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Social Pressure: 5

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Cover Story

TELEHEALTH

is dialing up the dollars

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Chairman’s Letter

Telehealth: a creator and a creature of disruption

Technology can be a disruptive force in healthcare, upending tried-and-true ways of doing things. Look at how laparoscopic techniques changed many forms of surgery and how MRI scans fundamentally altered medical imaging.

But the causality can go in the opposite direction, with disruption creating an opening for technology. That’s what has happened with telehealth and remote care. Sure, it was available before March 2020 and the beginning of the COVID-19 pandemic in the United States. As Susan Ladika reports in our cover story this issue, Teladoc went public way back in 2015. Amwell, which used to be American Well, was founded in 2006 by Ido and Roy Schoenberg.

But until last year and the upending of healthcare delivery, telehealth utilization was trundling along at single-digit levels. Ladika reports on how use has mushroomed and describes the enormous sums of money flowing into — and through — the industry. Teladoc and Livongo, the digital monitoring company, merged last fall in a $18.5 billion deal. Amwell went public in September, and GoodRx acquired HeyDoctor for an undisclosed amount a year earlier. The trend line for Teladoc’s stock price over the past five years looks like a side view of a topographical map of the American West: pretty flat in the plains, rising foothills in 2018 and 2019, and then the soaring Rockies in 2020.

But stock prices are wagers on the game, not the game itself. In an op-ed piece for Harvard Business Review last month, Jessica Dudley, M.D., and Iyue Sung, Ph.D., of Press Ganey, wrote about telehealth’s spacious room for improvement. Their suggestions for healthcare organizations focus on standardization: creation of “central resource teams” to scale up telehealth operations, for healthcare organizations focus on standardization: creation of “central resource teams” to scale up telehealth operations, all specialties having telemedicine capabilities, and training “to support the goal of delivering a consistent, cross-specialty patient experience.” One of their more specific recommendations is to have a common “waiting room” experience.

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(Will we still have our choice of old magazines to flip through, albeit virtually, while we wait to be seen?)

Payers are still puzzling through how to cope with telehealth. More than a few experts believe it could disrupt payment arrangements. Telehealth might create a tipping point and usher in an era of valued-based payment with some aspects of capitation.

There are many things to look forward to in 2021. Watching how telehealth will fare is one of them.

Mike Hennessy Sr.
Chairman and Founder of MJH Life Sciences™
Mission Managed Healthcare Executive® provides healthcare executives at health plans and provider organizations with analysis, insights and strategies to pursue value-driven solutions.
A conversation with Kevin Ronneberg, M.D.

Kevin Ronneberg, M.D., is vice president and associate medical director for health initiatives at HealthPartners, a nonprofit integrated healthcare delivery system headquartered in Bloomington, Minnesota. Ronneberg has been on the MHE editorial advisory board since 2015.

Q Could you tell us about your career and what motivated you to go into healthcare?

I grew up in a small community in Minnesota and knew a number of physicians. That had an impact on me, and I had the opportunity to shadow some of them. I really saw that medicine was the way that I could be a teacher, like my dad was, and help people and contribute to people living a better and healthier life.

That led me into family medicine. And I practiced family medicine — everything from delivering babies to making rounds at nursing homes to working in the ER and ICU for several years. I moved into a sports medicine practice and then moved over into the administrative side of leadership. I spent three years at Target leading retail clinics and pharmacies. I have been at HealthPartners since 2015. I work with our commercial group insurance — large employers — and also inside the organization with our product development, marketing teams and medical management teams.

Q Do you think the shift to remote care and telehealth is permanent?

I think now that consumers have tried it, they will want this after the pandemic. I don't think that this is going to go away. It's really more of a question of, what's the operating model? What's the business model? What's the scope? Where is it most effective? And then how do we balance those who want a relationship with the same provider but who also may benefit from both a model where it's virtual and in person? So I think there are a number of challenges that lie ahead, but it will not go away.

Q HealthPartners closed seven clinics last summer. Was that a consequence of more virtual care?

When you switch to virtual care, one of the things that is readily apparent is that the resources you need, particularly bricks-and-mortar facilities, are very different. We have a number of clinicians in our own care system, as well as the care systems we contract with, who have been able to work from remote settings. And that certainly reduces the footprint you need to have available.

We've seen shifts over the last decade or so to a lot of care occurring in the outpatient setting. And we're fortunate at HealthPartners that our square footage at hospitals is lower than at a lot of healthcare systems. I think we're in pretty good shape there.

We're going to continue to assess the needs that we have. So as we deliver more virtual care, what role do the bricks-and-mortar clinics play? We're thinking that about 30% of care can be delivered virtually. And over the next probably 12 to 24 months, depending on how the pandemic plays out, we're going to test some of the hypotheses on what it takes to deliver a new model of care.

Q Have protests regarding racial injustice opened your eyes to health disparities in a new way? And how has HealthPartners responded?

I'm glad you brought that up. George Floyd's death happened here in Minnesota, just a few miles from where I'm sitting right now. It was an amplifier and drew attention to something that I think needs serious attention.

Personally, it's really driven a lot of focus on friendships that I have. I played football in college. And I've made phone calls to some of my friends who have diverse backgrounds, and I've been remembering conversations or settings we were in when I had no idea what they were experiencing. And it's really deepened some of those long-term relationships.

I'm really proud that over the last several years, HealthPartners has been raising conversations about race, both within our leadership group and within our employee population, and having an open dialogue about unconscious bias. One of the things that we're doing is developing a cabinet at the senior executive level, with representation of diverse leaders across our organization, that is focused on equity, inclusion and antiracism.

The focus is on more than avoiding people who are racist and moving toward recognizing where racism occurs and taking action to reduce that racism. So we have some lofty goals over the next few years. I feel really proud to be part of an organization that has raised this issue of racism to the senior executive level and raised awareness across the organization.
The limits of DTC telehealth

Telehealth holds the promise of increasing access to care. But research findings concerning direct-to-consumer (DTC) telehealth, reported in *JAMA Network Open* last month, suggest that it might not be as simple as that.

Ateev Mehrotra, M.D., M.P.H., an associate professor of health policy and medicine at Harvard Medical School and a member of Managed Healthcare Executive’s editorial advisory board, and Tara Jain, M.D., MBA, a physician at Brigham and Women’s Hospital in Boston, conducted a cross-sectional study of telehealth usage by using de-identified data from a DTC telehealth company (they don’t name the company). The company’s services were available in 20 states, and the data Mehrotra and Jain used in the analysis were for about 35,000 visits between Oct. 1, 2019, and Dec. 31, 2019. Comparing the telehealth users with the overall population in those states, the researchers found that the telehealth patients were more likely to live in urban areas and high-income ZIP codes. Only 14.4% of the visits were for patients living in areas identified as having a shortage of primary care.

When Mehrotra and Jain looked at why people used the company’s services, they found that 87% of the visits were for one of three conditions: urinary tract infections (53%), erectile dysfunction (21%) and contraception (13%).

Mehrotra and Jain put barriers to access into different categories and suggest that their findings indicate that DTC telehealth helps with some barriers (accommodation barriers and acceptability barriers) but not others (clinician availability or affordability barriers). “Those seem like important barriers, and telehealth isn’t addressing them,” Mehrotra said.

But Mehrotra also stressed that “telehealth” is an umbrella term: “DTC is just one distinct form of telehealth,” he said. “In this application, the advantage was the convenience and avoidance of embarrassment. I think that is an important finding, but there are many other forms of telehealth.”

Biden equity leader emphasizes data

Collecting high-quality data is critical to addressing healthcare equity issues, according to Marcella Nunez-Smith, M.D., M.H.S., whom President-elect Joe Biden has chosen to lead a new White House task force on the issue.

“There is violence in data invisibility. We cannot address what we cannot see,” Nunez-Smith, an associate professor of medicine and epidemiology at the Yale School of Medicine, said during an online forum on racism and discrimination in healthcare last month that was sponsored by Kaiser Family Foundation and the Morehouse School of Medicine’s Satcher Health Leadership Institute. “We are making a choice every time we allow poor quality to hinder our ability to intervene on racial and ethnic minorities.”

Nunez-Smith discussed the lack of compliance with a requirement that race and ethnic group information be included when COVID-19 cases are reported to public health officials and a similar absence in data about COVID-19 testing.

Nunez-Smith, whom Biden appointed earlier to be one of three co-chairs of his COVID-19 task force, also mentioned representation in the physician workforce and collection of data about patients’ experiences of discrimination as crucial to addressing healthcare inequities.

“Healthcare is a right, not a privilege. Healthcare free from racism and discrimination is a right, not a privilege,” she said.
In Brief

**Year ends in a ‘double peak’**

Utilization crashed last spring during the initial weeks of the COVID-19 pandemic. The result for many insurers was a lot of black ink. Blue Cross and Blue Shield of Minnesota was among those with a large margin. In August 2020, the not-for-profit insurer announced a giveback package that included $38 million in premium relief and $31 million in medical-loss ratio rebates from 2019 that ordinarily would have been paid later in the year.

But in an interview with *MHE* in early December, CEO Craig Samitt said he was expecting the company’s financial performance “to be on par” and for premium increases next year to be in the mid-single digits. Utilization bounced back, he said, partly because after putting off care, some people are sicker than they might have been. As a result, Minnesota is experiencing a “double peak,” Samitt explained. “We’re seeing a high number of COVID cases,” said Samitt. “And we’re seeing a high number of non-COVID cases, which puts us in a very tenuous spot in terms of hospital capacity. We’re at a very challenging time.”

**Lilly, UHG become research bedfellows**

Eli Lilly and UnitedHealth Group announced early last month that they are teaming up to conduct a “pragmatic” study of Lilly’s bamlanivimab, a monoclonal antibody developed as a treatment for COVID-19. The FDA’s emergency use authorization of bamlanivimab limits its use to patients who have not been hospitalized.

UnitedHealthcare Medicare Advantage members will be invited to participate. Study volunteers will use a symptom-checker app developed by Optum, which is part of UnitedHealth. If they experience symptoms, they will take a self-administered test for SARS-Cov-2, the virus that causes COVID-19. An Optum Infusion Pharmacy nurse will oversee at-home infusions of bamlanivimab. Many non-COVID-19 patients getting treated at infusion centers are immunocompromised, so home infusion of this treatment might very well have some safety advantages. The primary outcome measure is hospitalizations in the 28-day period after the drug is infused.

One of Managed Healthcare Executive’s latest episodes in the “MHE Talks: Improving Patient Access” podcast series features Kevin Lewis, president and CEO of Community Health Options in Lewiston, Maine. Senior Editor Peter Wehrwein spoke with Lewis about how the health plan, one of the three surviving ACA co-op plans, is working to improve patient access by pushing for cost-effective care and use of telehealth.

The “MHE Talks: Improving Patient Access” podcast is a series within *MHE*’s main podcast “Tuning In to the C-Suite.” You can listen to the patient access series every other Tuesday on “Tuning In to the C-Suite” on iHeartRadio, Apple and Spotify or on the *MHE* website.

All “MHE: Talks: Improving Patient Access” podcast episodes can be found at https://www.managedhealthcareexecutive.com/podcasts.

“Tuning In to the C-Suite” podcast episodes can be found at https://www.managedhealthcareexecutive.com/podcasts.
This year stands to be a pivotal one for HIV/AIDS prevention and treatment. Many researchers and advocacy groups are heartened by President-elect Joe Biden’s selection of Rochelle Walensky, M.D., M.P.H., to be the CDC director in the new administration. Walensky, chief of infectious diseases at Massachusetts General Hospital and a professor at Harvard Medical School, is a well-known HIV/AIDS researcher. The CDC director does not require Senate confirmation so there’s no reason to believe that Walensky won’t be heading up a federal government agency that plays a central role in HIV/AIDS policy.

Walensky will be taking the CDC at a crucial time in the course of the HIV/AIDS epidemic. Many people infected with HIV don’t have a diagnosis. That said, it is notable that the number of diagnosed cases has been declining. In 2018, the latest year for which a complete tally is available, 37,968 new cases were diagnosed, 2,868 fewer than the 40,836 diagnosed in 2014.

Here are three possible developments in HIV/AIDS treatment in 2021 could have a major effect on the disease and people it affects:

1. **Awaiting a decision from the FDA on long-acting injectable Cabenuva**

   So far, treatment for HIV involves taking pills that need to be taken daily. That may change this year with the advent of treatments that can be injected. The FDA is expected to issue its decision on ViiV Healthcare’s injectable Cabenuva—a combination of cabotegravir and rilpivirine—sometime in the next few months. ViiV Healthcare, a joint venture by GlaxoSmithKline and Pfizer, is seeking approval for the regimen in adult patients with HIV whose viral load is suppressed and who are not resistant to cabotegravir or rilpivirine.

   In phase 2 and 3 clinical trials, the treatment combination, given as two paired injections once a month by a healthcare provider, was shown to be equally as effective as traditional oral options. While caused injection-site reactions, patients still preferred Cabenuva over the alternative daily oral option.

2. **Inching closer to a twice-yearly injectable for treatment-resistant patients**

   Gilead is expected to complete regulatory filings this year for their long-acting self-injectable HIV treatment lenacapvir. Gilead’s long-acting injectable only has to be injected once every six months. If approved, the HIV-1 capsid inhibitor will be the first treatment of its kind on the market. It is meant for heavily treated patients who have become resistant to multiple drugs—a particularly difficult-to-treat group of patients—in combination with other treatments.

   The anticipated regulatory filings will come on the heels of Gilead releasing topline results from the phase 2/3 CAPENTA trial of 36 patients. The data showed patients receiving lenacapvir were significantly more likely to meet the study’s primary endpoint of a 0.5 log₁₀ or greater reduction in viral load compared with placebo.

3. **Seeing how cabotegravir by itself plays out**

   Excitement is also mounting for the very real possibility that a long-acting injectable to prevent HIV will soon be approved. As 2020 came to a close, the FDA granted breakthrough designation to ViiV Healthcare’s cabotegravir—one of the two drugs in HIV treatment candidate Cabenuva—for the prevention of HIV.
Prescription Digital Therapeutics in Behavior-Driven Conditions

A Multi-Stakeholder Roundtable Recap

Over the past several decades, the US health care system has increasingly gone digital, from the rise of electronic health records to the now-standard practice of using patient portals for communication. One of the markers of this transition is digital therapeutics, which use software to deliver clinical grade medical interventions for patients to treat, manage, and prevent a wide variety of diseases and disorders.

With the increasingly prominent role that digital therapeutics play in patient care and management, it is important that they adhere to core principles of health care—particularly when it comes to clinical evaluation, rigorous product design, human factors testing, patient privacy and security, and regulatory oversight. This is especially important in the care of patients with behavior-driven conditions, given the challenge of objective measurements in psychiatric health.

In a recent multi-stakeholder video roundtable—available at www.managedhealthcareexecutive.com/view/several thought leaders discussed the optimal use and benefits of prescription digital therapeutics, specifically in behavior-driven conditions. The roundtable was moderated by Megan Coder, PharmD, MBA, Executive Director of the Digital Therapeutics Alliance. Panelists included: John Luo, MD, Clinical Professor of Psychiatry at the University of California, Irvine; Steven Peskin, MD, MBA, FACP, Executive Medical Director, Population Health and Transformation at Horizon BCBS New Jersey; and Nidal Moukaddam, MD, PhD, Associate Professor at Baylor College of Medicine.

This article recaps key points from the discussion.

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| Steven Peskin, MD, MBA, FACP |
| Executive Medical Director, Population Health and Transformation |
| Horizon BCBS New Jersey |

| Nidal Moukaddam, MD, PhD |
| Associate Professor |
| Baylor College of Medicine |
“Digital therapeutics are delivering an active intervention to a patient, but they’re working alongside of and in conjunction with remote patient monitoring and telehealth, and all these other products to enable holistic care. I think what [we are] really getting at is this notion of holistic care and something that you can actually have actual data to make a decision on and not feel like you’re working in a vacuum.”

**The Benefits of Prescription Digital Therapeutics**

Digital therapeutics present many potential benefits to clinicians, according to Dr. Moukaddam.

“The ideal digital therapeutic is something that is based on solid scientific [and] diagnostic ground, and that is helpful for the patient when they are outside of the clinician’s office,” she notes.

When it comes to the details regarding application, Dr. Moukaddam suggests that it may be helpful to think of digital therapeutics in terms of teaching skills and enforcing certain behaviors. “This is where digital therapeutics would fit best, and in that sense, you can see it in terms of preventing self-harm, preventing cutting or self-injurious behavior; you can see it in the realm of addiction.” For example, Dr. Moukaddam notes that the reset app uses cognitive behavior principles that reinforce many of the things we teach our patients. In order to pick the right digital therapeutic, she stresses the importance of knowing what you want to measure, given the difficulty of quantitatively measuring things in psychiatry and mental health. Thus, context is key. “The first level of context is: What am I prescribing this for, or what am I recommending this for? The second level of context will be: What do I expect this to achieve? If I’m expecting it to teach a new skill, there [will need to be] a starting point in the clinical encounter. An app cannot do it by itself.”

From an integration perspective, digital therapeutics may help to address several unmet needs respective to managed care. According to Dr. Peskin, digital therapeutics can supplement, augment, and compliment the work of clinical partners of behavioral health, including primary care providers, internists, social workers, and counselors. “Primary care and behavioral health are very much team-based efforts, and digital therapeutics have the opportunity to enhance [and improve] that interaction,” he says.

The use of digital therapeutics could also positively affect patient satisfaction, according to Dr. Moukaddam. “We know that literature tells us people are happy, typically, when they have some sort of digital follow-up, technology follow-up, whether it be for wound care or for diabetes. It decreases loneliness tremendously, so the patient satisfaction element is there,” she notes.

Another point worth noting, according to Dr. Peskin, is that digital therapeutics are generally cost-effective. “The relative low cost of digital therapeutics can have a positive impact on what we look at, which is total medical expense.” The notion of using digital therapeutics that are scalable and accessible to patients is critical to what this industry can provide.

The benefits of digital therapeutics may also reach health care providers, according to Dr. Luo. “Providers are looking for a way to help their patients, especially when [they’re] very busy and have a huge panel of outpatients. When there’s a crisis, how do you squeeze in the time to go see the patient? If there is a digital therapeutic that can serve as a bridge until the next time that you can interact with the patient, whether in person or via these videoconferencing solutions, posed a great adjunct,” says Dr. Luo. You want this to
“The first level of context is: What am I prescribing this for, or what am I recommending this for? The second level of context will be: What do I expect this to achieve? If I’m expecting it to teach a new skill, there [will need to be] a starting point in the clinical encounter. An app cannot do it by itself.”

Integration of Digital Therapeutics
When it comes to integration, some companies have begun to integrate digital therapeutics into clinical workflows and electronic health records. Dr. Moukaddam emphasizes that this is a nascent field, though. “There are a lot of liability issues because if you add another source of information, you are adding liability. It will be a potential problem if you miss a finding that could have alerted you to a bad patient outcome,” she notes. While the liability aspect remains to be properly explored, it is also important to consider the element of time. “Everything you do will add time, and I don’t think people have time in their schedules for this,” says Dr. Moukaddam.

For these reasons, Dr. Luo states that it is likely that many patients are ahead of providers when it comes to integrating the technology. “Patients are really looking for solutions, especially if there is going to be a wait to see their provider, or to get access to the next appointment,” says Dr. Luo. “I’ve seen this over the last 20 years, where patients were slow at adopting technologies, and now people download apps without thinking, checking on issues of privacy, or [how] their data is being used.” According to Dr. Luo, patients want some hope that something they use will help them feel or live better.

From the provider perspective, Dr. Luo believes that the field is getting better at adopting technology, “It used to be said that psychiatrists were notorious for being the least tech savvy, but I don’t think that’s the case anymore, though we still exercise more of a critical judgment [regarding] the scientific basis of this app or digital therapeutic. Has it been proven in a clinical trial? Does the theory make sense? We’re much more hesitant, I think, only because we really want it to be effective when we offer it to the patient, and the other part, too, is—especially with using apps as an example—it’s really hard to know what works well for people and all the security and privacy concerns. We want to see the studies. We want to see what the reports are in terms of benefits and side effects before we’re comfortable with prescribing it,” says Dr. Luo.

Dr. Peskin adds that digital therapeutics offer an opportunity for harmonization among health care professionals, which is especially important in the field of behavioral health. “We know that a majority of behavioral health in the United States is delivered by family physicians and general internists,” he states. “Psychiatrists are significantly overwhelmed, and it would be great to give psychiatrists an opportunity to do more than just prescribe drugs. Maybe digital therapeutics can be a tool that the provider has confidence in and helps with their particular style or method versus having the patient going off on their own.

Despite the potential of digital therapeutics to aid clinicians, there is more work to be done to ensure that it can increase satisfaction, according to Dr. Moukaddam. “You need to teach people and then reinforce that they’ve understood... you need to ask them if they’ve used it, and if they haven’t, you then have to track that behavior down... I don’t think the clinician satisfaction is as high.”
help bring back some of the cognitive behavioral therapy and talk therapy that I think is so important. We know that in depression, SSRIs [selective serotonin reuptake inhibitors] and SNRIs [serotonin and norepinephrine reuptake inhibitors] are just barely better than placebo, so I’m optimistic about the prospect of digital therapeutics improving outcomes in major depressive disorder, generalized anxiety disorder, bipolar 1 and 2, and substance use disorder.”

Additionally, the fact that many of these technologies have been cleared by the FDA is another level of confidence for providers, particularly knowing that it has undergone a study, has clearance, and is facing scrutiny for other aspects of security to protect patients. “The FDA approval is really, if you will, a gold stamp that says, ‘Yes, this is actually a product that we have confidence in,’ and that would definitely help providers [with] recommending them to patients,” says Dr. Luo.

**Payer Perspective on Digital Therapeutics**

There are several considerations that payers make when it comes to digital therapeutics, according to Dr. Peskin. “One, [in my organization] we have our own behavioral health, so we have a number of physicians, and we have an entire team that are now part of Horizon as opposed to using a third party. We are what’s called a managed behavioral health care organization. There are [several of] what I would call enhancers—telemedicine, telehealth—which differ from digital therapeutics, so we’re constantly scanning the environment in behavioral health and physical health,” says Dr. Peskin. “We also have an investment arm, and we sometimes look at making investments in these types of companies.”

Regarding the question of specific benefits or coverage, it will be important to differentiate whether digital therapeutics would be covered under pharmacy-, medical-, or even value-based contracting. “Some of our partners are, again, adopting digital therapeutic-type innovations. They are in a value-based model, so they’re saying this is worth investing when we look at how it can affect total cost of care and total medical expense,” Dr. Peskin offers. “We’ll evaluate any digital therapeutic just as we evaluate any technology, with evidence-based [data], FDA [clearance status], [and] what any authoritative organizations are saying, such as the American Psychiatric Association. We’ll approach digital therapeutics just the way we approach a new cancer drug or a new medical device or something new in wound care.”

**Patient Engagement in Behavioral Settings**

Ultimately, the success of digital therapeutics depends on the extent to which clinicians/providers can work together with patients on making the technology useful. Thus, patient engagement is critical toward the utility of digital therapeutics.

To reach a point in which providers can work with patients on using a specific product, Dr. Moukaddam comments that comfort with the technology and understanding its tools is important. “I would like to be able to try it out, use it, [and] know that it’s beneficial, and the scalable part comes in when I say that as a specialist, I can give it to everybody who’s a [primary care provider], everybody who is doing this on a larger scale. That is really important,” she says. In mental health, outcomes are more subjective, which can make the measurement of improvement
difficult in conditions such as insomnia and addiction, says Dr. Moukaddam. “Psychiatry still follows a categorical approach. If I say you’re depressed, it might mean that you look sad, but technically, what it means is that you meet the criteria for a certain number of symptoms in a certain duration,” says Dr. Moukaddam. Although digital therapeutics may not be useful for measuring these criteria, they can be supportive tools that provide important details. “Digital therapeutics give you a wealth of information about how much you move, [as well as] your sleep duration and quality. It gives information about how many times you’ve turned your phone on or off. This is the kind of thing that I can use to track your activity and your sleep cycle. In our research, we use privacy preserving methods. But, even with those, I don’t know who you talked to, but I could still draw a social map, and therefore, I could see how this could help predict the relapse,” Dr. Moukaddam explains.

“The field of digital therapeutics really ought to give me something objective that would be useful practically,” says Dr. Moukaddam. “Let’s assume your phone, wristband, and other wearables are all things that are very intimately paired with your lifestyle. This device can give you 2 sorts of inlets. It can ask you how you’re feeling, and that is called ecological momentary assessment. It asks you if you cough in your sleep [or] what you’ve eaten, if you’ve had a problem physically, a particular symptom, or it doesn’t have to ask you anything. It just detects your patterns, and that pattern detection is a super prolific and powerful tool that what we need as clinicians. We need that analysis to bridge the gap of what we think of as symptoms,” Dr. Moukaddam explains.

In a sense, digital therapeutics can offer an active intervention to a patient and enable holistic care in which providers and payers can actually have data to aid in decision-making. One of the ways digital therapeutics can do this, according to Dr. Moukaddam, is through adjusted time intervention. “It takes a typical AI algorithm between 10 and 14 days to learn and track patterns,” she says. “The idea of adjusted time intervention is to take this pattern and say, ‘Today, you’re not doing what you usually do. Today, you did not do your usual 2 miles of walking.’ And then you link it to whatever condition you think this patient has. Are you sick? Are you depressed? Are you not feeling well? Is your asthma acting up... you have the detection component,” says Dr. Moukaddam. “Now, the diagnostic component is obviously a lot trickier, and you have to have a lot of regulatory oversight for that because we don’t want to jump from detection to diagnosis. That’s a big area, but we first have to get those algorithms and validate them.” For mental health and addiction specifically, Dr. Moukaddam mentions that the field is going to see a much larger switch from categorical diagnosis to dimensional diagnosis. “The dimensional would be more like: Rate your depression, just your depression. Rate your appetite. We’re not talking about the symptom cluster, but rather one particular symptom.”

As the integration of digital therapeutics continues, fostering education and awareness will be critical to the utility of this technology in behavior-driven conditions, according to Dr. Luo. “Finding a way to reach the psychiatrists and help them be comfortable with prescribing it, using it, or showing their patients [is important],” he states. “It reminds me, too, of electronic health records, in that a lot of medical education has been sort of outsourced to third party vendors that create
videos to help the patients [learn]. You could certainly have the same vendor do that about teaching to use digital therapeutics.” As far as the technology goes, Dr. Luo believes that patients are ready for the integration. “I think the patients are way ahead of us. They’re eager. They really want this, especially as access to mental health providers is somewhat limited,” Dr. Luo explains.

Digital Therapeutics in the Age of COVID-19

The heightened use of remote platforms in health care amidst the COVID-19 pandemic has signaled important shifts in the adoption of technology in the practice of medicine. According to Dr. Peskin, the use of telemedicine and digital therapeutics to help deliver health care solutions will continue to increase. “We did a tremendous amount on telemedicine, working with some of our clinical partners to expand access for urgent care, primary care, acute care, as well as longitudinal care for patients with diabetes and those with chronic conditions,” says Dr. Peskin. Although a payment scheme has not yet been developed for digital therapeutics, Dr. Peskin believes that COVID-19 has accelerated efforts within the managed care community to look at what might be called “non-traditional,” other ways to provide or deliver services in a non-face-to-face fashion. “[These avenues] are very compelling, and COVID-19 is certainly an accelerant.”

Dr. Luo adds that high volumes in emergency departments and hospitals across the country may also precipitate increased development and utilization of technologies, such as digital therapeutics. “I actually work on the consultation service, both in the emergency [department] and in the main hospital, and I can tell you that our volumes are really high,” he says. “We have many patients who had no pre-morbid psychiatric conditions that now have depression and anxiety related to COVID-19, and our systems of mental health care, especially here in Southern California, due to the high numbers of COVID-19, are stretched thin.” Bridging the gap of care among patients who have been dissatisfied by phone appointments and who are not compliant is also important, Dr. Luo suggests. “I would argue that providers like myself and also my colleagues in outpatient settings, as well as inpatient, desperately want more tools in our toolbox. We want to provide patients [with] a way to keep them out of reaching the need for either inpatient hospitalization or showing up in our emergency department.”

Dr. Moukaddam adds that COVID-19 may have simply accelerated the need for the utilization of already-existing technology for detection, diagnosis, and treatment. “For detection, we are woefully underusing telemedicine, and I don’t mean we’re not doing enough telemedicine,” she says. “Your screen can measure your vital signs, but no big system has adopted it. It’s actually very hard to get through 3 IRBs to do that. You can also use it to measure gait. There are a lot of gait measurements that can be done remotely, and that way, you could use your encounter to actually have some gait-based measurement that would be super helpful, but we don’t do that either. Your phone has a little sensor here that can actually measure blood flow; therefore, you can measure flushing. That’s how they measure vital signs. We don’t do that either, so we are woefully underusing technology for detection,” says Dr. Moukaddam.

In terms of detecting mental issues, Dr. Moukaddam believes that phone apps and wearables could help significantly. “We have a study going on called COVID Sense at covidsense.org, and our question was: Can we follow people and see who’s actually getting depressed? We’re seeing a very distinct pattern in who [falls in] that depression/anxiety group that we didn’t have before,” she says. The conversion into depression/anxiety has been very clear for individuals with pre-existing conditions, even if the condition is arthritis, according to Dr. Moukaddam. “We have more than 1,000 people in that study, and we’re measuring due to the quiz for depression, and you can see that conversion so clearly,” Therefore, she notes, “The digital therapeutic could help us with detection, and even with diagnosis, because we are able to do a questionnaire that’s fully validated, and we are able to diagnose in the emergency department.” Dr. Moukaddam adds that a treatment component can also be added to digital therapeutics, which, she notes, may be accelerated because of the significant need arising from the pandemic.
What’s on the horizon for drug development in 2021?

The industry is adjusting to the pandemic, but FDA approvals could dip this year. Several new drugs for atopic dermatitis may get the agency’s green light. by JAIME ROSENBERG

LIKE SO MUCH ELSE IN HEALTHCARE AND BEYOND, a large question hangs over drug development in 2021 and the pace of FDA approvals: How much of an effect will COVID-19 have?

Because the majority of FDA approvals in the latter part of 2020 were based on results of trials conducted before the pandemic, the full impact of the pandemic on approvals may not become evident till this year. When the pandemic reached the United States in March and lockdowns throughout the country began, some active trials paused, many trials set to start were delayed, and new COVID-19-focused trials commenced. In just March and April, 905 clinical trials were suspended as a result of the pandemic, according to a study published in the September 2020 issue of Annals of Surgery. Meanwhile, a slew of others were rapidly launched to assess potential COVID-19 vaccines and treatments.

Between 20% and 25% of trials suspended enrollment as a result of the pandemic, according to a study published in the September 2020 issue of Annals of Surgery. Meanwhile, a slew of others were rapidly launched to assess potential COVID-19 vaccines and treatments. Between 20% and 25% of trials suspended enrollment as a result of the pandemic, according to Kenneth Getz, MBA, the deputy director of the Tufts Center for the Study of Drug Development in Boston. But Getz says that following delays of four to six months, most of those trials have now resumed as trial investigators adapted to using more remote or virtual methods. Approximately one-third of ongoing clinical trials started moving to a remote model very soon after the pandemic hit, but almost half (45%) continued following the original protocol approach, with patients coming into trial centers for visits, says Getz. Most of the trials that stuck with in-person visits were testing drugs for serious diseases such as cancer.

Getz says institutional review boards, ethical review committees and regulatory agencies deserve credit for helping with recruitment by allowing for some adjustments to trial design. Although some delays in getting the studies underway were inevitable, anecdotal reports suggest that once people were enrolled in a trial, they stayed enrolled, says Getz.

It remains to be seen how new, more virtual trial models will affect collection and reporting, says Getz. While conducting trials with more remote checks and monitoring makes participation more convenient for study volunteers and may reduce the number of dropouts, recruitment amid the pandemic is likely to be a struggle. “A lot more people are more aware of clinical trials, but they think that participation may be riskier or less safe, especially if there might be some exposure to the coronavirus if they’re involved in a hybrid study that involves some in-person visits as well as some at-home visits,” says Getz.

Another worry of drug developers is whether the FDA is so focused on COVID-19 vaccines and treatments that review of other drugs will languish, notwithstanding Prescription Drug User Fee Act timelines. Drug developers and others are concerned that the agency is spread too thin and, as a result, fewer drugs will be reviewed and approved.

Aducanumab’s fate to be determined

Aside from additional COVID-19 vaccines, perhaps the most anticipated (and possibly most controversial) approval decision this year concerns aducanumab, a monoclonal antibody developed by Biogen and Eisai Co. Ltd., a Japanese company, as a treatment for Alzheimer’s disease. Current treatments for Alzheimer’s are only modestly effective, and recent attempts to find better ones have foundered in late-stage trials. With baby boomers entering old age, the market for an effective drug for Alzheimer’s disease would be enormous.

Aducanumab looked like it was going to join the long list of failures when Biogen and Eisai said in early 2019 early that they were shelving the drug after negative results from in two trials. Later that year, though,
they reversed course and said further analysis suggested efficacy.

The agency seems to agree with the companies, judging by a document that became public late last year. But a watchdog group, Public Citizen, accused the agency of “inappropriately close collaboration” with the drug’s developers. Days after the positive FDA assessment, the up-and-down prospects of aducanumab took a downturn when an advisory committee of outside experts voted overwhelmingly against approval. Aimee Tharaldson, Pharm.D., senior clinical pharmacist of Emerging Therapeutics at Express Scripts, says she believes that approval is unlikely. A final decision is expected by March, but the schedule may hinge on the timing of President-elect Joe Biden’s selection of an FDA commissioner and the Senate confirmation needed for that person to assume the top post at the agency.

**Atopic dermatitis drugs in the offing**

Another therapeutic area to keep an eye out for in the coming year is atopic dermatitis, the most common type of eczema. There are drugs in late-stage clinical development for moderate-to-severe atopic dermatitis. Several of these drugs are Janus kinase (JAK) inhibitors, a type of disease-modifying antirheumatic drug. Pfizer’s abrocitinib seems headed for approval by April. AbbVie’s JAK inhibitor, Rinvoq (upadacitinib), which is currently approved as a treatment for rheumatoid arthritis, is expected to get an added indication for atopic dermatitis by June. Eli Lilly and Company’s Olumiant (baricitinib) may also be approved for atopic dermatitis this year. In November 2020, the FDA issued an emergency use authorization for a combination of Olumiant and remdesivir as a treatment for COVID-19. In addition, Leo Pharma’s tralokinumab, a novel treatment given as subcutaneous injection every two weeks, is expected to be approved this year as a treatment for atopic dermatitis.

**CAR-T for multiple myeloma?**

Chimeric antigen receptor (CAR) T-cell therapy involves taking a patient’s T cells, altering them in a laboratory so they attack cancer cells and then reinfusing them. Currently approved as a treatment for acute lymphoblastic leukemia and several different types of lymphoma, CAR-T treatment is edging its way into the mainstream and may be approved for multiple myeloma this year. Researchers presented positive results for two CAR-T trials for the blood cancer last month at the annual meeting of the American Society of Hematology (ASH). Janssen’s ciltacabtagene autoleucel, which is expected to be approved in the second half of the year, showed a near perfect (97%) overall response rate over 12.4 months in patients whose disease had worsened after multiple treatments. At a median follow-up of 12.4 months, the median length of response and progression-free survival endpoints were not reached.

Bristol Myers Squibb and Bluebird bio’s CAR-T therapy, idecabtagene vicleucel, is expected to be approved in March as a treatment for multiple myeloma. Results of a phase 1 trial, which came out ahead of the ASH meeting but were also presented there, showed a response rate of 76% and a complete response rate (no detectable cancer after treatment) of 39%. The median length of response was 10.3 months.

**Rare disease treatments**

Also in the offing this year are possible approvals for treatments for two rare diseases. Orphazyme’s arimoclomol is an HSF1 stimulant pending approval for the treatment of Niemann-Pick disease type C, a rare, progressive lysosomal storage disorder that affects approximately 200 people in the U.S. With no approved treatments for the disease, most patients die by age 40. An FDA decision on the treatment is expected March 21.

PTC Therapeutics’ eladocagene exuparvovec is a gene therapy for the treatment of aromatic L-amino acid decarboxylase deficiency, which has been identified in approximately 100 patients in the U.S. The one-time infusion is expected to be priced somewhere between $2 and $3 million.

Jaime Rosenberg is a freelance writer based in Jersey City, New Jersey.

“Between 20% and 25% of trials suspended enrollment as a result of the pandemic.”

— KENNETH GETZ, MBA

Between 20% and 25% of trials suspended enrollment as a result of the pandemic.
For years, heart failure was the unsolvable problem of healthcare. Patients with heart failure cannot adequately pump blood through the body, causing fatigue, persistent cough, weakness or other symptoms. They have long hospital stays. When they are discharged, they often return. Most have other health problems, diabetes being among the most common. Half of patients with heart failure will die within five years of showing symptoms.

Heart failure is so costly — the tab reached $30.7 billion in 2012 — that it got special mention in the Patient Protection and Affordable Care Act, which tried to compel the delivery system to stop the revolving hospital door by imposing readmission penalties. Meanwhile, drug manufacturers have been searching for better treatments, partly because any products they come up with will enjoy a growing market. Heart failure is a disease of old age, and tens of millions of baby boomers are now in their 60s and beyond. Even so, a 2014 heart failure breakthrough received a lukewarm reception. Results from the pivotal PARADIGM-HF trial showed that patients taking Novartis’ Entresto (sacubitril/valsartan) had a 20% lower risk of death from cardiovascular causes than those taking enalapril, an ACE inhibitor. But sales fell short of expectations, and heart failure lost some luster as a therapeutic area. “If a ‘blockbuster’ therapy with demonstrable mortality reduction benefit was seldom prescribed for patients who would benefit, how could future investments be justified?” wrote Tariq Ahmad, M.D., M.P.H., FACC, and Nihar R. Desai, M.D., M.P.H., of the Yale School of Medicine, in JACC: Heart Failure.

But in 2020, Novartis’ patience with Entresto paid off. Third-quarter results showed U.S. sales had climbed 45% for the year. Marie-France Tschudin, president of Novartis Pharmaceuticals, told investors that in a pandemic, “Entresto delivers on its value proposition of keeping patients out of the hospital. This, of course, is especially important right now.”

Two types of heart failure
Patients in the PARADIGM-HF trial had heart failure with reduced ejection fraction, also called systolic heart failure, which occurs when the heart’s left ventricle becomes enlarged and fails to push blood out into the circulatory system properly. At the time the Entresto results were reported, other treatments for this type of heart failure were already available. It took time for Entresto to be embraced as a first choice, but Tschudin said this is finally happening.

Keeping patients out of the hospital is the goal of other heart failure treatments under development, including Amgen’s omecamtiv mecarbil, which targets a protein that powers the pumping function. Omecamtiv mecarbil, for reduced ejection fraction, is among a new wave of drugs being studied that addresses cardiac damage without causing adverse events. Another is Merck and Bayer’s vericiguat, which has a different mechanism of action.

Some patients, however, have heart failure with preserved ejection fraction: The left ventricle has enough pumping power but the heart is stiff, so the chamber doesn’t fill up with enough blood. This year, it looks like heart failure with preserved ejection fraction is where the action will be as far as drug development, approval and marketing.

Novartis got a head start by filing an application with the FDA in June 2020 to market Entresto as a treatment for heart failure with preserved ejection fraction. Novartis’ strategy for Entresto seemed to pay off on Dec. 15 when an FDA advisory committee voted 12-1 to be the first drug approved for heart failure with preserved ejection fraction. An FDA staff recommendation, and the positive committee vote, came despite trial...
results that fell short of reaching statistical significance. The advisory panel debate highlighted some of the problems with dividing heart failure into reduced and preserved ejection fraction. By the end of the discussion, Norman Stockbridge, M.D., Ph.D., director of the FDA’s Office of Cardiology, Hematology, Endocrinology and Nephrology, said that coming up with a meaningful label may require a different way of describing “the heart failure spectrum.” Steven Nissen, M.D., of Cleveland Clinic, discussed a label that would include reducing heart failure hospitalization. Cynthia Chauhan, M.S.W., the panel’s consumer representative, called for a new trial that would have greater representation of minorities and patients with common comorbidities. Novartis’ David Soergel, global head of cardiovascular, renal and metabolic drug development, said the need for diversity is recognized within the company and across the industry.

Both the FDA staff and the panel weighed the fact that results from the phase 3 PARAGON-HF trial supporting the preserved ejection fraction indication did not reach statistical significance for reducing morbidity and mortality. But Novartis’ supplemental new drug application included data from PARADIGM-HF and made the case that the “totality of the evidence” supported approval with ejection fraction in the “overlap HFrEF (heart failure with reduced ejection fraction) and the lower end of HFpEF (heart failure with preserved ejection fraction).”

Novartis is studying Entresto for yet another indication in the phase 3 PARAGLIDE-HF trial. This trial looks at whether the drug works in patients with preserved ejection fraction with acute decompensated heart failure — a sudden worsening of heart failure — after stabilization during hospitalization. This indication could have important implications for insurers because of the penalties for hospital readmissions. But results from this trial aren’t expected until early 2022. The next day the committee made a similar recommendation for the blood pressure medication spironolactone but by a narrower vote of 8-4. Spironolactone is currently approved to treat heart failure with reduced ejection fraction.

Hot on Novartis’ heels are the SGLT2 inhibitors, which started as diabetes drugs but have crossed over and are fast becoming heart failure drugs too. AstraZeneca’s Farxiga (dapagliflozin) is approved as a treatment for heart failure with reduced ejection fraction, and Eli Lilly and Boehringer Ingelheim’s SGLT2 inhibitor Jardiance (empagliflozin), may join Farxiga based on strong results presented at European Society of Cardiology Congress 2020. Results of trials assessing both of them as treatments for heart failure with preserved ejection fraction are expected to be reported this year.

Most likely, the effective treatment of heart failure — for both reduced and preserved ejection fraction — will not be a single drug but a combination of drugs. Ahmad and Desai endorsed “quad therapy” for heart failure with reduced ejection fraction, arguing that a cocktail of Entresto, Farxiga, a beta blocker and a mineralocorticoid receptor blocker would be greater than the sum of its parts.

Burkert Pieske, M.D., a German heart disease researcher, says the same is true in preserved ejection fraction: “I do believe in the future, a combination therapy of Entresto and an SGLT2 inhibitor and, in addition, a (mineralocorticoid receptor) antagonist — as an anti-fibrotic and blood pressure lowering agent — could be the ideal combination.”

The only thing to do now, he says, is wait for the data.

The prevalence of heart failure is increasing as the demographic profile of the American population gets older. An estimated 6.2 million American adults, age 20 and older, had heart failure between 2013 and 2016, compared with an estimated 5.7 million between 2009 and 2012.

Of incident hospitalized heart failure events, approximately half are characterized by reduced ejection fraction and half by preserved ejection fraction. The prevalence of heart failure with preserved ejection fraction, compared with prevalence of heart failure with reduced ejection fraction, appears to be increasing along with aging of the population.

Source: “Heart Disease and Stroke Statistics—2020 Update,” American Heart Association
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As the COVID-19 pandemic has pushed much of life — including healthcare — in a digital, virtual direction, companies that provide telehealth services have prospered, raking in major investments in initial public offerings (IPOs). Telehealth provider Amwell raised $742 million in September 2020, after bumping up both the number of shares it planned to sell and its price because of strong demand, while GoodRx, which helps consumers find deals on prescription drug prices and has a telehealth operation, raised $1.1 billion with a stock price well above what was initially anticipated. The following month, telehealth giant Teladoc Health completed its $18.5 billion merger with Livongo, a digital health company that helps patients monitor chronic conditions.

Already this year, the healthcare sector has seen almost $30 billion in merger activity, with more than half coming from Teladoc and Livongo. The activity already exceeds the previous five years, according to Brian O’Rourke, senior analyst at S&P Global Market Intelligence.

The financial moves in the healthcare sector mark “a realization that consumers are going to start to really drive healthcare in a way they haven’t been able to before,” says Bill Fera, M.D., a principal at Deloitte.

The pandemic has meant a sea change for telehealth, which “had been the technology of the future for decades,” O’Rourke says. But with COVID-19, many consumers have been reluctant to get in-person healthcare and, instead, flocked to virtual care. A study of telehealth visits by Epic Health Research Network, us-
ing electronic medical records from 22 health systems covering 7 million patients, found telehealth visits increased 300-fold from spring 2019 to spring 2020. An updated study by Epic released in August 2020 — ahead of the fall spike in COVID-19 cases — found that in mid-April, telehealth made up 69% of total visits but by late summer accounted for 21% of all visits. Still, that is a sharp contrast from pre-pandemic usage, when less than 0.01% of visits were virtual.

Much was driven by changes at CMS, which expanded telehealth access for Medicare beneficiaries under an emergency declaration because of the pandemic. State-level rules have also had an effect, with some states mandating private insurers reimburse for virtual visits at the same rate as in-person care. Several major insurers — Florida Blue and Humana, to name just two — began offering virtual visits with no copayments, and a number are continuing to offer telehealth with no copayments for 2021. Clarifying that providers can be reimbursed for offering telehealth services “added lighter fluid to the smoldering fire that was telehealth,” says Kristen Hallam, healthcare news desk manager for S&P Global Market Intelligence.

Amwell advances

As a result of the pandemic, telehealth is “very quickly maturing from a sideshow to the mainstream,” says Ido Schoenberg, chairman and CEO of Boston-based Amwell. “Telehealth was not born because of COVID-19, and it will not die after COVID-19.” Amwell offers telehealth technology solutions for providers and has its own virtual doctor’s visits for $79, covering a wide range of medical and behavioral health conditions. With its IPO, Amwell originally planned to sell 35 million shares at $14 to $16 each, according to its filings with the Securities and Exchange Commission. Instead, it offered 41.2 million class A shares at $18 each, and the stock price opened at $25.51 per share. Shortly before its IPO, Amwell announced that Google Cloud was investing $100 million in the company and that the two would partner on technology and innovation. In a press release, the companies said they see room to improve telehealth experiences by doing everything from automating waiting rooms and checkout to assisting payers and providers with routine tasks to triaging cases.

Amwell’s dealings will be more transparent as a public company, Schoenberg says, and that creates “an increased level of confidence to very large customers. They know who you are, what you do.” During Amwell’s conference call for third quarter 2020, Schoenberg said that the company had more than 1.4 million virtual visits for the quarter, compared with 255,000 the year before, and that revenue soared 80%, to $62.6 million. The number of providers offering telehealth on its platform also soared — to 62,000, from just 6,000 the previous year. He also talked about a hybrid healthcare model with patients consulting with their own physicians either in person or virtually: “They won’t focus on your sore throat; they focus on your full continuum of care.” Telehealth will also open up the possibility that anyone, including those in rural areas, will have access to high-quality care. “Care is divorced from location,” he says.

Other deals

GoodRx, the online prescription-drug bargain finder, also went public in late 2020. The company planned to sell 34.6 million shares at $24 to $28 per share; instead, they sold for $33. GoodRx, which is headquartered in Santa Monica, California, had third-quarter 2020 revenue of $140.5 million, an increase of 38% compared with the previous year. Almost 90% of revenue came from prescription transactions.

In September 2019, GoodRx acquired telemedicine company HeyDoctor. Terms of the deal were not disclosed. Visits start at just $20, and consumers don’t need health insurance to get care. HeyDoctor providers saw more than 1,000 patients per day last summer for conditions ranging from primary care services to behavioral health care, and prescriptions can be mailed to a patient’s home.

The company says more than 15 million consumers each month use GoodRx to find discounts and prices for their healthcare needs. “The huge growth in usage creates more investor enthusiasm. It has a bit of a snowball effect,” Hallam says.

At least one more telehealth company is expected to go public soon. Charles Jones, chairman and CEO of MDLive, told Stat that he expected his company would go public in January or February. That news came after the company announced in September 2020 a $50 million crossover equity investment from Sixth Street Growth, which will primarily be used to expand MDLive’s virtual primary care platform. Headquartered in Miramar, Florida, MDLive also secured $25 million in debt investments.

“Telehealth is not a playground for small, niche startups. You need serious investments.”

— IDO SCHOENBERG, CHAIRMAN AND CEO OF BOSTON-BASED AMWELL
For behavioral health, virtual becomes reality

Although virtual visits as a whole have dropped off since their peak last spring, visits for behavioral health issues are still going strong, a reflection, in part, of the toll the COVID-19 pandemic has taken on the mental health of Americans. A survey by the CDC found that by late June 2020, 40% of Americans were struggling with mental health or substance abuse issues. More than 10% of those surveyed said they had seriously considered committing suicide during the previous 30 days. With COVID-19 cases and deaths increasing this winter, the mental health consequences of the pandemic are likely to continue.

Providing mental health services virtually can increase access to providers who, even before the pandemic, were in great demand, as well as reduce the stigma that can surround mental health care. Rather than going to a therapist’s office, patients can access care from their mobile phone or home computer.

MDLive reported its behavioral health business grew by nearly 50% during the first months of the pandemic, and the company expanded its network of board-certified psychiatrists and licensed therapists by 50% to meet the surging demand.

Teladoc Health reported in its third-quarter earnings call that virtual visits for anxiety and depression, along with hypertension and back pain, represented more than half of its volume, compared to a third of visits in 2019. “Demand for dermatology and behavioral health services continues to significantly outpace overall volume growth,” the company reported.

At Optum, which is part of UnitedHealth Group, patients made more than 1 million virtual visits from the start of the pandemic until late October 2020, said Optum CEO Wyatt Decker, M.D., MBA, during a recent press briefing. In spring 2020, the majority of all visits were virtual. While that number has dropped off, demand for virtual behavioral healthcare has remained high. Decker said half of all visits are still done virtually.

Through July 2020, it handled almost 1 million patient visits — a 500% increase for behavioral health and a 350% increase for dermatology.

In a conference call with analysts before the Livongo merger was completed, Teladoc CEO Jason Gorevic said the companies would join forces “to deliver a level of patient insight that has been previously unavailable. Combining meaningful, data-driven insights with clinical expertise will enable better care delivery, better outcomes and lower costs.”

Teladoc providers conducted more than 2.8 million virtual visits in the third quarter of 2020, more than triple the number of visits provided in 2019, Gorevic said.

The company, which is based in Purchase, New York, said revenue for the third quarter of 2020 was $289 million, up almost 110% from the previous year. For the year, Gorevic said he expected revenue to top $1 billion. Just five years ago, when Teladoc went public, it raised a fraction of that amount: $156.8 million.

Depends on reimbursement

Healthcare’s pivot to telehealth is remarkable; collectively, American healthcare is saying, “Why didn’t we think of this before?” But the future of telehealth depends on whether public payers — especially Medicare, as the largest buyer of healthcare — are willing to pay for it. If the government continues to reimburse for virtual care, ‘O’Rourke at S&P Global Market Intelligence says he expects telehealth to continue to grow, but if the government doesn’t continue its reimbursement, “that could have a really adverse impact.”

Reimbursement remains an open issue. When CMS released its annual physician fee schedule in December 2020, it permanently expanded only the telehealth services that covered Medicare patients in rural areas, although CMS officials said they were commissioning a study to look at creating more telehealth flexibilities.

Fera at Deloitte says value-based care may accelerate the adoption of telehealth because of its cost effectiveness, noting that people with chronic conditions such as diabetes can be monitored more or less constantly with telehealth: “You’re getting care every day, potentially,” Schoenberg says he sees these new care models as a way to monitor conditions and “use artificial intelligence to raise very sophisticated (red) flags.”

The days of scrappy startups may be dwindling in telehealth. As the telehealth market matures, Fera expects to see more consolidation: “Larger companies are really going to start taking hold of the market and acquiring other companies,” Schoenberg, now leading one of those larger companies, says, “Telehealth is not a playground for small, niche startups. You need serious investments.”
New state accumulator laws complicate the coupon landscape

by JOHN S. LINEHAN, J.D.

In recent years, the federal and state legal requirements governing drug distribution and reimbursement have become increasingly discordant. This has stemmed in part from a politically divided Congress, which has made it difficult to pass comprehensive federal legislation, and the fact that many states have pioneered ahead with ambitious reforms. It also stems from the differing incentives and concerns facing federal and state lawmakers. While the federal government is the sole funder of Medicare and a large portion of Medicaid, and therefore acts primarily as a payer, state governments regulate insurance on the local level and are more susceptible to the influences of patients and prescribers.

This federal-state dynamic has become especially pronounced with regard to the copay coupons promoted by drug manufacturers and the copay accumulator and maximizer programs that health plans and pharmacy benefit managers (PBMs) have employed to mitigate the negative effects that coupons can have on their costs. On the one hand, coupons are prohibited under federal healthcare programs, but the U.S. government has afforded plans significant leeway to implement accumulators and maximizers. At the same time, coupons are generally permitted at the state level, but a growing number of states have quietly passed laws prohibiting fully insured plans from using accumulators and maximizers. As a result, the industry battle between drug manufacturers and payers continues to play out over an increasingly complicated and inconsistent compliance landscape.

The conflict over copay coupons

Drug copay coupons, which may be used to reduce patients’ out-of-pocket costs, are used by drug manufacturers to promote access to branded drugs. By 2015, drug manufacturers were offering coupons to boost sales for more than 700 branded drug products, and manufacturers are estimated to have provided approximately $13 billion in copay coupons in 2018. Health plans and PBMs have vigorously opposed coupons due to concerns they may undermine cost-sharing requirements designed to incentivize economical drug prescribing and purchasing choices.

State legislatures have, understandably, struggled with the role that copay coupons play in healthcare because they present difficult trade-offs. Providers and patient advocacy groups have fiercely defended coupons as essential to facilitating access to expensive drugs, especially for beneficiaries in high-deductible health plans. The countervailing argument from health plans and...
PBM's is that coupons are a marketing tool that can incentivize the use of higher-cost therapies and lead to higher premiums. Several states have considered legislation that would curb coupon use, and California and Massachusetts have enacted laws that would restrict coupons in circumstances where generic alternatives are available.

Divergent rules, deepening controversy
As health plans, PBMs and employer group sponsors have increasingly employed copay accumulators and maximizer programs in recent years, the controversies associated with copay coupons have deepened. Under a copay accumulator program, the health plan prevents a copay coupon from counting against the beneficiary's deductible or out-of-pocket maximum. Once the coupon's value is exhausted, the beneficiary must cover the entire amount of their deductible before plan benefits are triggered. With copay maximizers, the plan increases a drug's copay amount so that it approximates the copay coupon's monthly value. The total value of the coupon is applied evenly throughout the benefit year but is not applied against the beneficiary's cost-sharing obligations.

Health plans have embraced these new benefit designs as a means to reduce their financial liability by drawing from the value of the coupon and the beneficiary cost-sharing amounts before providing drug coverage. However, opponents have raised concerns that beneficiaries may lack adequate understanding of how these programs work and be surprised by having to pay high deductibles once their coupons are exhausted. Accumulators have been especially criticized for abruptly shifting a large portion of costs to beneficiaries. Maximizer programs, which have more varied and flexible designs, are often tailored to apportion costs in a more equitable manner among the plan, beneficiary and manufacturer. Nonetheless, accumulators and maximizers are alike in that they prevent the coupon from applying in some manner to the cost-sharing obligations.

In 2019, CMS issued a rule restricting the use of accumulators by health plans subject to the Patient Protection and Affordable Care Act’s essential health benefits rules. However, CMS subsequently reversed course by issuing a new rule in May 2020 that removed these restrictions to “enable issuers and group health plans to continue long-standing practices with regard to how and whether direct drug manufacturer support accrues toward an enrollee’s annual limitation on cost sharing.” Accordingly, under federal law, commercial health plans and PBMs enjoy substantial leeway in how they structure accumulator programs.

While the legal landscape for accumulators has become clearer at the federal level, it has gotten cloudier at the state level. Patient advocacy and provider groups have begun to have some success shaping state-level laws and policy regarding accumulators. In the past two years, bills have been introduced in close to 20 states that would affect accumulator programs, and five states — Arizona, Georgia, Illinois, Virginia and West Virginia — have enacted laws.

The state accumulator laws are largely alike in that they require plans to consider payments made by a beneficiary, or on behalf of a beneficiary, when calculating their overall contribution to any cost-sharing obligations. This serves to broadly restrict accumulator and maximizer programs by prohibiting plans from blocking the value of a manufacturer coupon (i.e., a payment made on behalf of a beneficiary) from counting against a beneficiary’s deductible or annual maximum out-of-pocket limit. Some slight differences in wording among the various pieces of legislation could impact their scope and application. For instance, the laws in Arizona and Georgia include exceptions that would allow plans to apply accumulators when there is a medically appropriate generic. Some of the state laws only seem to refer to outpatient prescription drugs, whereas others appear to apply more broadly to drugs reimbursed under both a plan’s pharmacy and medical benefits. Finally, some of the laws specifically reference PBMs, whereas others only refer to...
health plans. Nevertheless, plans affected by these laws may need to ensure that any contracting PBMs similarly comply with prescribed restrictions when administering their drug benefits.

**A growing divide**

So far there has been strong bipartisan support for accumulator restriction bills in state legislatures, indicating that a growing number of states will likely be considering and adopting these laws. This is testament to the power that patient and prescriber advocacy groups have had in influencing state lawmakers with stories about how patients can be disadvantaged, sometimes unexpectedly, by accumulators. By contrast, plan and PBM opposition to coupons and support for accumulators and maximizers have been based on more abstract arguments relating to the need to manage costs and promote economical prescribing practices.

If additional states join the ranks of those states restricting accumulator programs, then the place for coupons will be increasingly secure, at least with respect to beneficiaries covered under fully insured plans regulated under state insurance codes. In the meantime, a growing legal asymmetry is arising as health plans (particularly self-insured plans) will have significant latitude to impose accumulators and maximizers under federal law but fully insured plans will need to thoroughly understand state laws before administering them. In addition, health plans must grapple with the nuances of other laws and regulations, including, but not limited to, IRS rules governing high-deductible health plans eligible for health savings accounts; disclosure rules under the Employment Retirement Income Security Act of 1974; and a variety of consumer protection, anti-discrimination and benefit uniformity standards.

Looking forward, stakeholders should expect more uncertainty and fluctuation in the legal treatment of coupons and accumulators as well as in other areas impacting drug reimbursement and distribution. If commercial health plans and PBMs are restricted in their ability to use accumulators and maximizers to mitigate the effects of coupons, then some premiums may increase and formulary offerings may narrow. If this were to happen, some lawmakers may decide to reverse course by pulling back on the accumulator restrictions that have been put in place. On this and other matters concerning pharmaceutical pricing, reimbursement and distribution, applicable laws may continue to zig and zag with uneven cost-shifting effects for competing stakeholders.

John "Jack" Linehan is a member of the health care and life sciences practice group at the law firm Epstein Becker & Green.

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**While the legal landscape for accumulators has become clearer at the federal level, it has gotten cloudier at the state level.**

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1 Coupons have long been barred under federal healthcare programs because they can be categorized as unlawful inducements under the Anti-Kickback Statute and beneficiary inducement provision of the Civil Monetary Penalties Law. Accordingly, copay coupons have been directed to patients taking branded drugs who are reimbursed in the private insurance market.


5 See, e.g., Va. Code Ann. § 38.2-3407.20(B) (“To the extent permitted by federal law and regulation, when calculating an enrollee’s overall contribution to any out-of-pocket maximum or any cost-sharing requirement under a health plan, a carrier shall include any amounts paid by the enrollee or paid on behalf of the enrollee by another person.”).

6 State insurance codes generally do not apply to self-insured employer-sponsored group plans governed by the Employment Retirement Income Security Act.
When the COVID-19 pandemic spread to the U.S. last spring and the country went into lockdown, the utilization of healthcare services came to a screeching stop. Many experts are concerned that this “hiatus” will lead to greater illness — and healthcare costs — this year because care, especially for chronic conditions, was deferred or canceled.

Another unintended consequence of COVID-19’s hitting the pause button may be the elimination or attenuation of “low value” care: the wasteful tests, prescriptions and procedures that result in little, if any, improvement in outcomes. By some estimates between about $75 billion and $100 billion is spent on low-value care and overtreatment each year, a relatively small fraction of the $3.6 trillion in annual healthcare spending but, nevertheless, a great deal of money. Some experts see the pandemic and the resumption of healthcare as a rare opportunity to reset U.S. healthcare without so much low-value care.

Low-value care takes many forms. Walt Ellenberger, a senior director of healthcare business development and innovation at SAP, a software company, lists a few classic examples: overprescribing brand-name drugs when generics are available, prescribing antibiotics for viral infections and moving too quickly to surgical procedures for conditions such as back pain that can be managed with medications or physical therapy. The Choosing Wisely campaign launched by Consumer Reports and the ABIM Foundation in 2012 is aimed at rooting out low-value care. The publication and the foundation have worked with the specialty societies to develop lists of tests and procedures for physicians and patients.

Low-value care has ripple effects beyond the direct cost of care that doesn’t improve health. Low-value services may have harmful adverse effects. And they can trigger a cascade of follow-up tests or services that can lead to anxiety; the risk of still more adverse effects; and, of course, more higher healthcare costs.

Some experts see low-value care commanding resources that might otherwise go to more healthful interventions. “This unnecessary spending crowds out resources available to pay for high-value care or other important priorities outside of healthcare, such as education and transportation,” says Corinna Sorenson, Ph.D., M.H.S.A.,
M.P.H., an assistant professor of population health sciences at Duke University School of Medicine in Durham, North Carolina.

Says Ellenberger: "Many clinicians are already overburdened. Removing unnecessary testing and procedures frees them up for work they really need to do. It also frees up resources in the laboratory and diagnostic departments, which helps move patients through the health system more efficiently."

Patient demand is one of the causes of low-value care. People are swayed by advertisements or believe that a low-value intervention is effective — the antibiotic prescription for a viral upper respiratory infection, for example. But, as Ellenberger notes, unnecessary services can backfire, lowering patient satisfaction and eroding trust in providers. "That can manifest itself in distrust in a specific provider or distrust in the entire healthcare system," he says. "Either way, it can lead to poor outcomes and higher costs later."

Physicians and other providers order low-value tests, treatments or procedures for a wide variety of reasons, says Sorenson, ranging from the inertia around established clinical practices and workflows to the volume incentives inherent in fee-for-service payment to fear of malpractice.

Avoiding reintroduction
When the pandemic first hit in March/April 2020, many hospitals and other providers pivoted to tests and procedures that were needed and postponed elective procedures (although how "elective" they really are is open to debate). Furthermore, many people avoided going to the hospital or doctor for nonemergency health issues because they didn’t think it was worth the risk of infection. "Although this likely prevented them from receiving tests and scans they didn’t need, on the flip side, many people likely suffered because they didn’t get necessary care," says Vikas Saini, M.D., president of Lown Institute, a healthcare think tank in Brookline, Massachusetts, that focuses on low-value care.

Sorenson says that some people may never seek out low-value care that was postponed. She also notes that the pandemic may shift perspectives on what care is truly necessary and whether there are better ways of delivering care that lowers costs and improves, or at least maintains, health outcomes. That said, Sorenson says the industry is at high risk of reverting back to "business as usual" given the pervasiveness of low-value care in American healthcare, partly because many providers are under financial strain.

But there’s an opposing point of view that disruption wrought by the pandemic is likely to mean less low-value care. David Nickelson, Psy.D., J.D., vice president of client growth-healthcare for Nerdery, a digital business consulting firm, believes healthcare won’t return to the way it was before COVID-19. "There has been an immense growth for digital health services as well as an emphasis on using data to improve the patient experience that will reduce the use of low-value services," he says. "Many more people are now willing to receive services via telehealth or virtual care platforms, which can free up healthcare providers to focus on more pressing challenges or critical patients."

This more optimistic take on the pandemic is that it has served as a kind of seminar of teachable moments about low-value care and a host of other festering issues. "It exposed the vulnerabilities of a healthcare system designed to be reactive in treating patients," Ellenberger says. "A fragmented industry used to working independently had to collaborate with other stakeholders to effectively combat a common enemy in order to survive."

Sorenson says the pandemic exposed long-standing flaws in the healthcare system, such as its fragmentation, inefficiencies and glaring disparities, as well as how susceptible these flaws leave the system and economy to crisis. But she also sees some positive developments: The pandemic has showcased that, with sufficient will and collective action, the health-
Population Health | Will COVID-19 wring low-value healthcare out of the system?

“Relying on data-driven systems ... will reduce unnecessary or low-value services.”

— DAVID NICKELSON, PYSD., J.D., VICE PRESIDENT, NERDERY

The care system can make innovative payment and care delivery changes swiftly as long as there are sufficient will and collective action. Sorenson points to telehealth and coverage for its use: “Coupled together, there seems to be a growing awareness that we don’t want and can’t afford to return to our pre-pandemic health system.”

Sorenson says that the pandemic has created a natural experiment to better understand the short- and long-term impacts of eliminating low-value care on health outcomes, quality of care and costs. Rather than just springing back thoughtlessly to prior practices, she says steps should be taken to sideline low-value care. “If a service is truly low-value care (and its absence will have) minimal or no negative effects on health or quality of care ... steps should be taken to ensure it’s not reintroduced into the system or, at minimum, its use should be reduced,” she says.

In a commentary piece published in NEJM Catalyst Innovations in Care Delivery in August, Sorenson and three of her colleagues at the Duke-Margolis Center for Health Policy suggest the development of “do not restart” lists to educate providers and patients about low-value care services that should not be reinstated. Other possibilities include low-value services and reminders in electronic health records and clinical decision support tools that steer providers away from ordering or using low-value care services. Low-value care can also be discouraged by upping patient cost sharing while decreasing cost sharing for high-value care, notes Sorenson.

**Televalue’ arrives**

One of the truisms of the COVID-19 pandemic is that it accelerated the shift from in-person care to digital platforms. That switch, many believe, can help rid the system of some low-value care. “Relying on data-driven systems that transfer information more quickly to healthcare professionals and prioritizing patients’ needs will improve the overall quality of care in the healthcare system and reduce unnecessary or low-value services,” Nickelson says.

Nathan Ray, director of healthcare and life sciences at West Monroe, a management and technology consulting firm headquartered in Chicago, says that COVID-19 highlighted the possibility for sustained virtual care. “It has allowed for the reduction of volume, meaning not less interaction but, rather, more timely interaction with physicians,” he says. “Consequently, more patients can get the drug or therapy they need faster than booking multiple in-person appointments.”

Farzad Mostashari, M.D., Sc.M., is co-founder and CEO of Aledade, a company that operates accountable care organizations with and for primary care practices. He says that the value-based care that his company implements is built “to support virtual care tools in a responsible, high-value way.”

The pandemic, in Saini’s view, may also speed the move away from fee-for-service to value-based payment: “I foresee a greater openness and interest in capitated payment models in which providers are paid a flat fee per patient per month.”

Sorenson says that the COVID-19 pandemic has shown that value-based care and reducing low-value may go hand in hand. “Providers practicing within these models have been more successful in responding to the pandemic and weathering the ongoing economic uncertainties as a result of more predictable financial structures and associated investments in infrastructure, staff, programs and data systems to improve population health and care delivery,” she says. “These same capabilities are needed to reduce low-value care in the long term.”

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.
Despite — or maybe because of — the COVID-19 pandemic, the pace of mergers and acquisitions (M&A) in the provider healthcare sector was brisk last year, and some of the same forces may be at play this year.

While M&A activity paused briefly in the spring, it returned to historic averages by summer. According to a recent report by Kaufman Hall, M&A activity crescendoed in 2020, with a high level of activity by not-for-profit hospitals and health systems. The report shows that 19 transactions with a value of about $8 billion occurred in the third quarter, a level on par with historical averages and significantly higher than the 14 transactions in the second quarter.

Those with healthcare M&A expertise see the same pattern: a COVID-19-related pause early last year followed by an increase in deal-making as the year went on. John Fanburg, a managing member and chair of healthcare law at Brach Eichler, a law firm in Roseland, New Jersey, says M&A activity was high in 2020 till mid-March, when COVID-19 hit and transactions either slowed dramatically or came to a complete halt. "Activity recommenced in June, and deals picked up from where they stopped," he says.

Gay Casey, a managing director at Berkeley Research Group, a consulting firm in Philadelphia, notes that transaction activity reported through the third quarter is a leading indicator that healthcare providers are moving beyond the immediate impacts of the COVID-19 pandemic. "We are seeing a lot of M&A activity in the post-acute healthcare setting, including physician group partnerships and joint venture agreements between hospitals and home healthcare/hospice providers," she says.

Anu Singh, a Kaufman Hall managing director, says the pandemic has, in fact, strengthened the rationale for strategic partnerships, leading to a potential uptick in M&A.

"The reality is, COVID was a clinical impact item to a lot of organizations, but what was happening inside and outside the industry pre-COVID was a bigger story," he says. "We’re seeing whole new ways of delivering care, whole new ways to collaborate, find value and deal with new reimbursement models. COVID has certainly accelerated these pursuits, but the most forward-thinking systems were already charting this path before the pandemic."

Singh says providers are facing the fact that pre-pandemic revenue streams may not return. "In order to compete moving forward — whether it’s investing in telehealth or an urgent care presence in their communities — many organizations are realizing they need more capabilities and resources and are working with other organizations on a path to viability," he says.

Four major mergers were announced in the third quarter of last year:

2. Lifespan and Care New England, both in Providence, Rhode Island, after years of on-again, off-again talks.
The major M&A trend, Singh notes, is large organizations thinking more strategically around partnership opportunities. “I think we’re going to see some systems who appreciate where they need to be from a geographical standpoint with facilities and now want to build out more services,” he says.

Pandemic effects
The pandemic has created an environment ripe for an increase in M&A, especially among smaller systems, rural hospitals and independent practices, says Brandon Edwards, CEO of ReviveHealth, a health communications company in Nashville, Tennessee. “While the CARES Act helped some, and elective care and routine care are picking up, many are still likely to need a partner to survive,” he says. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, is the $2.2 trillion economic stimulus bill passed in March 2020.

Edwards says M&A in the healthcare sector definitely slowed because providers have been consumed with managing through the pandemic, but as operations have trended upward, that will likely change. “We’re seeing some of the normal activity with larger systems looking to expand their geographic footprints,” he says. “But we also saw some newer dynamics like Novant and UNC (University of North Carolina) creating a partnership so they could go after New Hanover Regional Medical Center in eastern North Carolina. As the industry evolves, so will the definition of a partner.”

Edwards points to CHI Franciscan and Virginia Mason as a possible template for future pairings — an innovative system and a community hospital, respectively, joining forces.

Edwards says it’s worth noting that some deals fell apart last year. Beaumont Health in Michigan and Summa Health in Northeast Ohio called off their plans to combine in 2020. Advocate Trinity Hospital, Mercy Hospital & Medical Center, South Shore Hospital and St. Bernard Hospital, four money-losing hospitals serving a largely poor patient population on Chicago’s South Side, abandoned their plans for merging after funding from the Illinois Legislature fell through.

There are some centrifugal forces at play, notes Nathan Kaufman, a healthcare consultant in San Diego. He points to Hoag Memorial Hospital Presbyterian, a two-hospital system in Newport, California, that is seeking to separate from the Providence Health system headquartered in Renton, Washington.

Looking ahead
Kaufman says it’s difficult to make predictions for 2021 other than that it is shaping up to be a tough year for healthcare systems. “What is certain is we will have more uninsured, more Medicaid, and very tough negotiations with complicated and very greedy commercial insurance companies,” he says. According to the Kaiser Family Foundation, preliminary Medicaid data show that total enrollment had grown to 75.5 million by July 2020, an increase of 4.3 million beneficiaries from in February. Edwards at ReviveHealth also sees tough times as the number of uninsured climbs. “Though not certain, it’s highly likely we’ll see a surge in M&A, as large systems can capitalize on this current dynamic to increase market share and geography as well as efforts to place tighter restrictions on M&A activity like we’ve seen in California,” he says, adding that payers may also see acquisition opportunities as some practices struggle.

Edwards notes that Optum, under its parent company UnitedHealth Group, is the second-largest employer of physicians behind Kaiser Permanente and one of the largest managers of surgery centers. “They are using their physician and insurance presence to cherry-pick the most profitable parts of the market, which are Medicare Advantage and ambulatory surgery, leaving everything else for the hospitals,” he says.

Casey at Berkeley Research Group notes that consolidation has been the trend among providers for the past five years; she expects that to continue this year: “We could see an increase in the number of healthcare providers exploring partnerships as a means to recover from the impacts of the pandemic.”

Fanburg at Brach Eichler sees tension between healthcare systems and their physicians. “They are seeing their doctors move in a direction that they cannot control or legally influence in the years to come,” he says. “As hospitals move more toward an outpatient strategy, controlling their medical staff members will be critical to their future strategic goals.”

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Eric Whitaker, M.D.
From influences to influencer

Eric Whitaker, M.D., credits influences in high school and medical school with his success. Now he wants to turn his new Medicare Advantage plan, Zing Health, into a training ground for Black and Latino health insurance executives — and has his sights set on unicorn status.

by KEITH LORIA

Eric Whitaker, M.D., is a nationally recognized authority on public health and an expert in the health issues of African American communities, and he is using his influence and knowledge to lead Zing Health, a physician-led Medicare Advantage HMO plan that helps underserved seniors.

An internal medicine physician by training, Whitaker has had a career that includes running the Illinois Department of Public Health and founding the investment firm TWG Partners. He also is a friend of former President Barack Obama. Whitaker was a student at the Harvard T.H. Chan School of Public Health when he met Obama, who was a student at the university’s law school.

“I actually didn’t know his name until I saw his name in a Boston newspaper as the first Black president of the Harvard Law Review and realized that though we were in Boston, we both had a connection to Chicago,” says Whitaker.

Over time, his relationship with both Barack and Michelle Obama opened his eyes to the immense possibilities in the future. Whitaker knew he wanted to do all he could to make a difference.

That was a catalyst for forming Zing Health, which he started in 2019 along with Kenneth Alleyne, M.D., FAAOS, a board-certified orthopedic surgeon. The company, which got its start in the innovation lab at the American Medical Association, markets Medicare Advantage plans to underserved communities, with a focus on Black and Latino communities. The company has branched out from its home base in Chicago and Cook County and is now marketing plans in Indiana and Michigan.

“Whereas a lot of insurance companies run away from diverse populations, we’re running toward them because we’re giving our experience to vulnerable populations,” Whitaker says. “Even with Medicare Part D, we focus on the low-income segment of that population. We feel we have a unique
experience to deliver stellar health outcomes for these underserved populations.”

**Early influences**
Whitaker, 55, was the middle of three boys raised by his mother, Charlotte, a nurse administrator and head nurse at Chicago’s Michael Reese Hospital, now closed and demolished. She graduated from the hospital’s nursing school, which at the time was one of only two nursing schools in the city that accepted Blacks. “In another age, she would have been a physician, but that path wasn’t open to her,” Whitaker says.

Whitaker grew up in Morgan Park, a neighborhood on Chicago’s South Side, and attended St. Rita of Cascia High School, taking four buses to get there each day. “I got a basketball scholarship to go there, but I tested into the top honors class, though they didn’t care,” he says. “They just wanted me to play basketball.”

Whitaker’s mother used to joke that she would whisper in her boys’ ears that they should become doctors. “I was the only one who listened to her,” he laughs. Whitaker says the experience that led to him becoming a physician occurred during his junior year in high school.

“I was enrolled in this program at the Illinois Institute of Technology called CHAMPS (Chicago Area Health and Medical Careers Program), which aimed to identify minorities who were good in sciences and expose them to the health professions,” he says. “In CHAMPS, I saw my first African American doctor — and that was an inspiration — and I learned the importance of role models. It changed my life.”

During that time, Whitaker also learned about what everyone in healthcare is now calling the social determinants of health. “There was a little clinic, and there were pregnant women lined up outside the door,” he says. “There’s this thought that poor people don’t want healthcare, and here I saw with my own eyes that folks were out in the sun waiting to be seen in what I consider inhumane conditions. That image has rested in my mind to this day and really has been a driver for how I’ve approached my career. I knew I wanted to be a physician, but I wanted to be a physician for communities and populations.”

Whitaker went on to major in chemistry at Grinnell College in Iowa and then earned his medical degree from the University of Chicago Pritzker School of Medicine and master’s in public health from the Harvard T.H. Chan School of Public Health.

While in medical school, Whitaker took a break from his studies to devote time to being president of the American Medical Student Association, a group that represents approximately 30,000 medical students around the country. “I ended up testifying in front of Congress twice,” he says. “The people that I met are now running institutions, hospitals, foundations, government — they’re all over the place. It’s been a powerful network of folks that I’ve been able to collaborate and work with to improve healthcare for vulnerable populations.”

A mentor recommended that he do his residency at San Francisco General Hospital (now Zuckerberg San Francisco General Hospital and Trauma Center) because he could make a difference there during the HIV/AIDS epidemic. In the early ’90s, the epidemic’s disproportionate effect on African Americans was becoming apparent. “One of the things that I saw was that in the Black community, HIV was growing and spreading, yet a lot of the community was really ignoring it and not being proactive about preventing HIV spread,” he says.

**Committed to a cause**
Whitaker has spent most of his career in Chicago — and he makes a point of mentioning that he lives on the South Side today by choice. He worked first with Cook County Health’s Woodlawn Health Center, which was just a few blocks from the University of Chicago. Whitaker then started Project Brotherhood, which encouraged Black men to use community healthcare services. “It was really about men accepting their responsibilities to go along with the rights they think they have as men,” says Whitaker. To erase the stigma associated with going to the doctor, Whitaker and his colleagues added

“**I want Zing to be an exemplar of what’s possible, because if someone sees us do it, then they can think they can do it themselves.”**

— ERIC WHITAKER, M.D.
a barbershop in the clinic.

Whitaker credits the work he did setting up Project Brotherhood with leading to his appointment as Illinois state health commissioner in 2003, a post he held for four years. “I’d say it was some of the most fun I’ve had in my life,” Whitaker says, “because it’s one thing to have a lot of ideas, (but) it’s another to be able to change a policy that impacts millions of people.” As state health commissioner, he worked on HIV prevention as well as reducing the burden of breast cancer among the state’s Black women and increasing preparedness for bioterrorism and a flu pandemic.

During the next chapter of his career, Whitaker returned to the South Side where he served as executive vice president for strategic affiliations and associate dean for community-based research at the University of Chicago Medical Center.

In 2018, he helped establish the Creating Pathways and Access for Student Success (CPASS) Foundation. Like CHAMPS before it, CPASS offers students, through its SMASH Academy, a five-week experience on the Illinois Institute of Technology campus, exposing them to a STEM (science, technology, engineering and mathematics) program of study and fostering interest in both health professions and technology.

Whitaker’s wife, Cheryl, is also a physician. When they aren’t working (and before the COVID-19 pandemic), the Whitakers enjoyed eating out and traveling, often accompanying the Obamas on vacations to Martha’s Vineyard and Hawaii. They have two teenage children, Caleb and Caitlin. “Cheryl has been on a lot of the journey with me — training at the same hospitals — and did a lot of the same things,” Whitaker says.

“The road to Zing

Whitaker had been involved in several businesses prior to Zing. “I consulted with a healthcare company, and when that owner sold that business, he said he enjoyed working with me and wanted to find something we could work on together,” Whitaker says. “We looked at a lot of options and decided to get into the Medicare Part D business. It was based on our skill sets.”

The first insurance company he founded was Symphonix Health Holdings, which was sold to United Healthcare; his second was NextLevel Health, which he co-founded with his wife, who was CEO and chair of the board. NextLevel Health sold its assets to Centene Corporation last year.

With Zing Health, Whitaker says he’s working against a health insurance system that is often complicated to navigate and access, especially for minorities in low socioeconomic communities. Zing Health uses a community-based approach oriented toward the social determinants of health to keep individuals and communities healthy. In May, Newlight Partners, a private investment firm in New York, announced that it had taken a $150 million equity position in Zing. Newlight Partners has also invested in Oak Street Health, the primary care business headquartered in Chicago that that went public in May.

Zing Health started selling coverage two years ago in Cook County and subsequently expanded to six additional counties in Illinois, three in Indiana and three in Wisconsin, and has plans for more expansion in Michigan.

“What is unique about our approach is that our company is really designed to be mindful of social determinants of health,” says Whitaker.

One of Whitaker’s hopes for Zing Health is that it becomes a training ground for African American and Latino executives in the health insurance industry so that they can move on and rise to positions of influence in the industry.

Another one of Whitaker’s goals: Have Zing reach unicorn status by crossing the $1-billion-in-value threshold that the unicorn label denotes.

“Few African Americans founders get access to venture capital, and few certainly get access to the significant capital that Zing Health has,” he says. “I want Zing to be an exemplar of what’s possible, because if someone sees us do it, then they can think they can do it themselves. So that’s a pretty lofty goal, but it’s one that I would love to reach in the next four or five years.”

— ERIC WHITAKER, M.D.