CHALLENGES AHEAD IN 2021

COVID-19 is the biggest one, but other twists and turns await.

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Challenges and the change that is possible

In many respects, the results of our reader survey about the healthcare challenges in 2021 are not all that surprising. We are still very much in this pandemic and COVID-19 loomed large in the reader responses.

Almost half (45%) of the respondents listed challenges posed by COVID-19 transmission as among the top three facing their organization. Just over half (54%) listed managing COVID-19-related changes in their organizations among the top three challenges they have as healthcare leaders and executives.

When we pulled back and asked about challenges facing American healthcare as a whole, deferred care, public health measures to curb transmission and managing the distribution of the COVID-19 vaccines dominated the answers.

If this were a solar eclipse, 2021 would seem to be in the COVID-19 path of totality.

But not entirely, because respondents to our survey also indicated that they have plenty else on their plates. The Biden administration brings a whole new set of healthcare policy and regulatory considerations. The project of shifting from fee for service to value-based care is an ongoing grind.

We also asked respondents about their level of optimism. Perhaps COVID-19 fatigue is setting in, because more are sipping from a glass half empty than one half full: 37% rated their optimism as low or somewhat low compared with 34% who rated their optimism level as high (just 1%) or somewhat high.

“Challenges” is a word that many prefer to “problems” because motivation is baked into it. Amanda Gorman, the National Youth Poet Laureate whose reading at President Biden’s inauguration drew so much praise, wrote about challenges in a previous poem, “Fury and Faith.”

“Whether we prevail,” wrote Gorman, “is not determined by all the challenges present but by all the change that is possible.”

So here is to all the change that is possible in 2021.

Mike Hennessy Sr.
Chairman and Founder of MJH Life Sciences
Cover Story

Challenges Ahead in 2021

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Mission

Managed Healthcare Executive provides healthcare executives at health plans and provider organizations with analysis, insights and strategies to pursue value-driven solutions.
What is the new normal?

TPG International Health Academy held a one-hour virtual educational summit on Dec. 2, 2020, comparing how Sweden, Japan and the United States are responding to COVID-19. Faculty for the summit included two physicians who have dealt with COVID-19 in their respective countries: Zayed Yasin, M.D., of Sweden, and Sayaka Hikida, M.D., of Japan, who is currently deployed to the CDC.

Background

Two important risk factors for COVID-19 severity are age and obesity. Both Sweden and Japan have populations significantly older than that of the U.S. Japan has the greatest proportion (28%) of people older than 65 in the world. Sweden ranks 12th with 20%, and the U.S. is 36th with 16%. Based on the age of its population, Japan would be expected to be hardest hit by COVID-19.

But obesity is a major contributing factor to diabetes, hypertension and other morbidities associated with poorer prognosis for those who have received a diagnosis of COVID-19. Just over 36% of the U.S. population is obese — the largest proportion in the world, and greater than in Sweden (20.6%) and Japan (4.3%).

The exact course of the pandemic is difficult to predict, but as of Dec. 14, 2020, COVID-19’s impact on the Japanese, Swedish and American populations was dramatically different. Japan had significantly fewer cases and deaths on a population basis than the U.S., whereas Sweden had one-third fewer cases and one-fifth fewer deaths per million people. On a population basis, the U.S. has among the highest number of cases and deaths of any country in the world.

Discussion

Q How did your country initially respond to COVID-19?

Yasin: Unlike the U.S., Sweden took what many considered a controversial and dangerous hands-off approach that did not include lockdowns or mandatory use of masks. The country also kept its schools open. The initial spike in cases and deaths was largely in nursing homes and among the elderly. The attitude among the country’s health officials was to treat the COVID-19 response as a marathon, not a sprint. Doing too much too quickly would cause people to get tired of the requirements and actually make things worse in the long run.

Swedish officials encouraged working from home and banning large gatherings but did not impose lockdowns or face masks. These steps were based on our goals of not overwhelming the healthcare system, minimizing the negative impact on the economy and not exhausting society’s resilience before the pandemic is over. Sweden’s relatively healthy population and the normal social distancing in our culture, the approach of moderation seemed the most effective way to go. (Note: This approach has not been as effective as once thought. Sweden currently has one of the highest rates of COVID-19 death in the world on a deaths per million population basis.)

Hikida: Japan immediately put five strategies in place. The first involved offering easy access to care through the government’s national healthcare system; the second, assuring high-quality care even in the rural and more remote areas; the third, reinforcing the Japanese citizens’ high trust in the government. Anders Tegnell, M.D., the very controversial Swedish equivalent of Anthony Fauci, M.D., had an extremely high approval rating – people were even getting tattoos of him. Combined with

A Japanese poster about the 3 C’s of COVID-19 prevention, translated into English.

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standard of personal hygiene; the fourth, focusing on early detection of COVID-19; and, the fifth, prospective tracing and follow-up with close contacts of anyone diagnosed.

Culturally, Japanese people are very open to, and experienced with, wearing masks and practicing social distancing, even prior to the pandemic. Building on this, the government’s focus has been to promote avoidance of the three Cs: closed spaces, crowded places and close-contact settings.

What is the plan for vaccinating people in your country?

Yasin: We will start the vaccination process in either late winter or early spring 2021. Our expectation is that the Swedish people will walk and not run to be vaccinated because many remember a swine flu vaccine (2009) that left some children with narcolepsy.

Hikida: Because there is much emphasis on holding the Summer Olympics in Japan in 2021, there is a strategy to move quickly with vaccinations. The government has contracts with AstraZeneca, Pfizer and Moderna. People have a high trust in the vaccines if they have been approved by the FDA.

Is the vaccination going to be enough to get through this pandemic?

Yasin: My personal opinion is that because we’ve never used mRNA vaccines before and we have developed these vaccines much more rapidly than any previous one for a new disease, no one really knows how this will go. The best case is that we will still be dealing with COVID-19 until the summer and that we won’t see a fourth wave in the fall of 2021.

Hikida: While the vaccine is important, we won’t be relying on it alone. The public health measures and the need to continue the three Cs will still be important. We expect to be through it and safely host the Olympics in the summer.

What changes in the healthcare system, including telemedicine, and in the economy do you expect to continue after the pandemic is over?

Yasin: Sweden is already a leader in telemedicine, and the use of remote technologies for healthcare will continue to grow. I expect to see online retail to increase and more remote offices going virtual.

Hikida: Japan does not depend on telemedicine because so much healthcare is delivered in the home.

But the interest level has been very high, and we will be moving toward increasing telemedicine.

Perry Cohen is CEO of The Pharmacy Group and the TPG family of companies and a member of the Managed Healthcare Executive® editorial advisory board.

TPG International Health Academy hosts educational summits around the world for U.S. healthcare executives about healthcare conditions and systems in other countries. Future summits, both virtual and in person, will focus on COVID-19 and its impact on Colombia, Estonia, Iceland, Japan, Italy and Sweden.
Plot twists for ‘mabs’ as COVID-19 treatment

Where the monoclonal antibody treatments will fit into the day-to-day reality of the COVID-19 pandemic is difficult to say. In early January, it became apparent that a relatively small proportion — some press reports put it at 30% — of the available doses were actually being used. One of the main reasons is that the “mabs” need to be administered relatively early on in the course of a case of COVID-19. Delays in getting test results or a prescription for one of the monoclonal antibody treatments — or both — can put people outside the window when the treatments will be effective. The fact that the monoclonal antibodies are administered intravenously is another impediment to their use.

Those practical problems stand in sharp relief to a spurt of encouraging results from clinical trials. The monoclonal antibodies are living up their billing as perhaps the most effective COVID-19 treatment. There are, though, some twists to the storyline.

Take for example the results of a study funded by Eli Lilly published online in JAMA on January 21. They showed that a combination of a pair of Lilly’s monoclonal antibodies, bamlanivimab and etesevimab, reduced the SARS-CoV-2 viral load of people with mild-to-moderate cases of COVID-19. But viral loads did not decrease when patients took the bamlanivimab alone.

Results reported the same week in the New England Journal of Medicine suggested that a middle-level dose of bamlanivimab may be the most effective and that, regardless of the dose, the monoclonal antibody treatment reduced hospitalizations. Meanwhile, Lilly put out a press release trumpeting results that showed that bamlanivimab prevented COVID-19 infections among the staff and residents of nursing homes and assisted-living facilities. Lilly said it will have the study published in a peer-reviewed journal. If the results hold up, bamlanivimab could wind up wearing a second hat as COVID-19 prophylaxis.

COVID vaccines OK for immunocompromised

As distribution of the COVID-19 vaccines sputters along, this question will be asked: Should people who are immunocompromised get vaccinated?

Mostly, the answer is yes, according to the FDA and CDC. They both weighed in when the Pfizer-BioNTech and Moderna vaccines received emergency use authorizations (EUAs) from the FDA in December. Anthony Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases and now the chief medical adviser in the Biden administration, offered this caveat while speaking to a group of hematologists just before the approval of the Pfizer-BioNTech vaccine: Taking immunosuppressants might mean a less robust response from the vaccine, but “some degree of immunity is better than no degree of immunity. So, for me, it would be recommended that these people do get vaccinated.”

The American College of Rheumatology echoed Fauci’s endorsement, saying that for those taking drugs such as prednisone, “even partial protection will be of benefit both to patients and the general public.”

The American Association of Cancer Research (AACR) went further, saying that not only should patients with active cancer get vaccinated, but they also should be among the first in line. The American Society of Clinical Oncology has taken a similar position.

As the AACR noted, neither of the vaccines with EUAs nor the ones in phase 3 trials use live virus, which could, theoretically, overwhelm a compromised immune system and result in infection.
Shrank, others propose community health workers workforce

Creating a national workforce of community health workers should be a priority for the new HHS secretary, argue William H. Shrank, M.D., and six co-authors in a commentary published in the February 2021 edition of Health Affairs. Shrank is the chief medical and corporate affairs officer of Humana and a member of the Managed Healthcare Executive® editorial advisory board.

Community health workers could help with contract tracing and help people navigate insurance choices, wrote Shrank and his colleagues, who had several other suggestions for the Biden administration. Theirs was one of six commentaries published by Health Affairs that made recommendations to the new administration.

Shrank and his colleagues said community health workers should be recruited from historically disadvantaged communities. Creating such a workforce would have the added benefit of providing “valuable economic opportunity for the workers themselves,” they noted.

Next Gen ACOs: savers or spenders?

The Next Generation ACO program, was supposed to end in 2020, but it was granted a one-year reprieve because of the COVID-19 pandemic. The National Association of ACOs (NAACOS) wants that extension to become permanent and says the “Next Gen” ACOs save the Medicare program a lot of money. Former CMS Administrator Seema Verma begs to differ.

Last month, NAACOS said 37 of the 41 participating Next Gen ACOs collectively saved Medicare a total of $559 million in 2019. The association’s math is based on performance year 4 numbers. Once shared savings — the money that ACOs get back if they beat financial benchmarks — are factored in, the net savings were $204 million.

ACOs have bipartisan support, but the CMS ACO programs came to be under the ACA, and the NAACOS and the Trump administration didn’t see eye to eye. In a January 10 Health Affairs blog post, Verma, citing an evaluation report, said that the Next Gen ACOs didn’t lead to a statistically significant difference in spending during their first two performance years and, what’s more, in 2017, actually led to an increase of $115.6 million in Medicare spending once shared sharings were included.

Listen to our podcast!

Managed Healthcare Executive® featured Kermit Randa, CEO of Syntellis Performance Solutions, in one of its most recent “Tuning In to the C-Suite” podcasts. Senior Editor Peter Wehrwein and Associate Editor Briana Contreras spoke with Randa about a recently released Syntellis report, the “2021 Healthcare Financial Trends Survey Report,” which highlights how healthcare finance leaders pivoted in 2020 and the ways in which they will continue to adjust to changing circumstances this year.

“Tuning In to the C-Suite” features healthcare professionals, leaders and executives talking about the most important healthcare issues of the day. The podcast is also home to our “Meet the Board” and “MHE Talks: Improving Patient Access” podcast series. You can catch a regular episode of “Tuning In to the C-Suite” every Wednesday on iHeart Radio, Apple Podcasts and Spotify or on the MHE website.
Addressing the mental health needs of seniors with a value-based care team approach

By Renee’ Buckingham, president and Marlyce Hill Ali, M.D., medical director, Partners in Primary Care

Caring for seniors means attending to both their physical and emotional health. Unfortunately, the mental health of older patients is rarely evaluated and treated. Multiple barriers to care exist, including availability and access to mental health practitioners, as well as the stigma associated with psychological conditions that may prevent patients from seeking help.

A Prevalent and Growing Problem

One in four older adults in the U.S. experiences at least one mental health disorder, with that number expected to double over the next decade. Depression is the most common mental health problem in seniors, but anxiety is also very prevalent among this population, affecting as many as 10%-20% of older people.

Physical and mental health are inextricably intertwined. Living with a chronic illness, as most seniors do, can bring about or aggravate depression and anxiety. At the same time, poor mental health among seniors with chronic conditions can reduce adherence to treatment, exacerbate physical health conditions and lead to poorer quality of life and outcomes.

The healthcare costs for individuals with mental illness are high. Older patients experiencing depression use 50%-100% more healthcare services than nondepressed seniors and have about 50% higher healthcare costs.

Hurdles to Treatment

Despite the high prevalence of mental health disorders, few older adults receive treatment. Seniors are 40% less likely to seek or receive mental health treatment than younger individuals, and as many as two-thirds of the elderly with mental health conditions do not get needed treatment. There are myriad reasons behind this deficit of care.

Mental health problems in seniors often go unrecognized. Depression is commonly seen as a normal part of aging—a natural response to loss—or mistaken as a sign of frailty or dementia. Seniors are often too ashamed to admit that they’re having emotional difficulties. Additionally, mental disorders frequently present as physical ailments in older adults; rather than mention feelings of sadness, older people will likely complain about a headache or fatigue.

A severe shortage of mental health specialists, especially those trained in treating the elderly, is a further deterrent for getting adequate care.

Integrating Mental and Physical Health Care

In order to fully address patients’ mental health issues, it’s important to dedicate sufficient time and resources that allow you to get the big picture of their needs and of where they are in life.

Our experience at Partners for Primary Care, a network of senior-focused primary care practices, shows that a value-based, care team approach enables us to focus on both the physical and mental health needs of patients. Our doctors spend 45 minutes on average per visit—more than twice the typical doctor visit. That enables primary care physicians to build trusting relationships with patients and have in-depth conversations that help identify mental health problems. Training care team members to recognize signs of mental health disorders, as well as using psychological screeners, are other important components for getting patients the care they need. Another key factor is having the ability to refer patients to a behavioral specialist on the team for further evaluation and counseling.

Having these services under one roof has proved beneficial. Research shows that patient utilization of mental health services, as well as reductions in depressive symptoms, are much greater for patients in integrated settings than when outside referrals are made.

We see those positive effects each day. A patient who had been experiencing extreme anxiety related to the pandemic, but was closely monitored and in frequent contact with her physician and the team’s behavioral specialist, sums up the benefits of our integrated care approach: “I have never in my life had any doctor office take such good care of me during the scariest time of my life.”

It takes a care team to address both the mental and physical health needs of older patients—a vital component for improving patient outcomes.

Renee’ Buckingham is president of Humana’s Care Delivery Organization, which includes Partners in Primary Care, a wholly owned medical group of senior-focused, payer-agnostic primary care clinics. Buckingham is responsible for business operations, performance and national expansion of Partners in Primary care, as well Humana’s other Primary Care businesses.

Marlyce Hill Ali is an internal medicine physician and corporate medical director of Humana’s Care Delivery Organization, which includes Partners in Primary Care. In that role she is responsible for physician education and training course development for all Care Delivery Organization physicians, as well as the development of the integrated provider-driven model of care with an ancillary care team providing wraparound services.

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The COPD Foundation is calling for a change in clinical trial design that would test experimental therapies in subsets of patients. by JAIME ROSENBERG

As many as 30 million people in the United States are estimated to have chronic obstructive pulmonary disease (COPD), although approximately half don’t have a diagnosis. Until the COVID-19 pandemic, COPD was consistently the fourth leading cause of death in the U.S. Diagnosis and treatment are complicated by the fact that COPD is really something of an umbrella category for lung disease that is characterized by difficulty breathing. The two most common conditions that fit under the COPD rubric include emphysema and chronic bronchitis.

The current treatment choices for COPD are varied and complicated, mirroring the condition itself. But in broad strokes, they can be grouped into three main medication categories:

- Bronchodilators, which help relax the tight muscles in the airway, making it easier to breathe. They are typically administered through an inhaler or nebulizer. Bronchodilators are categorized by the duration of their effect: short-acting treatments that last a few hours and long-acting ones that keep airways open for 12 hours or more. The long-acting bronchodilators include long-acting beta agonists (LABAs) and long-acting muscarinic antagonists (LAMAs) that need to be administered only once or twice a day.
- Inhaled corticosteroids (ICS) that reduce inflammation in the airways.
- Triple inhaled therapy, which combines a LAMA, a LABA, and an ICS.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy recommends bronchodilators as first-line treatment for COPD and preferably a LABA or LAMA. Treatment with bronchodilators can include LABA or LAMA alone or a combination of the two. Some of the combination therapies include Anoro Ellipta (umeclidinium and vilanterol), Duaklir Pressair (aclidinium bromide and formoterol fumarate) and Stiolto Respimat (tiotropium and olodaterol). Ruth Tal-Singer, Ph.D., president and chief scientific officer of the COPD Foundation, a nonprofit that promotes COPD research and improved care, explains that the proponents of the LABA-LAMA combinations argue that pairing the medications often produces the best outcome. But there is an opposing “minimalist” school of thought, says Tal-Singer, that argues that “these are drugs, and you want to minimize the number of drugs people are on.”

There are many forks in the COPD treatment road. Patients whose COPD flares up can be treated with ICS in combination with a LABA. Triple inhaled therapy is an option for people whose COPD doesn’t respond to the ICS-LABA combination. That’s a large group: About 1 in every 3 patients with COPD end up on triple inhaled therapy within a year of diagnosis.

The FDA approved the first triple inhaled therapy, GlaxoSmithKline’s Trelegy Ellipta, in 2017. Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid; umeclidinium, a LAMA; and vilanterol, a LABA. AstraZeneca’s triple therapy product, Breztri Aerosphere, was approved last year. Breztri Aerosphere is a combination of budesonide, an inhaled corticosteroid; glycopyrrolate, a LAMA; and formoterol fumarate, a LABA.

The GOLD strategy makes note of the fact that COPD is complex and multifaceted, which means a
Some treatments for chronic obstructive pulmonary disease in late-stage clinical trials

- Verona Pharma’s ensifentrine is a potential first-in-class inhaled treatment that combines bronchodilator and anti-inflammatory properties in one compound. Researchers who conducted two phase 3 trials, ENHANCE-1 and ENHANCE-2, have recently started assessing the safety and efficacy of the treatment across approximately 800 patients with severe, symptomatic COPD.
- Sanofi and Regeneron’s dupilumab (Dupixent), currently approved for allergic diseases such as asthma, is being studied in a phase 3 study assessing the safety, tolerability and efficacy in patients who have moderate-to-severe COPD with type 2 inflammation.
- AstraZeneca and Amgen’s tezepelumab is a potential first-in-class drug that blocks thymic stromal lymphopoietin. The phase 2a COPD Exacerbation Study is comparing the tezepelumab’s impact on COPD exacerbations with a placebo. Subjects will receive tezepelumab, or placebo, administered via subcutaneous injection over a 52-week treatment period. The study is scheduled to be done in early 2023.

Managed Healthcare Executive.com
One lesson learned from the ACA is that the risk of failure for the law’s health insurance co-operatives was quite high. All but three of the ACA’s 23 co-op insurers have failed since 2015, one year after the ACA exchanges were launched.

The three survivors are Maine’s Community Health Options (CHO), Mountain Health CO-OP in Montana (which also offers coverage in Idaho and Wyoming) and Common Ground Healthcare Cooperative (CGHC) in Wisconsin. Called the “little miracles” for their ability to survive despite the risks and increased competition, each reported a profit in 2018 and 2019 after suffering big losses in their first three years of operations. All three were profitable again in 2020, but it is too early to say by how much.

Although insurance is always risky, all three co-ops entered 2021 with stronger balance sheets thanks to three years of profits and much larger reserves after getting some long-overdue risk corridor funds that the federal government promised insurers under the ACA. Those funds were delayed for four years because the government illegally limited what HHS could pay out, says Kevin Lewis, CHO’s president and CEO. (The GOP-led Congress had blocked the risk corridor payments.) The three co-op insurers sued HHS, and each received a multimillion dollar settlement last year.

In interviews, executives with the three co-ops talked up the value of operating nonprofit, co-operative insurers, which, by design, must focus on meeting members’ needs. “I don’t think a for-profit operation is a good model for running a health insurance company,” says Mountain Health CEO Richard Miltenberger. Before joining Mountain Health in 2018, Miltenberger had decades of experience as an executive running for-profit health care companies and health insurers. “You shouldn’t be mixing Wall Street demands with how much care we’re going to give members,” he adds. CGHC’s CEO Cathy Mahaffey agreed, saying, “Individuals and employers need a nonprofit, member-centric health insurance company that puts members’ needs first.”

Lewis comments, “Being a nonprofit, we win on service, our local knowledge and having a local presence. Our only calling is being focused on doing what’s right for our membership.”

The co-op model has stimulated competition among health insurers, as Congress intended when it included provisions allowing for co-ops in the ACA, which was signed into law by President Barack Obama in 2010. Seeking to remain competitive in Maine, for example, other insurers have adopted some of CHO’s benefit designs, Lewis notes. “In addition, the state has mandated that in some cases, all insurers need to adopt some of our benefit designs,” he says. “Also, the more competition there is, the better consumers are served.”

**Risk corridor payments arrive**

All three co-ops will be able to serve members’ needs more effectively because, in April 2020, the U.S. Supreme Court ruled in Maine Community Health Options v. United States that the three co-ops and one other insurer were entitled to more than $12 billion the government had not paid them from 2014 to 2016 under the ACA’s risk corridor provisions. Established to encourage health plans to participate in the ACA’s Marketplace, the risk corridor program required the federal government to shift some of the profits from high-earning insurers to stem losses among insurers with deficits.

As a result of the Supreme Court ruling, Mountain Health received $56 million in August 2020 and used about 15% of the sum to pay legal fees. About 10% went to policyholders in the form of premium credits. The remainder went into reserves and for marketing to attract more members, including employers in...
the small group market (those with fewer than 100 workers), Miltenberger says. CGHC received $90 million at the end of November and used a portion to repay an obligation to an unnamed organization that provided what Mahaffey calls a financial lifeline of $30 million in 2016. Those funds helped CGHC continue operations when it otherwise might have closed in 2016, she says.

CGHC used the risk corridor funds in multiple ways. “We used part of that money to pay our legal fees, four our obligations for the financial lifeline and to issue rebates to our members,” Mahaffey says. Any amount left over will go into reserves, she says.

At the end of September, Lewis’ CHO received $59 million in risk corridor payments. As in Wisconsin and Montana, some of those funds went to pay legal expenses, 16% went to policyholders in the form of rebates, and the remainder will go into reserves, Lewis says. “Having a healthy reserve allows an insurer to weather whatever comes up in the market,” he adds. “If you don’t have sufficient capital reserves, that could lead an insurance company into trouble.”

Pursuing growth

The risk corridor funds also allow the co-ops to market health insurance to more individuals and to employers, as Mountain Health has done. After it was founded in 2014, Mountain Health moved into Idaho in 2015, offering individual and small group coverage. This year it began selling similar plans in Wyoming. Mountain Heath is the only co-op to offer health insurance in more than one state, Miltenberger says.

In late December, Miltenberger says, enrollment had increased in Wyoming and Montana, but the numbers were changing because many enrollees still needed to make their first premium payments in January.

Until this year, Blue Cross Blue Shield (BCBS) of Wyoming was the only insurer offering major medical coverage in the state and had an enrollment of about 25,000 individuals. Once Mountain Health entered the market, BCBS of Wyoming dropped its rates by about 10% for this year, according to Louise Norris, an insurance broker in Colorado who tracks insurance rates for Healthinsurance.org.

CHO is also seeking to add new members. After Maine expanded its Medicaid program rules in 2019, enrollment in ACA exchange plans declined from 71,000 individuals in 2019 to 62,000 in 2020, according to Norris’ figures. That drop affected the Maine co-op; the number of individuals it insured declined slightly from 26,800 in 2020 to about 25,500 this year, nearly half of whom are in the employer market, Lewis says. “That modest decline is due to a shrinking individual market and aging into Medicare,” he says. CHO’s competitors are Anthem, which reentered the Maine market in 2019 after leaving in 2017, and Harvard Pilgrim. Despite this competition, CHO expects to report a profit for 2020, Lewis says.

CGHC is continuing to expand, Mahaffey says. In 2018, the Wisconsin co-op was the only health insurer in seven Wisconsin counties, but as of last year it had 54,000 members (down from 62,000 in 2019) in 20 of the state’s 72 counties. In December, Mahaffey estimated the co-op would have 50,000 covered lives, although CGHC did not yet have numbers for the small group market.

Joseph Burns is an independent journalist in Brewster, Massachusetts, who writes about healthcare.
COVID-19 is the biggest one, but other twists and turns await.

We conducted our Challenges Ahead reader survey in January and had 101 respondents. Their answers provide understanding and insight into the thinking of healthcare executives about what lies ahead for them, their organizations and the country in 2021. Many thanks to everyone who participated!

Q: Which of these do you expect to be your organization’s greatest challenges in 2021? Please pick three.

- Managing challenges posed by COVID-19 transmission: 45%
- Responding to policy and regulatory shifts under the Biden administration: 36%
- Managing the shift to value-based care: 34%
- Responding to continued declines in the utilization of healthcare services: 33%
- Managing the shift to virtual care: 32%
- Managing challenges posed by distribution of the COVID-19 vaccines: 26%
- Managing layoffs and furloughs: 21%
- Other: 11%
Which of these do you expect to be your greatest challenges as a healthcare leader and executive in 2021? Please pick three.

- Managing change in my organization that is a result of the COVID-19 pandemic (54%)
- Managing my organization’s response to new policies and regulations under the Biden administration (46%)
- Managing my organization’s shift to value-based care (29%)
- Managing the end of work-from-home policies and practices (25%)
- Managing my organization’s role in COVID-19 vaccine distribution and administration (25%)
- Managing permanent work-from-home policies and practices (24%)
- Managing growth and workforce additions (23%)
- Managing workforce reductions (21%)
- Managing my organization’s shift to telehealth and virtual care (19%)
- Other: 3%

Which of these do you expect to be the greatest challenges in American healthcare in 2021? Please pick three.

- Managing the consequences of care deferred because of the COVID-19 epidemic (49%)
- Managing public health measures to prevent the transmission of SARS-CoV-2 (45%)
- Managing and responding to the consequences of an economic downturn (38%)
- Managing the distribution of the COVID-19 vaccines (37%)
- Managing high drug prices (33%)
- Managing changes in policy and regulation under the Biden administration (28%)
- Managing the shift to value-based care (17%)
- Managing changes to deal with healthcare disparities and racism (15%)
- Managing the shift to virtual care (11%)
- Other: 1%
Please rate your level of agreement with the following statements about possible developments in healthcare in 2021.

- **COVID-19 vaccination will result in herd immunity and the pandemic will end in 2021.**
  - Strongly disagree: 16%
  - Somewhat disagree: 25%
  - Neutral: 28%
  - Somewhat agree: 29%
  - Strongly agree: 3%

- **COVID-19 vaccination will be only partly successful, so the pandemic will continue through 2021.**
  - Strongly disagree: 2%
  - Somewhat disagree: 10%
  - Neutral: 14%
  - Somewhat agree: 18%
  - Strongly agree: 56%

- **The Biden administration will be successful in strengthening the ACA as the principal means of expanding health insurance coverage.**
  - Strongly disagree: 5%
  - Somewhat disagree: 15%
  - Neutral: 31%
  - Somewhat agree: 32%
  - Strongly agree: 18%

- **The Biden administration will be successful in adding a public option to the ACA.**
  - Strongly disagree: 2%
  - Somewhat disagree: 16%
  - Neutral: 47%
  - Somewhat agree: 25%
  - Strongly agree: 10%

- **Meaningful steps will be taken to address healthcare disparities and racism.**
  - Strongly disagree: 5%
  - Somewhat disagree: 16%
  - Neutral: 42%
  - Somewhat agree: 30%
  - Strongly agree: 8%

- **Value-based care arrangements will have a meaningful impact on healthcare spending.**
  - Strongly disagree: 9%
  - Somewhat disagree: 16%
  - Neutral: 33%
  - Somewhat agree: 34%
  - Strongly agree: 9%

- **Telehealth will become entrenched as one of the main ways of delivering healthcare.**
  - Strongly disagree: 3%
  - Somewhat disagree: 14%
  - Neutral: 33%
  - Somewhat agree: 36%
  - Strongly agree: 15%

Please rate your level of optimism about U.S. healthcare in 2021.
For several years, the Association of American Medical Colleges (AAMC) has presented data showing that the United States faces a shortage of physicians in almost every specialty. In June 2020, the association issued its sixth annual report on the shortage, predicting that in just over a decade, the U.S. healthcare system would face a shortage of between 54,100 and 139,000 physicians in primary and specialty care.

Commenting on that report, AAMC president and CEO David J. Skorton, M.D., said the gap continues to widen between the available supply of physicians and the number of doctors the country needs. Michael Dill, the association’s director of workforce studies, cited several factors that contribute to the shortage, including a wave of retirements of older physicians and increased demand for physician care because of an aging population and COVID-19.

Christopher Kerns, MBA, executive vice president, and David Willis, MBA, vice president, both at the Advisory Board, took the opposite position in a Harvard Business Review article published in March 2020. They argued that the nation should have more than enough primary care physicians based on reports from HHS and other organizations. Many issues keep the U.S. healthcare system from using the existing supply of physicians more efficiently, they wrote, including an uneven distribution of doctors, high rates of uninsurance that decrease access to primary care physicians and inflexible care-delivery models.

Managed Healthcare Executive interviewed Dill and Kerns about these opposing points of view on the potential shortage of physicians.

Team-based care
Kerns says that health insurers and healthcare systems need to adopt innovative care delivery models that give physicians more support for delivering team-based care with other providers, such as nurse practitioners (NPs) and physician assistants (PAs). “One of the problems is a shortage of courage to disrupt the healthcare system that we have,” says Kerns. Healthcare professionals need to deliver care at the top of their license, he adds, and patient care should be organized more carefully according to the kind of healthcare professional who could meet patients’ needs.

If patient care were segmented this way, physicians could manage the care of patients who have the most chronic and pressing healthcare needs, and other members of the care team would care for patients who have less pressing needs, Kerns says. “If we segment patients, we can move them through the health system faster because physicians will be specializing in one type or just a few types of patient care, such as senior care, for example,” Kerns comments.

But Dill says the association’s projections of a shortage take into account an expanded role for PAs and NPs. “Making greater use of the entire team of health professionals is crucial to meeting our healthcare needs,” he says. “Our baseline projections assume that PAs and NPs will continue to contribute to meeting the nation’s healthcare needs at the level they are currently doing so and that their numbers will continue to grow. We also include two scenarios that include an increased role for them in meeting those needs. In those scenarios, we clearly see smaller shortages in the future — but we still see shortages.”

Uneven distribution
Kerns and Willis argue that the physician shortage is more a matter of how physicians are distributed than a shortage in total numbers. Organizations that employ physicians, such as health systems, large medical groups and major health plans, have a significant role to play in ensuring adequate primary care coverage, Kerns says. “Most of these organizations have enough leverage to locate physicians in high-need areas and...
provide options such as telehealth and advanced practitioners (NPs and PAs) in low-density regions,” he notes.

In response, Dill says medical schools have no control over where physicians choose to practice. “We need more physicians to meet the demands in some rural and other underserved areas, but even if we add more physicians, that factor alone doesn’t guarantee that they’re going to locate in any particular place,” he observes. “Therefore, we need to spend less time figuring out how to get exactly the right number of physicians in exactly the right places. Instead, we need to spend more time determining how to connect people who don’t have access to physicians.”

**Value-based payment**

Wider use of risk-based payment for physicians throughout the healthcare system would help foster greater use of team-based care, says Kerns. Patient-centered medical homes, accountable care organizations and other care models that have some degree of capitation would push the healthcare system — and physicians — to become more efficient. Shifting care away from physicians to other sorts of providers is a necessary ingredient of that efficiency, he notes.

“Value-based care will encourage greater use of NPs, PAs and other midlevel providers, and, in turn, that greater use will decrease the need for more physicians,” Kerns adds. “Value-based care helps provide the necessary incentives to match patient need with provider expertise and can help increase the effective reach of primary care providers.”

Kerns sees growing enrollment in Medicare Advantage (MA) as having a similar effect. “Medicare Advantage is a form of risk-based payment, and that means that those physicians who specialize in treating seniors in MA plans are more likely to employ behavioral health clinicians as a way to keep utilization to manageable levels.”

Dill counters that the shift to more team-based care has been happening for some time. “We see it as ‘necessary but not sufficient’ to address projected shortages,” he says. “In fact,” he continues, “for years, some observers have made the assertion that changing the way we pay for care will solve the shortages. Yet shortages persist because the underlying driver of the shortages is a growing and aging population, not a lack of efficiency.”

**Telehealth**

The COVID-19 pandemic has increased the use of telehealth, and many see telehealth becoming a permanent part of American healthcare. Kerns says telehealth allows physicians to reach more patients. “The use of artificial intelligence combined with telehealth can reduce the amount of time needed to see certain low-acuity patients, thereby helping increase effective physician capacity,” he explains.

Dill says greater use of telehealth has helped offset the decreased access to in-person care brought on by the pandemic and could improve access in rural and other underserved areas. “We continue to look at the data on how telehealth affects the demand for an effective supply of physicians, but they remain inconclusive,” Dill comments. “However, to the extent that telehealth expands access to previously underserved populations and areas — which is a good thing — we would also see an increase in demand for physician services when we are already projecting growing shortages. In fact, underserved
populations are one of our primary concerns during a shortage.

**Aging population**

While not dismissing Kerns’ and Willis’ numbers, Dill says the statistics they cited in their Harvard Business Review article seem akin to making back-of-the-envelope calculations that lack the rigor of the research that AAMC has done. “We’ve worked with an expert consulting company called IHS Markit to develop a sophisticated model of the physician workforce based on current utilization patterns and the likely factors that will affect future utilization of care,” says Dill. “Based on those numbers, our projections show there are shortages now, and we will see more shortages based in part on the aging of the population. Most baby boomers are now in their 60s and 70s, and health problems tend to accrue as people age.”

Kerns counters: “The Advisory Board’s calculations are not meant to show how primary care demand will manifest given current expectations about what physician distribution and patient complexity are likely to look like in the coming years. In fact, we agree that at (the) current course and speed, the country is likely on track for shortages in many regions. Rather, our modeling exercise was intended to show how emerging innovations in care delivery — scaled broadly — could help mitigate current and future shortages.”

“It’s certainly true that demand for care increases with age, but it’s also true that much of that care tends to be chronic in nature,” Kerns notes. “Remote patient monitoring plus regular remote check-ins can reduce the need for both more frequent doctor visits and, crucially, more trips to emergency departments.”

—CHRISTOPHER KERNS, MBA, EXECUTIVE VICE PRESIDENT, ADVISORY BOARD

**Deferred care**

Recognizing that Americans have postponed the use of healthcare services during the pandemic, Dill says those postponements will lead to an increased demand for care later. Much of that pent-up demand will come from those who have chronic and multiple comorbid conditions, along with those who need behavioral healthcare services. In addition, he predicts that the burden of dealing with this surge will fall disproportionately on primary care physicians.

Kerns doesn’t disagree entirely: “We’re already seeing the effects of deferred care on patient acuity, with oncologists reporting spikes in higher-stage cancers presenting at their offices. That increased intensity also increases physician burnout, likely contributing to an increase in physician retirements. These effects only accelerate the need for new care models (that allow) for more efficient and more equitable care — for all patients everywhere.”

Joseph Burns is an independent journalist in Brewster, Massachusetts, who writes about healthcare.

**Remote patient monitoring plus regular remote check-ins can reduce the need for both more frequent doctor visits and, crucially, more trips to emergency departments.**
Using behavioral economics to influence healthcare decisions
Insight into people’s irrational choices can improve healthcare.

by KAREN APPOLD

Behavioral economics is the study of how individuals analyze economic choices and make decisions. It recognizes that they are not the rational, reasoned people described in classic supply-and-demand economic theory. Instead, because they are emotional and full of cognitive quirks, they do not weigh risk-and-reward issues very well.

“The goal of behavioral economics is to identify the various triggers that shift behavior and then use those triggers to create an environment that makes it easier for individuals to make healthy decisions,” says Rick Leander, CEO of LFB Holdings, a behavioral insights consulting company in Winston-Salem, North Carolina.

Within behavioral economics, techniques and programs exist to help people make decisions that are presumably better, or at least more rational. The health insurance industry has used these tools to influence behavior in various ways.

One tool is the nudge, a slight tweak of the environment to guide decision-making. Health insurers can use nudges to get members to choose in-network care over out-of-network care by decreasing coverage of the latter. “While the insured party can still choose an out-of-network provider, the higher price orients them toward an in-network provider,” says Preet Anand, co-founder and president of Snug, an app-based daily check-in service for seniors living alone.

Another tool, hyperbolic discounting, offers something for a limited time after which the offer is gone, says Lisa Freeman Foote, M.A., director of health engagement design at HMS, a healthcare technology company based in Irving, Texas. Freeman Foote says an insurer might, for example, tell members with diabetes, “We have a limited number of free kits to send to members today to help them manage their blood sugar. Would you like one, before they are no longer available?” The key is to create a sense of urgency.

Another tool in behavioral economics plays on people’s perceptions of time. Often that means strategically timed emails and text messages to help jog the memory. “For many people, time passes quickly without them realizing it,” Freeman Foote says. “This causes them to sometimes forget that they need to do something because they feel like they just did it.” For example, a woman might forget that it has been two years since her last mammogram.

Success stories
One of the most noted success stories in behavioral economics concerns organ donations. There is a dearth of critical organs for transplant, both domestically and internationally, says Thomas Rice, Ph.D., a professor at the UCLA Fielding School of Public Health in Los Angeles. States and countries have set “organ donor” as the default on driver’s licenses as a way of increasing donors.

Researchers have found that people rarely choose the cheapest health insurance plan, even when the benefits of alternative plans are identical. When plan benefits are not identical, people often do not comprehend the differences because of cognitive overload. “There are ways to cut down on information overload, including reducing the number of choices available to a manageable number by removing uncompetitive or unpopular plans, removing extraneous information from comparison tables … and
Using behavioral economics to influence healthcare decisions

“Every intervention should be viewed as a way to learn, to get smarter and to test assumptions that earlier interventions may have supported.”

— RICK LEANDER, CEO OF LFB HOLDINGS

Using star ratings rather than exact dollar figures to catch the eye,” Rice says.

But researchers have discovered that the success of interventions predicated on behavioral economics is sensitive to context — meaning what worked in one environment may not work in another, even if the new environment appears identical. “Every intervention should be viewed as a way to learn, to get smarter and to test assumptions that earlier interventions may have supported,” says Leander. “Most behavioral economists consider every one of their interventions an experiment.”

“I am a huge fan of Paul Saffo’s concept of strong opinions weakly held,” Leander continued. “We know that every opinion is based on incomplete information, and that a smart way to think about that reality is to be willing to formulate an opinion based on early and incomplete information and then systematically look for insights that would tear that opinion apart.”

A study published in 2019 in the Journal of General Internal Medicine hints at the limitations of behavioral economics. Neither reminders from electronic pill bottles nor bidirectional text messaging about medication adherence improved blood pressure control. But Anand does not see the study as evidence that behavioral economic interventions don’t work, because there was already a high level of adherence. “There was very little to improve upon, especially because there were only 150 people in the study,” he says. “In general, medication adherence is thought to be around 50%. (Those are) the conditions and control I would test this against.”

Freeman Foote notes that the goals of the two different messages being sent to the pill bottle group were to provide encouraging nudges to either celebrate the “victory” of taking the pill yesterday or to urge people to take it today, she says. “There is room to improve the messaging by providing stronger language,” says Freeman Foote. “If they tested different messaging, they may have seen that by addressing the severity of not taking the medication exactly as it should be taken. There may have been shifts in adherence or blood pressure levels.”

Often cheaper

The COVID-19 pandemic has led to an unexpected increase in the use of telehealth. Freeman Foote says behavioral economics could provide some useful insights into telehealth usage and those who are reluctant to use it: “If we could ascertain more about people’s motivations or lack thereof by addressing barriers, then smart communications and content could be developed using behavioral techniques to continue growing adoption.”

When reflecting upon the successes and failures of behavioral economics used in healthcare, Freeman Foote says she has learned the pitfalls of generalizations. “It’s important to develop tailored and specific communications to meet individuals where they are in their current healthcare journey and plan for that unpredictability,” she says. “There will never be a one-size-fits-all solution, because all people act differently. When taking a more personalized approach, the odds of driving positive behavioral change are greatly increased.”

Leander has learned that shifting behaviors is difficult. “People are wired for instant gratification, yet in healthcare we often ask people to shift behaviors now for benefits that will not show up for years or decades, such as ‘don’t drink sugary sodas to avoid getting diabetes in 20 years.’ We need to find ways to provide shorter-term benefits for these kinds of behavioral shifts.”

Rice has realized that it is difficult to predict how effective a new behavioral economic strategy will be because there is no underlying theoretical model that helps gauge the impact of specific interventions. “One thing that’s great about behavioral economics is that interventions are often very cheap compared to traditional economic incentives,” he says. A study in Africa, for example, found that if a person with HIV has a good chance of winning a very small prize in a lottery, they are more likely to take antiretroviral medications.

The bottom line is that many principles of behavioral economics can be applied to healthcare. “Some work better than others, but all of them have their place and purpose and should be applied and tested appropriately in the industry,” Freeman Foote says.

Karen Appold is a medical writer in the Lehigh Valley region of Pennsylvania.

Managed Healthcare Executive.com
Interoperability is coming — at last

Enforcement of rules to encourage the freer flow of healthcare data were delayed because of the COVID-19 pandemic. They are now scheduled to go into effect this year. by JARED KALTWASSER

Perhaps no industry better straddles the dichotomy between cutting-edge technology and inefficient obsolete devices than the healthcare industry.

In one corner of a hospital, a physician in another room (or another state) can perform precision surgery using state-of-the-art robotics, while just down the hall a nurse receives the patient’s medical records via fax machine and the patient’s spouse uses a pen to fill out paperwork.

Those throwbacks exist for many reasons, but perhaps the most important is the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which requires providers and health plans to protect a patient’s health data. Say what you will about fax machines, but they are sturdily HIPAA-compliant.

But if government regulation to protect patient privacy is the root cause of the vestigial methods for transferring healthcare data, then new regulations might pull them into the 21st century.

New regs, new era

The agents of change are new healthcare data interoperability rules from HHS Office of the National Coordinator for Health Information Technology (ONC) and CMS. Enforcement of some parts of the ONC rule is scheduled to begin in April after HHS delayed enforcement last year because of the COVID-19 pandemic. Other parts will go into effect in 2022 and 2023. The CMS rule will be enforced starting in July.

The intent of the ONC rule is to make it easier for patients to access their own health information and for patient healthcare information to circulate easily among providers and provider organizations. It is also supposed to ease the way for design and use of healthcare-oriented computer and smartphone applications.

Nilesh Chandra, MBA, a partner in healthcare strategy at PA Consulting, an international consulting firm, says the changes could have life-or-death implications. He paints the scenario of someone coming to the emergency department with a rapidly worsening case of COVID-19. Because of the interoperability rules, the patient’s records will be readily accessible.

“The attending physician cannot speak to the sedated, intubated patient but can pull medical history to understand underlying health conditions and risk factors while administering care,” he says. In the past, providers of health-related services have used “information blocking” to keep data in-house in hopes of creating some kind of competitive advantage. Under the new rule, that will be illegal, with a limited number of exceptions, such as when requests are infeasible or pose privacy concerns.

The ONC rule also requires covered entities to adopt the Health Level 7 Fast Healthcare Interoperability Resources (FHIR) standard for application program interfaces (APIs). This change will make data sharing easier by standardizing the way data are stored and transmitted between payers, providers and other healthcare entities.

John D’Amore, M.S., co-founder and president of Diameter Health, a health information company, explained in an interview with Managed Healthcare Executive that once the FHIR — pronounced “fire” — standards are universal, healthcare records won’t function like a single document but, rather, as separate pieces of information. That will make information about, say, a patient’s allergies or current medications more easily extracted from those records.
“It’s really going to bring us a lot more into the 21st century for how data exchange occurs,” D’Amore says noting that easily shareable data have made other industries fertile grounds for innovation. He points to the financial industry and its ability to access and aggregate a user’s financial data to provide financial tracking and insights.

CMS changes
The new CMS rule leverages the new API requirements to force payers and plans to share claims and other health information securely with patients in a secure, user-friendly, electronic format. The rule applies only to clinical information already made available to payers and does not create a requirement for payers to access additional data from providers.

The CMS rule also requires participating hospitals to send electronic notifications to other providers anytime a patient is admitted, discharged or transferred from the hospital. The goal is to spark better care coordination and, ultimately, better patient outcomes. Starting in April 2022, states must begin sending daily data reports on Medicare and Medicaid beneficiaries, a requirement that is also supposed to lead to better coordination and more accurate billing.

These new requirements technically apply only to payers and plans that participate in Medicare, Medicaid or other federally facilitated exchanges. D’Amore says they’re likely to carry over into the private market — even the self-insured one — because the insurance industry’s major players are all so deeply involved in the public payer programs. Although proponents of the new regulations say they merely bring healthcare in line with patient expectations for data access and functionality, the insurance and hospital industries have pushed back on them. Matt Eyles, M.S., president and CEO of America’s Health Insurance Plans, the industry’s main trade group, is on record as saying the new rules could threaten patient privacy. “We are seriously concerned that patient privacy will still be at risk when healthcare information is transferred outside the protections of federal patient privacy laws,” he said in a press release last year.

Although providers, insurers and their business partners are covered by HIPAA, HHS acknowledged that the new rules raise the potential for health information to be sent to third parties that may or may not have sufficient data security protections. Eyles noted in the statement that even de-identified health information could easily be traced to individuals by combining it with other available personal and health information.

The American Hospital Association has voiced similar concerns. In March 2020, Rick Pollack, the association’s president and CEO, said in a prepared statement that the rules lack “the necessary guardrails to protect consumers.” HHS partially addressed this concern by publishing a guidance indicating that covered entities would not be held responsible for leaks related to the transfer of patient health data to noncovered entities, such as third-party applications. Chandra concedes that there is risk associated with the transfer of data, particularly if the third-party applications don’t have secure data-transfer channels. But he believes the primary risk to patient privacy is the intentional theft of data, using ransomware or malware, not the incidental leakage of it. “I think those risks are substantially greater and pose a much greater risk to patient data than the accidental exposure through a poorly configured data interface between two HIPAA-covered entities,” he says.

Pandemic delays
As for the timing of enforcement, most agree that the delays were wise. The healthcare industry had more than enough to deal with last year with the COVID-19 pandemic. But the reality is that the covered entities have been preparing for the change for years. After all, the legislation authorizing the new rules, the 21st Century Cures Act, was passed in 2016.

Chandra says the time has come for meaningful interoperability: “The pandemic has further exacerbated the need for data sharing with public health officials and also to coordinate care for patients affected by COVID-19.”

Jared Kaltwasser is a healthcare reporter in Iowa.
One of the hard truths about the COVID-19 pandemic is the disproportionate effect it has on people with diabetes, a group that includes more than 34 million in the United States, or roughly 10% of the population.


Getting patients on a statin seems to help, according to a study published in the *Journal of the American Heart Association*. Researchers at Montefiore Medical Center in Bronx, New York, found that patients with diabetes who were hospitalized with COVID-19 experienced a 12% lower (adjusted) risk of in-hospital mortality if they were taking a statin.

Catherine Rolih, M.D., medical director at Novant Health’s Diabetes Center of Excellence in Winston-Salem, North Carolina, says that diabetes, coronary heart disease, obesity and chronic obstructive pulmonary disease are the top four comorbidities associated with mortality due to COVID-19. Among Novant Health’s patients, diabetes is the most prevalent chronic condition associated with mortality and COVID-19. Rolih tells her patients that the impact of diabetes starts with the immune system. Various organ systems are damaged as a result of poorly controlled diabetes — everything from blood vessels in the eyes to a person’s nerves — and that can lead to a greater likelihood of infection in general.

Paul Sherman, M.D., chief medical officer at Community Health Plan of Washington in Seattle, a nonprofit insurer that markets Medicaid and Medicare managed care plans, says that “providers and insurers face the probability of their patients (and) members with diabetes having a much higher disease burden, worse outcomes and greatly increased healthcare expenses. This will increase the burden on already overtaxed primary care systems and hospitals, including (intensive care units).”

Targeting the right patients for outreach is a good first step, says Robert Gabbay, M.D., Ph.D., chief scientific and medical officer for the American Diabetes Association. The first question to ask: “Which patients with diabetes haven’t been seen in the last six months?” Within that patient population, he recommends focusing resources on patients whose last glycated hemoglobin (A1C) level was greater than 9%. “If their diabetes was poorly controlled then, they really need help. Then staff at provider organizations need to hit the phones to set up video and telephone visits with patients,” Gabbay says. He also suggests providing free delivery of medications to patients.

Priority Health in Grand Rapids, which covers 1 million Michigan residents, embraced this approach early in the pandemic, says James Forshee, M.D., the insurer’s senior vice president of medical affairs and chief medical officer. In addition to eliminating copays and coinsurance on care related to COVID-19, the nonprofit health insurer coordinated with large pharmacy chains in the state to provide free delivery of medications to patients.

A role for payers

Many patients with diabetes have gained weight; Rolih calls it the “COVID 20.” That’s in addition to losing control of their diabetes and high blood pressure and missing screenings for complications. She says payers should maintain coverage for telehealth-based care and expand access to diabetes education for the duration of the pandemic.

Rolih has facts to back up her suggestions. In 2019, participants in Novant Health’s class for people with type 2 diabetes experienced COVID-19 and diabetes.

Diabetes education has shifted from in-person classes to Zoom meetings. by AINE CRYTS
a 1.4% reduction in their A1C levels, exceeding the 1% reduction typically seen with many medications. The health system’s diabetes education program includes an initial 60- to 90-minute assessment between a patient and a diabetes educator. Also included are eight hours in a group class that covers the ADA-specified curriculum. Before the pandemic, there were approximately 10 to 20 people in each in-person group, according to Rolih. Currently, patients participate in the program virtually, and there are fewer participants in each group. More than 2,000 patients completed at least part of Novant Health’s program in 2019. Participation is down this year, presumably due to the pandemic.

However, coverage by payers is iffy at best. Some payers may not continue with telehealth coverage except by arrangement with individual employers, says Rolih. “This may cause many issues, especially since it’s clear COVID-19 will be around for a while, and poor diabetes management is a big risk factor for poor COVID-19 outcomes.”

**Education has gone virtual**

Andrew Ahmann, M.D., director of the Harold Schnitzer Diabetes Health Center at Oregon Health & Science University, says that provider organizations should be assessed on their ability to track patients with prediabetes and diabetes and direct them to education programs in much the same way they’re held accountable for tracking patients’ cholesterol and blood pressure levels. The CDC defines prediabetes as a serious health condition in which blood sugar levels are higher than normal but not high enough to be diagnosed as type 2 diabetes. About one-third of Americans meet the criteria for prediabetes. Ahmann says managing prediabetes is especially important now because of the pandemic and the vulnerability of people with diabetes to serious cases and death. The pandemic may tip some people with prediabetes into full-blown diabetes because of lack of exercise and less healthful eating habits.

Ahmann says payers should waive copays for prediabetes and diabetes education after the pandemic. Gabbay at the ADA agrees, while praising diabetes educators: “Diabetes education specialists are worth their weight in gold. They’re underappreciated and underreferred to, but they’re a part of helping (patients) deal with the overwhelmingness of (managing their diabetes).”

Ahmann says the diabetes prevention education program at his facility follows the CDC’s National Diabetes Prevention Program. Educators teach the participants about caloric intake, healthy eating, increasing physical activity, managing negative thought patterns, healthy approaches when eating out, managing stress and staying motivated.

During the pandemic, patients have participated in education sessions on Zoom video calls. While class facilitators prefer in-person meetings, attendance and interaction have been successful on Zoom, says Ahmann, a contributor to the ADA’s “Standards of Medical Care in Diabetes,” a compilation of the association’s prevention, screening and treatment recommendations. Three separate groups of between 10 and 20 patients participate virtually in the diabetes prevention program, says Ahmann. Participants are required to upload reports from their insulin pumps, sensors and meters.

The pivot to virtual education for patients with prediabetes and diabetes first required training and certifying diabetes educators on the virtual platforms. During the pandemic, diabetes education has transitioned between virtual and face-to-face formats. For example, in late June, participants were moved to 25% face-to-face and 75% virtual interactions. Ahmann says he expects a hybrid of in-person and online sessions to be the model in the future.

Keeping the virtual platform “as simple as possible for patients” is important, says Ahmann. He’s confident that virtual delivery of diabetes education will increase access to care, while improving patient knowledge and adherence to care plans. Payers are currently covering virtual visits and diabetes education, but Ahmann says he doesn’t know if this will continue after the pandemic.

“Diabetes education specialists are worth their weight in gold.”

— ROBERT GABBAY, M.D., PH.D., CHIEF SCIENTIFIC AND MEDICAL OFFICER FOR THE AMERICAN DIABETES ASSOCIATION

Ahmann says the diabetes prevention education program at his facility follows the CDC’s National Diabetes Prevention Program. Educators teach the participants about caloric intake, healthy eating, increasing physical activity, managing negative thought patterns, healthy approaches when eating out, managing stress and staying motivated.
How ‘white bagging’ affects patients, physicians and 340B funding

Having specialty pharmacies fill prescriptions may lower costs, but critics of the practice see safety issues and other drawbacks.

by DEBORAH ABRAMS KAPLAN

In healthcare, one action often begets another. A patient is treated for cancer, resulting in nausea, and then is treated for nausea. Changes in payer policies also can trigger a cascade of events affecting patients, providers and payers in unanticipated ways. An example is “white bagging,” in which a prescription is filled by a third-party specialty pharmacy and then administered by the provider without the provider taking ownership. The seemingly minor change of using a third-party pharmacy can raise patient copays and plan sponsor bills, disrupt scheduling and treatment, affect the provider’s bottom line, disrupt pharmacy receiving and storage systems, and introduce safety concerns. It can also save the payer a lot of money.

The white bagging model is a change from traditional buy-and-bill in how the prescription is filled and payment is processed. With buy-and-bill, the provider’s in-house pharmacy often fills the prescription from stored supply or through normal ordering. The treatment is typically billed under the patient’s insurance medical benefit. Commercial payers reimburse a negotiated amount for the drug and administration. Medicare usually covers these therapeutics under Part B, with the reimbursement rate set at the average sales price plus 6%.

With white bagging, the prescription is filled by a contracted specialty pharmacy that collects needed copayments or coinsurance and settles the claim with the payer. It’s typically billed under the pharmacy benefit. The medication is sent directly to the provider to prepare and dispense.

**White bagging trends**

White bagging is not new, but many people working in the pharmacy sector see evidence of it increasing. “It has increased significantly in the past year and a half. I think the big insurance companies are trying to use it as leverage during the contract period to drive down their contract pricing,” says Thomas Lausten, MBA, director of pharmacy services at Children’s Wisconsin, a children’s hospital in Milwaukee. White bagging is primarily driven by an area’s biggest payer, he says, “but I’ve heard from people across the country having the same issue we’re having.”

The practice has been around in some form for the past decade or two, though less so in oncology, says Jonas Congelli, RPh, chief of pharmacy for Hematology-Oncology Associates of Central New York (HOACNY). He’s seen slight momentum recently, given pharmacy benefit manager (PBM) and payer integrations, he says: “They’re seeing the potential opportunity to insert themselves into the whole distribution process.”

The practice is concerning enough to HOACNY that it instituted a policy in 2017 not to administer drugs unless they were directly purchased from a manufacturer or an accredited wholesale distributor.

White bagging usage varies widely based on site and treatment type. A 2019 survey about infused therapies included 48 commercial plans, representing 126.6 million covered lives. It showed that at physician-affiliated clinics, 11% of oncology and 43% of nononcology treatments were obtained via white bagging. For hospital outpatient departments, 28% of oncology and 31% of nononcology infusions were from white bagging. That’s only infused drugs. A 2018 report estimated that 9% of drugs administered in hospital outpatient settings were white bagged and 26% of those in office settings.

**The downsides**

Physicians and clinicians don’t
have many good things to say about white bagging. Here are some of the downsides, from their point of view:

**Drug waste**
Therapeutics obtained through white bagging are purchased and sent specifically for that designated patient. If the treatment regimen changes last minute or the entire vial is not used, the medication must be discarded, even if unopened. “The specialty pharmacy won’t take it back,” Lausten says. “It was bought and paid for by the patient. We can’t reuse it. Think of the healthcare dollars literally thrown away because of that system.” Although not an everyday occurrence, “it happens enough,” Lausten says. His hospital recently threw out two doses of Spinraza (nusinersen), the spinal muscular atrophy treatment drug, priced at $125,000 per dose.

The disposal may require special handling, which can be costly because of government compliance requirements. Still, white bagging still may be worth it for the payers. “We heard from payers, even with drug waste, it’s still a lower-cost practice,” says Sara Sadownik, deputy director of research and cost trends at the Massachusetts Health Policy Commission (HPC). Sadownik co-authored a 2019 HPC report on white bagging.

**Pharmacy management**
White bagging focuses on expensive specialty drugs, says Lausten, with some payers mandating that specific therapeutics be acquired this way. But that is not always the case. A major health plan in Lausten’s area requires white bagging for commonly used drugs, such as Remicade (infliximab) and Botox (onabotulinumtoxinA). That presents pharmacy management issues. Traditionally, the pharmacy checks regular shipments against the bar codes in its system. “When [white bagging medications] come in, there’s nothing to bar code against,” says Lausten. The items are already labeled for the patient, requiring a manual bar code and entering them into the pharmacy management system as the patient’s own medication, he explains.

Storage is an issue, too. Children’s Wisconsin may buy 50 to 100 vials of Remicade at a time, handling them once and storing them together. When the hospital pharmacy receives a patient order, the pharmacist pulls out the needed vials to dispense and prepare, according to Lausten: “We control purchasing, dispensing and billing for the drug.” The hospital pharmacy’s technology doesn’t easily track drugs coming from a specialty pharmacy, all of which must be handled individually. A separate refrigerator is needed, as well. These medications can’t be stored with the buy-and-bill drugs, because they are designated for specific patients. The hospital pharmacy is struggling to manage a few white bagging drugs, Lausten says, but the health plan is asking it to do so for up to 60 drugs. “It creates a tremendous storage problem. It’s a difficult situation to manage,” he says.

**Safety**
Because specialty pharmacy medications are entered as the patient’s own medications, they don’t go through the same order-entry system checks and balances. There is no automated drug interaction checking, because that’s built into the system only for hospital pharmacy’s medications. “From a quality and safety perspective, it’s not good for the patient,” says Lausten.

He has seen some occasional problems like the specialty pharmacy sending the wrong dosage or strength, or sending a drug for the wrong patient.

**Scheduling and patient treatment**
With white bagging, the drugs are not always delivered to the right place or in time for the patient’s

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**THE DOWNSIDES**
- Drug waste
- Pharmacy management
- Safety
- Scheduling and patient treatment
- Provider income
- Cost sharing

**THE UPSIDES**
- Lower costs
- Helpful to small organizations
appointment. With the buy-and-bill model, the pharmacy typically has the drugs or ensures the distributor delivers them in time. If the white-bagged medications aren’t available when needed, the patient must reschedule, which can result in less adherence and scrambled treatment plans. “The biggest unintended consequence is the impact on patients that is not captured in dollars to the healthcare system,” says Sadownik. “It’s wasted travel time, time off work, childcare and frustrations of navigating a more complex system.”

Sometimes the white-bagging medication arrives in time but the doctor changes the treatment. The drug is now wasted, and the needed therapeutic isn’t available. With buy-and-bill, it’s easier for the on-site pharmacy to make that change. “People don’t understand how disruptive it is,” Congelli says.

Provider income
White bagging can also affect provider reimbursement, and some critics say much of the criticism from providers is, to some degree, animated by the fact that white bagging means they lose out on the markup that comes with buy-and-bill. Lausten says that with white bagging, “we’re managing the order and dose, making sure it’s drawn up correctly in USP (United States Pharmacopoeial Convention) sterile product rooms, which are expensive to operate and maintain. We get no reimbursement for drawing them up.”

The white bagging also affects the 340B program, Lausten says. The federal 340B program means providers can get drugs at discounted prices if a substantial fraction of their patients have low incomes, are uninsured, or both. “Those (drug) savings pay for unfunded programs we provide at our hospital,” he says. “When the drug comes through the specialty pharmacy, those 340B savings go away.” But 340B program has plenty of critics, who say it has been distorted by health systems for financial gain.

Cost sharing
The reimbursement system is different for each drug acquisition model. Buy-and-bill typically is reimbursed under medical benefits. White bagging is typically reimbursed under pharmacy benefits. The pharmacy benefits reimbursement is often much higher, Congelli says. “We see the difference in what it would be to the payer and to the employer by running it through pharmacy benefits. It always costs them more,” he says.

The upsides
There is another side to the white bagging story, one that shows that it has benefits, particularly with respect to cost. Of course, lower costs benefit payers and, depending on the particulars, perhaps some patients. Specialty pharmacies use lower cost as one of their chief selling points.

Lower costs
Specialty pharmacies may be able to negotiate better discounts on the high-priced medications with volume pricing. Sadownik’s research showed that with white bagging, one payer was able to lower per-unit drug prices by between 15% and 38% for several of the drugs, compared with buy-and-bill (excluding rebates). When the payer implemented a site-neutral payment policy, there was still a price discrepancy between the two methods, but it decreased slightly.

The report noted one example where a drug cost $4,000 a month through traditional billing methods versus $1,000 a month from white bagging, saving the payer $36,000 per patient on a yearly basis.

Helpful to small organizations
Some providers, especially small ones, may not have the infrastructure to take the financial risk of stocking expensive drugs, particularly if they are rarely prescribed. An organization without that cash flow can rely on the specialty pharmacy for distribution, knowing the financials won’t affect them.

No white bagging policies
Children’s Wisconsin has a policy against white bagging, although Lausten says “in certain situations, we are forced to” accept white bagging because the patient may not have another treatment option. Congelli says HOACNY’s policy has worked well but on occasion must be enforced with a payer outside the area. The payers usually don’t get very far into the process before they agree to buy-and-bill. If the payer mandates white bagging, the HOACNY physician notifies the patient and with the patient’s permission, the physician reaches out to their employer’s human resources. Usually that’s the end of the matter.

If white bagging is still mandated, the patient would need to receive treatment at the hospital or an alternate facility. “We’ve never had to admit the patient or find an alternative care center to do that,” Congelli says.

Deborah Abrams Kaplan covers medical and practice management topics.
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SDOH: how they affect cancer rates, care and payment

Adjustments to payment models are beginning to take social determinants into account. by KAREN APPOLD

Where people work, live and play can greatly affect their health and the quality of healthcare they receive. Research already has shown that these social determinants of health (SDOH) are potent. Now researchers are digging deeper and learning how SDOH affect diseases, including risk for certain cancers and their outcomes after treatment, says Katherine Reeder-Hayes, M.D., M.B.A., M.S., chair of the American Society of Clinical Oncology’s Health Equity Committee. The considerable differences between poor and wealthier patients, as well as between Black and White patients, can often be traced to SDOH, says Reeder-Hayes, who is also an associate professor and chief of breast oncology at the University of North Carolina-Chapel Hill School of Medicine.

Here’s a closer look at how SDOH affect cancer rates in certain populations, how these disparities influence cost and payment of cancer care, and how new payment models are better addressing SDOH.

Incidence, mortality differences

According to American Cancer Society research, Black males have the highest cancer incidence (549 per 100,000) and death (240) rates of any group identified by race and ethnicity and by gender. Black females have higher cancer death rates than non-Hispanic white females despite a lower incidence rate.

Comorbidities such as diabetes, chronic obstructive pulmonary disease, hypertension, obesity and heart disease affect cancer treatment options and outcomes. Black patients have higher rates of comorbidities, some of which can be attributed to SDOH. Obesity, for example, is more common among Black women and is a risk factor for endometrial cancer. Obesity is linked to SDOH such as food affordability and access to healthy food options or safe spaces for physical activity in patients’ neighborhoods, notes Reeder-Hayes.

Some of the largest racial disparities occur in breast, prostate and colorectal cancers. “It’s notable that all of these cancers are screen-detected, and that social determinants at the health system level and individual level — such as access to insurance, proximity to a screening facility, availability of time off work or transportation — can all affect how likely someone is to get screened and therefore how early their cancer is caught and their chance of being cured,” says Reeder-Hayes. But incidence and mortality patterns differ among cancers. For instance, the risk of prostate cancer for Black men is much higher than for White men, whereas breast cancer incidence among Black women and White women is roughly the same. However, the mortality rate for both cancers is higher for Black patients, which appears related to differences in access to treatment, Reeder-Hayes says.

Oncology Care Model could help

Insurance coverage is another variable in access to cancer treatment. A 2017 study found that only 41% of plans sold on the ACA exchanges had networks that included one of the 71 cancer centers designated by the National Cancer Institute.

“A patient’s choice to go to a top-tier cancer center was essentially cut off because they had insurance through the Affordable Care Act, which, in turn, disproportionately insures minority and lower-income patients and the working poor,” says Reeder-Hayes. “This is an example of social determinants working through the structure of the health system to shunt certain patient groups toward or away from certain types of care — often away from higher quality care.”

Keely Macmillan, M.S., senior vice president for policy and solutions management at Archway Health in Boston and a member of the Managed Healthcare Executive editorial advisory board, says...
Oncology payment systems haven’t done enough to incentivize care that would address health inequities. “This is partly a reflection of outdated fraud and abuse laws that are prohibitive to innovative ways to address SDOH,” she says. For example, healthcare providers might run afoul of the federal Anti-Kickback Statute if they were to offer transportation or housing assistance, because the statute prohibits offering anything of value in order to get business.

Some good news is that new payment and delivery models are being designed to improve the effectiveness and efficiency of specialty care, including cancer care. CMS’ Center for Medicare and Medicaid Innovation (CMMI) developed the Oncology Care Model (OCM), which aims to incentivize higher quality and more highly coordinated oncology care at the same or lower cost. Under this model, physician practices have entered into episodic payment arrangements that include financial and performance accountability for the total cost of care for patients undergoing chemotherapy.

CMMI is also partnering with commercial payers under the model. Practices participating in OCM have committed to providing enhanced services to Medicare beneficiaries, such as care coordination, navigation and national treatment guidelines for care. As of the beginning of last year, 138 practices and 10 commercial payers were participating in OCM.

Some features of OCM could potentially address health equity issues, says Macmillan. Program requirements include a documented care plan for each patient containing the 13 components of the Institute of Medicine’s Care Management Plan, including estimated out-of-pocket costs and a plan to address psychosocial needs. Providers who participate in the model receive real-time monthly enhanced oncology services payments — above and beyond fee-for-service payments — to effectively aid in managing and coordinating patient care. Practices can use this additional funding to hire social workers, patient navigators, community health workers and other staff to support patient care plans.

Other features of the OCM’s pricing methodology that might start to address health inequities include an upward price adjustment for patients who are eligible for Medicaid or who qualify for a low-income subsidy. The adjustment reflects higher costs that come with social risk factors. Macmillan says. In addition, an OCM risk adjustment is scheduled to go into effect February 2021 based on whether the patient has metastatic cancer at diagnosis, according to Macmillan. Because Black patients are more likely to receive a diagnosis of metastatic cancer, the risk adjustment might translate into higher-quality care for Black patients with cancer.

OCM also ties part of the payment to providers to the number of comorbidities a patient has, which acknowledges that care for patients with cancer who have comorbidities may be more complex and expensive. Macmillan says. Because many comorbidities can be traced to SDOH, the additional payment is an indirect way of addressing SDOH in the context of oncology payment.

**Incentives for healthcare providers**

Incorporating a greater focus on SDOH through value-based payment models that are designed to reward quality of care over quantity could help close the widening disparity gap, says Melanie Teske, senior director of provider payment and network innovation at Blue Cross and Blue Shield of Minnesota. The Minnesota insurer is putting a strong focus on shifting to value-based payment models that enable reimbursement based on health outcomes instead of just the number of billable services provided. As a result, providers are rewarded for addressing SDOH issues outside of services paid for under traditional fee-for-service payment, Teske says.

“Value-based payments incentivize healthcare providers to develop and implement care delivery plans that address health inequities and close gaps in care related to SDOH.”

—MELANIE TESKE, BLUE CROSS AND BLUE SHIELD OF MINNESOTA
Blues plan is in the early stages of implementing SDOH programs through these agreements. Teske said the insurer created a pilot program with one local care system in 2020 aimed at measuring the impact of SDOH screenings and refining the payment model accordingly. The Minnesota insurer is planning to expand this and other SDOH-focused payment models broadly in the near future.

The alternative payment models that CMMI has created include waivers to fraud and abuse laws under certain conditions. “However, it is challenging for providers to implement initiatives to address SDOH when the waiver only applies to a subset of their patient population and when they’re unable to reliably identify attributed patients protected under the waiver,” Macmillan says. “With recent reforms to Stark law [the Physician Self-Referral Law], the Anti-Kickback Statute, and Beneficiary Inducement Civil Monetary Penalty Law, hopefully, there will be novel approaches implemented to achieve health equity.”

Other payment models
Other payment models go further in addressing SDOH. CMMI’s new Direct Contracting Model allows direct contracting entities to offer beneficiary engagement incentives, subject to certain limitations, including vouchers for transportation services, vouchers for nutrition and meal programs, telehealth, and other items and services to support chronic disease management, Macmillan says. CMMI has another payment model, Geographic Direct Contracting Model, that allows providers to offer additional enhancements, including subsidies for Part B premiums, Macmillan says.

In the Oncology Care First model, a successor to the Oncology Care Model, CMMI announced its intent to continue paying prospective payments for enhanced services. “These capitated payments could be used to address SDOH,” Macmillan says. More information on the new model is expected in spring 2021.

The Program of All-Inclusive Care for the Elderly, a joint Medicare-Medicaid program designed to keep senior citizens living in their homes, is another payment model that can result in resources going toward mitigating harmful effects of SDOH. Participants and their caregivers meet with an interdisciplinary team that includes physicians, nurses, therapists, social workers, dietitians, personal care aides, transportation drivers and others, Macmillan says. Their needs are assessed, and an individualized care plan is developed.

More needs to be done
Although some see the aperture of oncology payment slowly beginning to widen to consider SDOH, the focus remains on medical services. In future models, Macmillan says CMS must adopt better ways to account for the effect of SDOH on cost: “The current methodology relies on comorbidities that have been previously documented, and SDOH can inhibit access to care and reduce the likelihood that comorbidities have been previously documented.”

According to Reeder-Hayes, “The strongest predictor of a patient’s chances of beating cancer should not be his or her location, race, income or occupation. Every person deserves a fair opportunity to get high-quality cancer care that’s matched to their needs and values. With some of the most advanced healthcare technology in the world, that is possible.”

“We need to figure out how to design the health system to deliver that fair opportunity,” Reeder-Hayes continues. “If we care enough to invest in data collection about the social circumstances of patients, measure differences in the care delivered based on social factors, make adjustments based on findings, try again and remeasure, we can continue to learn how to be better.”

Along these lines, Manali I. Patel, M.D., M.P.H., M.S., assistant professor of medicine at Palo Alto Veteran Affairs Health Care System, says it will take a village to overcome barriers influenced by SDOH on cancer payments. “It’s important to consider how to ensure that SDOH are identified for patients,” she says. “In some cancer settings, navigators or community health workers have served in that role. Addressing SDOH requires a team-based approach between patients and their caregivers, oncology providers, community-based organizations, payers and policymakers to ensure that multi-level interventions are enacted.”

Karen Appold is a medical writer who lives in the Lehigh Valley region of Pennsylvania.