It Will Not Be Your Pre-pandemic Office

Work is shifting to a hybrid: part remote and part in person.
INOMAX® DELIVERY SYSTEMS
Devoted to Delivering Ongoing Innovations in Critical Care

The INOmax DS® Plus Delivery Systems provide innovative design and user experience to support the ever-changing demands of the critical care space and keep patient safety a top priority.¹ ²

• Delivering specialized, redundant, and customizable alarm features designed to help mitigate the risk of device-related rebound pulmonary hypertension

• Advanced features enable delivery of therapy specifically for the MRI suite

• Integration with neonatal transport systems to support seamless delivery of therapy

Applications
The INOmax DS® Plus Delivery Systems deliver INOMAX® (nitric oxide) gas, for inhalation. The INOmax DS® Plus Delivery Systems must only be used in accordance with the indications, usage, contraindications, and warnings and precautions described in the INOMAX package inserts and labeling. The approved patient population is limited to neonates. Refer to the INOMAX Full Prescribing Information prior to use.

Device Warnings
• Abrupt discontinuation of INOMAX can lead to worsening oxygenation and increasing pulmonary artery pressure (rebound pulmonary hypertension syndrome). To avoid abrupt discontinuation, use the INOblender® or backup mode immediately to reinstate INOMAX therapy and refer to the INOMAX package insert.

• If the high NO₂ alarm activates, the delivery system should be assessed for proper setup while maintaining INOMAX delivery.

• Do not connect items that are not specified as part of the system.

• If an alarm occurs, safeguard the patient first before troubleshooting or repair procedures.

• Use only INOMAX, pharmaceutical grade NO/N₂.

Use in an MR Environment
• Only use a size “88” (1,963 liters) cylinder that is marked “MR Conditional. Keep cylinder at 100 gauss or less.” with the DS® Plus MRI while in the scanner room. Use of any other cylinder may create a projectile hazard.

• The INOmax DS® Plus MRI is classified as MR Conditional with MR scanners of 1.5 or 3.0 Tesla strength ONLY in areas where the field strength is less than 100 gauss.

• This device contains ferromagnetic components and hence will experience strong attraction close to the magnet. It should be operated at a fringe field of less than 100 gauss.

• A strong magnetic field such as that from an MRI system can affect the ability of the INOMAX system to detect if the cylinder valve is open. This can cause a “Cylinder Valve Closed” alarm to occur when the cylinder valve is actually open. If this alarm occurs, reposition/rotate the INOmax DS® Plus MRI cart outside the 100 gauss area to reduce the magnetic interference in the area of the INOMAX unit. This will resolve the “Cylinder Valve Closed” alarm. Typically the required INOMAX DS® Plus MRI cart location adjustment is less than 6 inches (15 cm)/90 degrees. Note that interruption of INOMAX therapy will occur one hour from point when the “Cylinder Valve Closed” alarm is activated if the alarm is not resolved.

Rx Only
Consult the Operation and Maintenance Manual, which may be found at www.inomax.com/training-and-education/device-support-resources, for complete information. For technical assistance, call (877) 566-9466.

For additional information, technical assistance, or a complete list of warnings regarding use of validated ventilators, please refer to the INOMAX DS® Plus Operation Manual at inomax.com/dsirplusmanual

While you take care of patients, we remain dedicated to helping advance critical care.
Learn how at inomax.com/inomax-delivery-systems/device-innovation

¹No longer in use for commercial application.  ²This may relate to a medical device and software in development that have not yet been cleared by the FDA.

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**INOMAX®** (nitric oxide gas)  
Brief Summary of Prescribing Information

**INDICATIONS AND USAGE**

**Treatment of Hypoxic Respiratory Failure**  
INOmax® is indicated to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilator support and other appropriate agents.

**CONTRAINDICATIONS**  
INOmax is contraindicated in neonates dependent on right-to-left shunting of blood.

**WARNINGS AND PRECAUTIONS**  
**Rebound Pulmonary Hypertension Syndrome following Abrupt Discontinuation**  
Wear from INOmax. Abrupt discontinuation of INOmax may lead to worsening oxygenation and increasing pulmonary artery pressure, i.e., Rebound Pulmonary Hypertension Syndrome. Signs and symptoms of Rebound Pulmonary Hypertension Syndrome include hypoxemia, systemic hypotension, bradycardia, and decreased cardiac output. If Rebound Pulmonary Hypertension occurs, reinstate INOmax therapy immediately.

**Hypoxemia from Methemoglobinemia**  
Nitric oxide combines with hemoglobin to form methemoglobin, which does not transport oxygen. Methemoglobin levels increase with the dose of INOmax; it can take 8 hours or more before steady-state methemoglobin levels are attained. Monitor methemoglobin and adjust the dose of INOmax to optimize oxygenation.

If methemoglobin levels do not resolve with decrease in dose or discontinuation of INOmax, additional therapy may be warranted to treat methemoglobinemia.

**Airway Injury from Nitrogen Dioxide**  
Nitrogen dioxide (NO2) forms in gas mixtures containing NO and O2. Nitrogen dioxide may cause airway inflammation and damage to lung tissues.

If there is an unexpected change in NO2 concentration, or if the NO2 concentration reaches 3 ppm when measured in the breathing circuit, then the delivery system should be assessed in accordance with the Nitric Oxide Delivery System O&M Manual troubleshooting section, and the NO2 analyzer should be recalibrated. The dose of INOmax and/or FiO2 should be adjusted as appropriate.

**Worsening Heart Failure**  
Patients with left ventricular dysfunction treated with INOmax may experience pulmonary edema, increased pulmonary capillary wedge pressure, worsening of left ventricular dysfunction, systemic hypotension, bradycardia and cardiac arrest. Discontinue INOmax while providing symptomatic care.

**ADVERSE REACTIONS**  
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The adverse reaction information from the clinical studies does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates.

Controlled studies have included 325 patients on INOmax doses of 5 to 80 ppm and 251 patients on placebo. Total mortality in the pooled trials was 11% on placebo and 9% on INOmax, a result adequate to exclude INOmax mortality being more than 40% worse than placebo.

In both the NINOS and CINRGI studies, the duration of hospitalization was similar in INOmax and placebo-treated groups.

From all controlled studies, at least 6 months of follow-up is available for 278 patients who received INOmax and 212 patients who received placebo. Among these patients, there was no evidence of an adverse effect of treatment on the need for rehospitalization, special medical services, pulmonary disease, or neurological sequelae.

In the NINOS study, treatment groups were similar with respect to the incidence and severity of intracranial hemorrhage, Grade IV hemorrhage, periventricular leukomalacia, cerebral infarction, seizures requiring anticonvulsant therapy, pulmonary hemorrhage, or gastrointestinal hemorrhage.

In CINRGI, the only adverse reaction (>2% higher incidence on INOmax than on placebo) was hypotension (14% vs. 11%).

Based upon post-marketing experience, accidental exposure to nitric oxide for inhalation in hospital staff has been associated with chest discomfort, dizziness, dry throat, dyspnea, and headache.

**DRUG INTERACTIONS**  
**Nitric Oxide Donor Agents**  
Nitric oxide donor agents such as prilocaine, sodium nitroprusside and nitroglycerine may increase the risk of developing methemoglobinemia.

**OVERDOSAGE**  
Overdose with INOmax is manifest by elevations in methemoglobin and pulmonary toxicities associated with inspired NO2. Elevated NO2 may cause acute lung injury. Elevations in methemoglobin reduce the oxygen delivery capacity of the circulation. In clinical studies, NO2 levels >3 ppm or methemoglobin levels >7% were treated by reducing the dose of, or discontinuing, INOmax.

Methemoglobinemia that does not resolve after reduction or discontinuation of therapy can be treated with intravenous vitamin C, intravenous methylene blue, or blood transfusion, based upon the clinical situation.

**ADDITIONAL INFORMATION**  
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Chairman’s Letter

A new phase of innovation

Throughout the COVID-19 pandemic, the American economy, and especially the healthcare sector, have been remarkably resilient and innovative. When all of the activities and services that we assumed needed to take place in person had to be canceled or postponed because of the pandemic, remote and digitally delivered alternatives seemed to pop up overnight. Until 2020, for people of a certain age, Zoom was a public television kids show in the 1970s. Teams? They wore uniforms and had mascots. Now they are videoconferencing platforms that have become part of everyday life, both at work and outside of it.

In healthcare, telehealth and remote patient monitoring were fairly marginal activities until last year, catnip to early adopters but not in the mainstream. But now … well, it hardly needs saying in these pages. And in this issue of Managed Healthcare Executive® we have a story about digital behavioral health, which may be the hottest ticket in telehealth and is attracting millions of dollars of investment — and British royalty (take a look at our story).

But now we are in a new phase of innovation, one that requires blending the pre-pandemic, in-person ways of doing things with our pandemic-acquired, more digital mores. As our cover story discusses, many healthcare companies are in the thick of this adjustment, especially insurers, PBMs and other parts of the industry that employ office-based workers. Many healthcare entities are revisiting their need for office space and taking steps to reduce their footprint. Work-from-home policies are being revised. Office space itself — and how it should be used — is being reimaged and redesigned. It is an exciting time.

Necessity, they say, is the mother of invention.

Innovation, though, comes from a big, rowdy family. The members include flexibility, commitment, enterprise, investment, creativity, collaboration, and trial and its sibling, error. The entire family will need to get involved as we start this new hybrid chapter, neither fully in person nor fully digital but some chimeric combination in between.

Mike Hennessy Sr.
Chairman and Founder
of MJH Life Sciences®
Mission Managed Healthcare Executive® provides healthcare executives at health plans and provider organizations with analysis, insights and strategies to pursue value-driven solutions.
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*Live in-person attendance will be limited.

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» Designing the Drug Benefit
» Best Practices in Care Management Strategies
» Best Practices in Cost Containment
» Quality Improvement

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» Opportunity to earn continuing education credits.
» Learn real-world strategies for cost containment workflow efficiency, and quality improvement.
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In Partnership with
**Herd immunity may depend on persuading “conspiracy believers”**

The supply side of the COVID-19 vaccine rollout has garnered most of the attention. But a recent survey on American beliefs about the vaccines suggests that the bigger problem may be on the demand side of the equation.

After the pool of “enthusiastic” adults is vaccinated, vaccination rates are likely to start to plateau starting this month, according to Surgo Ventures, a behavioral science and artificial intelligence company. Because of holdouts, only about 52% of Americans will be vaccinated by July, according to Surgo’s projections — well short of the estimated 70% to 90% needed to achieve herd immunity.

The projection is based on the company’s analysis of results of a survey it conducted in March. Based on the respondents’ answers, Surgo groups them into five psychobehavioral categories: enthusiasts, watchful, cost-anxious, system distrusters and conspiracy believers. Surgo’s survey shows the proportion of respondents in the watchful and cost-anxious groups is shrinking compared with an earlier survey, but the proportion of system distrusters (7%) and conspiracy believers (16%) is about the same.

Surgo classifies system distrusters as being persuadable but says some of the conspiracy believers will need to get vaccinated if the U.S. population is to reach herd immunity. The company’s suggestions include tapping trusted figures to communicate risk-benefit ratios of vaccination and giving employees paid time off to get vaccinated.

**AIDS group says ACA plan copay accumulators are more common than not**

Copay accumulators are a common feature in health insurance plans sold on the ACA exchanges, according to a recent report from an AIDS advocacy group that wants the Biden administration to reverse a decision made by the Trump administration that allowed continued use of accumulators.

The AIDS Institute issued a report in March that says that at least two-thirds of the ACA health plans in 35 states include a copay accumulator and that in 14 states, every plan does.

Copay accumulators remove any copay assistance that members receive from spending that would count toward a health plan’s deductible. Patient advocacy groups say accumulators undermine copay assistance and protection against the high cost of drugs. And the AIDS Institute says in its report that they doubly benefit insurers and PBMs because they receive the copay assistance funds and then the amount the member spends until the plans out-of-pocket maximum is reached. The counterargument from insurers and PBMs is that accumulators sabotage formularies and wind up making healthcare and premiums more expensive.

Last year, the Trump administration moved to limit accumulators and then reversed course. The AIDS Institute wants the Biden administration to change the Trump administration’s policy and rein in the use of accumulators.
In Brief

MJH Life Sciences™ has officially launched Medical World News®, a first-of-its-kind 24-hour online program for healthcare professionals, by healthcare professionals. With easy viewing access on all our sites, you will be among the first to hear about the following:

• Breaking healthcare news
• Live updates and opinions on what’s happening, with leading experts answering the tough questions
• Cross-specialty feedback for multidisciplinary approaches to treatment and guidelines

MJHLifeSciences.com/news-network

Listen to our podcasts!

Managed Healthcare Executive® featured Lenny Castiglione, CEO of Ob Hospitalist Group, in a recent episode of our “Tuning In to the C-Suite” podcast. Associate Editor Briana Contreras spoke with Castiglione about how and why hospitals and health systems are increasingly working with third-party providers for their obstetric and other services.

“Tuning In to the C-Suite” features healthcare professionals, leaders and executives discussing current developments in the cost and delivery of healthcare. The podcast also comprises two sub-series, “MHE Talks: Improving Patient Access” and “Meet the Board.” To listen to episodes of “Tuning In to the C-Suite” or the sub-series, go to Apple, Spotify and iHeart Radio podcasts and search on the title.

Listen in. Learn a lot.

Scan this QR code to listen to our “Tuning In to the C-Suite” podcast.

Urgent care a bargain?
Researchers find that it is quite the opposite

One of the arguments for urgent care centers is that they help people avoid time-consuming, costly trips to hospital emergency departments for relatively minor injuries and illnesses. But findings reported in the April issue of Health Affairs suggest that decreases in emergency department visits may be offset by large increases in the use of urgent care centers.

One less emergency department visit for a low-acuity problem was associated with 37 additional urgent care center visits, according to a research team that included Ateev Mehrotra, M.D., M.P.H., an associate professor at Harvard Medical School and a member of the MHE Managed Healthcare Executive® editorial advisory board. Emergency department visits cost 10 times more than urgent care visits, but because of the increase in urgent care centers, Mehrotra and his colleagues found that each $1,646 in savings from an emergency department visit not occurring was associated with a $6,327 increase in urgent care center costs.

Other studies have found that less expensive care, if it is more convenient, can lead to greater utilization, thereby blunting expectations that the less expensive care is going to translate into cost savings. Mehrotra and his colleagues say their findings argue for a comprehensive approach and not just simply depending on urgent care center centers to reduce emergency department visits for care that could occur elsewhere. They mention triage lines staffed by nurses, augmented by machine learning, as way to direct patients to the appropriate care setting.

The study did not encompass primary care visits. As Mehrotra and his co-researchers acknowledge, urgent care visits may replace primary care visits, not just trips to the emergency department, and that substitution, which could result in some cost savings, was beyond the scope of their research.

Mehrotra and his colleagues used a database of healthcare claims from a large national healthcare insurer to conduct their study. They looked at the relationship between the number of lower-acuity (rashes, muscle strains) emergency department visits per enrollee to the number of urgent care visits. The association between increasing urgent care visits with decreasing emergency department visits was strongest in urban and high-income ZIP codes and in those with higher baseline use of emergency department visits.
New hemophilia treatments look to cut number of infusions
Longer half-lives mean less frequent administration and improved quality of life. by JAIME ROSENBERG

A potential new generation of treatments for hemophilia may build on the progress made in treating the condition, which affects approximately 400 infants born each year, by reducing the burden that treatment can have on patients’ quality of life.

Hemophilia is a rare, genetic disorder in which a person’s blood does not clot normally, resulting in spontaneous bleeding internally and excessive bleeding after injury or surgery. The condition is more common in males than females, affecting 1 in 5,000 male births.

The condition may result in chronic joint disease from repeated bleeding into the joints, neurological damage and damage to other organ systems. Hemophilia can also lead to quality-of-life issues, including psychological and social issues.

The goal of treatment typically focuses on preventing bleeding. For patients with hemophilia A, the most common type of hemophilia, the inability of the blood to clot is caused by a shortage of a protein called factor VIII. Treatments focus on factor VIII replacement, which helps the blood clot. Thanks to the class of treatment, people with hemophilia A now live nearly as long as people without the condition.

However, there is still room for improvement in hemophilia treatment because of the relatively short half-life — a measurement of how long a drug will work based on the time it takes for the amount of the drug in your body to be reduced by half — of traditional factor VIII treatments. The shorter a drug’s half-life, the more often it needs to be administered.

With traditional factor VIII replacement options, the half-life ranges from 15 to 19 hours, so patients need to get treatment about every other day. Factor VIII is administered intravenously, so frequent administration has a major effect on the quality of life of patients.

One of the goals of the newer hemophilia A treatments is to lengthen the time between infusions. The newer treatments include:

- Biogen’s Eloctate, or antihemophilic factor (recombinant) Fc fusion protein, which in 2014 became the first approved treatment of its kind for adults and children with hemophilia A.
- Novo Nordisk’s Esperoct, or antihemophilic factor (recombinant) glycopegylated-exei, which the FDA approved in 2019 for adults and children with hemophilia A.
- Bayer’s Jivi, or antihemophilic factor (recombinant) PEGylated-auci, which was approved in 2018. Long-term results from a phase 3 trial of the treatment were recently released, confirming that the treatment safely prevents bleeds in young boys (under 12 years old).

An even newer generation of factor VIII replacements is aimed at further cutting the number of infusions needed. These treatments have a half-life up to four times that of traditional replacement therapies, so patients only need to be treated once a week.

Sanofi is currently recruiting patients for a phase 3 trial of its experimental treatment, provisionally named BIVV001, which is a fusion of several blood-clotting proteins and a protein polymer, XTEN, that extends the half-lives of therapeutic proteins. Although it remains to be confirmed how well the treatment works, positive results from a phase 1-2a open-label trial were reported in the New England of Journal of Medicine last year. The small, industry-sponsored study enrolled 16 men with severe hemophilia A who were treated with a single dose of BIVV001.

Other factor VIII products in development include CSL626 from CSL Behring, a biotech company headquartered in suburban Philadelphia, and OCTA101 from Octapharma, a Swiss company that focuses on products made from human plasma.

Jaime Rosenberg is a freelance medical writer based in Jersey City, New Jersey.
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*Based on commercial and Medicaid pharmacy lives and Medicare low-income subsidy lives. Unrestricted access defined as not requiring prior authorization, step edits, or mandatory buy and bill. Source: Fingertip Formulary 10/5/2020.

It Will Not Be Your Pre-pandemic Office

There’s no going back to the ways of working before COVID-19’s arrival, say many in the industry. Insurers and PBMs are reducing their footprint as work becomes part remote, part in person.

By LARRY HANOVER
Five years ago, Prime Therapeutics, a fast-growing pharmacy benefit manager (PBM) owned by 19 Blues plans, realized that its portfolio of leased office spaces had grown expensive and unwieldy. The company’s leaders decided to consolidate its four Twin Cities offices at a gleaming new headquarters in nearby Eagan, Minnesota, and keep seven floors of offices at a location in another suburb.

An analysis had revealed that much of the existing space went unused, so company executives designed the Eagan building with flexible workspaces to encourage collaboration and meeting spaces that could be made smaller or larger as required, says Kim Gibson, assistant vice president of real estate and facilities at Prime. They suspected telecommuting would become a growing trend and felt the new building could accommodate such a transition, she says.

Then the pandemic hit. A change intended to be gradual took place almost instantaneously and worked out better than expected. In a mid-2020 poll, almost all (93%) of Prime’s employees said they were faring well at home, and two-thirds wanted a hybrid arrangement that would allow working remotely part time when the Prime offices eventually reopen.

Thus was born the “hub and home” strategy. Prime recently announced that employees will work from home 50%-65% of the time when reopening occurs, rotating into the office on set days of the week or month. With teams sharing spaces, Prime will be able to vacate the Bloomington offices by mid-2022 when the lease expires, reducing its footprint by one-third.

“To be an employer of choice, we’ve got to listen to our employees and bring the work to them, and I think this hub-and-home model does that,” Gibson says. “I would even say that if we didn’t offer something like this, we might be losing out on talent in the future. I’d say it’s critical to our future. I would suspect other organizations are considering the same.”

Some reticence
Indeed they are. Many health insurers and PBMs have not announced plans, but those contacted by Managed Healthcare Executive indicated that they are either proceeding with or contemplating remote and hybrid work schedules.

“They’re definitely not planning to get everyone back in the office,” says Lisa Slattery, vice president of accreditation and recognition operations for the National Committee for Quality Assurance (NCQA), the nonprofit accrediting organization for health plans. “We hear some will be selling off properties, reducing footprint and continuing a lot of work from home. A lot of leaders didn’t think things could be as effective from a work-from-home perspective, but they’re seeing this is a viable solution that was accelerated by the pandemic.”

Companies in the healthcare industry that do not involve direct patient-clinician interactions are a microcosm of what is happening nationally. Target Corporation, headquartered in Minneapolis, announced that it will shed nearly 1 million square feet of office space, shifting 3,500 employees into other buildings and having many work from home. Michigan-based Ford Motor Company has announced plans to shed a significant office space.

A survey conducted by PwC in November and December 2020 showed that fewer than 1 in 5 executives wanted to return to the office as it was pre-pandemic. Most (87%) executives expected shifts in their real estate strategy, including consolidations, although many said they would open new satellite locations. Results of a June 2020 Gartner Inc. survey showed that 82% of company leaders intended to permit remote arrangements some of the time as employees return to the workplace.

Blue Cross and Blue Shield of North Carolina is among the handful of companies talking openly about upcoming shifts in their real estate. The company has allowed some office lease spaces to expire and will make real estate decisions based on how employees are working, not on cost.
“We do not anticipate ever going back to the traditional, pre-pandemic way of thinking that being in the office every day is necessary and/or expected,” the company said in a statement. Employees will work remotely at least through June.

Independence Blue Cross faces a major crossroads. In June 2020, it paid $360 million to repurchase its Philadelphia headquarters building, which it sold to Prudential Insurance Co. in the 1990s. The 45-story tower — the city’s eighth tallest building — houses 2,500 employees. Officials say they are not ready to announce plans.

“We are committed to this region and here for the long term,” the company said in a statement. “Purchasing our building at 1901 Market St. last summer was a further demonstration of that commitment.” The company did say employees would return in a phased approach.

Other companies are similarly reticent, perhaps to keep their options open. Optum, the PBM and care services subsidiary of UnitedHealth Group, said in a statement that they are “using this time to listen to our employees at all levels of the organization to best understand their preferences for the post-pandemic work environment. We are not rushing into any long-term decisions.”

A spokesperson for Centene Corporation, a publicly traded health insurer with headquarters in St. Louis, says the company will begin returning a small number of employees to the office Sept. 13. Employee schedules will include remote and in-person time as well as flexible start and end times.

Get the tech right
Erin Feigal, Prime Therapeutics’ chief human resources officer, says that a key part of the reopening plan involved a team designed to connect with employees, collect feedback and ensure that employees felt ownership of the hub-and-home approach. “It was an evolutionary process,” she says.

As a result, 2,200 workers local to Minnesota will cycle through the single Eagan campus, including 700 shift-

To keep a strong culture, employees should be in the office...

| About one to three days per month | 6% |
| One day per week | 5% |
| Two days per week | 15% |
| Three days per week | 29% |
| Four days per week | 18% |
| Five days per week | 21% |

Employees don’t need to be in the office to maintain company culture. 5%

Source: PwC US Remote Work Survey

Manitoba Health, Wellness and Social Development (WHS) has offered a hybrid work plan, which allows employees to choose the days they want to work in the office or remotely.

By having companies send screenshots and other documentation electronically, the organization has been able to perform accreditation work without conducting onsite visits.

Pattie Graves, human resources knowledge adviser for the Society for Human Resource Management (SHRM), says the healthcare sector and industries in general that perform office work are on the same wavelength. Companies are regularly making inquiries to SHRM about transitioning to hybrid work plans, and she sees no turning back: “I think it’s going to be the future.”

Larry Hanover is a freelance writer in southern New Jersey.
The COVID-19 pandemic has left some healthcare providers on shaky financial footing, which could accelerate the long-term trend toward consolidation and, in the process, drive up healthcare prices while decreasing the quality of care. Studies have found that “prices go up and quality stays where it was or becomes worse” when consolidation occurs, notes Lovisa Gustafsson, vice president of the Controlling Health Care Costs program for the Commonwealth Fund.

Because of the pandemic, hospitals could lose between $53 billion and $122 billion this year alone, according to a report for the American Hospital Association. That’s on top of the $323 billion they were predicted to lose in 2020 as Americans skipped care because of the pandemic. Meanwhile, a survey by the American Medical Association in October 2020 found that many physician practices were experiencing sharp declines in revenue. Physician revenue had dropped by nearly one-third since February. About one-fifth of doctors saw revenue decline by at least 50%. As revenue has declined, “some might have the financial resources to make it through. Others could be put out of business” or physicians could retire early, Gustafsson says. In other cases, providers could turn to “stronger organizations to acquire them,” says Gustafsson, who co-authored an article for Harvard Business Review in March with David Blumenthal, the president of the Commonwealth Fund, about the pandemic accelerating the consolidation trend. In 2020, 79 hospital mergers and acquisitions were announced, according to a report by the management consultancy Kaufman Hall, compared with 92 transactions in 2019.

Many small transactions, such as when hospitals or health insurers acquire physicians’ practices, often are overlooked, Gustafsson says. Local news media don’t cover them and regulators don’t get involved because of their relatively small size. Studies have shown that increased provider consolidation “tends to increase price in the commercial (insurance) market” because prices are a “product of negotiations between healthcare providers and insurers,” says Karyn Schwartz, senior fellow and lead author of a study on provider consolidation at the nonprofit Kaiser Family Foundation.

The evidence is mixed on whether consolidation improves the quality of patient care. Large systems tout the advantages of integration. Schwartz observes, “Just because there’s a merger, it doesn’t mean there’s true integration that leads to better quality of care.”

“There needs to be more scrutiny and better understanding of what happens,” Gustafsson says. That might happen with the Biden administration, Schwartz says. Xavier Becerra, the new HHS secretary, led a legal battle against Sutter Health last year when he was California attorney general, alleging a variety of alleging anticompetitive practices. A California superior court judge gave preliminary approval to a $575 million antitrust settlement in March. An HHS led by Becerra “could certainly work with the Department of Justice and the Federal Trade Commission on (antitrust) issues,” Schwartz says.

Susan Ladika is an independent journalist in Tampa, Florida.
How the new price transparency rules are affecting stakeholders

Providers are moving toward acceptance; the rules are here to stay. Payers recognize that people need to know prices.

by DEBORAH ABRAMS KAPLAN

Although the hospital price transparency final rule took effect in January, it will take time for it to get its sea legs, whether that means 100% hospital compliance, inspiring patients to use it for their own healthcare decisions or for hospitals to reevaluate their pricing based on their competition. Eventually, though, “I think it will open up the market and, hopefully, reduce the cost of healthcare,” says Sally Pipes, president of the Pacific Research Institute.

The rule requires hospitals and those meeting applicable licensing requirements to post standard charges and negotiated insurance rates for 300 “shoppable” services in a prominent place on a publicly available website. The format should be machine readable and contain plain language descriptions. Hospitals with existing price comparison tools can use those instead of creating all new files. According to a Guidehouse analysis published in early February, 60% of providers published data. Although the American Hospital Association sued, citing First Amendment issues, the federal courts have upheld the rule as constitutional.

The price transparency rule affects hospitals, payers and patients differently. But one thing is clear from gaining access to the numbers: Healthcare rates for the same services diverge wildly not only across the country but also sometimes in the same or similar markets. An analysis of Crowe Revenue Cycle Analytics data of pricing for 100 common outpatient procedures (each listed at $500-plus in gross charges) revealed a 297% average price differential between the lowest and highest gross charges per procedure. It also showed an average 236% differential nationally in allowable expected payment.

A review of Atlantic Health System’s data for its New Jersey hospitals by Managed Healthcare Executive® showed large differentials. For example, here are some prices for cesarean section without sterilization, without major complication or comorbidity:

- Morristown Medical Center: $24,927
- Overlook Medical Center: $27,806
- Chilton Medical Center: $38,013
- Newton Medical Center: $66,091

Morristown Medical Center and Newton Medical Center are 37 miles apart, and the drive time between them is about 45 minutes.

Compliance

Determining whether hospitals are complying depends on what data and analysis you’re looking at. According to a Guidehouse analysis published in early February, 60% of providers pub-
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The current price transparency rule is only the tip of the iceberg for carriers, though. By January 1, 2022, carriers must make standardized and updated data files available for research and healthcare innovation improvement projects.

charges were broken down by payer and plan. However, the “standard listing of charges” showed procedure names (e.g., “CESAREAN SECTION W/O CC/MCC MS”) and list prices for up to 8,838 procedures per hospital, but no breakdown of negotiated rates or procedure codes.

Even if hospitals comply by providing the files, some are making it difficult to find them on a web search. The Wall Street Journal noted that hundreds of hospitals use “no indexing” coding that prevents search engines from finding and displaying their price transparency pages.

The government can fine hospitals up to $300 a day for noncompliance. According to management consultant Guidehouse, some hospitals say they’re not complying because of lack of resources due to the pandemic or lack of compliance understanding, or they’re waiting to see what other hospitals do.

“If you hear a hospital saying it costs them hundreds of thousands of dollars, or COVID-19 was a barrier to complying with this, it’s untrue,” says Chris Severn, CEO of Turquoise Health. His company is offering the service for $10,000 per hospital, and he says it has helped some hospitals comply within a few days. “We talked to a few large health systems that said it’s too difficult to comply. If that’s the case, it speaks to the underlying brokenness of their infrastructure and revenue cycle.” CMS doesn’t expect perfection, he says.

Hospitals are accepting

Hospitals are not always used to providing rates for bundled services as a flat rate. “There’s a lot of math behind each service the patient gets at the hospital,” Severn notes. “The CMS rule forces hospitals and payers to quote rates like a case rate or flat rate” when those rates may be dependent on the amount of time the patient spends in the operating room or the type of device used.

Although hospitals may not like quoting list price and negotiated rates, “I think the industry is starting to accept it because they realize the rules are here to stay,” Severn says. If the prices are out of line with the market, or the value proposition isn’t there, it may make it tough for the hospital. “A one-star hospital with the most expensive orthopedic surgeon in town probably won’t be able to compete in the new managed care market,” he says.

Hospitals are curious to see how they compare in the market and how they drive volume to their facilities based on this rule. “Maybe you have the quality or clout in the market to demand these rates, maybe not. Maybe it’s an artifact of the old system,” Severn says. He recommends hospitals not wait until the next cycle to renegotiate rates.

Comparing apples to apples
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can be difficult, whether individ-ually looking up hospital rates or using price comparison sites. That’s because CMS didn’t specify what columns must be included, Severn says. “There’s variance with some providing all-inclusive rates with professional fees and lab fees,” he says. Rates may also vary based on location, like emergency room, inpatient or outpatient surgery. “For shoppable imaging, it’s mostly apples to apples,” he says.

**Payers are adjusting**

“Payers” can mean health plans, but it can also refer to individuals who pay for their own healthcare or employers with self-funded plans. Hospitals and insurance companies may not be excited about the price transparency rule, but Pipes says, “knowledge is a very important thing. The insurance companies need to realize that people want to know (prices).” Just as consumers know their mortgage rates when taking out a home loan, Pipes says, they want to know this information to make their healthcare decisions.

Revealing the price of care and the amounts different payers and hospitals negotiate for a service can change future negotiating strategies, says Nisha Kurani, senior policy analyst for the Program on the ACA at Kaiser Family Foundation. An insurer may see that another insurer has a higher negotiated rate and ask to adjust accordingly, she says: “It will be interesting to see how hospitals and insurers respond to the price information.”

The current price transparency rule is only the tip of the iceberg for carriers, though. By Jan. 1, 2022, carriers must make standardized and updated data files available for research and healthcare innovation improvement projects. Broader rules requiring disclosure of prices are scheduled to go into effect in 2023 and 2024, although in late April, the Biden administration CMS-proposed canceling a requirement that would have made hospitals disclose the prices they negotiated with Medicare Advantage plans.

“The rule requires hospitals to publish the payer-negotiated rates for a given service, but that doesn’t necessarily tell the patient what their out-of-pocket cost will be.” It also may not include additional services the patient will receive on top of what they’re shopping for. If they don’t get estimated charges for related services, they may be surprised later at the additional costs. Plus, she says, the tools don’t necessarily inform patients if their providers are in or out of network.

The disclosed hospital data includes primarily facility fees and negotiated rates for those fees, Severn says. “The facility fees are the lion’s share of what patients will owe,” he says, though the professional services component is often missing for most services. Therefore the negotiated price on the files should represent the minimum the patient will pay for a service, and they can at least use that as a guide.

Severn says he knows patients are using Turquoise Health’s price comparison software, as he sees website traffic spikes when the company gets press, and patients email questions, asking why their provider or a specific service isn’t listed. “That signals to us that patients are using this,” he says.

Whether the administration might attempt to pull back or modify other price disclosure requirements is unclear.

**Consumers are learning**

Consumers seem largely unaware of the price transparency rule, and price is not the only factor people consider when choosing a provider. “Uptake has been really low,” Kurani says. Patients may be able to use the tool only for services they can shop for in advance, which eliminates the usefulness of the figures for many emergency services.

The price tools also may not give the patient the full financial picture. “There are so many different aspects that go into the price of care,” Kurani says, including provider and hospital fees, and insurance co-pays and deductibles. “The rule requires hospitals to publish the payer-negotiated rates for a given service, but that doesn’t necessarily tell the patient what their out-of-pocket cost will be.”

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Formulary exclusions — a decision by a PBM not to include a drug on its list of covered drugs, called a formulary — are not new, but they are increasingly in the spotlight, partly because the PBM industry is increasingly consolidated. CVS Caremark, Express Scripts and OptumRx, the three largest PBMs, collectively process about 3 out of every 4 U.S. prescriptions. Attention to exclusions has grown as the number of drugs excluded from the national formularies of the three PBMs has risen. In 2014, CVS Caremark and Express Scripts excluded a relative handful of medications — 134 between them. By 2020, the three largest PBMs combined excluded 1,195 medications. According to a tally by Adam Fein, Ph.D., a drug pricing and distribution expert, 1,343 drugs are excluded from 2021 formularies of the three major PBMs.

Employers, unions and other “plan sponsors” that contract with the PBMs don’t have to follow the national formulary exclusions if they believe a drug should be covered for their employees or members. Still, the national formularies have clout, and the exclusions matter. PBMs say exclusions are a necessary check on the pharmaceutical industry’s pricing power and a way of keeping patients and plan sponsors from having to pay for medications with a high price and little, if any, clinical value. Critics say the exclusions limit patient access to needed drugs and that PBMs use them to negotiate higher rebates.

PBMs say exclusions are important for negotiating lower prices on behalf of health plans and members. Some payer and provider groups say they interfere with patient access to medicines. by MHE STAFF

The rise in formulary exclusions

Exclusions from national formularies may be making waves now, but they have been around for decades. In the late ’90s, state Medicaid programs started to institute “preferred drug lists” that excluded select medications in major drug classes as a way to manage Medicaid drug expenditures and maximize the value of pharmaceutical company rebates, including the large “supplemental rebates” offered to these programs. When Medicare Part D got started in 2006, the federal government established rules that enabled the exclusions across most drug classes on Part D formularies.

According to the Pharmaceutical Care Management Association (PCMA), the trade and lobbying organization for PBMs, formularies ensure that payers, providers and PBMs “promote clinically sound, cost-effective medication therapy options and positive therapeutic outcomes.” A study commissioned by PCMA showed that PBMs — in general, not just by using formulary exclusion — reduce prescription drug costs for health plan sponsors and consumers by 20% on average. Express Scripts says its national formulary and its exclusions saved clients and patients $14.5 billion between 2014 and 2020.

Jeannette Novatski, Pharm.D., a senior director of clinical program management at Express Scripts, described three scenarios in which exclusions might be used in an article posted on the company’s website in 2019. First, if new generics come on the market, then their more expensive brand-name counterparts may be potentially be excluded. Second, if new brand-name drugs in a therapeutic class enter the market, then the company may be able to negotiate lower pricing for all medications in the class and potentially exclude high-cost brand-name competitors. Third, if the FDA adds new indications to a drug, then a drug that had a clinical advantage may lose that edge, “enabling Express Scripts to negotiate better pricing for medications in the therapy class and potentially excluding high-cost brands,” according to Novatski.

Steve Miller, M.D., who was Express Scripts’ chief medical officer for many years before Cigna bought the company in 2018 and he became Cigna’s chief clinical officer, described Express Scripts’ process for putting together a formulary in
The rise in formulary exclusions

Formulary Development

What the critics say

The critics of formulary exclusions include patient advocacy groups and physicians, especially specialists who take care of patients with chronic diseases that are treated with medications coming off and on formularies.

Typically, formulary inclusions are based on complex negotiations among drug manufacturers, insurance companies and the PBMs, says Steven Newmark, J.D., M.P.A., chief legal officer and director of policy at the Global Healthy Living Foundation. A pharmaceutical company may bundle its medications and offer price concessions on some to get better placement on the formulary for others. One of the complaints about exclusions — PBMs more generally — is that those negotiations and their outcomes are secret. “PBMs and insurers do not publicly share this information,” Newmark says.

Another objection to exclusions is that they can lead to “nonmedical switching,” changing a patient’s medications for reasons other than safety, efficacy or adverse effects. “If you have a rheumatoid arthritis patient stable on drugs, you can’t just switch them to a generic and expect the same results,” says Robert Levin, M.D., president of Alliance for Transparent and Affordable Prescriptions, a group of rheumatology organizations pushing for more regulations of PBMs. “In a lot of patients, it causes worsening of medical conditions.”

The American Journal of Managed Care recently reported that Express Scripts offered patients a $500 debit card if they switched from Cosentyx (secukinumab), which it took off its formulary, to Taltz (ixekizumab) or other drugs for psoriasis and psoriatic arthritis. Cigna issued a statement that said patients were “offered several alternative medications that are equally effective and more affordable” and that it recommends that its clients offer an “efficient review process to assist those patients in obtaining a nonformulary medication in these instances.”

Formulary exclusions can work against the financial interests of patients, say the critics, when the excluded drugs have a lower list price than the drugs the PBM kept on its formulary. “They claim they’re watching out for patients and reducing costs. Reducing costs for whom? Not the patient. Prices keep going up,” Levin says. (Express Scripts says most of the plans on its national formulary have a tiered benefit with flat copays so patients shouldn’t experience a difference in cost.)

Patients need prior authorization for certain drugs, including those on the exclusion list. The insurer’s internal review process can take weeks, says Levin. “It’s a bureaucratic nightmare to get this stuff through.”

To improve patient protections, some states have enacted laws that help physicians appeal exclusionary decisions and ask for a protocol exemption for an individual patient, Newmark says. “However, these laws vary widely across states, and there is no set of uniform methods for physicians to apply for an exemption,” Newmark explains. “The laws may also lack enforcement penalties, he adds.

Formulary exclusions don’t expressly forbid patients from taking a medication. But if patients want access to an excluded medication, they must be able to pay out of pocket or their provider will need to seek a medical exception.

“Pharmacies are obligated to dispense prescribed medications aligned with what the patient’s insurance coverage covers.”

— STEVEN NEWMARK, J.D., M.P.A., CHIEF LEGAL OFFICER AND DIRECTOR OF POLICY AT THE GLOBAL HEALTHY LIVING FOUNDATION
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The COVID-19 pandemic has turned digital behavioral health into a hot field. Even Britain’s Prince Harry is getting in on the game, joining the digital coaching company BetterUp as chief impact officer just weeks after the company raised $125 million in additional funding.

Money is pouring into digital behavioral health companies. Investment has more than doubled from 2019 to 2020, reaching $2.4 billion in venture funding, according to a report by Rock Health, a venture fund focused on digital health. At the same time, the number of deals jumped from 40 to 67. The investment spree continued the first few months of this year, with hundreds of millions more pouring into companies. “It feels like the momentum created in the pandemic ... is still underway,” says Megan Zweig, Rock Health chief operating officer and co-author of the report. “The potential is accelerating.”

BetterUp said it will use its latest funding to support its new BetterUp Care, which offers businesses access to such services as coaching with behavioral health, parenting and sleep specialists. A month later, the company said Harry would work to drive awareness and advocacy around mental fitness.

The day after BetterUp announced that the prince would join the company in late March, the digital mental health company Ginger said it had received $100 million in financing. Investors are recognizing “the important shift of how we’re dealing with mental health,” says Andrew McCarthy, head of corporate marketing for Lyra Health, which provides mental health benefits for employers.

Lyra raked in $187 million in January, bringing the company’s value to more than $2 billion and making it the top-funded specialist behavioral health company, according to Rock Health.

Digital delivery

These investments are occurring as two trends in American healthcare take hold: the shift to digital delivering and the growing number of Americans with poor mental health due to the pandemic.

When the pandemic hit last spring, the delivery of healthcare services shifted across the board. As states went into lockdown, providers across all specialties scrambled to implement or expand their telehealth capabilities.

In a survey released last October, the telemedicine company Amwell reported that 80% of physicians had conducted a virtual visit in 2020 compared with 22% in 2019. At the same time, the number of consumers who had a telehealth consult rose from 8% to 22%.

In the past, most telehealth visits were for on-demand urgent care, but during the pandemic, most visits have been prescheduled, according to Amwell’s survey. The pandemic also ignited already-smoldering mental health issues as Americans grappled with the fear of contracting the virus and faced a host of other concerns, including isolation, job loss, caregiving and financial struggles.

More than 40% of Americans reported symptoms of anxiety or depressive disorder in January, 10 months after the pandemic began. Just 11% reported such symptoms during the first half of 2019, according to results of a study by the nonprofit Kaiser Family Foundation (KFF).

Findings of a KFF poll from July
showed that, due to the pandemic, about one-third of adults had sleep or eating issues and 12% reported increased alcohol or substance use because of worry and stress. The poll also revealed that young adults and people of color were more likely to struggle with pandemic-related mental health issues. The CDC reported that more than 10% of respondents to a survey had suicidal thoughts during the previous 30 days, including one-quarter of those ages 18 to 24.

Researchers have started to put some numbers to the widely recognized shift to digital behavioral health services. For example, results of a study published in *Neuropsychopharmacology* earlier this year found that in October, more than 40% of mental health or substance use disorder consultations were conducted virtually compared with less than 1% before the pandemic began. Because of COVID-19, “people almost instantly adopted telehealth counseling,” McCarthy says.

**Growth in niche businesses**

Even before the pandemic began, investment was growing in the digital behavioral health sector. In 2017, less than $500 million was invested in digital behavioral ventures. In 2018, investments almost tripled, to $1.4 billion, according to Rock Health.

The services were seen as a way to both decrease the cost of and better coordinate care, while enabling providers “to scale up help to mitigate the shortage of providers,” says Vin Phan, partner and practice leader of national healthcare transaction advisory services at BDO. There was also recognition that “the mental health system is really broken,” says Joe Grasso, Lyra’s clinical director of partnerships. Half of those seeking care couldn’t get it — or couldn’t get the right kind of care. Providers are in short supply, and many don’t take the amounts paid by insurers, so many people cannot afford mental health services.

Lyra matches clients with providers based on a range of needs, including suicide prevention, individual or group therapy, and wellness apps. “The money flowing into Lyra and other digital behavioral health companies recognizes “the important shift of how we’re dealing with mental health,” McCarthy says.

With its new investment, Lyra has added capabilities to deal with mental illness and substance abuse issues, he says. “Digital health has become the front door where individuals start their care journey,” says Bryan Vercler, director of partnerships at Modern Health, which also contracts with employers to connect employees with care. “People want to be met where they are.”

At the same time, “a lot of employers are realizing the link between mental health and physical health,” Vercler says. Modern Health received another $74 million in investment in February, boosting its value to $1.17 billion. “Mental health has been underinvested in,” Vercler says. “We’re in the very early stages of the transformation.”

Meanwhile, the online therapy app Talkspace in January announced it was going public through a merger with Hudson Executive Investment Corp., a deal valued at $1.4 billion.

Rock Health ranks Amwell as the largest generalist company in the digital mental health space, and last fall it raised $742 million in an initial public offering. Generalist digital behavioral health providers drew in $1.6 billion, and specialist companies brought in more than $800 million, Rock Health said in its report. From 2019 to 2020, the average deal size climbed from about $23 million to $36 million.

Demand for digital mental health solutions will continue even once the pandemic is under control, says Chandni Mathur, a senior industry analyst at Frost & Sullivan: “The WHO (World Health Organization) looks at this (mental health) as the next pandemic.” With so many people struggling with mental health issues, “the stigma associated with mental health has suddenly been overcome,” Mathur says. She expects the demand for services for children and adolescents to increase because the lockdown and the halt to in-person education has affected the mental health of younger people.

Phan says he is seeing increased investment interest in behavioral health services to serve those with autism and to treat substance use disorders. The number of niche behavioral health services also is expected to grow, Zweig says. For example, Omada Health, which focuses on diabetes management, has added mental health services to its client programming. Services also are cropping up to serve patients coping with a range of issues, including eating disorders and the trauma of racism, Zweig says: “It’s not one-size-fits-all. There are lots of opportunities to see curated solutions.”

_Susan Ladika_ is an independent journalist in Tampa, Florida.
Although COVID-19 vaccinations are now underway, the rollout has not been as seamless as people had hoped. Notably, issues with signing up and challenges with security in electronic health records (EHRs) have been reported across the healthcare system.

For instance, Michigan-based Beaumont Health allowed users to schedule unauthorized appointments and circumvent current state mandates because of a glitch, effectively letting 27,000 people cut in line. Other healthcare systems have discovered vulnerabilities in their security measures, which is why many are turning to new tech for help. In addition to downtime, systems have faced issues related to duplicate patient records and other problems due to EHR misconfigurations as they rush to scale with the demand.

A balance of security and usability is always critical, and that is up to each organization to manage. But solutions being rolled out need to have clearly identified security capabilities to secure data while also enabling a broad population to easily schedule their appointments.

Chris Gervais, chief technology officer and chief security officer at Kyruus, a healthcare scheduling and data management company, notes that health systems have limited abilities to easily scale because most EHRs are not built for the traffic patterns needed.

"Patient portals are generally not built to handle the amount of concurrent usage and can put undue pressure on the core EHR, compromising its ability to power core clinical workflows," he says. "As patient portals become unavailable due to load, that then puts pressure onto access center phone systems, which can, in turn, themselves become overloaded from the sheer number of incoming calls."

Gervais

Jacob Ansari, chief information security officer of Schellman & Company, a global independent security and privacy compliance assessor, says the distribution for COVID-19 vaccines provokes several interesting information security questions. For instance: Are we protecting the personally identifiable information (PII) of vaccine recipients, especially as vaccination sites are increasingly localized, at pharmacies and assisted living facilities, for instance? Are we protecting the PII of recipients answering survey questions? Are we protecting the actual distribution of vaccines from those who would seek to disrupt shipment or destroy supply? "These are questions I hope public health officials at all levels are asking themselves, and (I also hope they are) seeking expertise from information security professionals," Ansari says. "It’s very likely that there are already controls in place to protect these pieces of information from disclosure or misuse, but whether … any gaps remain or (whether) the protections in place are sufficient is hard to gauge without some inside knowledge of the process."

Security issues

According to a CI Security report based on publicly reported breaches to HHS, breaches were up by 35.6% in the second half of 2020 compared with the first half, and the number of patient records that were breached increased by more than 180%, although the bulk of those incidents are tied to business associates rather than providers directly.

Hari Prasad, CEO and co-founder of Yosi Health, a healthcare technology solutions company, notes that COVID-19 vaccination plans and schedules add another layer of complexity to the already challenging world of data protection with EHR systems. "One of the key challenges with the schedule management systems is that they may not be fully connected to the EHRs," he says. "As a result, their (ability) to offer real-time scheduling is minimized."

Plus, the simple fact that a person is scheduled in a given wave could expose data on their age or a particular health condition. Therefore, managing these schedules and

Playing it safe and secure

Breaches in online vaccination schedulers are among the security problems the healthcare sector is scrambling to fix. by KEITH LORIA

Gervais

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Plus, the simple fact that a person is scheduled in a given wave could expose data on their age or a particular health condition. Therefore, managing these schedules and
Playing it safe and secure | Technology

Managing patient communications with secure modern solutions is a must.

“It is crucial for health systems to ensure not only that they have the right protections — such as immutable off-site copies of their data — in place but, more importantly, that they are working with business associates who practice the highest security standards verified by standards organizations like HITRUST,” Prasad says.

Data accessibility
Jay Anders, M.D., a former internist and now chief medical officer of health data company Medicomp Systems, says one of the key issues is data accessibility and accuracy of that data. “Unfortunately, this is not a new problem. The industry has struggled with data entry and reporting into immunization registries for many years,” he says. “The issue is and remains: How do physicians give safe, proper care if they don’t have the data? If a vaccine is given on a Monday, but this is not reported accurately or completely, then it’s difficult for a treating physician to give proper care when that patient shows up to an office visit on Wednesday but with an incomplete medical record.”

Alastair Blake, M.D., vice president of clinical and commercial partnerships at Nference, which synthesizes biomedical knowledge, has looked into the de-identification of patient records to enable research into COVID-19. Nference has collaborated with partners at Mayo Clinic to publish extensively on the impact of the COVID-19 pandemic, leveraging its de-identification technology to fully harness the EHR data.

“Our de-identification solution, nCognito, is powered by algorithms and methods that were designed to satisfy and go beyond HIPAA (Health Insurance Portability and Accountability Act) Safe Harbor requirements,” Blake says. “The approach consists of two steps: automatic detection of PII, followed by transformations of these information elements.”

Step one involves detection of PII entities using an ensemble architecture of attention-based neural networks that identifies complementary features across different protected health information types (e.g., names, dates, ages) in both structured and unstructured data sources. These PII entities are then transformed and replaced with suitable surrogates, matched for features such as sex and ethnicity. “This approach does not use redaction, thus making data more intuitive to use while minimizing the risk of data users noticing a de-identification error if one occurred,” Blake says.

Dedicated landing pages
Some lesser issues are scheduling problems that result in people not knowing when vaccine appointments are available and in overloads of systems. This creates problems for those distributing the vaccines. Gervais says creating separate vaccine scheduling flows from patient portals with applications purpose-built for scheduling specifically can help solve some of the problems. “This has helped minimize EHR disruption and enabled healthcare organizations to manage surges in traffic more effectively,” he says. “When appropriate, it has also enabled organizations to make scheduling available to more than just their existing patients, who are the only ones able to access an organization’s patient portal.”

Additionally, creating dedicated landing pages that can quickly update messaging to relay vaccine availability throughout the day can help reduce confusion for patients and their families, as well as wasted time refreshing pages. “This will proactively reduce traffic to avoid systems being overloaded by people looking to obtain appointments when there are none available at that time,” Gervais says, noting that will also help with security. “It is also important for organizations to develop a load-balancing strategy with their public websites, patient portal and call centers,” Gervais adds. “They should use scalable platforms for vaccine scheduling to leave patient portals available for specific interactions and reduce the risk of downtime.”

Keith Loria is a freelance writer in the Washington, D.C., area.
Over the past 15 years, payers, healthcare purchasers (e.g., Medicare, state governments, employers and individuals), professional associations and state and federal agencies have led many patient-centered medical home (PCMH) or enhanced primary care demonstration projects. In fact, the Primary Care Collaborative (PCC) has compiled a list of more than 500 types of PCMHs or enhanced primary care initiatives that have been conducted nationwide.

The Agency for Healthcare Research and Quality (AHRQ) defines a medical home not simply as a place but as a model of the organization of primary care that delivers the core functions of primary health care: patient-centered, comprehensive, coordinated, accessible, and with a focus on quality and safety.

But not many definitive studies have been published on the results of these demonstration projects, and the articles that have been published have show positive and negative results, says Susan E. Pantely, FSA, MAAA, a principal and consulting actuary at management consulting firm Milliman in San Francisco. So what has become of these demonstration projects? This article will look at how the PCMH model got started, its successes and failures, and what the future holds.

How the model got started
The PCMH model gained momentum in response to several important trends in healthcare during the late ’90s and early 2000s, beginning with the need to transform from a system designed to provide acute care to one designed to provide better chronic and preventive care, says Bob McNellis, M.P.H., a senior adviser for primary care for the Center for Evidence and Practice Improvement at AHRQ in Rockville, Maryland.

When the Institute of Medicine’s (now National Academy of Medicine) published its 2001 groundbreaking report titled “Crossing the Quality Chasm,” it was a wake-up call to address the quality gaps in U.S. healthcare. The report proposed a vision for the future of healthcare with a focus on patient-centered care, says McNellis, whose federal agency funds health systems and quality research.

Following that report, many healthcare organizations, professional societies and health services researchers began looking to improve the quality of care and outcomes of care while decreasing costs, McNellis says.

Current models for the PCMH were developed from a model proposed in 2007 when four physician membership organizations released the Joint Principles of the Patient-Centered Medical Home, which lists the characteristics PCMHs should have, according to McNellis, who says the model of care has evolved considerably since then.

Pantely says over the years, PCMHs have been modified based on lessons learned in the early stages, such as expanding primary care physician responsibility, adding activities aimed at reducing costs and improving patient outcomes and expanding infrastructure. Some projects ceased to exist because of difficulties in implementation or producing favorable results.

What the model entails
The PCMH model provides comprehensive primary care by redesigning healthcare delivery processes. This is accomplished through an emphasis on team-based care delivery, a whole-person approach to patient care, collabor
rative relationships between individuals and their physicians, and the use of evidence-based medicine and clinical decision support tools, Pantely says. A PCMH typically consists of a variety of primary care providers: primary care physicians, physician assistants, nurse practitioners, social workers, and sometimes midwives. PCMH practices vary in size but are typically larger than non-PCMH practices because of the volume needed to implement the required infrastructure.

The goal of a PCMH is to put the patient at the center of and in control of their care by facilitating a continuous, healing relationship between the patient and their primary care clinician or team that is focused on the patient’s needs, values and preferences, McNellis says. The primary care team has a central role in ensuring access, coordination and comprehensiveness of patient care.

Pantely says PCPs take on larger roles in patient care in exchange for increased revenue. Additional roles may include making efforts to reduce unnecessary hospital admissions or screening, diagnosing and treating mental health conditions.

**Achieving Triple Aim goals**
Primary care also has an important role in achieving the Institute for Healthcare Improvement’s Triple Aim, which is designed to improve patient care, improve population health and reduce costs of care, McNellis says. Implementing the functions of a PCMH by addressing timely access to care, coordination and comprehensiveness, patient engagement, and continuous quality improvement can help achieve these goals.

Over the past few years, a fourth aim focused on improving the clini-
To put the word ‘patient’ in the name was a huge breakthrough.”

— DON A. GOLDMANN, M.D., CHIEF SCIENTIFIC OFFICER EMERITUS AND SENIOR FELLOW AT THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

Successes and failures

The number of PCMH demonstration projects conducted across the country and the ubiquitous nature of PCMHs in primary care practices today speak to the model’s success and adaptability, McNellis says.

The National Committee for Quality Assurance (NCQA) operates a thriving PCMH program. It now recognizes roughly 1 in 5 eligible primary care clinicians, totaling just under 70,000 individuals. “Its numbers are increasing, albeit not at the rate they did early in the program’s life cycle,” observes Frank Micciche, vice president of public policy and external relations at NCQA in Washington, D.C. “But this is to be expected with any product, and there are certainly factors beyond just how long the program has been out that affect the numbers.”

“To put the word ‘patient’ in the name was a huge breakthrough,” says Don A. Goldmann, M.D., chief scientific officer emeritus and senior fellow at the Institute for Healthcare Improvement in Boston. “Over the last decade, primary care practices and integrated healthcare practices have moved to greater patient centering or partnerships. It’s important that physicians and patients share decisions and that physicians help patients self-manage their conditions in order to create a healthier population, not one where patients only go to the doctor when they have a problem.”

Amel Hammad, MBA, managing director and leader of the healthcare industry practice at Conway MacKenzie, a nationwide restructuring firm in the Chicago suburbs, says that in order for a PCMH program to thrive, capital requirements must be met, infrastructure and technology upgrades are needed, and doctors and staff must buy in, and regulatory demands as well as patient compliance have to be met.

Meanwhile, outside organizations have come into the industry and disrupted the model, Hammad says. Here are some examples:

- The pandemic has exacerbated a move to virtual appointments as the first contact point for patient-doctor interactions. Patients and payers are seeing the value in this change.
- Large pharmacy chains have worked their way into the quick service appointment format.
- Payers are contracting with medication adherence companies to help support adherence.
- Emergency service house calls for minor issues are disrupting emergency room visits.

The future of PCMHs

Although the model for PCMHs is no longer new and has become part of the fabric of how primary care is expected to be delivered, there is still much to learn about the individual components, McNellis says: “We need to learn more about how to maintain patient-centeredness and have truly comprehensive and coordinated care. We know what a PCMH should look like; making it work is the real goal now.”

And the term “PCMH” may not be used as frequently because many programs do not meet the formal definition of PCMH or have not gone through a formal PCMH accreditation. “Many primary care programs are driven by large employers, large payers or large provider systems,” Pantely says. “All of these primary care programs begin with the broad concept of emphasizing primary care, but the details vary.”

PCMHs can serve Medicaid, commercial or Medicare populations; each of these populations has different needs. PCMHs have to develop different processes for each population. “PCMHs are a continuous learning cycle that will continue to evolve,” Pantely says.

Pantely sees a variety of primary care models (including but not limited to PCMHs) as a way to bring about affordable healthcare. “More advanced models will lead the way, which will increase reliance on sophisticated analytic tools and electronic health records in order to manage their membership effectively and efficiently.”

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

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Multiple sclerosis (MS), a disease characterized by damage to the myelin sheath encasing nerves in the central nervous system, is often unpredictable for the people who have the condition. Flare-ups and the symptoms they cause — loss of muscle control, balance issues, vision problems — often don’t have any easily discernible pattern.

But for insurers and others responsible for managing the cost of healthcare, MS is predictably one of the costliest chronic diseases despite it being a relatively rare condition. A study published earlier this year in *Advances in Therapy* found that the all-cause costs for patients with severe MS relapses was almost $88,000 per year, most ($70,000) of which was related to MS. Prime Therapeutics says MS is the fourth-highest drug-spend category among its commercially insured members.

The priorities when treating patients with MS are forestalling further injury to the nerves and managing symptoms, says Nicholas Lannen, M.D., a neurologist at Spectrum Health, a healthcare system headquartered in Grand Rapids, Michigan. Lannen says preventing further damage to the nerves may give a patient’s brain a chance to repair itself through neuroplasticity.

Here are three things healthcare executives need to know about treating MS while managing costs:

1. **Generics may not be such a good deal for patients**
   
   Switching to generics is a well-worn path to lowering prescription costs. Lannen says he’s not opposed to generics provided they benefit the patient. But a generic may mean higher out-of-pocket costs for a patient because of coupons and other measures that insulate patients from the cost of brand-name equivalents.

   Robert Bermel, M.D., a staff neurologist and director of the Mellen Center for Multiple Sclerosis at Cleveland Clinic, says the “patient gets lost in the middle of this.” Bermel says the generics are often only “marginally less expensive” than brand-name drugs.

2. **Some imaging and office visits are unnecessary**

   Ensuring patients receive an accurate diagnosis is one way to reduce costs, says Bermel, who advocates for having diagnoses made at healthcare centers with expertise diagnosing and treating MS, such as the Cleveland Clinic, for that reason. Reducing the number of imaging tests and office visits can also save money. Although both are helpful particularly after initial diagnosis, their value decreases over time. Bermel says. He also recommends home care, shared visits and virtual visits as lower-cost alternatives to physician visit.

3. **There are cost-effective options to consider**

   The price of disease-modifying agents increased annually at rates five to seven times higher than prescription drug inflation, according to a 2015 study published in *Neurology*.

   Bermel says the average wholesale cost of an oral agent is approximately $80,000 to $90,000 a year. Ocrevus (ocrelizumab), which is administered intravenously twice a year, costs about $60,000 to $65,000, and rituximab is one-third the cost of ocrelizumab. A review paper published in the *Journal of Neurology* earlier this year said that there is a growing body of evidence supporting rituximab as a treatment for MS, although it has not been approved by the FDA as treatment for MS.

Aine Cryts is a freelance writer in the Boston area.
Lung cancer screening has had few takers. Will updated recommendations make a difference?

A small fraction of those who were eligible under previous U.S. Preventive Services Task Force recommendations were screened with low-dose CT scans. New recommendations will make an additional 6.4 million Americans eligible, but a number of barriers to screening remain.

When the U.S. Preventive Services Task Force (USPSTF) recommended screening current and former smokers for lung cancer with low-dose CT scans in 2013, it held the promise of ushering in a new era of lung cancer diagnosis and treatment. Screening for other cancers has kicked up some controversies about overdiagnosis and the quality of evidence for a mortality benefit, and lung cancer screening is not entirely free of those. But USPSTF recommendations were based on a large, randomized trial that showed a 20% improvement in lung cancer mortality. Screening would mean catching many more cancers at an earlier, more treatable stage, and lung cancer remains, by far, the leading cause of cancer-related death in the U.S. About 8 million Americans were eligible for lung cancer screening, according to the recommendations that the USPSTF issued at the time.

But only a small percentage of Americans who met the criteria set by the USPSTF guidelines have gotten screened. Estimates of the proportion vary, but they range from 6% to 18%. The list of reasons is long: fear of radiation exposure, stigmatization of smokers, lack of insurance coverage, to name just a few. Aside from willingness, the eligibility criteria set by the USPSTF may have had some discriminatory effects. According to one study, the criteria would have excluded 67.8% of Black smokers who received a diagnosis of lung cancer compared with 43.5% of White smokers.

In March 2021, the USPSTF updated its lung cancer recommendations in two important ways. It lowered the age at which screening should be performed, from 55 to 50. It also lowered the number of “pack-years” from 30 to 20. Pack-years are a measure of how heavily someone smoked and for how long. For example, someone who smoked two packs of cigarettes a day for two years would have a four pack-year smoking history. By some estimates, the new guidelines will mean an additional 6.4 million Americans, or a total of about 14.5 million, will be eligible under the 2013 recommendations. A study published in JAMA at the time the new guidelines came out found that the percentage of Black smokers who would be eligible for screening would increase from 16.3% under the old guidelines to 28.8% under the new ones.

For proponents of lung cancer screening, the question now is how to turn expanded eligibility into more actual screening. John Bulger, D.O., chief medical officer at Geisinger Health Plan in Danville, Pennsylvania, says the health plan is implementing claims configuration and that there is no cost sharing. “The biggest challenges that we see are getting the word out to members and their doctors,” Bulger says. “Additionally, there is a need for clinical facilities that perform the testing. Geisinger’s clinical enterprise has a streamlined process set up to identify patients, get them tested, close the loop on results, and schedule any further testing. More programs such as this are needed.”

Reducing false positives

But some wariness about lung cancer screening is understandable given its history. Chest X-rays
Lung cancer screening has had few takers

“We’re catching more and more patients in the earlier stages — stage I and stage II — where surgery can have an impact at curing those patients.”

—MARK DYLEWSKI, M.D., CHIEF OF GENERAL THORACIC SURGERY AT BAPTIST HEALTH SOUTH FLORIDA’S MIAMI CANCER INSTITUTE

and sputum cytology also looked promising but were abandoned when more rigorous research showed they didn’t reduce lung cancer mortality. That background is one reason the National Cancer Institute conducted a $300 million randomized trial of low-dose CT scans. In 2011, results from the National Lung Screening Trial (NLST), which enrolled a total of about 53,000 study volunteers, were a “win” for lung cancer screening. They showed a 20% lower risk of lung cancer mortality among those randomized to be screened with the low-dose CT scans compared with those who were screened with chest X-rays. Other research has found a lung cancer mortality benefit from low-dose CT scans. Last year, results reported in *The New England Journal of Medicine* from the NELSON study, a large, randomized trial conducted in the Netherlands and Belgium, showed a 24% reduction in lung cancer mortality in the CT scan group compared with the control group that wasn’t screened.

Adam Saltman, M.D., chief medical officer at Eko, a cardiopulmonary digital health company, says low-dose CT scanning has revolutionized the field of lung cancer screening. “It has detected many small, early-stage cancers and facilitated curative treatment for many who would not have presented until much later in their disease,” he says.

Historically, between 60% and 70% of patients with lung cancer have stage 3 or 4 cancers, notes Mark Dylewski, M.D., chief of general thoracic surgery at Baptist Health South Florida’s Miami Cancer Institute. “That number is changing with the implementation of screening with CT scans,” he says. “We’re catching more and more patients in the earlier stages — stage 1 and stage 2 — where surgery can have an impact at curing those patients.”

As is true for many cancer screening tests, false positives are a drawback of lung cancer screening with low-dose CT scans. In the NLST study, just under 1 in 4 (23.3%) of the scans resulted in a false positive reading: The scan discovered a nodule — a small growth in the lung — that wasn’t cancer. Several years ago, the National Comprehensive Cancer Network and the American College of Radiology’s program to standardize lung cancer screening raised the size threshold for a positive nodule from 4 millimeters (mm) to 6 mm. When data from NLST were reanalyzed using 6 mm as the threshold, the false positive rate decreased to 13% and to 5% at subsequent readings. Saltman notes the progress that has been made in the follow-up tests. [That low-dose CT scans] have identified a lot of lung lesions that are not cancer is a bit of conundrum but the field is maturing through the use of thin-needle biopsies, PET/CT scanning, electromagnetic navigational bronchoscopy and others,” he says.

Even if the false positive rate were zero, some people will be reluctant to get screened because of the radiation exposure. It is called low-dose CT scan screening for a reason: The radiation is about one-fifth of the radiation a person receives during a diagnostic CT scan. However, the recommendations are to get screened every year, so there is some concern with the cumulative exposure and whether that might increase cancer risk. Several years ago, Italian researchers calculated that the benefit far outweighed risk; for every 108 lung cancers detected with screening, one radiation-induced cancer might occur, they reported in an article in *The BMJ*. Nonetheless, it is a risk and one that might increase with the new USPSTF recommendations to start screening at a younger age.

Overcoming barriers

In the U.S. and in many countries, smoking is now a behavior that is more common in disadvantaged populations; people living in poverty or with disabilities or behavioral health problems — or some combination of the three. Yet a 2018 review of 14 studies of lung cancer screening programs found that the participants tend to have a relatively high socioeconomic status. That review, which included studies of programs in other countries, also found that former smokers were more likely to be screened than current ones, a difference that may reflect, in part, the stigma attached to smoking.

In the U.S., lack of health insurance is a barrier for some. The USPSTF gave a B rating to low-dose...
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CT scan lung cancer screening, and the ACA requires that most health plans cover preventive services with a USPSTF services with an A or B rating. But those requirements don’t necessarily apply to people covered by Medicaid. An American Lung Association report showed that screening was not covered by Medicaid fee-for-service programs in 12 states. The report is based on information collected several years ago, so some states may have since changed their coverage. Also, managed Medicaid plans may cover the screening in states where the fee-for-service program doesn’t. Regardless, Medicaid coverage is patchy, and smoking rates are higher among people covered by Medicaid than among people covered by Medicare or commercial insurance. Medicare finalized a national coverage determination for low-dose CT scans in February 2015. But there are some hurdles in Medicare, too. For one, the program requires submission of data to a CMS registry. For another, CMS has a formal shared decision-making requirement for the low-dose CT scans that, in theory, might encourage screening but, in practice, may be an impediment.

Karen Winkfield, M.D., Ph.D., executive director of the Meharry-Vanderbilt Alliance, a partnership between Meharry Medical College and Vanderbilt University Medical Center, both in Nashville, Tennessee, notes although that although most insurance plans and Medicare cover low-dose CT scans for lung cancer screening, “the stinger is Medicaid is not requiring coverage, so it leaves a little bit of a gap for certain communities. Part of the challenge is many of the individuals on Medicaid are the same individuals who have lower socioeconomic status and tend to have higher rates of lung cancer.”

In states that have expanded Medicaid, cancer screening goes up, Winkfield notes. “But we are still struggling with what happens after you screen a patient, because lung cancer can be a very multimodal way about diagnostics if there is a finding on a scan. We need to make sure people have access to follow-up care. It cannot just be on the screening.” In a review article published last year in the Journal of Thoracic Oncology, lead author Jacob Sands, M.D., a lung cancer specialist at Dana-Farber Cancer Institute in Boston, and his colleagues wrote that a lung cancer screening program that uses low-dose CT scans should have a program navigator, a reliable database for patients and a nodule monitoring and multidisciplinary committee. Sands and his colleagues also mention the need to work with primary care physicians, partnership with community leaders and organizations, and standardization of radiology reporting as important aspects of a screening program.

**Racial differences**

Winkfield, who works on health equity issues and differences in health and access to healthcare among racial and ethnic groups, notes that 2013 USPSTF recommendations excluded a lot of African Americans. The “smoking intensity” — the number of pack-years — tends to be lower among Black Americans than White Americans, but Black Americans develop lung cancer at a younger age. There’s some evidence that Black smokers have a higher risk of developing lung cancer than White smokers at relatively low levels of smoking. Black smokers tend to smoke menthol cigarettes more than White smokers, and some explanations of the lung cancer differences at the same level of smoking cite menthol cigarettes as the reason because of evidence that they may lead to more nicotine and carcinogen exposure per cigarette.
than other cigarettes. The new USPSTF recommendations may narrow the eligibility gap between Black and White smokers but may still mean that Black (and Hispanic) smokers are underrepresented in screened populations. Some research shows that adding assessments to those recommendations to identify “high-benefit” individuals would close the gap and possibly eliminate it.

Lung cancer screening may be particularly important for Black men. Lung cancer incidence and death rates are higher among Black men than among White men; it’s the reverse for Black women and White women. The differences may be related to smoking rates. According to the American Cancer Society, in 2017, smoking prevalence was higher among Black men than among White men (19% versus 17%) but lower among Black women than among White women (12% versus 15%). “If you look at the data related to the number of new cases related to lung cancer, Blacks had a much higher incidence a couple of years ago but the numbers have evened out more recently,” says Winfield, “although Black men still have a higher rate of developing lung cancer than White men, and we see Black men are dying at a much higher rate of lung cancer.”

That’s why it’s so important to prioritize the African American community for screening, Winfield says. She has also been thinking about other groups. “Part of the challenge in any screening program is awareness and getting the word out that individuals are aware of the recommended health promotion things to do,” she says. “You have to think about our underserved communities, whether that’s our Black and Brown individuals or those in rural communities or LGBT-plus communities.” Moreover, many in underserved populations are disproportionately uninsured and don’t have a primary care provider. Those providers play a crucial role in screening uptake because they advise and refer patients. Winfield says the broader use of lung cancer screening could also be an opportunity to get patients who are currently smoking into cessation programs. “Cancer is going to be the No. 1 killer in the U.S. very soon,” she says. “We have to use every opportunity to talk to individuals around risk reduction.”

**Keith Loria**, a frequent contributor to Managed Healthcare Executive®, is a freelance writer in the Washington, D.C., area.

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**Racial differences in lung cancer**

Rates per 100,000 and age adjusted to the 2000 U.S. standard population.

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<tr>
<th></th>
<th>Black men</th>
<th>White men</th>
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<tr>
<td>Incident</td>
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Source: Cancer Facts & Figures for African Americans, 2019-2021, American Cancer Society