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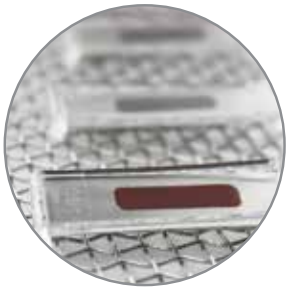

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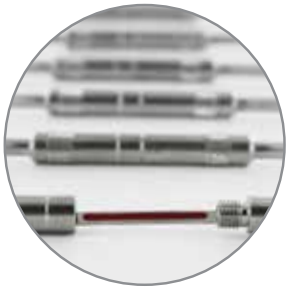

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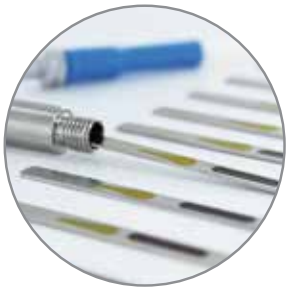

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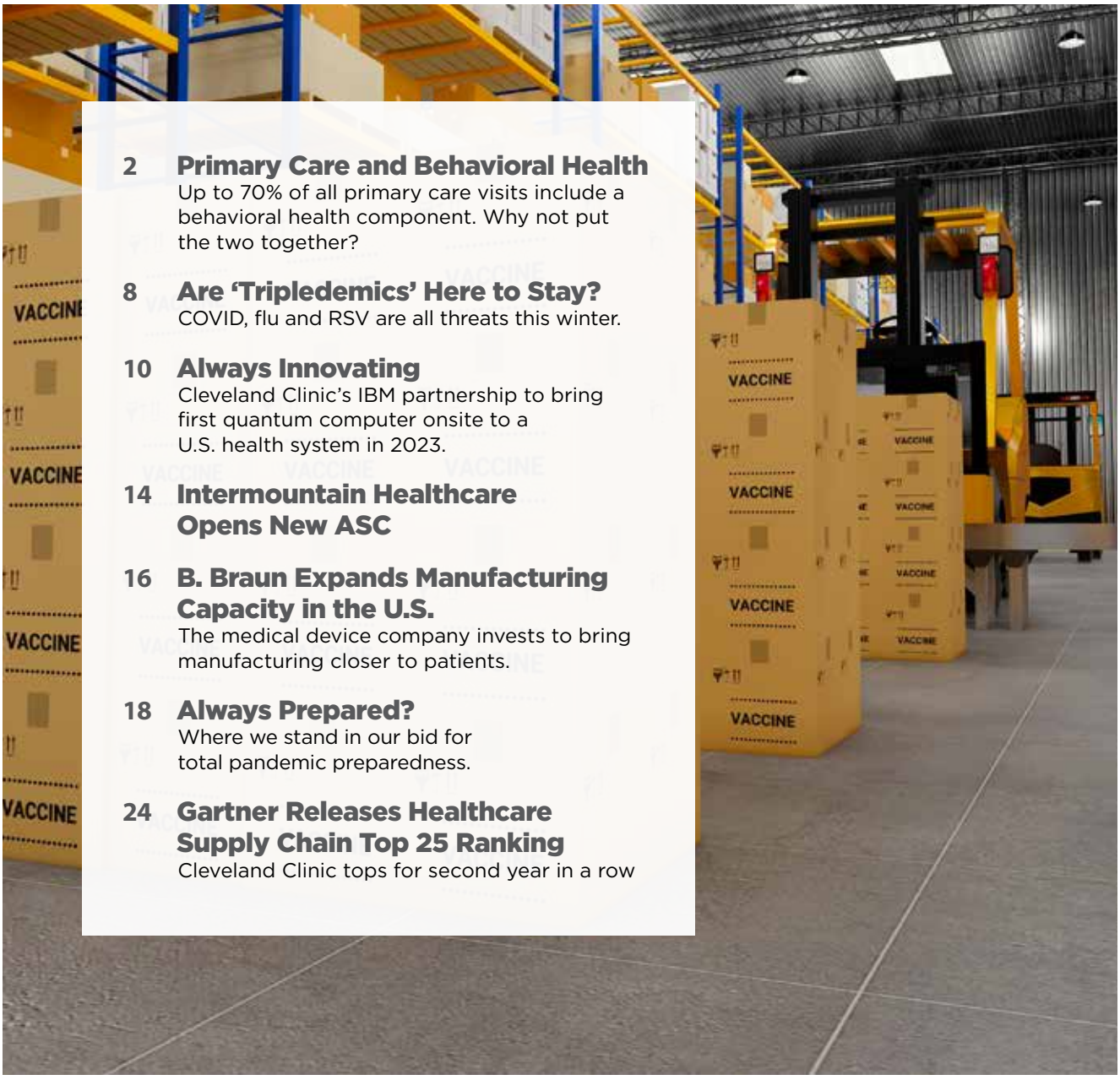

The Journal of Healthcare Contracting is published bi-monthly
by Share Moving Media
1735 N. Brown Rd. Ste. 140
Lawrenceville, GA 30043-8153
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The Journal of Healthcare Contracting (ISSN 1548-4165) is published bi-monthly by Share Moving Media, 1735 N. Brown Rd. Ste. 140, Lawrenceville, GA 30043-8153.

Primary Care and Behavioral Health

Up to 70% of all primary care visits include a behavioral health component. Why not put the two together?

Accessing behavioral health services in the United States is becoming increasingly difficult even as the need for such services keeps growing. Some healthcare decision-makers believe that primary care practices can help fill that void. But can they shoulder the task, given the staffing and reimbursement challenges of behavioral health?

"Integrating behavioral health with primary care aims to increase access as well as reduce the stigma associated with seeking mental health treatment," says Sterling Ransone, M.D., FAAFP, president of the American Academy of Family Physicians. "Without a system in place to routinely screen for behavioral health conditions and substance use disorder in the primary care setting, we will miss opportunities to address problems that threaten the health and well-being of our patients, families and communities."

Fifteen to twenty percent of adults in the United States report diagnoses of depression or mental illness, and 10% to 15% report suffering severe psychological distress in the past year, according to a recent report from the Robert Graham Center for Policy Studies in Family Medicine

and Primary Care, a Washington, D.C.-based clinical research group.

COVID-19 exacerbated the situation. Data from the U.S. Government Accountability Office shows that the pandemic increased social isolation and stress, and contributed to higher rates of anxiety and depression symptoms and increased substance use in the U.S. Yet fewer than 50% of those with a mental illness reported receiving care in the past year.

Makes sense

The close relationship between physical and mental health is an oft-cited rationale for integrating behavioral health and primary care. Up to 70% of all primary care visits include a behavioral health component, write leaders of the Behavioral Health Integration (BHI) Collaborative in a recent issue of "Health Affairs." Founded in October 2021, the BHI Collaborative is led by several physician organizations and is intended to support physicians working to combine mental and physical health in their practices.

Behavioral health conditions are a leading contributor to disease burden in the United States, with depressive and substance use disorders among the top 10 causes of death and disability among adults. They are also a leading cause of preventable pregnancy-related deaths. Individuals with co-occurring physical and behavioral health conditions also tend to incur higher healthcare costs and experience worse health outcomes.

Undiagnosed and untreated behavioral health conditions often have physical manifestations, according to the Robert Graham Center. Patients with chronic diseases whose mental health conditions are left undiagnosed or untreated often experience poor management of these chronic diseases and worse clinical outcomes.

"Behavioral health is more than just mental health," says Yalda Jabbarpour, M.D., director of the Robert Graham Center. "It also means identifying the behaviors or thoughts that lead patients to poor health decisions. An example is a patient who just had a heart attack but continues to smoke and eat poorly. Behavioral health clinicians can help address the habits or underlying thought processes that lead someone to do this.

"But also, when patients have uncontrolled mental health issues such as depression or anxiety, their ability to care for their chronic diseases is diminished," she says. "A patient with uncontrolled major depressive disorder will have disordered sleep, disordered eating habits, lack of motivation to do things that used to bring them pleasure, and lack of motivation to leave the house for doctor visits or to take their medications."

'When patients have uncontrolled mental health issues such as depression or anxiety, their ability to care for their chronic diseases is diminished.'

Where we stand today

Today, 118,500 primary care physicians are co-located with nearly 140,000 behavioral health clinicians in 23,000 primary care practices (20% of primary care physicians, 19% of behavioral health clinicians, 38% of primary care practices), according to the Robert Graham Center.

"If co-location means actual integration, this is a great start," says Dr. Jabbarpour. "But a couple caveats. Just because a primary care physician and behavioral health clinician are co-located does not mean they are on the same floor or in the same office. Even if they were, it does not necessarily mean that they work hand-in-hand. Also, the distribution of these providers may not be equal. There may be areas of high behavioral health need that lack integrated behavioral health practices, and areas with lower need that have more than one BHI practice. BHI is growing but I would not say supply is sufficient to meet the demand."

Begins with screening

Behavioral health integration offers convenience for the patient and family, efficiency in consultation, better communication, treatment adherence, co-management, family buy-in and reduction of stigma, says Marian Earls, M.D., MTS, FAAP, chair of the American Academy of Pediatrics Council on Healthy Mental and Emotional Development and chair of the AAP Mental Health Leadership Group, which is focused on mental health integration in pediatric practice. "In addition, it eliminates the knee-jerk reaction of immediately referring for concerns. The wait times for a referral can be significant. Even if a referral is made, primary care intervention ... and follow-up can begin immediately."

Routine screening optimizes prevention and early identification, she says. "Every child should have a social/emotional screen, appropriate for age,

at each of their well visits. Regardless of result, the screen is discussed with the family. If it shows concerns, engaging the patient and family in secondary screening and planning, providing diagnostic evaluation (or referring for evaluation), management, co-management with a mental health specialist if indicated, and regular follow-up would occur."

No single model

Successful integration of behavioral health care can occur along a spectrum, from coordinated to fully integrated care, with the Collaborative Care Model (CoCM) being one of the models.

In the Collaborative Care Model, a care manager coordinates care of the patients with significant mental health concerns which call for the consultation of a psychiatrist, says Dr. Earls. This model requires that the practice maintain a contract with a psychiatrist and a registry of such patients. The care manager communicates with the psychiatrist and shares recommendations with the primary care provider.

"But this model has limited use in pediatrics," she says. "Most mental healthcare in the pediatric setting involves children and adolescents with functional issues or concerns that don't rise to the level of a DSM-5 diagnosis," that is, a standard classification of mental health disorders. "For those who do have a DSM-5 diagnosis, the needs are primarily mild to moderate. In addition, the significantly limited number of child and adolescent psychiatrists makes wide availability for contracting with practices unlikely.

A second model – the Primary Care Behavioral Health Model – is more consistent with pediatric practices, say Dr. Earls. In this model the mental health clinician is a member of the family-centered medical home team and:

- Participates in morning "huddles."
- Partners during routine visits and provides immediate triage and response to positive screens.
- Gets involved routinely in visits for children with chronic/complex conditions.
- Provides self-management counseling for patients with chronic medical conditions.
- Engages in "warm handoffs," that is, handoffs conducted in person between the medical and behavioral health team, often in front of the child and family.
- Provides liaison with the mental health specialty system, schools, and agencies.
- Monitors the child's/adolescent's course.

up and understanding community resources. Meanwhile, mental health clinicians become more knowledgeable about routine preventive care, development and the mental health needs associated with chronic conditions.

"When we first decided to do this, people knew we needed help but didn't know the model," says Dr. Earls, speaking of her experience with behavioral health integration dating back 20 years. At the time, she was medical director of Guilford Child Health (now Triad Adult & Pediatric Medicine), a nonprofit practice in Greensboro, North Carolina, which primarily served kids from families living under 200% of the federal poverty level. "We knew if we just put a mental health clinician down the hall and referred kids, their schedule would fill up quickly, limiting capacity. So we didn't want a traditional model," she says.

'Before behavioral health integration, we might refer a family to a mental health agency, but we didn't know who they were going to see, and we could only hope they would be matched with someone with expertise with the age group.'

Doctors benefit too

Behavioral health integration benefits doctors and staff as well as patients and their families, according to adherents.

Integrating a mental health professional in pediatric practice provides cross-fertilization, or bi-directional learning between primary care clinicians and mental health clinicians, says Dr. Earls. "Primary care clinicians become more comfortable interpreting screening, having conversations with patients and families, providing follow-

"Our practice had a fairly large percentage of children and adolescents with chronic medical conditions. One example would be those with sickle cell disease – a main stressor. They may miss school because of pain, and their parents might miss work to take care of them. Add to that the stress of hospitalization." Pediatric practices deal with a host of other issues, such as the adolescent with type 2 diabetes who has decided to stop taking

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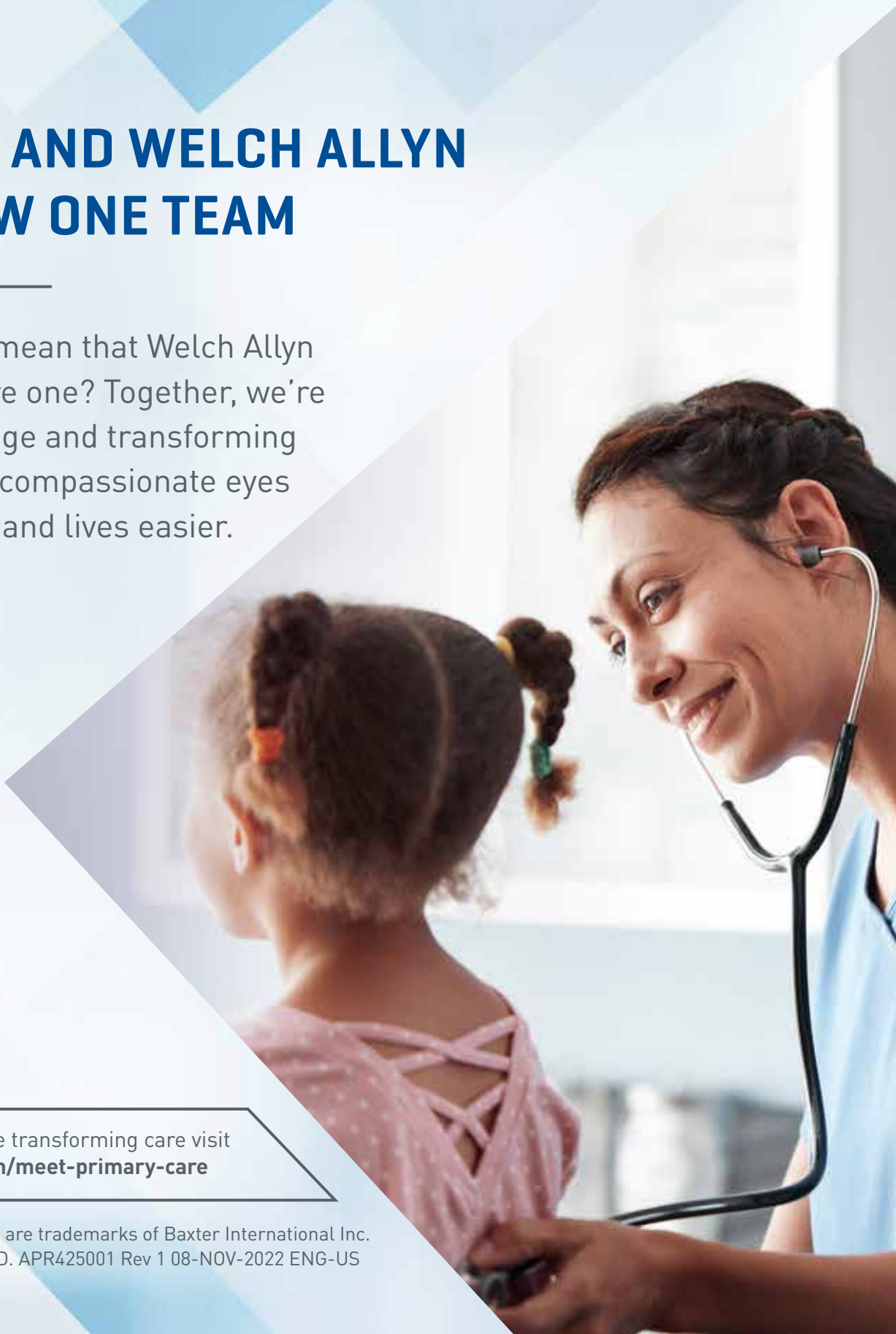

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meds, or children with severe asthma or developmental issues.

"Before behavioral health integration, we might refer a family to a mental health agency, but we didn't know who they were going to see, and we could only hope they would be matched with someone with expertise with the age group," says Dr. Earls. "That was especially difficult because at the time, a lot of public mental health work was done predominantly with adults, often with significant issues. Kids and their parents can feel very uncomfortable in a waiting room full of adults with diagnosed mental health issues. And later we might find out they never got to a mental health clinic at all, or they weren't satisfied with the care they received.

"With an integrated mental health clinician, we were better able to make a 'warm handoff' to a community mental health clinician for treatment when indicated, and to co-manage."

The Primary Care Behavioral Health Model was a good fit for Guilford. Soon clinicians were clear that they would not want to practice any other way again, she says.

Moving forward

Primary care practices often find that reimbursement for behavioral health is inadequate.

"When a clinician has a visit with a patient, they get paid," says Dr. Jabbarpour. "This leaves out non-billing members of a healthcare team who are essential to behavioral health, like social workers and therapists. Additionally, if a clinician wants to collaborate with a billing behavioral health provider, such as a psychiatrist, they don't get paid sufficiently for that time.

'In order for these practices to stay viable, we need payment reform that moves us towards paying for teams to deliver care.'

"In order for these practices to stay viable and serve patients in their communities, we need payment reform that moves us towards paying for teams to deliver care and not clinicians to deliver services."

The BHI Collaborative points out other obstacles that primary care practices face when trying to implement behavioral health integration:

- Lack of necessary upfront capital, including required training and resources.
- Complex and burdensome billing requirements, particularly in fee-for-service situations and narrow/carveout networks.
- Out-of-pocket patient costs associated with integrated services, which can deter patients from seeking such support.
- Difficulty estimating the net effects of behavioral health integration. "Without a convincingly calculated return on investment, it is challenging for physicians to confidently invest in resources to sustain BHI efforts in their practices," according to the Collaborative.
- Federal and state regulations that make it difficult for practices to share patient information across care team members.
- Difficulty finding and retaining a workforce trained in integrated care.

"More people than ever are struggling with their behavioral health, including both mental health and substance use disorders," write the authors from the BHI Collaborative. "By working collaboratively to address both physical and behavioral patient concerns in primary care, we can begin to properly use BHI to enable holistic health care for all."

Says Dr. Jabbarpour, "Just as there is a shortage and maldistribution of primary care, there is a shortage and maldistribution of behavioral health providers. Both workforces need to be bolstered to meet the demands of the population." ■

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BY PETE MERCER

Are 'Tripledemics' Here to Stay?

COVID, flu and RSV are all threats this winter.

Since early 2020, the word pandemic has been a part of our everyday ver-nacular. Even after almost three years, the pandemic is technically still not over, just entering new phases.

In the last few years, those phases have been variants that were more or less contagious than the previous iterations. Each new wave posed a threat to the uninfected and unvaccinated, perpetuating stages of social distancing. As we spent more time isolated from each other, we weakened our immune systems to infectious respiratory illnesses like the common cold and the flu.

As social distancing has largely fallen to the wayside, the positive cases for the flu have skyrocketed, leading experts to predict a more contagious flu season than the last could of years. Now, some infectious disease experts have forecasted what could be the next phase of pandemic – the tripledemic.

What is a tripledemic?

The tripledemic is the intersection of the flu, COVID-19, and RSV during the holiday season, an already primetime slot for respiratory illnesses. The flu got an early start, as the CDC began reporting seasonal flu activity in the early fall, with an increase in activity in the southeast and south-central parts of the country.

As of November 12, the CDC FluView reported that there were 15,308 (14.7%) positive flu cases and 8,707 hospitalizations in the United States. In the same week, the weekly CDC COVID report found that the average of weekly new cases dropped 3.2% (40,102 cases) compared to the previous week.

"COVID cases are expected to rise during the winter. This will be occurring at the same time we expect to see influenza rates increase while we are already seeing an early start to RSV season," said Dean Blumberg, chief of pediatric infectious diseases at UC Davis Children's Hospital in a press release. "With all three viruses on the rise, we are worried about an increase in the rates of viral infection that may lead to an increase in hospitalizations."

According to a report from WebMD, experts are saying that flu and RSV are "playing catchup" from taking a backseat to COVID in the last few years. Elizabeth Murray, DO, a pediatric emergency medicine doctor at the University of Rochester Medical told WebMD, "RSV has always come around in the fall and winter. It's a perfect storm for all the germs to spread now. They've just been waiting for their opportunity to come back."

Can we avoid it?

While the possibility of infection in a tripledemic might seem more likely than a pandemic, there are still plenty of ways to avoid getting sick this winter. RSV can infect anyone, but children under the age of five and adults over 65 are most susceptible. Because the flu, RSV, and COVID are respiratory infections, symptoms can overlap for each illness.

At the end of the day, the best way to avoid getting infected or spreading infection is to stay home if you're feeling sick. As always, washing hands and getting vaccinated are great ways to protect yourself this season.

Mandy De Vries, a respiratory therapist and director of education at the American Association for Respiratory Care, said to WebMD, "It's important to seek medical attention for any concerning symptoms, but especially severe shortness of breath or difficulty breathing, as these could signal the need for supplemental oxygen or other emergency interventions."


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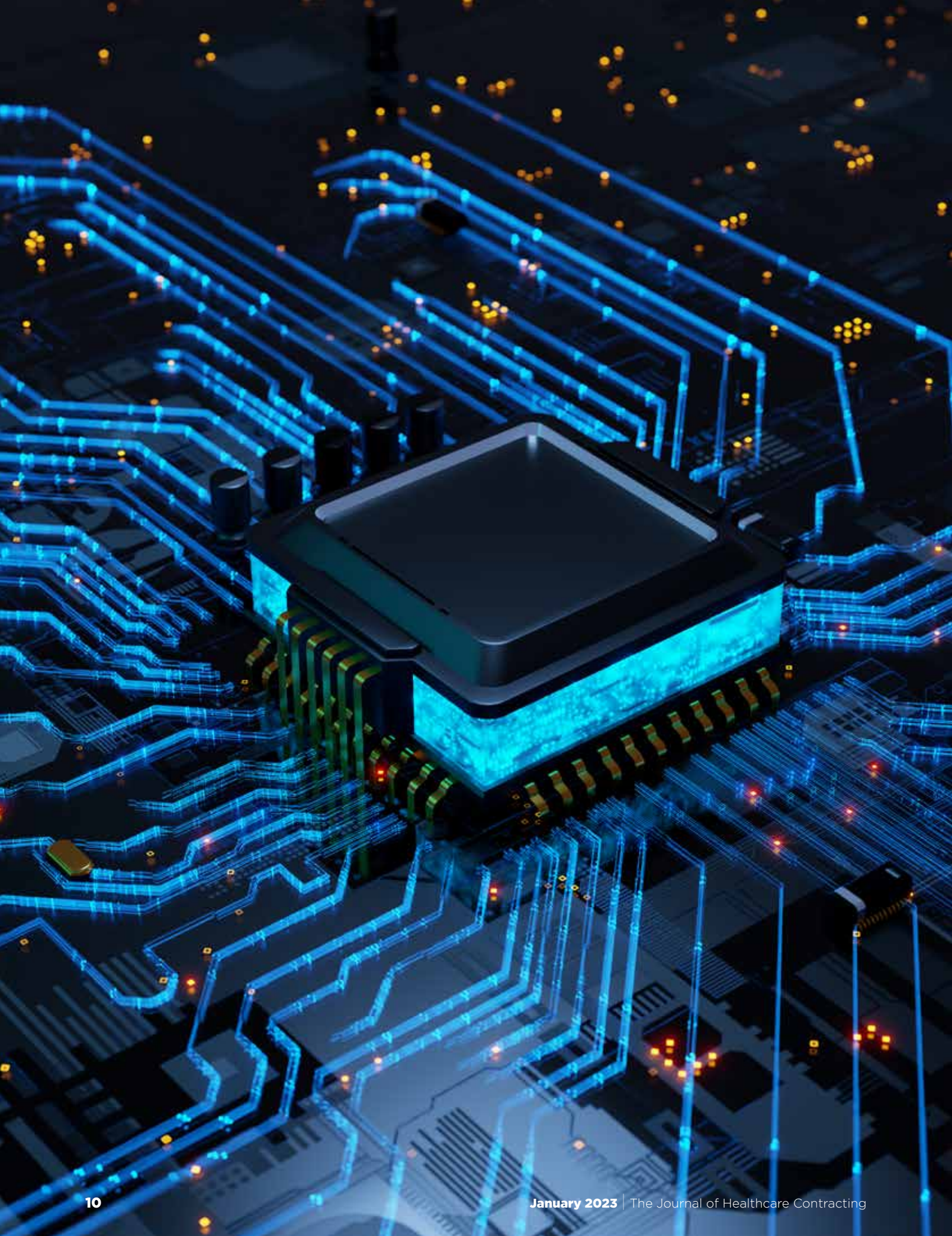

Always Innovating

Cleveland Clinic's IBM partnership to bring first quantum computer onsite to a U.S. health system in 2023.

The first onsite quantum computer in U.S. healthcare is set to be located on Cleveland Clinic's main campus by early 2023. It is a key part of a 10-year partnership between Cleveland Clinic and IBM aimed at fundamentally advancing the pace of biomedical research through high-performance computing.

The Cleveland Clinic-IBM Discovery Accelerator is a joint center that leverages Cleveland Clinic's medical expertise with IBM's technology expertise. The IBM-managed quantum computer will advance high-performance computing in healthcare through:

- A Generative Toolkit for Scientific Discovery and other generative modeling capabilities leveraging AI to infer knowledge gaps and generate hypotheses, and ultimately aim to speed up the research process in therapeutics and biomarkers discovery.
- RXN, a cloud-based platform that combines AI models and the ability to directly control robotic labs to enable end-to-end design and synthesis of new chemical compounds.
- Deep Search, a next-generation AI tool for generating insight from large amounts of structured and unstructured technical literature.
- High-performance hybrid cloud computing technologies that enable researchers to "burst" their workloads into the cloud and access the resources they need at scale.

"Cleveland Clinic is always innovating," Steve Downey, chief supply chain and patient support services officer for Cleveland Clinic, told an audience at IDN Insights East in Philadelphia, hosted by *The Journal of Healthcare Contracting*, this fall. "We're encouraged to, and IBM's quantum computing is the latest example of that."

The lab team at Cleveland Clinic is working on a good manufacturing practice (GMP) facility for individualized medicine to work in tandem with the Discovery Accelerator, according to Downey.

"It's in the future, but you'll show up, get your DNA scanned, figure out the best possible treatment for you, which might include a gene correction, and we'll be able to manufacture it right next door," he added. "You'll be treated before you go home with an individualized therapy."

The Discovery Accelerator has already developed a quantum computing method to screen and optimize drugs targeted to specific proteins, improve a prediction model for cardiovascular risk following non-cardiac surgery, and use AI to search genome sequencing findings and large drug-target databases to find effective, existing drugs that could help patients with Alzheimer's and other diseases.

Educating the supply chain team

Just as Cleveland Clinic leans on IBM for its technology expertise, it also leans on its manufacturers and suppliers to educate its supply chain team about new products.

"Supply chain leaders are sitting at board meetings now," Downey said. "So, any insights that manufacturers and suppliers can provide us about their products or their processes allows us to have better conversations at board meetings."

Cleveland Clinic uses Excelerate Strategic Health Sourcing, a joint venture with Ohio Health and Vizient, to work with other health systems on products, education and innovation. "We work with them on what's happening in sourcing and what's new," Downey explained.

Imagine Cleveland Clinic as a three-wheeled bicycle, Downey said – like an old Big Wheel from childhood. The patient carries the big wheel at the front and that's what matters most, but the back two wheels are education and innovation at the Cleveland Clinic.

"It's always on the cutting edge," he said. "With IBM, we're getting the first quantum computer. With Oracle, it was a development agreement to do new things. And for a lot of our suppliers, it's what extras can be done."

Supply chain is the bridge in the organization and in the chain of many business relationships for Cleveland Clinic. "Suppliers can help educate our supply chain team in being that bridge," Downey said. "It's our sourcing team's job to know what's happening in the market. It helps them to learn from the suppliers about their latest products and their latest technology."

The Life Sciences and Healthcare Quantum Innovation Hub

Thanks to its work in advancing medical research through quantum computing, Cleveland Clinic was selected as a founding partner and the leading health system in a new initiative meant to spur collaboration and innovation in the quantum computing industry. The Life Sciences and Healthcare Quantum Innovation Hub, based in Greater Washington, D.C., is set to prepare the industry for the burgeoning quantum era and align with key national and global efforts in life sciences and quantum technologies.

Cleveland Clinic's role is to define the future of quantum computing in healthcare and disseminate education to other health systems about the possibilities. The Discovery Accelerator center on Cleveland Clinic's main campus was supported by a $500 million investment from the state of Ohio, Jobs Ohio and Cleveland Clinic.

"The current pace of scientific discovery is unacceptably slow, while our research needs are growing exponentially," said Dr. Lara Jehi, chief research information officer for Cleveland Clinic, in a statement. "We cannot afford to continue to spend a decade or more going from a research idea in a lab to therapies on the market. Quantum offers a future to transform this pace, particularly in drug discovery and machine learning." ■

The Life Sciences and Healthcare Quantum Innovation Hub, based in Greater Washington, D.C., is set to prepare the industry for the burgeoning quantum era and align with key national and global efforts in life sciences and quantum technologies.

The collaboration between Cleveland Clinic and IBM is also focused on educating the workforce of the future and creating new jobs. An educational curriculum has been designed for participants from high school students to professionals, offering training and certification programs in data science, machine learning and quantum computing to build a skilled workforce.

"AI learning is needed by everyone," Downey said. "Clinicians will run decisions through AI guidance in the future, but risk is always clinicians' biggest worry. So, keeping them up to date on new improvements in products is critical."

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Intermountain Healthcare Opens New ASC

As healthcare costs continue to rise throughout the country, consumers and patients are looking for lower cost options without sacrificing the quality of care that they need. Ambulatory surgery centers provide that exact type of care experience that so many people in this country are looking for, providing an alternative care route that is financially feasible and efficient.

Intermountain Healthcare recently opened a state-of-the-art ambulatory surgery center at St. George Regional Hospital in St. George, Utah. Intermountain Surgery Center – St. George will offer same-day urology and orthopedic surgeries in four specialized operating rooms, and most patients will be able to recover at home shortly after surgery.

Dr. Jordan Ash, anesthesiologist and medical director for Intermountain Surgery Center, said in a media release, "I'm excited to work in a facility that will be streamlined with the latest technology and designed for specific surgeries. This will also help lower the cost for some of our most common orthopedic surgeries."

"The high cost of healthcare is daunting for many members of our community," said Katie Allsop, the administrator of the Ambulatory Services Center at Intermountain St. George Regional Hospital. "The Intermountain Surgery Center St. George provides a cost-effective surgical outpatient service. Patients know the cost of their surgery up front, which will not change even though there are variabilities like surgery times, supplies used and recovery."

This facility, like many ambulatory sites throughout the country, is designed to provide outpatient care that includes various orthopedic surgeries, neurological surgeries, urological procedures and gynecological surgeries.

Intermountain Surgery Center is equipped with the latest technology to improve patient care and staff workflow.

Improving efficiency without sacrificing care

Part of the value that ambulatory sites provide both patients and providers is an increased sense of efficiency, without the care processes suffering. Intermountain Surgery Center is equipped with the latest technology to improve patient care and staff workflow.

Allsop said, "The surgery center improves efficiencies for Intermountain by moving appropriate healthy patients to the ASC where they can receive their surgeries and be discharged home without being delayed due to the unpredictability of the hospital OR. Additionally, it frees up operating room time in the hospital for patients who require a higher level of care due to health issues and more complex surgeries."

By adding this ambulatory site, St. George Regional Hospital is able to provide an experience that is not interrupted by emergent add-ons for the providers. "They are partnered with ASC caregivers who know them and are able to anticipate their needs, facilitating great time management during surgery and rapid turn-over between cases," Allsop said. "It benefits patients by providing lower costs, shorter waiting times, lower risk of infection and expert, compassionate care from nursing caregivers trained especially for the fast-paced ASC environment."

Intermountain is adding ambulatory sites across their system. Similar facilities have been developed or are under development in Murray, Logan, Park City, Provo, Saratoga Springs and Ogden, and several more are planned. ■

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The medical device company invests to bring manufacturing closer to patients.

The pandemic and the supply chain crisis exposed vulnerabilities in the healthcare supply chain during the past three years as the U.S. was hit with shortages of critical therapies and medical supplies. International healthcare manufacturers with U.S. customers reassessed their strategies to become more resilient, and reshoring manufacturing back to North America became critical.

B. Braun, an international medical device maker with its global headquarters in Germany, has operated in the Lehigh Valley region of Pennsylvania since 1979. It opened its Allentown, Pennsylvania, campus in 1985 and recently expanded there with a more than $200 million, 310,000-square-foot addition. The expansion will add over 200 jobs to B. Braun's existing 1,500 workforce in Allentown and aims to revolutionize manufacturing of medical devices, including life-sustaining infusion therapy devices to treat millions of patients in the U.S.

"Years before anyone heard of COVID-19 or the supply chain crisis, B. Braun made a commitment to expand its manufacturing capacity in the U.S. by investing more than $1 billion in new and modernized production facilities," said Jean-Claude Dubacher, chairman and CEO of B. Braun of America Inc., in a statement. "The purpose was to increase the production of healthcare products needed to deliver critical care

to patients in the U.S., to keep our manufacturing operations close to our customers and to reduce the potential for future supply disruptions that could put patients at risk."

U.S. plant commitments

B. Braun's U.S. commitments were seen across five states – Pennsylvania, Florida, California, Arizona and Texas – as well as in the Dominican Republic.

The recent Pennsylvania expansion nearly doubles B. Braun's footprint in Allentown, and it includes state-of-the-art digitalization and automation technologies to improve efficiencies and connect all production steps and business processes.

"It will be the medical device plant of the future," Dubacher said.

In Florida, B. Braun recently opened a 218,000-square-foot pharmaceutical manufacturing facility in Daytona Beach. It helps fulfill the manufacturer's commitment to alleviate intravenous (IV) fluid shortages that have recently disrupted basic medical care delivery in the U.S.

B. Braun's operations in California have expanded and modernized in recent years, including its pharmaceutical manufacturing plant in Irvine. These investments increase and improve the security supply of IV solutions, premixed drugs, antibiotics and nutrition products in strong demand by hospitals and healthcare facilities across the U.S.

Its CAPS® business in Arizona – Central Admixture Pharmacy Services Inc. – has significantly expanded the company's ability to meet hospital needs for high-quality, safe and readily available sterile compounding drugs, many of which have been in short supply. A 250,000-square-foot 503B sterile compounding outsourcing facility has been recently completed in Phoenix.

And in Texas, B. Braun's operations in Carrollton are growing. They include investments to modernize and expand the manufacturing and service of automated infusion and pharmacy compounding systems used by U.S. health systems.

STEM education commitments

"We're incorporating the latest digitalization and automation technologies to operate these smart factories," Dubacher said. "We need highly skilled craftspeople and technicians. So, we're investing in our people and partnering with community colleges and technical training schools to improve mechatronics offerings."

B. Braun is also expanding its apprenticeship programs and promoting STEM education – Science, Technology, Engineering and Mathematics – through schools and nonprofit organizations. It has partnerships in Pennsylvania with the Pennsylvania Department of Community & Economic Development, Lehigh Valley Economic Development Corp., Pennsylvania Apprenticeship & Training Office and Workforce Board Lehigh Valley. And it's collaborating with other manufacturers like OraSure, Lutron and Crayola to create a region-wide apprenticeship program that will provide career opportunities for students across the Lehigh Valley region.

"These investments are the building blocks of healthcare in the U.S.," Dubacher said. "They show that manufacturing in America is alive and well. Most of all, they represent B. Braun's promise that we will be there for healthcare providers and the millions of patients who depend on our products."

B. Braun has also recently celebrated the latest expansion of its medical device manufacturing plant in the Dominican Republic. That also allows the manufacturer to increase capacity to manufacture critical IV therapy products and keep the supply chain close to its U.S. customers.

"These investments are the building blocks of healthcare in the U.S. They show that manufacturing in America is alive and well. Most of all, they represent B. Braun's promise that we will be there for healthcare providers and the millions of patients who depend on our products."

– Jean-Claude Dubacher, chairman and CEO of B. Braun of America Inc.

"These investments weren't easy, especially in the middle of a pandemic, but B. Braun followed through on these commitments and we're seeing the results emerge across the country," Dubacher concluded. ■

Always Prepared?

Where we stand in our bid for total pandemic preparedness.

The Girl Scouts, the Boy Scouts and the U.S. Coast Guard have the right idea: They're always prepared. It says so in their mottos. How about the healthcare supply chain? Not quite, as COVID-19 demonstrated. However, since March 2020, lawmakers and supply chain organizations have instituted and promoted many safeguards to better prepare us for next time. They include:

- CARES Act.
- Trucking Action Plan.
- Freight Logistics Optimization Works initiative.
- Ocean Shipping Reform Act of 2022.
- PREVENT Pandemics Act.
- A "fast pass" system for medical supplies and equipment.

So, can we say we are "always prepared?" Maybe not. But it's safe to say we are better prepared.

"Partnerships and information-sharing between the commercial market and federal agencies have never been stronger," says Linda Rouse O'Neill, vice president, supply chain policy, and executive branch relations, Health Industry Distributors

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Association (HIDA). Over 10 federal partners participated in discussions with supply chain executives at HIDA's Pandemic Preparedness Summit on how to continue to build on the partnership, the future of data sharing and communications, she says.

Mike Schiller, senior director of supply chain for the Association for Health Care Resource & Materials Management (AHRMM) of the American Hospital Association, says, "We are better prepared in several aspects, and in others, the changes have been slower to come.

"The biggest factor contributing to our increased preparedness is the amount of public/private collaboration that is taking place – more than I can recall during the tenure of my career. Supply Chain and clinical professionals, trade associations and other subject matter experts are working alongside regulatory experts as we identify the failure points and determine what resiliency is and what steps are necessary to build it into the health care supply chain."

David Mintz, chief supply chain officer for NDC, believes COVID-19 has increased volatility, uncertainty, complexity and ambiguity (VUCA) for supply chains. But, he adds, "Through this experience, most supply chain professionals have improved their expertise and acumen to better manage in this environment. Similarly, processes and technologies have evolved over the last couple of years to better cope with challenges brought to light during the pandemic."

Still, there's plenty of work to be done, he says. "As we bolster the supply chain and continue to address both domestic and global vulnerabilities exposed during the pandemic, achieving a balance between onshore and offshore partnerships will be critical. The onshoring movement was accelerated by the pandemic, and the instabilities uncovered in the supply chain triggered a re-evaluation of costs, risks and resilience that will drive us into a better preparedness plan."

CARES Act

Enacted in March 2020, the CARES Act gave the FDA's Center for Devices and Radiological Health (CDRH) statutory authority to help mitigate and prevent device shortages during or in advance of a public health emergency. It is the first time the FDA was given such authority.

'Long term, we are working on legislation to establish a fast pass pilot program for critical cargo such as medical products.'

The Act requires certain medical device manufacturers to provide information to the FDA on product availability and potential meaningful supply chain disruptions, during or in advance of a public health emergency. With that authority, CDRH can better understand and monitor the complex web of supply chains that feed the medical device industry and be more proactive in solving problems before they occur, according to the FDA. For example, the agency worked with testing and diagnostics manufacturers to help ease shortages of resins that were the result of the February 2021 Texas winter storm.

CDRH reports it is working with over 1,000 manufacturers and suppliers in 12 countries to manage and monitor supply chain shortages identified on the FDA shortages list, as well as other devices deemed critical to public health during the pandemic. The agency also says it has repurposed 130 employees to work full- or part-time on shortages.

Trucking Action Plan

In December 2021, the U.S. Departments of Transportation and Labor announced a Trucking Action Plan, intended to address shortages in the trucking workforce. Seventy-two percent of goods in America are shipped by truck, and in most communities, trucks are the only form of delivery, according to the White House. "But outdated infrastructure, the COVID-19 pandemic, and a historic volume of goods moving through our economy have strained capacity across the supply chain, including in trucking."

The Action Plan is intended to accelerate the expansion of Registered Apprenticeship programs for drivers, take steps to address pandemic-driven delays in getting a commercial driver's license, curb the proliferation of low-quality training, and expand more seamless paths for veterans and underrepresented communities, such as women, to access good driving jobs.

Freight Logistics Optimization Works

Though not specifically targeting healthcare, the Biden administration's

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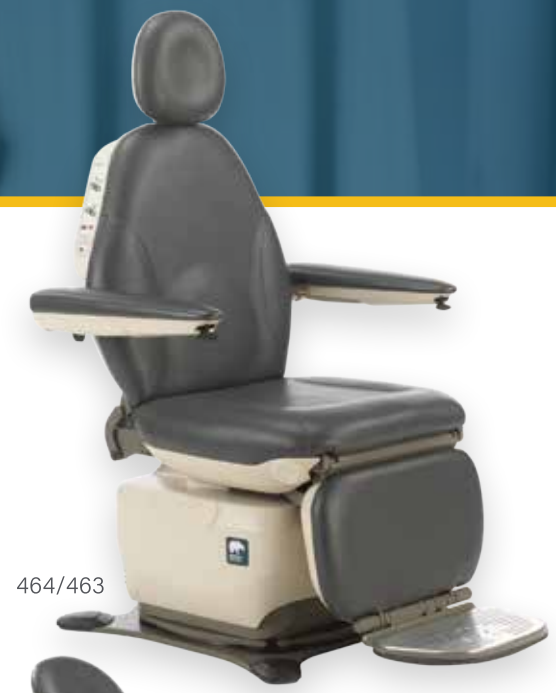

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Freight Logistics Optimization Works (FLOW), led by the Department of Transportation, will pilot the exchange of key freight information among 18 participating supply chain companies, including ports, ocean carriers, terminal operators, businesses, trucking firms and logistics/warehousing firms.

"The goods movement chain is almost entirely privately operated and spans shipping lines, ports, terminal operators, truckers, railroads, warehouses, and cargo owners such as retailers," according to the White House. "These different actors have made great strides in digitizing their own internal operations, but they do not always exchange information with each other. This lack of information exchange can cause delays as cargo moves from one part of the supply chain to another, driving up costs and increasing goods movement fragility."

Ocean Shipping Reform Act

Like FLOW, the Ocean Shipping Reform Act, signed into law in June 2022, is not healthcare-specific, but its provisions will have an impact on importation of medical goods.

The Act is intended to control "demurrage and detention" fees for shipping containers, which rose dramatically during COVID-19. ("Demurrage" refers to charges raised when a full container is not moved out of the port terminal for unpacking within the allowed free days offered by the shipping line, according to Chicago-based logistics firm project44. "Detention" refers to fees raised when the importer picks up the container for unpacking but has not returned the empty container to the depot within the agreed free-time.)

FLOW increases the authority of the Federal Maritime Commission to investigate complaints about detention and demurrage charges charged by common ocean carriers, and order refunds for unreasonable charges. It also prohibits common ocean carriers, marine terminal operators or ocean transportation intermediaries from unreasonably refusing available cargo space.

PREVENT Pandemics Act

In March 2022, two U.S. senators introduced the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Pandemics Act), intended to strengthen public health and medical preparedness and response systems in the wake of COVID-19.

'The PREVENT Pandemics Act takes a comprehensive approach to the lessons learned from the federal response to the COVID-19 pandemic.'

Among other provisions, the Act – which was pending in the Senate as of mid-September – calls for establishment of an Office of Pandemic Preparedness and Response Policy (OPPRP) within the Executive Office of the President to advise on pandemic preparedness and response policy and support coordination within the federal government related to it.

If passed, the Act would pick up several pieces from earlier proposed legislation to improve the Strategic National Stockpile (SNS). For example, it would:

- Amend the SNS Annual Threat-Based Review to include an assessment of the supply chains and any vulnerabilities for products that SNS plans to purchase.
- Clarify that the Department of Health and Human Services should ensure that items in the stockpile are in working condition so they can be readily deployed when needed.
- Require that HHS issue guidance on how states, territories, and Tribes can access the SNS.
- Authorize HHS to enter into contracts for the SNS to enhance surge capacity and supply chain flexibility through vendor-managed inventory and warm-base domestic manufacturing arrangements.
- Authorize HHS to sell excess products from the SNS to other entities when the cost of maintaining these products in the SNS is not appropriate to meet the needs of the SNS.

The PREVENT Pandemics Act has received endorsements from HIDA as well as the National Governors Association.

"The PREVENT Pandemics Act takes a comprehensive approach to the lessons learned from the federal response to the COVID-19 pandemic," says Patrick Bailey, vice president, Congressional relations, HIDA. "It includes input from industry, including HIDA, that recognizes

the vital role of public-private partnerships in managing medical supplies during a pandemic."

The National Governors Association expressed its support for the PREVENT Pandemics Act in a letter in April to the sponsoring senators. "During the early phase of the pandemic, when PPE shortages were widespread, governors did not have transparency into what was in the Strategic National Stockpile and how decisions were being made on the distribution of these critical supplies," they wrote. "States scrambled to find essential medical supplies and competed against ourselves and the federal government to procure those scarce supplies.

"It is critical that the federal government be transparent with governors as to what is in the SNS, assist states in maintaining adequate and updated medical supplies in their state stockpiles, incentivize domestic manufacturing of PPE and medical supplies, and ensure an equitable and fair distribution of federal support in order to mitigate the spread and reduce the impact of future pandemics."

Fast Pass

HIDA and two other groups – the Advanced Medical Technology Association (AdvaMed) and International Safety Equipment Association (ISEA) have expressed support for a Critical Cargo Program, or "fast pass" system, which would prioritize critical medical supplies and equipment during current and future pandemics, and align transportation operations – shipping, railroad, trucking and small parcel carriers – to support healthcare during public health emergencies.

In an October 2021 letter to the U.S. Department of Transportation, HIDA's Linda Rouse O'Neill pointed out the plan, if implemented, would:

- Prioritize critical supplies for container access and sea freight space.
- Ensure first available railcar and chassis.
- Provide for 24/7 transportation operations during a public health emergency.
- Develop an intermodal communication plan on when and how medical products can be accessed.

"Through our Shipping Council, HIDA has brought together distributors with port officials to expedite medical products through ports such as Los Angeles, Long Beach, Savannah and the Port Authority of New York & New Jersey," O'Neill said in September. "We have brought the issue to the attention of federal officials at the Federal Maritime Commission and U.S. Department of Transportation. We are encouraged by this outreach. Long term, we are working on legislation to establish a fast pass pilot program for critical cargo such as medical products."

What's next?

While the U.S. healthcare system may be better prepared than it was before the pandemic, it must sustain certain "touch points," such as strengthening of the Strategic National Stockpile, says O'Neill. "Otherwise, we will lose the 'muscle memory' of crisis response that can be used during the next adverse event.

"As leaders in our industry, it is incumbent on us to keep this synergy going so the next set of stakeholders won't have to reinvent the wheel for the next challenge. Additionally, we need to work with policymakers for constant and reliable funding to carry forward the partnerships and collaborative work done through the COVID-19 response."

Says Mintz, "In addition to the many initiatives, time will also be a factor towards improving U.S. preparedness. The pandemic continues to significantly change demand patterns and supply capacities, often creating meaningful imbalances that lead to shortages. Over time, as specific markets become more stable, market forces coupled with technological innovations will naturally drive supply and demand into better alignment."

Mike Schiller of AHRMM believes that "many moving parts need to be aligned before a comprehensive resiliency solution is in place – not just within the U.S. health care supply chain, but the global supply chain. Resiliency comes at a cost. Onshore/near-shore manufacturing, multisource contracts, building buffer inventory within the existing supply chain infrastructure, aligning incentives and the thoughtful adoption of technology will all require culture change, considerable financial and human resources, and process redesign." ■

Gartner Releases Healthcare Supply Chain Top 25 Ranking

Cleveland Clinic tops for second year in a row

Cleveland Clinic was named the top supply chain in the annual Gartner Healthcare Supply Chain Top 25 ranking. Banner Health, Corewell Health (formerly Spectrum Health/BHSH), Advocate Aurora Health and Ochsner Health rounded out the Top 5

Gartner's ranking, now in its 14th year, focuses on U.S.-based health systems and includes an environmental, social and governance (ESG) measure for the first time. This year, increasing financial pressures was identified as a key challenge weighing on healthcare chief supply chain officers (CSCOs).

"While in years past we have seen an emphasis on cost and efficiency related to capabilities, this year is different," said Eric O'Daffer, vice president analyst with the Gartner Supply Chain practice. "Costs are higher and margins are decreasing. The expectation is for supply chains to drive cost savings, while simultaneously adding services and increasing resiliency."

Cleveland Clinic is tops in the ranking for the second consecutive year. "In its second consecutive year in the number one position, Cleveland Clinic continues to demonstrate leadership in many facets of supply chain," O'Daffer said. "This includes their work on supply chain initiatives focused on supplier diversity, clinical integration, a resiliency program and workforce optimization."

Four healthcare providers made their debut in the 2022 ranking: Stanford Health Care, Allina Health, CommonSpirit Health and Sutter Health. Providence returned to the ranking for the first time since 2018.

The Healthcare Supply Chain Top 25 for 2022:

1. Cleveland Clinic
2. Banner Health
3. Corewell Health
4. Advocate Aurora Health
5. Ochsner Health System
6. AdventHealth
7. UPMC
8. BJC HealthCare
9. Geisinger
10. Baylor Scott & White Health
11. Trinity Health
12. Northwestern Medicine
13. Stanford Health Care
14. Bon Secours Mercy Health
15. Rush Health
16. Scripps Health
17. Mercy
18. Novant Health
19. Ascension
20. Allina Health
21. CommonSpirit Health
22. Duke Health
23. Sentara Healthcare
24. Providence
25. Sutter Health

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