaulted to in-person office visits—again, because they’re billable—in cases where a phone consultation might suffice.

“Everyone’s trying to do what’s right for the patient,” Hertler says. “But you’re also painfully aware that you are running a business, and you need to keep it solvent.”

He suggests payment models based on case rates with shared savings and incentives tied to quality and outcomes—but not total risk allocated to providers. “The payer and provider must work in partnership to craft a fair model. While providers have been reluctant to adopt value-based pay in the past, it’s time to make the change, he says.

“Physicians are not insurance companies, and they have a small volume of patients,” he says. “The trick is to offer incentives for good outcomes, pay for the services provided, but not expect them to take on total risk. No one would start an insurance company with 1,000 cancer patients. That’s obviously not a great business model.”

Leverage data

“Value-based care requires that everyone has command of the data,” Page says.

His practice uses an artificial intelligence tool that stratifies patients to determine who might be at the highest risk for pain, hospitalization, readmission, physical decline, or death within 30 days. Weekly reports prompt case-manager outreach to help mitigate risks and refer patients to services, such as pain management or palliative care.

He says preliminary results seem positive, but the program is a work in progress.

Henschel agrees that providers are going beyond traditional medical records to integrate more advanced technology stacks that provide predictive analytics as well as other holistic data points, such as social determinants of health. Being responsible for outcomes means treating more than just the cancer diagnosis.

“When I was a young oncologist three decades ago, I pretty much walked around with most of the treatment options in my head,” Hertler says, but now there is far too much information for any provider to maintain from memory alone. He says machine learning is becoming more important because it’s able to work out algorithms quickly in the background, suggesting optimal care plans.

“Value-based care requires that everyone has command of the data.”

— RAY D. PAGE, DO, PHD, FACOI, AN ONCOLOGIST AND HEMATOLOGIST

Avoid treatment that doesn’t work

Many cancer patients face terminal prognoses. Forecasts predict about 607,000 Americans will die of cancer in 2019, according to the American Cancer Society.

Making the decision to end treatment and opt for hospice care is often an intense ethical debate for the patient and loved ones. But experts believe palliative care can offer physical, emotional, and financial benefits in advance of moving a patient into hospice.

“The data is very strong,” Hertler says. “When they don’t have any more options—rather than trying more therapies that don’t work—patients who get palliative care have a better quality of life and surprisingly live longer. Why? Because they’re not getting the side effects of therapy that isn’t going to help.”

Julie Miller is a freelance writer based in Cleveland.
After analyzing data about risk of death and emergency department usage for its cancer patients, Northwest Medical Specialties opened a walk-in clinic. A nurse practitioner staffs the clinic, which is open from 9 a.m. to 5 p.m. on weekdays. The goal is to treat the acute symptoms that cancer patients experience—such as pain, dizziness, and diarrhea—and avoid trips to the emergency department.

The practice—with six locations in the Tacoma, Washington area—plans to hire a second advanced practice provider to staff the acute-care service at a second location.

Before launching the clinic, the practice conducted a six-month pilot, demonstrating sufficient patient demand and satisfaction with the service to justify the cost.

"This was an example of a practice transformation—of how this practice took information and made a dramatic change in the clinic," says Sibel Blau, MD, medical director, hematology and oncology divisions at the 10-physician practice. The overall goal, she says, is to position the practice for success under value-based reimbursement models.

Northwest Medical Specialties is not alone. As value-based payment arrangements become more common, community cancer providers are installing data-analysis tools to help them figure out how to meet cost and quality targets. Payers and providers are focusing on improving the quality and efficiency of cancer care because of the disease’s prevalence and treatment costs. The American Cancer Society projects that there will be more than 1.7 million new cancer cases and 606,880 cancer deaths in the United States in 2019.

The costs to treat those patients keep rising. The National Institutes of Health estimates that the United States will spend at least $158 billion on cancer care in 2020, a 27% increase over expenditures in 2010.

Because a significant proportion of those patients are Medicare beneficiaries, CMS developed a five-year pilot project, the Oncology Care Model (OCM), which began on July 1, 2016. Nearly 200 physician groups and 17 commercial payers are participating in the program, according to CMS.

CMS reimburses providers based on their performance during six-month episodes of care for chemotherapy treatment using either a one-sided or a two-sided risk model.

West Palm Beach, Florida-based Integra Connect, which develops information technology solutions for healthcare providers, has tracked the performance of its customers involved in the OCM program, which totals about 16 practices and 1,000 oncologists. "What we see is a steady improvement," says Charles Saunders, MD, CEO, Integra Connect. With each successive performance period, more of the practices have kept their actual costs of care under the target cost set by CMS, he says.

Nonetheless, Saunders says some of his clients did not earn a bonus payment during any of four performance periods, ending with the first half of 2018. Those practices would have decided by December 2019 whether to accept two-sided risk, or drop out of the program.

In cancer care, the largest buckets of costs are chemotherapy and other medications; facility services, such as hospitals and skilled nursing facilities; and care at the end of life, says Saunders, who regularly writes...
and speaks about value-based cancer treatment. CMS isn’t the only payer applying value-based care models to cancer treatment. In April, Humana announced its value-based program for oncology in which it will reward oncology practices for exceeding quality and cost benchmarks over a one-year period.

Like Northwest Medical Specialties, Texas Oncology—a large cancer treatment and research provider in Texas specializing in hematology, pediatric and radiation oncology, which also participates in CMS’ OCM—has worked to decrease rates of hospital admissions and emergency department visits.

For example, the oncology practice analyzed data on telephone calls and response times for patients reporting acute medical issues. What Texas Oncology learned was that when patients called, they usually left a voicemail but often for the wrong department. The inefficient approach made it difficult for staff to return calls quickly.

Call back times are “a huge barrier,” says Lalan Wilfong, MD, executive vice president of value-based care and quality programs, Texas Oncology. If patients don’t receive a timely return call, they go the emergency department for help, he says.

To solve the problem, Texas Oncology, with more than 460 physicians and 210 locations, is in the midst of implementing an electronic triage platform from Navigating Care.

This is how the new process works: When a patient calls, a locally based operator working with an electronic dashboard determines which department should respond to the call. If it is a nursing issue, the operator asks targeted questions to triage the patient. “Somebody who calls in with a fever of 102 [degrees] is a higher risk than somebody who calls in because his or her toe hurts,” Wilfong says.

When dedicated triage nurses return calls, they also have access to the pre-screened patient information on an electronic dashboard, Wilfong says. Because the tool is electronic, nursing managers monitor the dashboards, and assign additional staff to return calls on unusually busy days, he adds.

The objectives of the electronic triage program are straightforward: A “live person” answers the calls. When the call involves an acute medical issue, triage nurses call the patient back within 30 minutes, Wilfong says.

In addition to improving acute symptom management, oncology practices nationally are also using data analytics to improve their care coordination programs.

Northwest Medical Specialties uses a machine learning–enabled tool from Jvion to risk stratify patients. The tool produces lists of patients at risk of clinical deterioration on seven vectors, including 30-day mortality and avoidable hospital admissions. The tool also details the clinical and non-clinical factors driving the risk and recommended actions to mitigate the risk.

By feeding data from its electronic health record into the tool, Northwest Medical Specialties gets a daily list of patients who score high on at least five of the seven vectors. A care coordinator works with those patients to schedule the appropriate services, such as evaluation and treatment for pain, distress, or depression; completing advance directives; or referral to hospice care.

By risk stratifying patients and acting on the information, Northwest Medical Specialties has increased referrals for palliative and hospice care by 81%, depression screenings by 68%, and case management evaluations by 80%.

In addition to heading off adverse events before they occur, it’s also important to quickly find out when patients visit an emergency department or are admitted to a hospital or skilled nursing facility.

To gain reliable access to that type of information, Regional Cancer Care Associates recently implemented software from PatientPing, which electronically notifies the 34-location cancer provider when one of its patients receives care outside of its facilities in New Jersey, Maryland, and Connecticut.

Using the software, staff at Regional Cancer Care Associates can also drill down to find out “the working diagnosis” for each of its patients, says Lani Alison, vice president, clinical affairs, Regional Cancer Care Associates.

The tool also allows Alison to look for opportunities to improve performance by analyzing aggregated data, such as how often a patient has been admitted to a hospital or how many of a doctor’s patients have been hospitalized.

Before implementing PatientPing, gaining access to such timely data was haphazard, manually driven, and didn’t lend itself to data analytics. As Alison says, “It was clunky.”
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