Special Report: Improve the Patient Experience

Industry Disruptors

Prepare your business for these five game changers

AND

LEGISLATION TO WATCH

PLUS

TECHNOLOGY FOR CHRONIC PAIN

October 2018  VOL. 28  NO. 10
You know something called H.R. 1628 Section 12 might change everything.

No one knows your business better than you. And with how quickly healthcare changes, you also know that you have to evolve with it. MB’s expanded healthcare team is here to offer your business creative ideas on how to stay on top of changing healthcare regulations and technology to better help the people you care for.

MB Financial Bank
Disruption is the one true constant in healthcare.

In the managed care market, words like logical, predictable, or stable are seldom used. Instead, disruption is the norm. The usual change drivers, such as an aging population dealing with more chronic illnesses coupled with other disrupters make it even more difficult to find the right course. These disruptors include:

**Chaos at the federal level**
While the federal government has long been a disruptive force in healthcare, this has generally been related to new policies, programs, or approaches. We’ve entered an era with no clear federal policy except eliminating and destabilizing previous approaches such as the ACA.

**State-level innovations**
Due to the lack federal direction on healthcare, some states are considering new approaches to cover their residents, including Medicaid buy-in programs and even Medicaid for all. Others are evaluating moving from Medicaid capitation to fee-for-service, increasing emphasis on value-based contracts, and expanding their focus on quality and outcomes.

Many new states are pursuing Medicaid expansion. This includes work and other requirements that force health plans into roles beyond their expertise.

**Social determinants of health**
The awareness that a person’s social conditions has a greater impact on their health than their genetics has emerged as a significant driver for how health plans approach member services. Lack of food security, housing, transportation, or a safe environment are enormous contributors to preventable morbidity and mortality and are beginning to be incorporated into care plans and health plans’ outreach efforts and community initiatives. Insurers are forging new partnerships with community partners to ensure access to these services.

**Precision medicine**
This rapidly emerging approach to treating disease considers individual genetic, environmental, and lifestyle variability and is reshaping how many medical conditions are treated. While usually more effective than previous approaches, precision medicine is often more expensive and has fewer provider network options. While many health plans aren’t covering precision medicine, clinical studies demonstrating effectiveness will push consumer demand for its coverage.

**Entrance of eBusiness**
With Amazon’s announcement of its intent to purchase PillPack and its partnership with JP Morgan Chase and Berkshire Hathaway to establish a disruptive new healthcare enterprise, Jeff Bezos is clearly eyeing healthcare as a market open to business opportunities. Apple and Google also have investments in healthcare initiatives. Even unintentionally, ebusiness is disrupting healthcare as demonstrated by Uber’s impact on reducing traditional ambulance services.

**Why so much disruption?**
At $3.5 trillion, the healthcare industry comprises 21% of the U.S. economy. Despite investing far more in Americans’ healthcare than any other country does, the United States delivers poor results in terms of affordability, quality, access, and outcomes. Until there’s a balance between the dollars invested in healthcare and the results obtained, significant changes in products, strategies, competitors, and federal and state regulation will continue. Disruption is not going away, it will only become more frequent and rapid.

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THERE’S EYLEA—a treatment option that can fit your plans for proven visual acuity outcomes

- EYLEA has proven outcomes as demonstrated in phase 3 clinical trials in patients with Wet AMD, Macular Edema following RVO, DME, and DR in patients with DME
- With monthly and every-other-month dosing, EYLEA offers flexible dosing options to meet the needs of your providers and your members

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS
- EYLEA® (aflibercept) Injection is indicated for the treatment of patients with Neovascular (Wet) Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR) in Patients with DME.

CONTRAINDICATIONS
- EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WARNINGS AND PRECAUTIONS
- Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including EYLEA. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with EYLEA. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with EYLEA compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with EYLEA compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with EYLEA in the first six months of the RVO studies.

ADVERSE REACTIONS
- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with EYLEA including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous floaters, intraocular pressure increased, and vitreous detachment.

*The FDA-approved indications for EYLEA are Wet AMD, Macular Edema following RVO, DME, and DR in Patients with DME.
†After an initial monthly dosing period for certain indications.


Please see brief summary of full Prescribing Information on the following page.

EYLEA® (aflibercept) Injection
For Intravitreal Injection

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2.7 Preparation for Administration. EYLEA® (aflibercept) Injection should be inspected visually prior to administration. If particulates, cloudiness, or discoloration are visible, the vial must not be used. Using aseptic technique, the intravitreal injection site should be cleaned with an alcohol pad, and the vial should be opened with a clean needle. After injection, any unused product must be discarded.

3 Dose Forms and Strengths. Single-use, glass vial designed to provide 0.05 mL of 40 mg/mL solution (2 mg) for intravitreal injection.

4 Contraindications. EYLEA® (aflibercept) Injection is contraindicated in patients with:

- Ocular or periocular infections
- Active intraocular inflammation
- Known hypersensitivity to aflibercept or any of the excipients in EYLEA. Hypersensitivity reactions may manifest as severe intraocular inflammation.

5 Warnings and Precautions. 5.1 Endothelial and Retinal Detachments. Intravitreal injections, including those with EYLEA, have been associated with endothelial detachments and retinal detachments (see Adverse Reactions). Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed in proper aseptic techniques and suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately (see Dosage and Administration and Patient Counseling Information).

5.2 Increase in Intraocular Pressure. Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA (see Adverse Reactions). Sustained increases in intraocular pressure have been observed in patients administered intravitreal doses with vascular endothelial growth factor (VEGF) inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately (see Dosage and Administration).
The success of performance-based retail pharmacy networks for Medicare Part D is prompting some PBMs to create similar ones for their commercial and Medicaid populations. Incentives for pharmacies that demonstrate improvement in medication adherence for certain conditions and increased engagement are at the core.

“These networks need to strike the right balance between cost and safety and can run the gamut of pay-for-performance to shared savings to risk-bearing models based on patient outcomes,” says Crystal Lennartz, vice president, pharmacy performance for Health Mart Atlas, a pharmacy services administrative organization (PSAO) under the McKesson umbrella.

Lennartz attributes these networks to the advent of preferred benefit structures, with performance and more dollars tied to contracts to improve health and reduce overall costs.

She says the trend began in 2016, when PBMs introduced variable direct and indirect remuneration (DIR) fee rates (e.g., based on a percentage instead of a flat dollar fee), in which pharmacies and PSAOs could achieve a lowered DIR amount if they met performance metrics.

Lennartz indicates that DIR makes performance-based networks in Medicare more punitive than in other populations. “A pharmacy could lose money when processing a claim through Part D, which is often correlated with arbitrary performance measures,” she says.

In 2018, all of Health Mart Atlas’ more than 6,800 pharmacies are in some type of performance-based network, including DIR designs. Lennartz says 2,000 of its pharmacies are eligible to participate in the true incremental, pay-for-performance programs across 47 states—nearly doubling over 2017. Total dollars committed to the program also have nearly doubled since last year.

Express Scripts launches Medicaid networks
Express Scripts is using its experience with value-based contracting in Medicare in 2017, and extending it to Medicaid and commercial populations. “We focused on Medicare initially because of Star Ratings and because our clients wanted solutions with pharmacy at the center,” says Jennifer Awsumb, senior director, network products.

Awsumb says that the PBM deliberately chose only three metrics for the pilot and five for the 2019 network because pharmacies indicated that too many measures could become overwhelming.

Retailers in the network pilot
and in the 2019 network will compete against each other, incentivizing them to continuously improve their performance through relative assessment, rather than pre-defined benchmarks. The lowest performers will be penalized, but not based on a benchmark.

**Prime Therapeutics focuses on quality**
Prime Therapeutics is seeing growth in adoption of performance-based networks by health plan clients and pharmacies who are looking to differentiate their plans, says Bretta Grinsteinner, assistant vice president, network management.

Prime has 11 health plans using performance-based networks for Medicare related to disease-specific conditions and specialty drugs. Like Express Scripts, the PBM also is expanding its system infrastructure to support commercial and Medicaid plans.

Prime’s quality program in Medicare uses metrics appropriate for the line of business and/or goals of each health plan, including measures such as adherence to oral diabetes, hypertension, autoimmune, and cholesterol medications; statin use in individuals with diabetes; high-risk medication dispensing; generic dispensing; and comprehensive medication review completion rates, says Grinsteinner.

**In Prime’s Medicare book of business from 2015 to 2017, adherence for performance-based network pharmacies improved by 3.7%, nearly twice as much as the non-performance-based network pharmacies, whose improvement increased by 1.9%.**

The PBM plans to add adherence to anti-retroviral medications and statin use in individuals with cardiovascular disease, along with building quality programs around HIV, specialty multiple sclerosis, and autoimmune diseases including rheumatoid arthritis.

Pharmacies are measured at the individual pharmacy location on a year-to-date score with three measurement periods and receive a performance rating on a scale of one to five for each measurement period. Performance in the higher two tiers earns incentives.

Pharmacies that receive a rating in the middle tier can earn incentives if there has been improvement over the course of the year. Prime meets monthly with pharmacies and clients to review performance ratings and identify pharmacies/measure that need attention.

Grinsteinner anticipates that performance networks will reduce hospitalizations and emergency visits, thus saving money.

**CVS Health follows suit**
In fall 2017, CVS Health initiated a new 30,000 store, performance-based, pharmacy network anchored by CVS Pharmacy and Walgreens, along with up to 10,000 community-based, independently owned pharmacies across the country. The network is designed to improve clinical outcomes and help lower costs for CVS Caremark PBM clients and their plan members, according to CVS spokesperson Christina Beckerman.

The performance network uses a value-based management approach to achieve improved outcomes through medication adherence for diabetes, hypertension, respiratory conditions, depression, and behavioral health. It also helps to provide cost savings through formulary compliance.

Savings will vary, but clients moving from a national network can expect to save up to 4% in gross pharmacy spending, Beckerman says. Pharmacies are encouraged to implement their own proprietary programs and work flow processes to achieve results, such as encouraging members to take their medications as instructed, improving overall health, and lowering costs for patients and payers, not just dispensing medication.

“Across healthcare, we are seeing a shift away from fee-for-service to more value-based reimbursement and payment models,” Beckerman says. “In pharmacy care, we expect network design options that align incentives and outcomes to also grow as payers look for new ways to help contain costs and drive better health outcomes for their member populations.”

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

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**Performance-based network challenges**
Nathan Ray, senior manager, West Monroe Healthcare Partners’ healthcare practice, says one of the biggest challenges is ensuring expansion across all pharmacies instead of using narrow networks.

Lack of standardization of metrics and transparency are on Lennartz’ list of challenges. “Pharmacies are not always aware of which patients are filling or refilling their medications because they are not receiving sufficient information from payers and PBMs,” she says.

Health Mart Atlas uses EQuIPP, a performance information management platform that provides dashboards that report scores and relevant benchmarks across the same key quality measures. Lennartz says the platform also supports multi-tier views of a pharmacy organization’s performance.
It’s not easy to retain talented millennials. By the time they hit age 35, 25% of these professionals will have five or more jobs, according to a 2014 CareerBuilder survey. What if your organization could not only create a plan to retain more millennials, but could hook them before they even graduate from school? That’s what Bon Secours Health System, a nonprofit Catholic health system with 19 acute-care hospitals and other facilities, is doing. Since 2003, the Marriottsville, Maryland-based health system has recruited graduate students from 20 colleges across the country in masters’ programs in health administration, business administration, and public health. Graduate students from these universities participate in the health system’s one-year administrative residency, and recent graduates participate in its fellowship program.

“I really got a unique opportunity to see how strategy is formed and then how it’s disseminated to local markets.”

SHEFALI CHUDGAR, BON SECOURS ST. FRANCIS

The goal is to build a good pipeline for leadership talent and increase diversity, says Stephanie Davidson, director of talent strategy and development.

Firsthand experience
Shefali Chudgar, director of performance management at Bon Secours St. Francis in Greenville, South Carolina, started working at the health system as an intern during her MHA program at Virginia Commonwealth University in 2008. She was a 2011 to 2012 participant in the residency program. Chudgar’s co-preceptors were Richard Statuto, president and CEO, and Timothy Davis, executive vice president and chief administrative officer. During her residency, she attended executive meetings and board meetings and traveled with Davis. She also performed project management and analysis for various initiatives.

“There was a lot of exposure, which was fantastic,” says Chudgar. “You usually don’t get that kind of exposure, definitely not at the corporate level … I really got a unique opportunity to see how strategy is formed and then how it’s disseminated to local markets.”

Chudgar now serves as a buddy to the resident or fellow assigned to her hospital.

Program results

- Bon Secours Health System doesn’t guarantee jobs to residents and fellows, but typically seven out of eight participants receive a job offer; most of those who receive a job offer accept it.
- Retention of residents and fellows is 80% for their first three years out of the program, says Davidson. At the three- to five-year mark, the retention rate is 63%.
- The program, which has included 65 participants since its start, last year received approximately 80 applications for eight roles.

Aine Cryts is a writer based in Boston.
Over the next five years, industry experts predict big changes that will significantly impact managed care. These range from state governments getting more involved in healthcare to more online retailers throwing their hat in the healthcare ring.

“As industries continue to blur, traditional healthcare companies will need to break down silos to drive value across the industry ecosystem,” says David Friend, MD, MBA, chief transformation officer and managing director, The BDO Center for Healthcare Excellence and Innovation, a healthcare accounting and consulting firm. “To compete with disruptors, healthcare companies will need to capitalize on data, maximize profitability, and innovate patient care all while managing growing risk in the areas of patient privacy and data security.”

It’s a daunting challenge, but preparation can help ensure success. Here are some of the biggest areas of disruption that could impact your organization.

**ONLINE RETAILERS**

This year a flurry of discussions and deal-making occurred between retailers and healthcare organizations, Friend says. This includes:

- Walmart’s reported early-stage talks to acquire Humana;
- The Amazon, JPMorgan, and Berkshire Hathaway venture that aims to transform its employees’ healthcare; and most recently,
- Amazon’s billion-dollar acquisition of online pharmacy PillPack.

Other companies disrupting healthcare include big retail pharmacy chains such as Walgreens and CVS, which are combining stores and walk-in clinics with e-commerce systems to create new digital healthcare delivery platforms.
says Kim A. Buckey, vice president, Client Services, DirectPath, LLC, which helps employees navigate healthcare. For example, Walgreens partnered with MDLive in 2015 to facilitate telemedicine offerings to consumers.

Health-specific retailers that have entered the space, such as FSASStore.com and healthwarehouse.com, offer price transparency and product delivery to consumers who are price-sensitive, Buckey says.

Another notable entrant is large employers that are working alongside or acquiring emerging health and wellness companies, Buckey says. UnderArmour, for instance, has invested heavily in wearable devices and, with the acquisition of companies such as MapMyFitness and MyFitnessPal, has become the major player in digital fitness. Under the umbrella of its Connected Fitness segment, UnderArmour has access to tremendous amounts of health data.

Traditional technology entities are building healthcare apps, wearables, and other connected devices, and consumers are using them to track their health progress and feed data back to their provider, payer, or both, says Friend. “Technology has brought healthcare to consumers' fingertips, putting them at the nucleus of care and blurring the definition of a healthcare organization.”

Retailers are partnering with pharmacies, to share data and reach more consumers, he adds. Insurers are partnering with pharmaceutical manufacturers to leverage patient data to improve outcomes and lower health costs. "Everyone is getting into everyone’s business and will continue to do so to provide improved patient outcomes and ensure survival in a consumer-centric industry."

The most valuable resource in healthcare is data, which online retailers—with their growing consumer health and wellness products—have in spades, says Friend. "Access to data and the ability to capitalize on that data is key to developing consumer-centric models of care, improving patient outcomes, and lowering costs."

Online retailers like Amazon are entering the healthcare industry on other fronts, Buckey says. For example, they are selling personal health equipment such as walkers directly to consumers and medical supplies such as gloves to providers. "We’ve already seen a shift away from brick-and-mortar stores in other sectors; it was only a matter of time before we saw something similar with healthcare,” Buckey says. “Healthcare services and supplies are just as much a commodity as electronics, clothing, or even cars. With more purchasing power leaning toward consumers, it’s no surprise to see them opting for more convenient options when shopping for the healthcare treatments, services, and products they need.”

PERSONALIZED, TARGETED THERAPIES

A new treatment, called immune effector cell therapy, allows physicians to harvest a patient’s T cells (a type of white blood cell), re-engineer them to target cancer cells by equipping them with receptors—proteins placed on the surface of T cells that allow them to bind more effectively to cancer cells—and then reintroduce them into that patient’s immune system, says Richard R. Barakat, MD, MBA, physician-in-chief and director of cancer, Northwell Cancer Institute. The institute is part of Northwell Health in Lake Success, New York, which is the state’s largest healthcare provider and private employer and treats 2 million patients annually. The engineered cells multiply in the patient’s body and recognize and kill cancer cells that harbor the receptor.

The most advanced therapy in clinical development in this space is chimeric antigen receptor T-cell (CAR T-cell) therapy. The FDA has approved two of these therapies:

1. **Yescarta (axicabtagene ciloleucel)** is approved for patients with refractory diffuse large B-cell lymphoma.

2. **Kymriah (tisagenlecleucel)** is approved to treat acute lymphoblastic leukemia in patients under age 25 years.

“These two treatments target small populations who have limited to no further treatment options, but [the treatments] pose challenges to the U.S. healthcare system due to their high up-front costs, uncertainty of effectiveness, and po-
tential adverse events,” says Brian Duffant, vice president, BluePath Solutions, a market access and health outcomes consulting firm.

CAR T-cell therapy is intended to be delivered as a one-time treatment. The cost of therapy for Yescarta (with a wholesale acquisition cost of $373,000—the list price set by the manufacturer) and Kymriah ($475,000) is front-loaded. “This may result in short-term budget impact challenges, which are particularly acute for smaller payers and employers,” Duffant says.

“The current U.S. healthcare system doesn’t have existing infrastructure for this type of cost dynamic, and will require innovative solutions such as payment over time, risk-share agreements, and indication-specific pricing.”

Although expensive, Amit Kumar, PhD, CEO and president, ITUS Corp., a cancer diagnostics and therapy company and board member of the American Cancer Society, says the overall impact of CAR T-cell therapies to the healthcare system is modest right now due to the small number of conditions it can treat. “Payers, including Medicare, are already working with providers and therapy developers to evaluate and institute new models for reimbursement,” he says. For example, CAR T-cell therapies may not be reimbursed unless there is an objective measure of efficacy.

Barakat says some payers already have policies for these two treatments. “Inpatient costs will likely be bundled into the total cost of the hospital stay,” he says. “While many institutions will likely launch their CAR T therapies in an inpatient setting due to the potential of significant toxicities … these therapies could possibly be performed in an outpatient setting as a pretreatment with an interleukin-6 (IL-6) receptor blockade—which could potentially result in less toxicity.”

SOCIAL DETERMINANTS OF HEALTH

Social determinants include economic stability, education, health and healthcare, neighborhood and built environment, and social and community context, according to Healthy People 2020, which provides 10-year national objectives for improving Americans’ health.

“These are the conditions in which people are born, grow, live, work, and age, as well as the circumstances that impact their health,” says Lori Tremmel Freeman, MBA, CEO, National Association of County and City Health Officials, which advocates for local health departments. “Social determinants of health undergird many current healthcare challenges, including obesity, heart disease, diabetes, and depression.”

While genetics plays a role in an individual’s overall health, most health outcomes are the result of circumstances outside the healthcare system. “The conditions in which someone lives, whether they have transportation to a clinic when needed, their support network, and other factors beyond the doctor’s office are as important to an individual’s overall health and well-being as being treated for an illness,” says Joseph Valenti, MD, board member, The Physicians Foundation, an organization that seeks to help physicians deliver high-quality care. “As the healthcare system effectively addresses these issues, the overall price of healthcare in the United States will decrease and people will generally be healthier.”

Some states, insurers, and hospitals are already factoring social determinants into healthcare by doing things like ensuring patients have adequate housing and access to needed resources and programs.

Freeman says more attention to social determinants would provide a more balanced approach to health. From a public health perspective, she says healthcare can be categorized as:

1/ Primary, focused on disease prevention;
2/ Secondary, treating disease in the early stages; or
3/ Tertiary, treating the effects of a disease or illness.

Primary, secondary, and tertiary care can be targeted at the individual, interpersonal, organizational, community, or public policy level, Freeman says. Naloxone, a medication designed to rapidly reverse opioid overdose, for example, is tertiary care at an individual level. On the oth-
er hand, given that unemployment is thought to contribute to patterns of opioid use, a strategy of increasing job opportunities becomes primary care at a community level.

Social determinants of health could impact how the healthcare industry conducts business. Instead of concentrating on tertiary care only, healthcare could participate more in community health, Freeman says. Eventually, as social determinants of health become a greater part of the healthcare portfolio, tertiary care spending would decrease while quality of life would increase for affected communities.

In many places, this has already begun, as hospitals and health insurers work with local health departments around community health concerns, she says. By law, providing community benefit has been central to the tax-exempt status of nonprofit hospitals. The ACA’s explicit requirement for nonprofit hospitals to consider input from those with public health expertise in the development of hospital community health needs assessment and implementation strategies has increased local collaborations around social determinants of health.

ARTIFICIAL INTELLIGENCE (AI)
As more electronic health data becomes available, AI can help ensure it is used to improve healthcare. “No more will ‘doctor knows best’ be sufficient,” says Jodi Daniel, a partner in Crowell & Moring’s Healthcare Group and a member of the firm’s Digital Transformation Practice. “Clinicians will need to apply their training and experience along with data and sophisticated systems that can identify new information that may not have been available or transparent before. This could lead to significant improvements in diagnosis and treatment and create efficiencies for provider and patient interactions and administrative functions.”

Daniel says AI applications include:

- **Population health management**, in which AI software can help clinicians and insurers better identify and prioritize patients.

- **Diagnostics**, in which AI is assisting with diagnoses. For example, this year, the FDA approved AI-based tools for detecting wrist fractures and diabetic retinopathy in patients, decreasing time from onset to treatment.

- **Patient care**, in which AI can help determine the best treatment approach. In February, for example, the FDA-approved clinical decision support software that uses AI algorithms to analyze images for indicators associated with a stroke.

AI health market growth is expected to reach $6.6 billion by 2021—a compound annual growth rate of 40%, according to Accenture. Trends driving that growth include:

1. **The continued increase in costs.** “Value-based payment requires that clinicians have actionable data to manage patients and that health plans have data and tools to evaluate performance and health outcomes,” says Daniel.

2. **Concerns regarding physician burnout and medical labor shortages.** “AI software can reduce the burden of providers when doing documentation and data management, and AI tools can help triage patients so that physician time is available to patients with the greatest need,” Daniel says.

3. **Technology advancements across all industries have increased patient expectations in their healthcare interactions.** “There will be a growing need for the healthcare sector to adopt AI technology to streamline services and to improve quality of those services,” Daniel says.

4. **A thirst for improving treatments and research.** “AI will be an important tool for analyzing vast amounts of data to develop future treatments,” she says.

Ultimately, Daniel says the single-most significant potential for AI is its power to change the standards of practice. “Better analytical tools for improved diagnosis and treatment and more data from outside the clinical care setting such as patient-generated health data and social determinants data can provide a more accurate picture of the patient and improve care decisions and outcomes,” she says.

STATE GOVERNMENT INTERVENTIONS
State governments have been operating the Medicaid program, which has become a fundamental driver of U.S. healthcare policy and service delivery, since 1965. Medicaid now covers 74 million people, including paying for more than half of the country’s births and more than 65% of nursing home residents.

Thirty three states and the District of Columbia have expanded Medicaid to cover childless adults under the ACA. Legislation introduced
by U.S. Sen. Brian Schatz (D-Hawaii) and U.S. Rep. Ben Ray Luján (D-New Mexico 3rd District) in October 2017 titled the State Public Option Act, would create a Medicaid-based public healthcare option on the insurance marketplace. Since then several states, including Nevada, Iowa, Massachusetts, Minnesota, Missouri, New Jersey, and Washington, have introduced Medicaid buy-in proposals to cover more uninsured or underinsured individuals, says Pamela Coleman, senior consultant, Sellers Dorsey, a national healthcare consultancy.

Having worked with the Medicaid program since the mid-1980s, Coleman has seen it evolve from one where states passively paid claims to one where the emphasis is on paying for positive healthcare outcomes. “The majority of states have implemented managed care models where health plans are put at risk for poor patient outcomes,” she says. “Performance measurement and continuous quality improvement are central to these models. Many healthcare delivery innovations have come from state Medicaid programs.”

Because states must balance their budgets, unlike the federal government, they must innovate to ensure their programs are sustainable and produce results for their Medicaid population, Coleman says. “In order to innovate, state policymakers must disrupt the status quo and develop and implement new ways to finance their Medicaid programs, reimburse providers by paying for value, not volume, and work with health plans to ensure providers are available to deliver healthcare services throughout a state.”

Given the current political climate, Coleman views Medicaid for All as more attainable than the Medicare for All proposal. Medicaid for All proposes the option for individuals to buy into Medicaid coverage and be eligible for premium subsidies and reduced cost sharing. In contrast, Medicare for All, as proposed by U.S. Sen. Bernie Sanders (Vermont), would create a national insurance system for single-payer coverage for all U.S. citizens.

A recent analysis by The Mercatus Center estimated that this proposal would lead to a $32.6 trillion increase in federal spending over a 10-year period. A Medicaid for All buy-in program would likely cost the federal government much less, says Coleman.

Also, unlike Medicare, states administer Medicaid, which covers populations from newborns to frail seniors and includes many individuals with mental health conditions and substance abuse disorders.

“Medicaid is leading the fight on the opioid epidemic by requiring health plans to develop innovative interventions to address problems at the community level,” Coleman says. “Medicaid initiatives that focus on social determinants of health such as housing, nutrition, obesity, and education are also expanding.”

As the ultimate safety net provider, Medicaid faces continuous challenges to provide quality services to beneficiaries while keeping costs down. New flexibilities offered through managed care models and waivers allow for payment of such things as minor home modifications for persons with disabilities, air conditioners for persons with asthma, and supportive employment for persons with intellectual disabilities. “These interventions are far more cost effective than traditional healthcare services and promote personal independence,” Coleman says.

In order to receive federal funding, states must provide a core set of services and beneficiary coverage. To manage these expenditures, states have developed creative solutions to reform healthcare service delivery, such as accountable care systems and value-based payment models. “These transformations can be truly disruptive as Medicaid will no longer pay providers on the basis of volume, but rather on the basis of value,” Coleman says.

Whether states adopt Medicaid for All strategies, they will continue to reform Medicaid practices to promote quality and cost-effective delivery, she says. “Large national Medicaid managed care organizations are agreeing to enhanced performance requirements and states are enacting more sophisticated and comprehensive oversight of managed care contracts.”

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Although the ACA is still the law of the land—despite being somewhat dismantled, other healthcare policies continue to take shape and are being implemented. Here, healthcare experts detail three policies that MCOs will want to keep a close eye on.

**Short-term Limited Duration Coverage Final Rule**

*What it is:* The Department of Health and Human Services, Labor, and Treasury issued a final rule that lengthens the time period that short-term, limited-duration health plans can remain effective from three months to three years. The August 1 ruling was developed in response to an executive order by President Trump in October 2017 that directed the federal government to expand access to short-term plans, association health plans, and health reimbursement arrangements, says Susan Feigin Harris, JD, partner at the law firm Morgan Lewis.

*Short-term plans are intended to fill gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another one, such as being in between jobs or needing coverage outside of an enrollment period, Feigin Harris says. These plans are exempt from federal market requirements that are applicable to health insurance sold on the exchange, because they aren’t considered health insurance.*

*Status:* Although some states requested a delay in implementation to allow them to put certain protections in place, "CMS appears to have ignored this request, as the rule becomes effective 60 days after publication in the Federal Register," Feigin Harris says.

*Potential implications:* As a result of the final rule, short-term, limited-duration health plans can now be offered for 12 months at a time with renewals that do not exceed 36 months. "Short-term issuers can charge higher premiums based on health status, exclude coverage for pre-existing conditions, or emergency room care, impose lifetime or annual caps, opt not to cover certain conditions and benefits, rescind coverage, and require higher out-of-pocket costs," says Feigin Harris.

With the expansion of short-term, limited duration coverage, Feigin Harris predicts a higher incidence of consumer confusion over what type of coverage they are purchasing and a fear by industry providers that patients who think they have coverage may not be aware of growing limitations in coverage and payment obligations.

"There will likely be a higher incidence of uninsured and underinsured individuals, as well as bad debt in obtaining and paying for healthcare coverage, especially emergency coverage."  

*SUSAN FEIGIN HARRIS, MORGAN LEWIS LAW FIRM*
expensive to provide health insurance on the market if young, healthy individuals abandon the market in favor of short-term limited duration plans due solely to cost. “With sicker patients who need access to the full protections afforded by insurance sold on the exchange, costs will rise, leading to what some economists have termed the ‘death spiral’ in insurance rates,” she says.

**Telehealth Coverage Proposal**

**What it is:** CMS issued an annual proposed Physician Fee Schedule on July 12 that included expanding telehealth options using communication technology.

Specifically, CMS recommended new billing codes to permit physicians to conduct virtual check-ins (i.e., brief phone or video calls) to assess whether an in-person visit is required and use asynchronous “store and forward” communications—in which patients upload basic medical history and clinical information via pictures or videos on a web-based platform, says Joyce Cowan, JD, a partner at Morgan Lewis.

The proposal is CMS’s first major foray into expanding telehealth services since the 2008 Medicare Improvements for Patients and Providers Act. “In the past decade, both providers and consumers have clamored for greater access to telehealth services,” Jacob Harper, JD, an associate at Morgan Lewis, adds. “States and insurers have recognized the value of expanding telehealth access and coverage, however, CMS has been limited by its existing statutory structure that covers (and pays for) telehealth services only when a patient is in an originating site that is located in a county outside a metropolitan statistical area or in a rural health professional shortage area.” Because of the existing statute that CMS must follow, it cannot alter the current telehealth requirements. Instead, it is creating a new category of telehealth-like services that it posits don’t fall under that statutory restriction.

“Although all states don’t permit this technology, CMS’s blessing will likely compel universal adoption of this technology everywhere.”

**Status:** The Final Rule will likely come out in late October or early November, Cowan says.

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**What is the biggest leadership challenge healthcare executives face?**

**58.0%** Navigating a changing environment (value-based care, policy changes, new government mandates, population health management).

**19.0%** Lack of resources (time, money, staff) to accomplish what they need to accomplish.

**16.0%** Dealing with unreasonable expectations (from their own organization or outside entities such as the government or payers or other partners).

**2.0%** Difficulty securing buy-in for initiatives from staff and other leadership.

**5.0%** Other

Source: Managed Healthcare Executive’s 2018 State of the Industry Survey. Full survey findings will be released in December.
Potential implications: "If adopted, CMS anticipates that these new services will incentivize physicians, particularly those monitoring established patients with chronic conditions, to treat patients without having an office visit," Cowan says. "Many managed care organizations have recognized that telehealth helps avoid unnecessary in-person services."

If a doctor thinks a complaint during a virtual check-in is serious enough to warrant an in-person visit, the patient is scheduled for an appointment and the virtual encounter is bundled into the in-person emergency and management code. However, if the physician can address the patient's needs virtually, the provider would receive separate, albeit much lower, payment.

"Although all states don’t permit this technology, CMS’s blessing will likely compel universal adoption of this technology everywhere," says Harper. “These technologies enable doctors to provide primary care services in a highly cost-effective manner.”

**Hospital Safety Reporting Ruling**

**What it is:** In May, CMS announced that it would no longer report 18 key quality and patient-safety indicators, such as hospital-acquired infections, to the Hospital Inpatient Quality Reporting Program (IQR). “This was concerning to payers and consumer groups, because it would limit transparency in hospital operations and make it more difficult for them to make informed judgments about the quality of services offered at hospitals,” says Robert H. Iseman, Esq, partner at the law firm Rivkin Radler LLP. The reports had been made to IQR since the George W. Bush administration.

But those concerns were dissipated when CMS announced on August 2 that the same information will be made available through Hospital Compare, a website developed by the Medicare program in conjunction with consumer advocates, Iseman says.

**Status:** CMS delayed implementing the rule until August 2019 in order to put the new public reporting procedures in place. "CMS attempted to save hospitals the cost of duplicate reporting by no longer requiring the subject metrics and reports to be made as part of IQR, while ensuring transparency by making the information publicly available elsewhere," Iseman says.

**Potential implications:** Leah Binder, MA, MGA, president and CEO, The Leapfrog Group, which promotes transparency of patient safety and healthcare quality data for consumers, payers, and purchasers, says CMS will also include these patient safety and infection measures in its Value-Based Purchasing (VBP) Program as well as the Hospital-Acquired Condition (HAC) Reduction Program. “This means hospitals will continue to receive payment incentives for these measures in both programs established under the ACA,” Binder says.

The new regulations preserve risk-adjusted infection rates and patient safety indicators that are not replicable by individual payouts, so CMS’ requirement to report them is a critical tool for payers, Binder says.

According to a CMS spokesperson, “It is important for all Hospital Compare users, including payers, to know that they will see no difference in the publicly reported data for these measures when they are removed from the Hospital IQR program and remain solely in the HAC Reduction Program and VBP.”

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

**“CMS attempted to save hospitals the cost of duplicate reporting by no longer requiring the subject metrics and reports to be made as part of IQR, while ensuring transparency by making the information publicly available elsewhere.”**

ROBERT H. ISEMAN, RIVKIN RADLER LLP
Ten Easy-to-Use Apps
These must-have apps for health execs will take only seconds to learn to use.

by AUBREY WESTGATE

1 **ColorNote**
Recently identified as the #1 app for business executives by the *Application Resource Center*—a publication dedicated to providing expert analysis, information, and research on the app economy—this app allows users to take notes and send them, password-protect them, color code them (for example, use different colors for personal notes vs. work notes), and set reminders so that notes appear on the user’s home screen at certain times. Users can also use the app to create checklists, and add notes and checklists to their phone’s home screen so they can access them quickly.

2 **Evernote**
If you’re looking for a bit more of a complex note-taking option with more features, check out Evernote. This app that ranges from free for a basic plan to $69.99 per year for a premium plan helps users document ideas, make checklists, save things found online, scan and digitize business cards, and annotate PDFs. Users can also use the app to share notes with friends and colleagues and sync information between devices.

3 **CamScammer**
This app turns your phone into a mobile scanner. Users can capture any hard copy document with their phone—such as meetings notes or a meeting agenda—remove the background, and generate a high resolution JPEG or PDF. Users can even extract text from images (such as the text from a PDF) and edit the text using their phone or tablet. Users can also sync files to other devices. Costs range from free to $6.99 per month. Also check out the CamCard app, which allows users to easily scan and store business cards.

4 **Headspace**
Finding time to de-stress and focus on what’s important can be difficult as a healthcare executive—but it’s crucial. This free app teaches the essentials of meditation and mindfulness to users who can sign up for a free "basics" pack (a 10-day beginner’s course that guides users through the essentials of meditation and mindfulness). Users can also subscribe (for a fee) to receive "bite-sized minis" and hundreds of meditations on everything from managing work to sleep to stress to anxiety.

5 **Lumosity**
If meditation isn’t your thing, another way to keep your mind energized is by using the
Lumosity app. The app is filled with games that challenge the user’s mind and train their memory. The app is free, but users can make in-app purchases.

Flightradar24
This free app makes it easy to keep tabs on upcoming flights. Users can search using flight number, airport, or airline; or they can tap on an airport icon to view arrival and departure boards, flight status, current delay stats, and detailed weather conditions. Users can also view terminal, gate, and baggage claim information when following a flight.

Plus, check out this cool feature: Users can point their phone at a plane in the sky and find out where it’s going and what kind of plane it is.

Flipboard
This free app aggregates content from social media, news feeds, and other websites based on a user’s preferences and prior selections.

It’s a favorite of Managed Healthcare Executive Editorial Advisor Mark Boxer, executive vice president and global chief information officer for CIGNA. “Given time constraints and the need for real time news, Flipboard as a news aggregation and social network aggregation platform meets my needs,” he says. “I really like the interface, and the artificial intelligence and predictive analytics create a truly personalized experience for the busy executive.”

Sworkit
With this easy-to-use exercise aid, there are no more excuses. The app guides users through video workouts for their specific needs, and workouts can be completed in as little as five to 15 minutes. Users can even discuss their needs with a personal trainer. The app is free, but plans range from about $7 to $13 per month depending on the payment plan selected.

Productive – Habit Tracker
So, you’ve downloaded Sworkit, but keep forgetting to use it? This app can help. It helps users recognize how effective they are at meeting daily goals. Users can use it to plan “habits” and schedule them for certain times. Users can also set reminders and receive feedback regarding progress. The app is free to download, but users can purchase various plans ranging from about $2 to $4 per month.

Expensify
If you spend much of your time on the road, on the rails, or in the air; this free app is a big timesaver. It makes capturing receipts, tracking mileage, and creating expense reports quick and easy. Users can even sync their credit card with Expensify to automatically pull transactions into their account.

Aubrey Westgate is editorial director of Managed Healthcare Executive.
Introducing

Delstrigo™
doravirine/lamivudine/
tenofovir disoproxil fumarate
100 mg/300 mg/300 mg tablets

Please read the adjacent Brief Summary of the
Prescribing Information, including the Boxed Warning
about posttreatment acute exacerbation of Hepatitis B.
Brief Summary of the Prescribing Information for DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use

WARNING: POSTTREATMENT ACUTE EXACERBATION OF HEPATITIS B
Severe acute exacerbations of hepatitis B (HBV) have been reported in patients who are coinfected with HIV-1 and HBV and have discontinued lamivudine or tenofovir disoproxil fumarate (TDF), which are components of DELSTRIGO. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who are coinfected with HIV-1 and HBV and discontinue DELSTRIGO. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

INDICATIONS AND USAGE
DELSTRIGO is indicated as a complete regimen for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history.

DOSEAGE AND ADMINISTRATION

Prior to or when initiating DELSTRIGO, test patients for HIV infection.

Prior to or when initiating DELSTRIGO, and during treatment with DELSTRIGO, on a clinically appropriate schedule, assess serum creatinine, estimated creatinine clearance, and uric protein in all patients. In patients with chronic kidney disease, also assess serum phosphorus.

Recommended Dosage
DELSTRIGO is a fixed-dose combination product containing 100 mg of doravirine (DRP), 300 mg of lamivudine (3TC), and 300 mg of TDF. The recommended dosage of DELSTRIGO in adults is one tablet taken orally once daily with or without food.

Renal Impairment
Because DELSTRIGO is a fixed-dose combination tablet and the dosage of lamivudine and TDF cannot be adjusted, DELSTRIGO is not recommended in patients with estimated creatinine clearance less than 50 mL/min.

Dosage Adjustment with Rifabutin
If DELSTRIGO is co-administered with rifabutin, take one tablet of DELSTRIGO once daily, followed by one tablet of doravirine 100 mg (PIELVIR™) approximately 12 hours after the dose of DELSTRIGO for the duration of rifabutin co-administration.

DOSE FORMS AND STRENGTHS
DELSTRIGO Film-coated tablets are yellow, oval-shaped tablets, debossed with the corporate logo and 776 on one side and plain on the other side. Each tablet contains 100 mg doravirine, 300 mg lamivudine, and 300 mg tenofovir disoproxil fumarate (equivalent to 245 mg of tenofovir disoproxil).

CONTRAINDICATIONS
DELSTRIGO is contraindicated when co-administered with drugs that are strong cytochrome P450 (CYP)3A enzyme inducers as significant decreases in doravirine plasma concentrations may occur, which may decrease the effectiveness of DELSTRIGO. These drugs include, but are not limited to, the following: the

Autoimmune disorders (such as Graves’ disease, polymyositis, and Guillain-Barré syndrome) have also been reported. Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy.

Neuropsychiatric adverse events in the pre-specified category of depression and suicide/self-injury were more frequent in patients treated with DELSTRIGO compared to EFV/FTC/TDF. The most frequent adverse reactions that were considered possibly or probably related to delavirdine, lamivudine or tenofovir disoproxil in combination were:

Immune Reconstitution Syndrome

In DRIVE-AHEAD (Protocol 021), 728 adult subjects received either DELSTRIGO (n=364) or EFV/FTC/TDF once daily (n=364). By Week 48, 4.3% in the DELSTRIGO group and 6% in the EFV/FTC/TDF group had adverse events leading to discontinuation of study medication.

Adverse reactions reported in greater than or equal to 5% of subjects in any treatment group in DRIVE-AHEAD are presented in Table 1.

Table 1: Adverse Reactions* (All Grades) Reported in ≥5% of Subjects in Any Treatment Group in DRIVE-AHEAD (Week 48)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Occasional</th>
<th>Occasional</th>
</tr>
</thead>
<tbody>
<tr>
<td>DELSTRIGO</td>
<td>EFV/FTC/TDF</td>
<td>EFV/FTC/TDF</td>
</tr>
<tr>
<td>N=364</td>
<td>N=364</td>
<td>N=364</td>
</tr>
<tr>
<td>Dizziness</td>
<td>7%</td>
<td>32%</td>
</tr>
<tr>
<td>Nausea</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Abnormal Dreams</td>
<td>5%</td>
<td>9%</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4%</td>
<td>5%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Rash</td>
<td>2%</td>
<td>12%</td>
</tr>
</tbody>
</table>

* Frequencies of adverse reactions are based on all adverse events attributed to trial drugs by the investigator.

† No adverse reactions of Grade 2 or higher (moderate or severe) occurred in ≥2% of subjects treated with DELSTRIGO.

The majority (65%) of adverse reactions associated with DELSTRIGO occurred at severity Grade 1 (mild).

Neuropsychiatric Adverse Events

† In DRIVE-AHEAD, the adverse events considered possibly or probably related to delavirdine, lamivudine or tenofovir disoproxil were:

The major adverse reactions associated with DELSTRIGO treated subjects compared to EFV/FTC/TDF-treated subjects included:

Table 2: DRIVE-AHEAD - Analysis of Subjects with Neuropsychiatric Adverse Events* (Week 48)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Occasional</th>
<th>Occasional</th>
</tr>
</thead>
<tbody>
<tr>
<td>DELSTRIGO</td>
<td>EFV/FTC/TDF</td>
<td>EFV/FTC/TDF</td>
</tr>
<tr>
<td>N=364</td>
<td>N=364</td>
<td>N=364</td>
</tr>
<tr>
<td>Sleep disorders and disturbances†</td>
<td>12%</td>
<td>26%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>9%</td>
<td>37%</td>
</tr>
<tr>
<td>Altered sensorium†</td>
<td>4%</td>
<td>8%</td>
</tr>
</tbody>
</table>

* All causality and all grade events were included in the analysis.
† The 95% CIs were calculated using Miettinen and Nurminen’s method. Categories pre-specified for statistical testing were dizziness (p < 0.001), sleep disorders and disturbances (p < 0.001), and altered sensorium (p=0.033).
‡ Predefined using MedDRA preferred terms including: abnormal dreams, hyposomnia, initial insomnia, insomnia, nightmare, sleep disorder, somnambulism.
§ Predefined using MedDRA preferred terms including: altered state of consciousness, lethargy, somnolence, syncope.

Neuropsychiatric adverse events in the pre-specified category of depression and suicide/self-injury were reported in 4% and 7% of subjects, in the DELSTRIGO and EFV/FTC/TDF groups, respectively.

In DRIVE-AHEAD through 48 weeks of treatment, the majority of subjects who reported neuropsychiatric adverse events reported events that were mild to moderate in severity (97% [83/86] and 96% [198/207] in the DELSTRIGO and EFV/FTC/TDF groups, respectively) and the majority of subjects reported these events in the first 4 weeks of treatment (72% [62/86] in the DELSTRIGO group and 86% [177/207] in the EFV/FTC/TDF group).
Brief Summary of the Prescribing Information for DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use (continued)

Neuropsychiatric adverse events led to treatment discontinuation in 1% (2/2364) and 1% (2/2364) of subjects in the DELSTRIGO and EFV/FTC/TDF groups, respectively. The proportion of subjects who reported neuropsychiatric adverse events through Week 4 was 17% (82/464) in the DELSTRIGO group and 49% (177/364) in the EFV/FTC/TDF group. At Week 48, the prevalence of neuropsychiatric adverse events was 12% (44/364) in the DELSTRIGO group and 22% (81/364) in the EFV/FTC/TDF group.

Laboratory Abnormalities

The percentages of subjects with selected laboratory abnormalities (that represent a worsening from baseline) who were treated with DELSTRIGO or EFV/FTC/TDF in DRIVE-AHEAD are presented in Table 3.

Table 3: Selected Laboratory Abnormalities Reported in Adult Subjects with No Antiretroviral Treatment History in DRIVE-AHEAD (Week 48)

<table>
<thead>
<tr>
<th>Laboratory Parameter Preferred Term (Unit/Limit)</th>
<th>DELSTRIGO Once Daily</th>
<th>EFV/FTC/TDF Once Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Chemistry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total bilirubin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1 - &lt;1.6 x ULN</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>1.6 - &lt;2.6 x ULN</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>&gt;2.6 x ULN</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1.3 - 1.8 x ULN or Increase of &gt;0.3 mg/dL above baseline</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>&gt;1.8 x ULN or Increase of &gt;3.1 x above baseline</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Aspartate aminotransferase (IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 - &lt;5.0 x ULN</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>&gt;5.0 x ULN</td>
<td>&lt;1%</td>
<td>2%</td>
</tr>
<tr>
<td>Alanine aminotransferase (IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 - &lt;5.0 x ULN</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>&gt;5.0 x ULN</td>
<td>&lt;1%</td>
<td>2%</td>
</tr>
<tr>
<td>Alkaline phosphatase (IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 - &lt;5.0 x ULN</td>
<td>0%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>&gt;5.0 x ULN</td>
<td>0%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Lipase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 - &lt;3.0 x ULN</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>&gt;3.0 x ULN</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Creatine kinase (IU/L)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.0 - &lt;10.0 x ULN</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>&gt;10.0 x ULN</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Cholesterol, fasted (mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;300 mg/dL</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>300 mg/dL - &lt;500 mg/dL</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>LDL cholesterol, fasted (mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;150 mg/dL</td>
<td>&lt;1%</td>
<td>2%</td>
</tr>
<tr>
<td>&gt;150 mg/dL</td>
<td>1%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Triglycerides, fasted (mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;500 mg/dL</td>
<td>&lt;1%</td>
<td>3%</td>
</tr>
<tr>
<td>UNL = Upper limit of normal range.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Change in Lipids from Baseline

For DRIVE-AHEAD, changes from baseline at Week 48 in LDL-cholesterol, non-HDL-cholesterol, total cholesterol, triglycerides, and HDL-cholesterol are shown in Table 4.

The LDL and non-HDL comparisons were pre-specified and are summarized in Table 4. The differences were statistically significant, showing superiority of DELSTRIGO for both parameters. The clinical benefit of these findings has not been demonstrated.

Table 4: Mean Change from Baseline in Fasting Lipids in Adult Subjects with No Antiretroviral Treatment History in DRIVE-AHEAD (Week 48)

<table>
<thead>
<tr>
<th>Laboratory Parameter Preferred Term</th>
<th>DELSTRIGO Once Daily</th>
<th>EFV/FTC/TDF Once Daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-Cholesterol (mg/dL)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>91.7</td>
<td>-2.1</td>
</tr>
<tr>
<td>Change</td>
<td>91.3</td>
<td>8.3</td>
</tr>
<tr>
<td>Change (95% CI)</td>
<td>-10.2 (-13.8, -6.7)</td>
<td></td>
</tr>
<tr>
<td>Non-HDL-Cholesterol (mg/dL)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>114.7</td>
<td>-4.1</td>
</tr>
<tr>
<td>Change</td>
<td>115.3</td>
<td>12.7</td>
</tr>
<tr>
<td>Change (95% CI)</td>
<td>-16.9 (-20.8, -13.0)</td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol (mg/dL)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>156.8</td>
<td>-2.2</td>
</tr>
<tr>
<td>Change</td>
<td>156.8</td>
<td>21.1</td>
</tr>
<tr>
<td>Change (95% CI)</td>
<td>-1.8 (-13.8, -10.2)</td>
<td></td>
</tr>
<tr>
<td>Triglycerides (mg/dL)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>118.7</td>
<td>-12.0</td>
</tr>
<tr>
<td>Change</td>
<td>122.6</td>
<td>21.6</td>
</tr>
<tr>
<td>Change (95% CI)</td>
<td>-4.3 (-9.4, 0.8)</td>
<td></td>
</tr>
<tr>
<td>HDL-Cholesterol (mg/dL)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>42.1</td>
<td>1.8</td>
</tr>
<tr>
<td>Change</td>
<td>41.6</td>
<td>8.4</td>
</tr>
<tr>
<td>Change (95% CI)</td>
<td>-7.8 (-16.3, 0.7)</td>
<td></td>
</tr>
</tbody>
</table>

Subjects on lipid-lowering agents at baseline were excluded from these analyses (DELSTRIGO n=15 and EFV/FTC/TDF n=10).

Subjects initiating a lipid-lowering agent post-baseline had their last fasted on-treatment value (prior to starting the agent) carried forward (DELSTRIGO n=3 and EFV/FTC/TDF n=4).

*P-value for the pre-specified hypothesis testing for treatment difference was <0.0001.

Postmarketing Experience

The following adverse reactions have been identified during postmarketing experience in patients receiving lamivudine- or TDF-containing regimens. Because postmarketing reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Hypersensitivity: anaphylaxis, urticaria
Musculoskeletal: myopathy, renal failure, rhabdomyolysis
Skin: pruritus, rash

TDI:
Immune System Disorders: allergic reaction, including angioedema
Metabolism and Nutrition Disorders: lactacidosis, hypoglycemia, hypophosphatemia
Respiratory, Thoracic, and Mediastinal Disorders: dyspnea

Gastrointestinal Disorders: pancreatitis, increased amylase, abdominal pain
Hepatobiliary Disorders: hepatitis, hepatic failure, increased liver enzymes (most commonly AST, ALT, gamma GT)
Skin and Subcutaneous Tissue Disorders: rash

Changes in Lipid Parameters

Based on data from a clinical study.

Table 5: Drug Interactions with DELSTRIGO*

<table>
<thead>
<tr>
<th>Concomitant Drug Class: Drug Name</th>
<th>Effect on Concentration</th>
<th>Clinical Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Androgen Receptors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>enzalutamide</td>
<td>↓ doravirine</td>
<td>Co-administration is contraindicated with enzalutamide. At least a 4-week cessation period is recommended prior to initiation of DELSTRIGO.</td>
</tr>
<tr>
<td>Anticonvulsants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>carbamazepine</td>
<td>↓ phenytoin</td>
<td>Co-administration is contraindicated with these anticonvulsants. At least a 4-week cessation period is recommended prior to initiation of DELSTRIGO.</td>
</tr>
<tr>
<td>Antimycobacterials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rifampin¹</td>
<td>↓ doravirine</td>
<td>Co-administration is contraindicated with rifampin or rifapentine. If DELSTRIGO is co-administered with rifampin, one tablet of doravirine (PIFELTRO™) should be taken approximately 12 hours after the dose of DELSTRIGO. At least a 4-week cessation period is recommended prior to initiation of DELSTRIGO.</td>
</tr>
<tr>
<td>Cytotoxic Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>mitotane</td>
<td>↓ doravirine</td>
<td>Co-administration is contraindicated with mitotane. At least a 4-week cessation period is recommended prior to initiation of DELSTRIGO.</td>
</tr>
<tr>
<td>Hepatitis C Antiviral Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ledipasvir/sofosbuvir</td>
<td>↑ sofosbuvir/velpatasvir</td>
<td>Monitor for adverse reactions associated with TDF.</td>
</tr>
<tr>
<td>Herbal Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>St. John’s wort</td>
<td>↓ doravirine</td>
<td>Co-administration is contraindicated with St. John’s wort. At least a 4-week cessation period is recommended prior to initiation of DELSTRIGO.</td>
</tr>
<tr>
<td>Other Agents</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sorbitol</td>
<td>↓ lamivudine</td>
<td>Co-administration of single doses of lamivudine and sorbitol resulted in a sorbitol dose-dependent reduction in lamivudine exposures. When possible, avoid use of sorbitol-containing medicines with lamivudine-containing medicines.</td>
</tr>
</tbody>
</table>

† Increase, ↓ decrease

*Not pre-specified for hypothesis testing.

Drugs are listed in alphabetical order by their common name. The drug interaction information provided is intended as a summary to assist in the assessment of potential drug-drug interactions.

Hepatic and Pancreatic: lactic acidosis and hepatic steatosis, posttreatment exacerbations of hepatitis B

Mycobacterium: an increase in lymphocytosis

Oral contraceptives: a decrease in the contraceptive efficacy of oral contraceptives

Potentially important drug interactions are described in the following sections.

Potentially important drug interactions are described in the following sections.
Brief Summary of the Prescribing Information for DELSTRIGO™ (doravirine, lamivudine, and tenofovir disoproxil fumarate) tablets, for oral use (continued)

Co-administration of DELSTRIGO with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of lamivudine, tenofovir, and/or other renally eliminated drugs. Some examples of drugs that are eliminated by active tubular secretion include, but are not limited to, acyclovir, adefovir, ganciclovir, valacyclovir, valganciclovir, amoxicillin (e.g., augmentin), and high-dose multiple NSAIDs.

No clinically significant changes in concentration were observed for doravirine when co-administered with the following agents: TDF, lamivudine, elbasvir and grazoprevir, ledipasvir and sofosbuvir, ritonavir, ketoconazole, aluminum hydroxide/magnesium hydroxide/simethicone containing antacid, pantoprazole, or metoclopramide.

No clinically significant changes in concentration were observed for tenofovir when co-administered with tacrolimus or entecavir.

Effect of DELSTRIGO on Other Drugs
No clinically significant changes in concentration were observed for the following agents when co-administered with doravirine: lamivudine, TDF, elbasvir and grazoprevir, ledipasvir and sofosbuvir, atorvastatin, an oral contraceptive containing ethinyl estradiol and levonorgestrel, metformin, methadone, or midazolam.

No clinically significant drug interactions have been observed between TDF and the following medications: entecavir, methadone, oral contraceptives, simvastatin, or tacrolimus in studies conducted in healthy subjects.

Lamivudine is not significantly metabolized by CYP enzymes nor does it inhibit or induce this enzyme system; therefore, it is unlikely that clinically significant drug interactions will occur through these pathways.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to DELSTRIGO during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Registry (APR) at 1-800-258-4263.

Risk Summary
There is insufficient prospective pregnancy data from the APR to adequately assess the risk of birth defects and miscarriage. Doravirine use in individuals during pregnancy has not been evaluated; however, lamivudine and TDF use during pregnancy has been evaluated in a limited number of individuals reported to the APR. Available data from the APR show no difference in the overall risk of major birth defects for lamivudine and TDF compared with the background rate for major birth defects of 2.7% in the U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) (see Data). The rate of miscarriage is not reported in the APR. The estimated background rate of miscarriage in the clinically recognized pregnancies in the U.S. general population is 15–20%. Methodological limitations of the APR include the use of MACDP as the external comparator group. The MACDP population is not disease-specific, evaluates individuals and infants from the limited geographic area, and does not include outcomes for births that occurred at less than 20 weeks gestation.

In animal reproduction studies, oral administration of lamivudine to pregnant rabbits during organogenesis resulted in embryolethality at systemic exposure (AUC) similar to the recommended clinical dose; however, no adverse development effects were observed with oral administration of lamivudine to pregnant rats during organogenesis at plasma concentrations (Cmax) 35 times the recommended clinical dose. No adverse developmental effects were observed when doravirine and TDF were administered separately at doses/exposures ≥8 (doravirine) and ≥14 (TDF) times those of the recommended human dose (RHD) of DELSTRIGO (see Data). Data

Human Data
Lamivudine: The APR has received a total of over 12,000 prospective reports with follow-up data of possible exposure to lamivudine-containing regimens; over 5,400 reports in the first trimester; over 5,500 reports in the second trimester; and over 1,800 reports in the third trimester. Birth defects occurred in 151 of 5,008 (3.0%, 95% CI: 2.6% to 3.5%) live births for lamivudine-containing regimens (first trimester exposure); and 210 of 7,356 (2.9%, 95% CI: 2.5% to 3.3%) live births for lamivudine-containing regimens (second/third trimester exposure). Among pregnant mothers in the U.S. reference population, the background rate of birth defects is 2.7%. There was no association between lamivudine and overall birth defects observed in the APR.

TDF: The APR has received a total of over 5,500 prospective reports with follow-up data of possible exposure to tenofovir disoproxil-containing regimens; over 3,900 reports in the first trimester; over 1,000 reports in the second trimester; and over 500 reports in the third trimester. Birth defects occurred in 62 of 3,325 (1.9%, 95% CI: 1.4% to 2.5%) live births for TDF-containing regimens (first trimester exposure); and 35 of 1,570 (2.2%, 95% CI: 1.6% to 3.1%) live births for TDF-containing regimens (second/third trimester exposure). Among pregnant mothers in the U.S. reference population, the background rate of birth defects is 2.7%. There was no association between tenofovir and overall birth defects observed in the APR.

Animal Data
Doravirine: Doravirine was administered orally to pregnant rabbits (up to 300 mg/kg/day) on gestation days (GDB) 7 to 20 and rats (up to 450 mg/kg/day on GD 6 to 20 and separately from GD 6 to lactation/postpartum day 20). No significant toxicological effects on embryo-fetal (rabs and rats) or pre/post-natal (rats) development were observed at exposures (AUC) approximately 9 times (rabs) and 8 times (rabs) the exposure in humans at the RHD. Doravirine was transferred to the fetus through the placenta in embryo-fetal studies. In the fertility/pre- and postnatal development study in rats, lamivudine was administered orally at doses of 180, 900, and 4,000 mg per kg per day (from prior to mating through postnatal Day 20). In the study, development of the offspring, including fertility and reproductive performance, was not affected by maternal administration of lamivudine.

TDF: Reproduction studies have been performed in rats and rabbits at doses up to 14 and 19 times the human dose based on body surface area comparisons and revealed no evidence of harm to the fetus.

Lactation
Risk Summary
The Centers for Disease Control and Prevention recommend that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking potential transmission of HIV-1 infection.

Based on limited published data, both lamivudine and tenofovir are present in human milk. It is unknown whether doravirine is present in human milk, but doravirine is present in the milk of lactating rats. It is not known whether DELSTRIGO or the components of DELSTRIGO affects human milk production, or has effects on the breastfed infant. Because of the potential for (1) HIV-1 transmission (in HIV-negative infants), (2) developing viral resistance (in HIV-positive infants), and (3) serious adverse reactions in a breastfed infant, instruct mothers not to breastfeed if they are receiving DELSTRIGO.

Data
Doravirine: Doravirine was excerted into the milk of lactating rats following oral administration (450 mg/kg/day) from gestation day 6 to lactation day 14, with milk concentrations approximately 1.5 times that of maternal plasma concentrations observed 2 hours post dose on lactation day 14.

Pediatric Use

Safety and efficacy of DELSTRIGO have not been established in pediatric patients less than 18 years of age.

Geriatric Use

Clinical trials of doravirine, lamivudine, or TDF did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. In general, caution should be exercised in the administration of DELSTRIGO in elderly patients reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

Because DELSTRIGO is a fixed-dose combination tablet and the dosage of lamivudine and TDF both components of DELSTRIGO, cannot be altered, DELSTRIGO is not recommended in patients with estimated creatinine clearance less than 50 mL/min.

Hepatic Impairment

No dosage adjustment of DELSTRIGO is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment. DELSTRIGO has not been studied in patients with severe hepatic impairment (Child-Pugh Class C).

OVERDOSAGE

No data are available on overdose of DELSTRIGO in patients and there is no known specific treatment for overdose with DELSTRIGO. If overdose occurs, the patient should be monitored and standard supportive treatment applied as required.

Doravirine: There is no known specific treatment for overdose with doravirine.

Lamivudine: Because a negligible amount of lamivudine was removed via (4-hour) hemodialysis, continuous ambulatory peritoneal dialysis, and automated peritoneal dialysis, it is not known if continuous hemodialysis would provide clinical benefit in a lamivudine overdose event.

TDF: TDF is efficiently removed by hemodialysis with an extraction coefficient of approximately 54%. Following a single 300 mg dose of TDF, a 4-hour hemodialysis session removed approximately 10% of the administered tenofovir dose.

For more detailed information, please read the Prescribing Information.

Delstrigo doravirine/lamivudine/tenofovir disoproxil fumarate 180 mg/300 mg/300 mg tablets
Technology to Treat Chronic Pain
New devices seek to curb addiction, costs by DONNA MARBURY

Up to 30% of patients prescribed opioids for pain misuse them, according to the National Institute on Drug Abuse, a division of the National Institutes of Health. Between 8% and 12% of patients who are prescribed opioids develop an addiction. In total, the institute states that 115 people in the U.S. die every day due to opioid overdoses.

“Given the nationwide emphasis on the opioid crisis, those living with chronic pain feel there is a stigma that comes with seeking out strong pain prescriptions,” says Shai Gozani, MD, PhD, president, CEO, and director of NeuroMetrix, Inc., the company that created Quell, a wearable neurostimulation device. “It’s important to provide individuals with long-term pain conditions with enough options to be able to find an effective relief system that works for them.”

Here are some technology solutions that are treating chronic pain, allowing patients to eliminate or decrease their dependence on opioids.

**Quell by NeuroMetrix**

By using neurostimulation technology to tap into the body’s natural pain response and block pain signals, Quell helps patients with chronic back, arthritic, nerve, leg, and foot pain. The wearable device is FDA-cleared for daytime and overnight use. It is inserted in a cuff that can be positioned on the body and has an accompanying app that helps people track pain management and sleep patterns affected by chronic pain.

A clinical study of 713 Quell users released by the *Journal of Pain Research* in April 2018 found that 80% reported improvement in their chronic pain and about 66% reported reduction in their pain medication use due to using Quell. On average, study participants used Quell for 35 hours per week.

“Because pain is extremely personal and is experienced differently by all people, those living with chronic pain often need a variety of treatments to find relief—what we call a ‘toolbox approach’ to chronic pain,” Gozani says.

**The SPRINT PNS system by SPR Therapeutics**

The SPRINT PNS system is designed to treat pain through peripheral nerve stimulation. The single thin, thread-like wire, or lead, is implanted through a needle introducer under ultrasound guidance and is placed approximately 1 centimeter from nerves for stimulation therapy delivery up to 60 days. The system is used to treat post-amputation, lower back, shoulder, and knee replacement pain.

“As a device there are no withdrawal symptoms, and consequently, no drug-related side effects,” says Mark Stultz, senior vice president of market development for SPR Therapeutics. “SPRINT is...”

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**More Online: Tech to Treat Migraine**

Promising new technology/biotechnology is on the horizon for migraine sufferers, according to one headache expert.

“Technological advancements are critically important in migraine because many of the pharmacological treatments have unwanted or intolerable side effects,” says Zubair Ahmed, MD, a headache specialist at Cleveland Clinic. “This is truly an exciting time in migraine treatment development.”

According to Ahmed, one of the newest technologies uses neuromodulation. “This is an excellent option for many because neuromodulatory devices have been shown to be much better tolerated, with far fewer side effects than traditional pharmacological medications,” he says. “Neuromodulation refers to the use of magnetic stimulators and currents to modulate electrical activity within the brain and preventing migraines altogether or stopping migraines after they occur.”

intended to provide pain relief directly to the nerve where it is needed, whereas opioids are systematic, have significant side effects, and are susceptible to addiction and diversion.”

The system is on the market, and the company recently launched its next generation, dual lead system (which allows for more thorough coverage of the pain area), SPRINT extensa PNS system, following FDA approval on July 31.

**BreatheVR by Neon**

Virtual reality (VR) provides a unique approach to pain management, as studies show that immersive distraction can de-escalate some chronic pain.

BreatheVR is an application available through Samsung Gear VR and Oculus Go headsets that helps patients with deep breathing and meditation exercises to alleviate pain.

Deepa Mann-Kler, founder and CEO of Neon, says a November 2017 pilot study of BreatheVR found that in less than three minutes, 80% of participants reported a de-escalation of pain.

“The biggest drop in pain was 50%, from 7 to 3.5 on the visual analog scale psychometric response pain scale,” Mann-Kler says.

The BreatheVR application engages users in an animated meadow, by having them listen to music and birds. The user is asked to inhale and exhale, and as their breath is detected by the headset’s microphone, leaves in the virtual reality environment move. This sequence is then repeat-

<table>
<thead>
<tr>
<th>Patients seek alternatives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>84.0%</strong> of respondents believe a stigma around prescription opioid use exists, and as a result 50% have lied or hidden their opioid use from others.</td>
</tr>
<tr>
<td><strong>39.0%</strong> prefer to treat chronic pain without prescription medicine.</td>
</tr>
<tr>
<td><strong>59.0%</strong> tried alternative treatment methods within the past year.</td>
</tr>
</tbody>
</table>

**StimRouter by Bioness**

This long-term pain solution treats chronic nerve pain through peripheral nerve stimulation. It has been used on 24 different peripheral nerves since launching in 2016. The device is 15 centimeters and “feels like a limp piece of spaghetti,” says Mark Geiger, global director of marketing implantables at Bioness, the company that produces StimRouter.

“By stimulating the target peripheral nerve with a small amount of energy that feels like a gentle tingling sensation, the nerve cannot communicate a pain signal. Over time, this stimulation may cause the nerve to perform more normally,” Geiger says. “So, the difference is targeted pain management at the source of the pain compared to global pain reduction with an oral or IV pain medication with all the typical, sometimes deleterious side effects.”

The StimRouter is implanted through the skin, while the patient is under local anesthesia. According to Geiger, patients can provide feedback to the physician implanting the device immediately.

“The StimRouter is a permanent solution meant to last a lifetime. In many cases, based on many hundreds of implants, patients use the StimRouter for shorter durations over time with increasing carry-over pain relief, meaning the pain relief lasts for hours/days after the StimRouter is shut off by the patient,” Geiger says.

Donna Marbury is a writer in Columbus, Ohio.

Prescription opioid misuse costs the United States **$78.5 billion** annually due to healthcare, addiction treatment, and criminal justice costs.

- OKE
Passion for work ebbs and flows, but if you’ve been stuck in a downward spiral for a long time, it may be time to make some changes. Here are some tips from executive coaches.

**Ask for what you need**

Sometimes just changing your responsibilities can shift your mindset in the right direction. Ted Beasley, lead instructor for Emergent Execs, has seen many companies demonstrate a willingness to change the roles and responsibilities of key contributors they want to retain.

“I have clients keep a journal for 10 working days. At the end of each day, they write down activities that brought them life and energy and a list of activities that they disliked,” he says. “At the end of the 10 days, we look at the themes and figure out what types of activities will fuel their passion and which feel like drudgery and could potentially be delegated to others.”

By taking this route, one executive he worked with found that she hated negotiating with healthcare providers and pharmacy chains on their member rates, but loved mentoring her team and creating training programs for members about their benefits. She pitched a revised job description to her executive team, and they were enthusiastic about empowering her to take on more of a training role.

“Of course, there are many mundane or painful aspects of your current job description that you won’t be able to change, but you may be surprised at how making a few tweaks can change your outlook and passion level,” Beasley says.

**Think bigger**

Rose Cartolari, a leadership strategist and executive coach, notes while nobody can fill you with passion, having meaning and purpose in your job can certainly go a long way.

“People get complacent. People don’t change just because they have more information, they change when there’s an emotional pull,” she says. “You should stand for something bigger than yourself and find the bigger picture in what you’re doing. It will help you connect more—with your purpose and with others.”

**Get personal**

Jennifer Palmieri, Cigna’s human resources officer, Global IT, defines passion as “a positive emotional connection to our work,” and while she believes your career passion may occasionally go on hiatus, it is never truly lost.

“Energy, creativity, and commitment are prerequisites to having an emotional connection to our work; it is perfectly normal for each of these to ebb and flow over our careers,” she says. “The catalyst for rediscovering that deep personal connection to our work is dependent on the root cause. It is hard to be passionate at work if we have deep personal challenges going on in our lives.”

For some this may mean addressing family needs or even your own needs, which may require taking time off, using family leave, or engaging a counselor.

“For others, the passion ebbs because perhaps we have gotten...
“It is hard to be passionate at work if we have deep personal challenges going on in our lives.”

JENNIFER PALMIERI, CIGNA

too comfortable in our jobs,” Palmieri says. “That implies it is time to take on new challenges; whether expanding our role, asking for additional project assignments, or getting more involved in corporate philanthropy. These serve as mechanisms for us as leaders to create greater impact.”

Know yourself well
Carrie A. L. Arnold, PhD, principal coach and consultant of The Willow Group, advises using yourself as a subject of study and determining your strengths, preferences, triggers, challenges, etc.

“When people are leveraging their strengths and preferences in an intentional way, they are less likely to lose their passion,” she says. “They are also able to make more intentional choices that help them recover when their energy wanes. I always recommend that leaders take all the assessments they can get their hands on and find ways to integrate what they learn about themselves.” She believes this is just being a good steward of the life and body you have been given.

“I also think it is important that leaders don’t leap to leaving. They may need to do self-work first before deciding to transition to another job or company,” she says. “Not everyone needs to leave to lead with passion. If that is not possible, they will at least have a good sense of what they are running to versus running from.”

Talk with others who have gone through this
Health executives need to realize that they are not alone in seeing a dip in their passion levels. That’s why Beasley recommends talking with current or retired healthcare executives whose careers you admire.

“We often struggle with passion alone, and don’t realize that many successful people have hit similar dips, and found meaning and renewed purpose in their healthcare careers,” he says. “Take some time to uncover these stories. Invite an individual to lunch or a coffee. In the email invite, explain that you are committed to your industry or company, but you are looking for ways to grow professionally and make your career more sustainable.”

“It won’t hurt to mention why you admire their longevity, accomplishments, and personal style, as well. In preparation for the interview, come up with a good list of five to 10 questions you want to ask that might shed light on your own journey.

“I find that successful people almost always say ‘yes’ to these interview requests, and tend to be quite candid in their responses,” Beasley says. “They love to give back and help the next generation of leaders. You’ll benefit from their wisdom. More importantly, you will learn that you’re not alone, and many exceptional executives have faced some of the very same challenges.”

Examine what strengthens you
The most important way to regain passion in our work, says Carol Vernon, a certified executive coach with Communication Matters, is to step back and ask, “What do we bring to our organization that energizes us and plays to our natural strengths?”

“I always recommend that leaders take all the assessments they can get their hands on and find ways to integrate what they learn about themselves.”

CARRIE A. L. ARNOLD, THE WILLOW GROUP

“I always ask my coaching clients to seek input from others about how we are ‘showing up.’”

CAROL VERNON, COMMUNICATION MATTERS

“A graduate of the University of Miami, Keith Loria is an award-winning journalist who has been writing for major newspapers and magazines for close to 20 years, on topics as diverse as sports, business, and healthcare.

“I always ask my coaching clients to seek input from others about how we are ‘showing up,’” she says. “When we know what energizes us and what others notice about us, we can start building and refining on those things and ultimately regain the passion that first brought us to our work.”
Many physicians overwhelmed by burnout

While members of the C-suite at healthcare organizations may struggle with burnout, the healthcare professionals who struggle with it most often may be physicians. A new physician survey from The Medicus Firm, a physician recruiting company, found that roughly 90% of physicians had experienced at least one symptom of burnout in the last year. The symptoms were described as mental or physical exhaustion, compassion fatigue, and lack of efficacy (in other words, a physician’s doubt as to the meaning and quality of his or her work). The economic costs of not addressing burnout are major. Christine Sinsky, MD, FACP, vice president of professional satisfaction at the American Medical Association and a practicing general internist, says data show that it costs between $500,000 and $1 million to replace an existing physician. This, she feels, is a conservative figure. “It doesn’t include many, many other sources of financial costs to burnout.”

In addition, burnout may lead to poorer quality care, she says. “We know that care is safer when physicians are satisfied with their work, and that safety hazards add costs to the organization."

Here are more findings from The Medicus Firm survey:

**FINDING:**
Few physicians escape feelings of burnout

<table>
<thead>
<tr>
<th>Exhaustion — physical or mental</th>
<th>Never in the past year</th>
<th>Some/occasionally experience</th>
<th>Frequently</th>
<th>Overwhelmingly</th>
<th>Not sure/neutral</th>
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<tbody>
<tr>
<td>11.33%</td>
<td>43.71%</td>
<td>34.93%</td>
<td>9.42%</td>
<td>1.15%</td>
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<tr>
<th>Compassion fatigue / depersonalization</th>
<th>Never in the past year</th>
<th>Some/occasionally experience</th>
<th>Frequently</th>
<th>Overwhelmingly</th>
<th>Not sure/neutral</th>
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<tbody>
<tr>
<td>18.66%</td>
<td>47.33%</td>
<td>25.3%</td>
<td>7.32%</td>
<td>1.56%</td>
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<tr>
<th>Lacking efficacy (Doubting the meaning or quality of your work)</th>
<th>Never in the past year</th>
<th>Some/occasionally experience</th>
<th>Frequently</th>
<th>Overwhelmingly</th>
<th>Not sure/neutral</th>
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<tr>
<td>26.83%</td>
<td>44.68%</td>
<td>19.31%</td>
<td>7.32%</td>
<td>1.86%</td>
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One of the consequences of this burnout is that more than one-third of survey respondents said they regretted or had doubts about their choice of career.

Q: Would you choose medical practice as a career if given a chance to re-start your career?

<table>
<thead>
<tr>
<th>1 in 5 physicians said they either probably definitely not choose medicine again</th>
<th>17% said they were unsure</th>
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<td>11.33%</td>
<td>43.71%</td>
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<td>7.32%</td>
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<tr>
<td>26.83%</td>
<td>35%</td>
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As a result of these stressors, the report also found that as many as 1 in 5 physicians said they would have chosen a different career if they could go back and do it again.

35% of physicians surveyed said they frequently experienced physical or mental exhaustion during the past year.
FDA’s approval of a new drug, Onpattro (patisiran) infusion, to treat peripheral nerve disease (polyneuropathy) in August also marks FDA’s first approval of a new drug class called small interfering ribonucleic acid (siRNA) treatment.

The drug, manufactured by Alnylam Pharmaceuticals, Inc., was approved for adults with polyneuropathy caused by hereditary transthyretin-mediated amyloidosis (hATTR), a debilitating and often fatal genetic disease. Affecting about 50,000 people worldwide, hATTR is a rare condition.

"The disease results in patients developing numbness and weakness in their limbs, difficulty with gut movement and digestion, and heart failure," says Michael J. Polydefkis, MD, professor of neurology at Johns Hopkins University in Baltimore and a lead investigator of the phase 3 APOLLO study for Onpattro.

A new way treatment
The treatment alters the genetic drivers of disease. RNA inhibitors (RNAi) can target any gene in the human genome and prevent it from turning on. "Targeting the disease's source (the expressed gene) versus a surface membrane protein (which is how biologics work) provides an off switch for the disease," says Kellie Rademacher, PharmD, vice president of Payer Access Solutions at Precision for Value.

"RNAi has the potential to be disease modifying not only for hATTR, but also for other diseases caused by gene expression, such as hemophilia, cancer, and age-related vision loss," Rademacher says. "RNAi technology is precision medicine at its foundation."

Currently, drugs to treat hATTR slow its progression, but don't stop it. "The gold standard of treatment is liver transplant or multi-organ transplant (depending on the disease's severity), because the TTR protein is primarily produced in the liver. Data released for Onpattro showed a reduction in the development and deposits of TTR amyloids, Rademacher says.

Polydefkis believes that patients who take Onpattro will experience less disability, be more productive, and ultimately live longer.

Cost considerations
The average annual list price for Onpattro before insurer discounts is estimated at $450,000. The effective net price is $345,000 annually, taking into account mandatory government discounts. According to a press release by the manufacturer, "As a therapy designed to treat less than 3,000 currently diagnosed patients in the United States, Onpattro is priced relative to the population it will treat."

Rademacher says the pricing isn't outside the realm of what she has seen with other rare disease agents. "Even though only a small number of people have this disease, payers will likely want to manage Onpattro carefully because of its cost and specificity," she says. "Onpattro is a lifelong therapy without any realized outcomes yet. Clinical trial data look promising, but whether or not real-world outcomes translate into savings for payers and patients remains to be seen."

Rademacher says how the system reimburses for Onpattro and other new exciting gene-related technologies needs to be reassessed. "Perhaps costly drugs could be financed similar to how other large purchases are financed," she says. "How the healthcare system provides access and reimburses for these advances will require all stakeholders to collaborate."

Karen Appold is a medical writer in Lehigh Valley, Pennsylvania.
Hard Reality of Cancer Treatment Costs

High costs raise problems for patients, families by MARK ROWH

Progress seldom comes without cost, and that’s certainly the case for treatment of lymphoma and other cancers. While promising new options keep entering the scene, high costs can be problematic to patients and their families.

Lack of upfront information is part of the challenge, according to Alan Tan, MD, clinical research medical director, medical oncologist and hematologist for Cancer Treatment Centers of America in Phoenix. In general, oncologists often discuss with patients any potential toxicity of their cancer treatment, he says, but only 27% of cancer patients report having had discussions with their oncologist about financial realities.

“Financial toxicity can lead patients not only into debt, depleted savings, and even bankruptcy, but also skipped medication doses and consequently shortened survival,” he says. He notes that in hematologic malignancies, many of the standard treatment regimens can run well over $100,000 per year with a single once-a-day pill that continues indefinitely. Many trials show incremental benefit with combination therapies as well, which tend to be very expensive.

Tan adds that developments such as CAR T-cell therapy further increase costs, with price tags reaching $373,000 and $475,000.

“These prices are only for the cost of extracting the patient’s T cells, engineering them to produce the CARs on the surface of the cells, and infusing them back into the patient,” he says. “When one includes hospital stays, supportive care for potential toxicity, and physician visits including consultants, the total cost can exceed more than $1 million per patient.”

27 million

The number of Americans who were uninsured in 2016. For these patients, cancer treatment poses significant challenges.

Money matters

Only 27% of cancer patients report having had discussions with their oncologist about financial realities.

“Added complexity

It’s important to have transparency around cost benefits of treatments, adherence to the best evidence, and a willingness to explore ways to link outcome and costs such as through the oncology medical home and other value-based approaches to pharmacy, Tan says. He also encourages careful consideration of treatment options.

“For very expensive treatments such as CAR T-cell therapy, we should only be offering this to the
“There are numerous barriers to coverage of advanced diagnostic technologies which . . . can potentially improve care and provide mechanisms for cost containment.”

CHARLES SANG, ADAPTIVE DIAGNOSTICS

sickest patients with the fewest options,” Tan says. “Patients with lymphoma overall do well with standard chemotherapy and may well be cured.”

Manish J. Dave, MD, who specializes in hematology and oncology at CareMount Medical, a large multi-specialty medical group in New York, New York, also notes that some treatments can be effective even though they are not at the high end of the cost scale.

“Rituximab is a commonly used treatment for many blood cancers,” he says. “Recent studies have shown that the medication’s cost per quality-adjusted life year has been falling within standard thresholds for cost-effectiveness.”

Resources that help
One way to manage appropriate treatment selection is by using novel clinical endpoints and highly accurate, standardized diagnostic tests, according to Charles Sang, senior vice president at Adaptive Biotechnologies. He encourages health executives to embrace standardized molecular diagnostic tests.

“There are numerous barriers to coverage of advanced diagnostic technologies, which results in limited adoption in the practice of medicine in ways that can potentially improve care and provide mechanisms for cost containment,” he says. “Diagnostics can play a role in leading to the identification of more effective treatments, as well as more cost effective use of those treatments.”

Tan points to the need to be able to identify high-risk groups of patients that biologically are sure to relapse and expose them to CAR T-cell therapy earlier.

“We need biomarkers that best select patients that have the highest likelihood of responding to CAR T-cell therapy,” he says. “It would be a shame to spend over a million dollars for a treatment that did not work at all.”

Tan also advocates a value-based pricing and use model. “Perhaps a million dollars is not that steep of a price if you can cure a patient with a one-time treatment,” he says.

Greater levels of competition should provide some relief, he predicts. “Encourage competition,” he says. “CAR T-cell pricing will surely go down as more competitors come to market. Stimulate generic and biosimilar market competition.”

The bottom line is that a patient’s well-being comes first, Dave says. “A cancer patient’s financial constraints and/or socioeconomic status should not compromise their health, longevity, or quality of life due to symptoms from cancer,” he says. “We recommend a multidisciplinary team of medical oncologists, pathologists, radiologists, and other clinicians review complicated cases to provide the best care possible to patients. We encourage patients to participate in clinical trials, which offer new, often groundbreaking treatments.”

Mark Rowh is a Virginia-based freelance writer whose interest areas include healthcare, business, and higher education.

Access concerns
The average age of oncologists is 51, with 18.4% of them age 64 or older. Replacement of qualified physicians will be a necessity in future years.

Source: American Society of Clinical Oncology

Five factors driving up the cost of oncology drugs

One of the key factors that leads to higher costs with all drugs—not just those for cancer treatment—is the way the cost of these drugs is reimbursed, says Anna Kaltenboeck, program director and senior health economist at New York City’s Memorial Sloan Kettering Center for Health Policy and Outcomes.

“The purchasing and reimbursement system that we have in place favors higher prices, because the purchasing and prescribing intermediaries that are involved in that supply chain have proportional incentives associated with the price of drugs,” she says.

Kaltenboeck says that pharmacy benefit management firms also have an impact on drug prices, in particular when it comes to rebates. “They also benefit from that higher list price that they can negotiate down from,” she says.

For four more factors that are driving up the cost of oncology drugs, visit: http://bit.ly/Five-Factors
Special Report

Improve the Patient Experience
Strategies from successful health systems

BY AINE CRYTS

Patients arriving at Cleveland Clinic’s Taussig Cancer Center are shielded from rain and snow by a 350-foot-long awning that hangs over the building entrance. They are greeted at the door by an employee who walks with them to their appointment. In waiting areas, they are surrounded by artwork and soothing natural light that flows in through the windows.

A patient-centric approach is also at play in the design of the exam rooms, where patients are situated in the center of rooms, surrounded by monitors that display their lab and imaging results and their care plans.

Cleveland Clinic developed this new cancer center, which opened its doors in 2017,

Spruce up your online rep

HCAHPS asks nine questions about patient experience during a hospital stay. But Reputation.com found that online reviews also shed light on important aspects of patient experience, such as caregiver competence, time to get an appointment, wait times, parking and administrative complaints, and experiences with billing and insurance.

Reports show that online reviews are also playing a growing role in health systems’ ability to attract and retain patients. A poll of patients by Reputation.com revealed that:

82% have read online reviews to evaluate a healthcare provider

80% claim the ratings and reviews influenced their choice of provider

68% have selected one provider over another based on ratings and reviews
by consulting a panel of former cancer patients who provided feedback on specific ways the space could create a welcoming and healing experience, says Adrienne Boissy, MD, chief experience officer at Cleveland Clinic Health System.

The center brings all outpatient cancer treatment services such as radiology and the lab to one location, reduces wait times, improves patient flow, and provides patients with a healing environment, says Boissy. Clinical teams include surgeons, nurses, genetic counselors, and social workers. The center also provides patients with access to yoga classes, free wigs and hats, and art therapy and music therapy appointments.

Cleveland Clinic’s Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) score has improved 16% since 2015 because of this and other efforts to improve the patient experience, says Boissy.

If you are hoping for similar results at your healthcare system, it’s time to consider making similar changes. Here are five to consider.

1/ THINK BEYOND PATIENTS’ CLINICAL NEEDS

Danville, Pennsylvania-based Geisinger Health System, a large network in Pennsylvania and southern New Jersey, has implemented “leadership rounds,” during which administrative and clinical leaders observe and ask about patients’ experiences.

While rounding one day, a member of the leadership team heard from a patient at one of the health system’s drug rehab facilities that he couldn’t sleep because his face kept getting stuck to his plastic pillow.

Immediately, the member of the leadership team went to a local store and bought 77 comfortable pillows for the rehab center’s patients, says Greg Burke, MD, chief patient experience officer at Geisinger. The staff member was later reimbursed by the health system.

Geisinger is also using a platform from Cipher Systems, which allows hospital leaders to enact virtual real-time fixes to problems. For example, if a nursing supervisor sees a dirty bathroom, she can use the platform to notify the facilities department.

As a result of this and other efforts to improve the patient experience, 73.3% of Geisinger patients were likely to recommend the health system in the second half of 2018, according to its HCAHPS scores. That’s an increase from 69.6% in 2015.

2/ SUPPORT PEDIATRIC PATIENTS WITH TELEHEALTH

To help support one of its college-aged patients, Lucile Packard Children’s Hospital Stanford facilitated ongoing behavioral health sessions with his psychologist via a telehealth platform.

“How this patient had a very tight therapeutic relationship with his psychiatrist,” says Natalie Pageler, MD, chief medical information officer. “He wanted to go away to his top-choice college in southern California, but the family was very fearful because of the distance between the college and the student’s psychiatrist.”

How patients respond to e-visits

Sixty-nine percent of patients say they would prefer a telehealth visit to an in-person visit, and 100% say they would participate in one in the future, according to a survey of 26 patients or family members by Stanford Children’s Hospital.

Patients say providers can improve satisfaction by:

- Shortening wait times
- Providing care costs in advance
- Ensuring patients do not feel rushed during appointments
- Demonstrating a high level of expertise in treating their specific illness
- Making it easier to schedule appointments
- Improving interpersonal or communication skills
- Offering more clarity on all of the available services they offer
- Having a friendlier and more accommodating staff
- Providing a wider range of treatment options
- Providing cleaner or more modern facilities
- Contacting patients via check-ins and follow-ups between appointments

Source: West’s “Prioritizing the Patient Experience Survey,” based on responses from more than 1,000 U.S. patients
The hospital also provides access to telehealth visits to pediatric patients with chronic conditions. For example, a young female patient with diabetes has taken part in telehealth sessions with her physician and uses a digital glucometer to monitor A1c levels. This data is used in conjunction with her telehealth visits to better manage her diabetes, says Pageler.

Pageler says extending the reach of providers to patients—whether they’re in a dorm room, in an after-school program, or at summer camp—allows for the continuation of care patients need.

“The alternative isn’t great,” she says. “[Patients with diabetes, for example] end up missing a lot of visits, and because they miss their visits, they may feel uncomfortable reaching out to their doctors. And that can lead to bad outcomes, such as ketoacidosis for patients whose diabetes is wildly out of control.”

3/ CREATE A FORMAL PROGRAM

“Healthcare should always, at its core, be about human relationships and relieving suffering,” says Burke, of Geisinger. But ensuring this is always top of mind for all employees can be challenging. That’s why the health system organized an employee training program called C.I. Care, which stands for:

- Connect
- Introduce
- Communicate
- Ask and anticipate
- Respond
- End with excellence

How does this translate to daily work? Take, for example, a patient who enters the health system and doesn’t know how to get to his doctor’s office. An employee will walk that patient to the office, rather than directing him.

“Everyone has to be a part of this mission. We’ve tried to emphasize that it doesn’t matter what your role is,” says Burke. “Whether you’re the chief patient experience officer or a cardiologist, you just deliver on what the patient needs.”

4/ COACH PHYSICIANS TO CONNECT

Primary-care doctors typically have approximately 20 minutes to see each patient, reports Reuters—and that doesn’t leave a lot of time for a personal connection.

Because strong patient-relationships can result in better health outcomes, New Orleans-based Ochsner Health System, Louisiana’s largest nonprofit health system, trains physicians in “caring communications.” This course, which provides CME credit, includes a didactic session during which physicians learn to communicate better with patients. Next, physician-coaches play the role of patients in various scenarios, and other physicians react, observe, and provide feedback about how physicians should react.

Pyles says physicians should be aware of their own emotional intelligence triggers, such as feeling stressed and overwhelmed.

“Once you recognize that trigger, you can decide to use emotional intelligence in your response,” she says.

As a result of this and other efforts, 77% of patients rank Ochsner’s hospitals as “exceptional” in HCAHPS, and 94% are likely to recommend their provider office in the Clinical Group Consumer Assessment of Healthcare Providers and Systems Survey.

5/ PROVIDE HEALTHY FOOD OPTIONS

Leaders at Dignity Health’s Sequoia Hospital in Redwood City, California, discovered during “happy hour” rounds, during which they go to patients’ rooms to inquire about their experience, that patients were looking for healthier options, says Sherie Ambrose, RN, vice president of patient care services.

In the San Francisco area where the hospital is located, many patients prioritize eating seasonal, fresh foods. They also tend to be concerned about reducing the carbon footprint, another reason they prefer locally sourced food.

Since February, Sequoia Hospital has purchased fresh fruits and vegetables from a distributor that sources from local farms in nearby Salinas and Watsonville, and those changes are reflected in menus, says Michael McBride, director of food and nutrition services.

As a result of this and other efforts to improve the patient experience, the hospital has witnessed consistent increases in all HCAHPS scores, in some cases more than 20%.

Aine Cryts is a writer based in Boston.
The anatomy of a good patient experience

What do patients mean when they say they want a “positive healthcare experience”? Results of a new survey from the Beryl Institute, a nonprofit promoting better patient experiences, reveal what patients are looking for when they make an appointment.

People, processes, and place are critical

Positive interaction with people—physicians, nurses, and front office workers—is considered extremely important to most patients. Next is easy-to-use processes for scheduling, payment, waiting time, referrals, prescriptions, and more. Finally, a comfortable and clean office space is key.

10 keys to a good patient experience

(percentage of patients who rated it “extremely important”)

1. Physicians and staff listen to you (71%)
2. Communicate clearly in a way you can understand (67%)
3. Treat you with courtesy and respect (65%)
4. Give you confidence in their abilities (64%)
5. Take your pain seriously (63%)
6. Practice/hospital provides an environment that is clean and comfortable (62%)
7. Provide a clear plan of care and explain why they are doing it (59%)
8. Ask questions and try to understand your needs and preferences (56%)
9. The ability to schedule an appointment or procedure within a reasonable time period (52%)
10. A discharge/checkout process in which your treatment plan and next steps in care are clearly explained (52%)

How patients describe bad experiences

How patients describe good experiences
Pharma Exec Defends 400% Price Hike

FDA commissioner issues stern reply

Reminiscent of former Turing Pharmaceuticals CEO Martin Shkreli, a different pharma executive recently defended his company’s 400% price hike on an antibiotic.

Nostrum Laboratories had a “moral requirement to sell the product at the highest price,” Nirmal Mulye, PhD, founder of Nostrum, told the Financial Times. Mulye was referring to the company quadrupling the price of a bottle of Macrobid (nitrofurantoin) from $474.75 to $2,392 in August.

Nitrofurantoin, used to treat bladder infections, is on the World Health Organization’s list of essential medicines.

The action—and Mulye’s comments—earned a stern tweet from Scott Gottlieb, MD, FDA commissioner. “There’s no moral imperative to price gouge and take advantage of patients,” he tweeted.

Mulye said Nostrum was responding to a price increase from Casper Pharma, which makes Furadantin, a branded version of the antibiotic. Casper increased the price of its product by 182% between the end of 2015 and March 2018. Now, each bottle is priced at $2,800.

Nostrum and Casper raised the price of nitrofurantoin after supply shortages of the liquid version. Several pharma makers removed their versions of the drug from the market temporarily to reformulate them, when the FDA issued new rules on impurities, resulting in shortages, Financial Times reported.

Mulye also defended the actions of Martin Shkreli, who raised the price on Daraprim for toxoplasmosis 5,000% in late 2015. Shkreli was sent to prison earlier this year on unrelated fraud charges.

“I agree with Martin Shkreli that, when he raised the price of his drug, he was within his rights because he had to reward his shareholders,” Mulye told Financial Times. Turing was the only company making Daraprim at the time, so “he can make as much money as he can,” Mulye said. “This is a capitalist economy and, if you can’t make money, you can’t stay in business.”

While Mulye said the price of the antibiotic could change again “according to market conditions,” he also launched an attack on the FDA. The agency is “incompetent and corrupt” and he said Nostrum has lost money for several years due to an increase in the fees that drugmakers are required to pay the FDA—tantamount to “highway robbery.”

“There’s no moral imperative to price gouge and take advantage of patients.”

- SCOTT GOTTLIEB, MD, FDA

Price transparency is increasingly a focal point across the healthcare industry, with action now occurring at the federal, state, and grassroots levels, according to a recent report from West Monroe Partners, “The 4 Market Forces Transforming Drug Pricing.”

The report highlights several key areas of action to support price transparency. They include:

- Growing bipartisan support for an amendment to H.R. 6147 at the federal level, which requires prescription drug advertisements to be more transparent by communicating costs, illuminating the profits gained in the downstream value chain, and exposing pricing discrepancies across states and health plans.

- The enacting of price transparency laws in a growing number of states such as Maine, California, Nevada, Oregon, and Vermont.

- New tools arising to help boost price transparency, such as a database from 4Brooklyn Research and the website Lowestmed.com.

As pricing transparency takes hold, the variance within the drug pricing value chain will likely narrow, according to the report.

A professional freelancer for 25 years, Christine Blank has been published in the nation’s leading newspapers and trade magazines, including The New York Times, Drug Topics, and Formulary Watch.
Spotlight on COPD

Latest trends, challenges, and opportunities by MICHELE MEYER

COST-EFFECTIVE MANAGEMENT STRATEGIES

COPD is the third deadliest disease in the U.S. It’s also among the costliest conditions to treat. Driving up the bill to $50 billion annually in the United States are aggravated symptoms, which can lead to hospitalizations, according to figures cited in Pharmacoeconomics Outcomes Research in 2011. Yet experts say small measures can bring major savings.

Switch from IV to oral steroids and antibiotics
Doctors at Florida Hospital in Orlando evaluated data from 354 patients admitted to the hospital from January 2009 through December 2011 with an acute exacerbation (AECOPD) of their disease. In one group, hospitalization averaged 2.8 days, versus 5.04 days in the other, says Sunil H. Advani, MD, lead author and then a resident at the hospital.

“We found three variables made a significant difference, two related to drugs,” says Advani, now an internal medicine and urgent care doctor at Providence Medical Associates in Manhattan Beach, California. In the shorter-stay group, 85% of patients received oral steroids versus IV, and in the longer-term group, only 8.9% received oral steroids versus IV.

“The GOLD standard of care for AECOPD primarily recommends oral steroids, which may explain the disparity,” Advani says.

Guidelines for antibiotics are less clear, as reflected in physicians’ practices, with 72% of shorter-term patients getting oral antibiotics, versus 33% among longer-term patients, he says.

Another benefit to oral medications is that patients are easier to transfer to home care, while shorter hospital stays lower the chance of catching an infection when making rounds, says Advani. The study findings, “Variations in practice patterns and resource utilization in patients treated for chronic obstructive pulmonary disease,” were published in the June 2018 issue of the Journal of Evaluation in Clinical Practice.

Courses of steroids and antibiotics often are lengthier (and thus more expensive) than needed, says Surya P. Bhatt, MD, MSPH, associate professor of medicine at the University of Alabama at Birmingham Division of Pulmonary, Allergy, and Critical Care Medicine. “Five days of steroids has been found to be as equally good as the former standard of 14 days. The same holds true for antibiotics,” he says.

“Often hospitals prescribe oxygen therapy more than needed. Sometimes patients are left on inhaled steroids far longer than necessary.”

SURYA P. BHATT, MD, UNIVERSITY OF ALABAMA AT BIRMINGHAM

What is COPD?
COPD refers to a group of diseases that cause airflow blockage and breathing-related problems. It includes emphysema and chronic bronchitis. COPD makes breathing difficult for the 16 million Americans who have this disease. Millions more people suffer from COPD, but have not been diagnosed and are not being treated.

Source: CDC

Managed Healthcare Executive.com
COPD treatment progress is stymied by many factors, including the nature of the ailment itself. "COPD is a very complex condition," says Timothy J. Scialla, MD, pulmonologist at Duke University’s Duke Asthma Allergy and Airway in Durham, North Carolina. "Not every person with COPD has the same underlying mechanism driving their disease. Nor does each patient have the same damage."

Most patients fall into two groups: Those whose troubles are mostly with the airways and those whose issues are with the air sacs, Scialla says. Of course, some patients have both problems. "The easiest way to explain it is to think of grape plants," he says. "The airways are the stems, while the air sacs are the grapes."

Improving their outcomes, that’s good," Adwani says. Otherwise, consultations pad time and expense of treatment. "Before ordering a consult, physicians should question whether it’s worthwhile."

**Promptly follow up**
The benefits of in-clinic doctor appointments post-discharge are many, including reviewing medications.

"Often hospitals prescribe oxygen therapy more than needed," Bhatt says. Sometimes patients are left on inhaled steroids far longer than necessary.

Smoking also should be addressed in clinical visits, Bhatt says. Among 39,038 COPD patients in one study, 36.4% were former smokers, 38.7% were current smokers, and 43.7% had a history of asthma, according to the CDC’s Morbidity and Mortality Weekly Report from 2012.

"Quitting smoking improves symptoms, leads to fewer acute exacerbations, slows lung function decline and the disease’s progression, and makes it more likely that patients will respond to medications," Bhatt says.

Also, doctors should make sure COPD sufferers are up to date with their flu and pneumonia vaccines, he says. People vaccinated against pneumonia are less likely to experience a COPD exacerbation.

**Skip unneeded consultations**
"Whenever a doctor consults with a specialist, hospital stays lengthen," Adwani says. Specialists—often in pulmonology or infectious disease—may not be at the hospital when the consult is requested. Any tests they order also affect length of admission.

Doctors at Florida Hospital in Orlando found that with no consults, patients were released in 2.58 days, versus 4.6 days for single consults, 5.4 days for two, and 10 days for three or more.

"If patients are sicker and this improves their outcomes, that’s good," Adwani says. Otherwise, consults pad time and expense of treatment. "Before ordering a consult, physicians should question whether it’s worthwhile."

**Treatment limitations**
While some medications can improve shortness of breath and thwart acute exacerbations in patients, none have been shown to slow or reverse lung damage, Scialla says.
Studies need to address phenotypes—the merger of genes and environment—since the way they combine alters disease traits in individuals, he says. “The future lies in personalized medicine. We need to be able to say individuals with certain characteristics will respond better to a certain medication than those without those characteristics.”

**Costly medications**
Further complicating matters, current COPD medication is costly, and patients can spend up to $300 to $400 monthly on inhalers and bronchodilators, says Scialla, noting that no generic versions of COPD drugs exist.

When patients cannot pay for their medications, they’re less likely to take them. In fact, as few as 40% of COPD patients take drugs as prescribed, according to “Medication Adherence Issues in Patients Treated for COPD,” a study published in 2008 in *International Journal of Chronic Obstructive Pulmonary Disease*.

Lack of adherence leads to acute exacerbations, which in turn, leads to costly hospitalizations. The bottom line: Providers may end up covering that expense, Scialla says.

COPD causes lasting lung damage even before symptoms show. By the time mild COPD is detected, patients already may have lost more than 40% of their small airways, according to researchers at the University of British Columbia in Vancouver, Canada, whose findings were published in 2018 in *The American Journal of Managed Care*. The researchers reviewed 30 years of specimens in a Canadian lung tissue registry.

“Many people have undiagnosed COPD, so the importance of screening is greater,” says Scialla, noting that six other medical conditions often accompany COPD, and providers should heed them as signs that COPD screening may be needed. “COPD is not just a disease of the lung,” he says. “It can affect your whole body.”

**Muscle weakness.** “The muscles become less efficient in exercise and especially in patients who are sedentary,” Scialla says. “That creates a vicious cycle: Patients are weak so they don’t move, and they don’t move so they get weaker.”

**Heart failure.** COPD and heart failure are chronic, progressive disorders that curtail a major organ’s ability to meet the body’s demands. COPD lowers oxygen levels in the blood, which in turn can induce heart failure. The two conditions share many symptoms, including shortness of breath with effort. They also have common causes: smoking, inactivity, and systemic inflammation. “The heart and lungs are bed partners, living in the same area of your body,” Scialla says. “When one is struggling, the other has to strain to do its job.”

**Dementia.** Smoking sparks not only COPD, but also gradual mental decline due to low oxygen and high carbon dioxide levels, as well as blood vessel damage, Scialla says.

**Osteoporosis.** COPD patients have a higher risk of bone brittleness and loss. The National Health and Nutrition Examination Survey, which included 14,828 subjects aged 45 or older, noted a 16.9% prevalence of osteoporosis in COPD patients compared with 8.5% in subjects without coexisting COPD.

**Lung cancer.** Smoking, genes, and chronic lung inflammation contribute to both COPD and lung cancer, Scialla says. Depression and anxiety. “Which comes first, COPD or depression? I don’t know,” he says. But depressed patients are less likely to exercise and more likely to stay indoors, thus decreasing their vitamin D levels, all contributors to COPD.

**SURPRISING RISK FACTORS**
Almost 15.7 million Americans (6.4%) are diagnosed with COPD, and many more may have it but are undiagnosed, according to 2014 figures from the CDC. Approximately 90% of COPD cases may be caused by cigarette smoking, according to the American Lung Association. Cigarettes release toxins that expose lungs to infections, narrow air passages, and ignite inflammation—all contributors to COPD.

Managed care organizations also should be on high alert for lesser known culprits:

1. **Outdoor pollution.** Long-term exposure to toxic chemicals, dust, car exhaust fumes, and secondhand smoke in the air spark inflammation within the lungs, which...
damages them, says Mark T. Dransfield, MD, medical director at the University of Alabama at Birmingham Lung Health Center.

2 **Emotional distress.** Even low levels of anxiety and depression spike the risk of COPD by 44%, while moderate levels raise it 125% and high levels increase it 148%, according to a study, “The effects of psychological distress and its interaction with socioeconomic position on risk of developing four chronic diseases,” in the Journal of Psychosomatic Research.

3 **Occupational hazards.** Coal miners, firefighters, factory workers, and pest control providers aren’t the only individuals exposed to dust and harmful chemicals such as formaldehyde, aerosol sprays, pesticides, and bleach. So are farmers, hair stylists, nail technicians, housekeepers, construction crews, painters—and healthcare providers. Doctors, nurses, and other hospital and medical office staff are often exposed to lung diseases including flu, tuberculosis, and severe acute respiratory syndrome.

4 **Childhood health issues.** Premature birth, low-birth weight, and childhood asthma, respiratory infections, or exposure to secondhand smoke hinder lung development in utero and up to age 25, Dransfield says. That could limit a patient’s lung growth and put them at risk.

5 **Adult asthma.** Four in 10 women with asthma develop COPD, according to a University of Toronto study that followed 4,051 women for more than a decade. The study, “Asthma and COPD Overlap in Women: Incidence and Risk Factors,” was recently published in the Annals of the American Thoracic Society.

6 **Ethnic heritage.** American Indians, native Alaskans, and multiracial non-Hispanics also have a higher likelihood of suffering COPD, according to the latest CDC figures.

7 **Genetic flaws.** Between 1% and 3% of people lack alpha-1 antitrypsin, a protein that helps protect the lungs, Dransfield says. There may be other genetic risks yet to be identified that increase susceptibility to COPD.

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**Michele Meyer** has covered COPD and medicine the past 25 years for major hospitals and associations, including Memorial Hermann Hospitals, American College of Obstetricians and Gynecologists, and the University of Texas.

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**Readmissions Rack Up Costs**

Readmissions are one of the costliest episodes to treat. In 2011, 3.3 million readmission visits occurring within 30 days after discharge cost hospitals $41.3 billion. Hospital costs reflect the actual expenses incurred in the production of hospital services, such as wages, supplies, and utility costs.

—The Agency for Healthcare Research and Quality

**Coverage Questions**

Over 56% of Americans polled were not sure whether their domestic health insurance plan would cover any emergency doctor or hospital visits while traveling outside the country.

—InsureMyTrip

**Career Path**

Five of the 15 most popular jobs among millennials, the largest generation in the workforce, are in healthcare. **Physician assistants** have the highest median annual wage among these jobs, at $104,860. Other healthcare jobs that made the list include:

- Phlebotomists
- Emergency medical technicians and paramedics
- Medical assistants
- Dental assistants

—LiveCareer

**Quotable**

“We’ve already seen a shift away from brick-and-mortar stores in other sectors; it was only a matter of time before we saw something similar with healthcare.”

—Kim A. Buckey, vice president, Client Services, DirectPath, LLC, pg. 14