YEAR-END REPORT - 2022

Published 19-Dec-2022
HPTS Issue Brief 12-19-22.4

Health Policy Tracking Service - Issue Briefs
Business of Health
Business of Healthcare

This Issue Brief was written by Melissa D. Berry, a principal attorney editor on the Publisher's Staff and a member of the Ohio bar.

12/19/2022

I. INTRODUCTION

Court Revives Health Worker COVID-19 Vaccine Mandate in 26 U.S. States

(Reuters) - A federal appeals court on Wednesday revived in 26 U.S. states a COVID-19 mandate issued by President Joe Biden's administration requiring millions of healthcare workers to get vaccinated if they work in facilities that receive federal dollars. [FN2]

In a rare win for Biden's pandemic strategy, a three-judge panel of the 5th U.S. Circuit Court of Appeals in New Orleans ruled that a lower court had the authority to block the mandate in only the 14 states that had sued and was wrong to impose a nationwide injunction.

The Biden administration mandate requires that healthcare facilities get staff vaccinated against the coronavirus or lose funding from the U.S. Centers for Medicare & Medicaid Services, which administers the two large government healthcare programs.

The rule initially required more than 2 million unvaccinated healthcare workers to be vaccinated by Dec. 6. It was blocked before the deadline and remains temporarily blocked in 24 states - the 14 states involved in the case reviewed by the 5th Circuit and 10 states where the mandate was blocked by a Nov. 29 ruling from a federal judge in St. Louis.

The 14 states that sued are: Alabama, Arizona, Georgia, Idaho, Indiana, Kentucky, Louisiana, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah and West Virginia.

The administration argued that the mandate will potentially save thousands of lives every month, with COVID-19 cases and deaths expected to spike with the onset of winter and arrival of the fast-spreading Omicron coronavirus variant. Numerous lawsuits have been filed seeking to block vaccine mandates issued by governments and businesses as public health measures amid a pandemic that has killed more than 800,000 Americans.

The 5th Circuit ruling said the Biden administration had not made a strong showing that it was likely to prove during the litigation that it has the authority to impose the rule. The panel included Judge Leslie Southwick, appointed by Republican former President George W. Bush, and Judges James Graves and Gregg Costa, both appointed by Democratic former President Barack Obama.

The rule is one of three far-reaching Biden administration requirements aimed at boosting vaccination rates in the United States, where infections are rising and deaths remain above 1,000 per day. Republican state attorneys general and conservative organizations and businesses have challenged the rules.

In November, the 5th Circuit blocked the administration's workplace vaccine-or-testing mandate for businesses with at least 100 employees. That mandate, issued by the Occupational Safety and Health Administration (OSHA), is being reviewed by the 6th U.S. Circuit Court of Appeals in Cincinnati, dominated by judges appointed by Republican presidents.

On Wednesday, the 6th Circuit sided with the Biden administration, agreeing to hear the case initially before a three-judge panel rather than all 16 active judges on the court.

Two Republican-appointed judges used their dissenting opinions from that order to spell out their opposition to OSHA's mandate, which could indicate the court is leaning toward reviving the agency's rule.

'The judges who wrote the opinions could be concerned the court is going to go the other way,' said Brian Abramson, an author on vaccine law.

U.S. Supreme Court Issues Contrasting Decision on Vaccine Mandates

(Regulatory Intelligence) - Two recent decisions by a divided U.S. Supreme Court present significant implications for future government action regarding vaccine mandates and its ability to contain the continuing COVID-19 pandemic. [FN3]

Health Agency Rule

In a 5-4 ruling, the Supreme Court lifted injunctions against the Omnibus Health Care Staff Vaccination Rule issued by the Centers for Medicare & Medicare Services (CMS) for all nursing home staff and federally funded health care facilities. Conservative Justices Roberts and Kavanaugh joined liberals in the majority arguing that the rule falls within the government's authority to impose conditions on Medicare/Medicaid funds and that ‘vaccination requirements are a common feature of the provision of health care in America.”

In a statement by CMS, Administrator Chiquita Brooks-LaSure expressed pleasure with the decision, citing that the vaccine will cover 10.4 million health care workers at 76,000 medical facilities. Brooks-LaSure underlined the importance of vaccinations for health care workers and the system at-large, stating that:

'The prevalence of the virus and its ever-evolving variants in health care settings continues to increase the risk of staff contracting and transmitting COVID-19, putting their patients, families, and our broader communities at risk. And health care staff being unable to work because of illness or exposure to COVID-19 further strains the health care system and limits patient access to safe and essential care.”

CMS said it is currently implementing the health care worker vaccination rule in 25 states and territories not covered by preliminary injunctions and that this decision will allow it to fully implement the rule nationwide.

National Nurses United (NNU), the largest union and professional association of registered nurses in the U.S., also praised the Supreme Court's decision in a press release:

'We are gratified with today's 5-4 court decision that, frankly, should have been unanimous, to support one important safety measure — vaccination for health care workers — which must be part of the total program of infectious disease containment measures NNU has long outlined,” said NNU President Zenei Triunfo-Cortez, RN.

OSHA Rule

In a simultaneous 6-3 decision, the Supreme Court rejected the Occupational Safety and Health Administration's (OSHA) rule requiring workers at large employers (100+ employees) to be vaccinated or tested regularly. The Court argued that the OSHA rule was not an ordinary use of federal power and that COVID-19 does not play as great of a risk in the general workplace, comparing it to daily crime and pollution hazards faced by everyone.

Both CMS and NNU criticized this decision.

'CMS is disappointed in the decision on the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard, and agrees with President Biden and Secretary Walsh: This is a major setback for the health and safety of workers across the country.”

NNU took issue with the majority's argument that the spread of infection in unsafe workplaces is not an ‘occupational hazard”:

'That twisted logic ignores the disproportionate number of infections, hospitalizations, and deaths among tens of thousands of essential workers over the past two years, from infections that have been contracted on the job,” said Triunfo-Cortez. ‘We will not beat this pandemic until we stop the spread of the pandemic at work.”

The National Federation of Independent Business (NFIB), which challenged the OSHA rule and represents employers, applauded the decision. ‘Today's decision is welcome relief for America's small businesses, who are still trying to get their business back on track since the beginning of the pandemic,” said Karen Harned, executive director of the NFIB's legal arm.

Next Steps

CMS has issued revised guidance that states must ensure that health care workers have at least one vaccination within 30 days and be fully vaccinated by March 15. Anyone in patient-facing positions in nursing homes accepting either Medicare of Medicaid funding are subject to the rule.

President Biden expressed disappointment with the OSHA rule decision and said it is now up to states and employers to decide whether to require workers ‘to take the simple and effective steps of getting vaccinated.”

Biden to Extend U.S. National Emergency Due to COVID-19 Health Risk

(Reuters) - President Joe Biden said on Friday the U.S. national emergency declared in March 2020 due to the COVID-19 pandemic will be extended beyond March 1 due to the ongoing risk to public health posed by the coronavirus. [FN4]

Biden said the deaths of more than 900,000 Americans from COVID-19 emphasized the need to respond to the pandemic with ‘the full capacity’ of the federal government.

Former President Donald Trump had declared a national emergency almost two years ago to free up $50 billion in federal aid.

'There remains a need to continue this national emergency,' Biden said in a letter on Friday to the speaker of the House of Representatives and the president of the Senate.

The letter was released by the White House.

The emergency would have been automatically terminated unless, within 90 days prior to the anniversary date of its declaration, the president sent a notice to the Congress stating it is to continue beyond the anniversary date.

Biden's step to extend the emergency comes even as a slew of local leaders in the United States are dialing back pandemic restrictions as the Omicron wave ebbs.

The governors of New York and Massachusetts announced last week that they would end certain mask mandates in their states, following similar moves by New Jersey, California, Connecticut, Delaware and Oregon.

U.S. health officials said earlier this week they were preparing for the next phase of the pandemic as Omicron-related cases decline.

Hospitals Seek Federal Protection to Curb Violence against Healthcare Workers

(Regulatory Intelligence) - The American Hospital Association has called on the U.S. Department of Justice to support legislation that would protect health workers from increased instances of workplace violence since the start of the COVID-19 pandemic. The trade association has called for similar protections that were extended to airline crews and airport workers last year, when the Biden administration raised fines and increased prosecutions for passengers accused of violating travel masks and testing mandates and attacking airline workers trying to enforce these requirements. [FN5]

Violence against hospital employees has increased significantly since the onset of the pandemic and is showing no sign of receding, the AHA said. Staff at hospitals have reported multiple instances of racist and violent physical attacks, sometimes resulting in grave injury over the last two years.

Studies indicate 44 percent of nurses report experiencing physical violence and 68 percent report experiencing verbal abuse during the pandemic, according to the AHA.

'For medical professionals, being assaulted or intimidated can no longer be tolerated as ‘part of the job.’ This unacceptable situation demands a federal response,” the association's Chief Richard Pollack said in a letter to Attorney General Merrick Garland.

Violence in hospitals not only harms health care workers but also makes it more difficult for them to provide quality patient care, the AHA said. Violent interactions at health care facilities also tie up valuable resources and can delay urgently needed care for other patients, the letter said.

HHS Takes Actions to Promote Safety and Quality in Nursing Homes

On April 11, the Centers for Medicare & Medicaid Services (CMS) issued its fiscal year (FY) 2023 Skilled Nursing Facilities Prospective Payment System (SNF PPS) proposed rule, which includes asking for public feedback on how staffing in nursing homes and health equity improvements could lead to better health outcomes.

The proposed rule builds upon the Biden-Harris Administration's commitment to advance health equity, drive high-quality person-centered care, and promote sustainability of its programs. The rule is an important step in fulfilling its goal to protect Medicare skilled nursing facility (SNF) residents and staff by improving the safety and quality of care of the nation's SNFs (commonly referred to as nursing homes). The SNF PPS provides Medicare payments to over 15,000 nursing homes, serving more than 1.5 million people. Medicare spending to nursing homes is projected to be approximately $35 billion in FY 2022. Through the SNF PPS proposed rule, CMS is continuing its work to transform the SNF payment system to a more patient-centered model by making payments based on the needs of the whole patient, rather than focusing on the volume of certain services the patient receives.

'Everyone deserves to receive safe, dignified, and high-quality care, no matter where they live,” said Health and Human Services Secretary Xavier Becerra. ‘Today we are starting the necessary work to ensure our loved ones living in nursing homes receive the best care at the staffing levels they need. We are working hard to deliver on President Biden's commitment to protecting seniors and improving the quality of our nation's nursing homes.”

The SNF PPS proposed rule aims to realize the President's vision for the nation's nursing homes as outlined in his State of the Union Address, with a focus on providing safe, dignified, and appropriate care for residents. As part of this vision, the Biden-Harris Administration recently set a goal to improve the quality of nursing homes so that seniors, people with disabilities, and others living in nursing homes get the reliable, high-quality care they deserve. A key part of reaching this goal is addressing staffing levels in nursing homes, which have a substantial impact on the quality of care and outcomes residents experience.

'The COVID-19 pandemic has highlighted serious problems at some of the nation's nursing homes that have persisted for too long. And we have seen the tragic impact that inadequate staff resources can have on residents and staff,” said CMS Administrator Chiquita Brooks-LaSure. ‘The Biden-Harris Administration has promised that we will work with all stakeholders to do better for nursing home residents, and today's proposed rule includes important steps toward our goal to promote safety and quality of care for all residents and staff.”

In the SNF PPS proposed rule, CMS is soliciting input to help the agency establish minimum staffing requirements that nursing homes will need to meet to ensure all residents are provided safe, high-quality care, and nursing home workers have the support they need. This input will be used in conjunction with a new research study being conducted by CMS to determine the optimal level and type of

nursing home staffing needs. The agency intends to issue proposed rules on a minimum staffing level requirement for nursing homes within one year.

CMS is also requesting stakeholder input on a measure that would examine staff turnover levels in nursing homes for possible inclusion in CMS' SNF Value-Based Purchasing (VBP) Program, which rewards facilities with incentive payments based on the quality of care they provide to people with Medicare. Looking at the relationship between staff turnover and quality of care, preliminary analysis by CMS has shown that as the average staff turnover decreases, a facility's overall rating on CMS' Nursing Home Five Star Quality Rating System increases, which suggests that lower turnover is associated with higher overall quality. CMS will use the stakeholder feedback to inform a proposal of this measure to include in the SNF VBP Program in the future.

In January, CMS began posting nursing home staff turnover rates (as well as weekend staff levels) on the Medicare.gov Care Compare website, and CMS will be including this information in the star rating system starting in July 2022. This information helps consumers better understand each nursing home facility's staffing environment and also helps providers to improve the quality of care and services they deliver to residents.

The proposed rule also proposes the adoption of 3 new measures into the SNF VBP Program:

· The Skilled Nursing Facility Healthcare Associated Infections Requiring Hospitalization (SNF HAI) is an outcome measure that assesses SNF performance on infection prevention and management.

· The Total Nursing Hours per Resident Day is a structural measure that uses auditable electronic data to calculate total nursing hours per resident each

· The Adoption of the Discharge to Community ? Post Acute Care Measure for SNFs (DTC) is an outcome measure that assesses the rate of successful discharges to community from a SNF setting.

To advance health equity and address the health disparities that underlie the U.S. health care system, CMS is requesting stakeholder feedback on the role health equity plays in improving health outcomes and the quality of care in nursing homes. Specifically, CMS is seeking comment on how to arrange or classify measures in nursing home quality reporting programs by indicators of social risk to better identify and reduce disparities.

CMS is proposing a 3.9%, or $1.4 billion, update to the payment rates for nursing homes, which is based on a 2.8% SNF market basket update plus a 1.5 percentage point market basket forecast error adjustment and less a 0.4 percentage point productivity adjustment. The proposed rule also contains a proposed adjustment to payment rates as the result of the transition to the SNF payment case-mix classification model ̶ the Patient Driven Payment Model (PDPM) that went into effect on October 1, 2019. When finalizing the PDPM, CMS also stated that the transition to PDPM would not result in an increase or decrease in aggregate SNF spending. Since PDPM implementation, CMS' data analysis has shown an unintended increase in payments. Therefore, CMS is proposing to adjust SNF payment rates downward by 4.6%, or $1.7 billion, in FY 2023 to achieve budget neutrality with the previous payment system. As a result, the estimated aggregate impact of the payment policies in this proposed rule would be a decrease of approximately $320 million in Medicare Part A payments to SNFs in FY 2023 compared to FY 2022.

Ohio Jury Finds Doctor Not Guilty of Murder in Fentanyl Case

(Reuters) - An Ohio jury on Wednesday found Dr. William Husel, who had been accused of giving patients lethal doses of fentanyl, not guilty of 14 counts of murder, the Columbus Dispatch newspaper reported. [FN6]

Husel, a former doctor with the Columbus-area Mount Carmel Health System, was accused in Franklin County of purposely causing the death of 14 patients between 2015 and 2018. He faced 15 years to life in prison for each count.

The jury, which initially could not come to an agreement, deliberated for a week after the seven-week trial ended.

Husel's defense attorneys argued that the doses of fentanyl - a potent painkiller - that he administered to patients was intended to comfort them and that death for critically ill patients was imminent, the Dispatch reported.

Prosecutors told the jury that Husel's actions hastened the death of the patients.

Husel faces more than 10 civil lawsuits from the families of patients who died while under his care, while several families have settled suits worth millions of dollars, the Dispatch reported.

Husel was part of a wave of U.S. doctors charged for their role in a public health crisis that the Centers for Disease Control and Prevention (CDC) said led to a record 47,600 U.S. opioid-related overdose deaths in 2017.

The CDC reported that more than 75,000 people died from opioids overdoses in the 12-month period ending in April 2021.

Fentanyl, often given for intense pain associated with cancer, is 100 times more powerful than morphine.

U.S. Health Agency CMS Updates Long-term Care Facility Health and Safety Standards

(Regulatory Intelligence) - U.S. health regulators have updated guidance the minimum health and safety standards that long-term care facilities must meet to participate in the federal Medicare and Medicaid health programs. [FN7]

The federal Centers for Medicare and Medicaid Services issued the new guidance in the State Operations Manual, used by the surveyors who perform inspections of LTC facilities to determine whether facilities are complying with CMS' requirements. The updates from CMS are intended to advance goals of President Joe Biden's administration outlined in conjunction with his State of the Union address in March. The manual will be updated online on October 24, when the changes take effect.

One of the more crucial updates will be the regulation of infection control in LTC facilities. The new guidance will require that all LTC facilities have an on-site infection-prevention professionals, who is to work at least part-time at the LTC facility. Such ‘infection preventionists' -- who specialize in preventing and stopping the spread of infections, are critical to mitigating infectious diseases in LTC facilities. The infection preventionist must have obtained specialized infection prevention and control training beyond their initial professional training or education prior to assuming this role. A free training course that meets these requirements is available through CMS.

Other issues addressed by the guidance include:

• Staffing requirements. Surveyors are to use the CMS payroll-based journal system to review whether a facility employed sufficient staff to provide care and services to residents. The change is intended to make it easier to identify potential noncompliance with CMS' nurse staffing requirements. CMS has provided further clarification to the guidance in the State Operations Manual that surveyors follow in determining whether a LTC facility is in compliance with staffing regulations.

• Mental health and substance abuse disorder. The updated guidance clarifies the minimum level of knowledge and skills of facility staff to ensure that the policies and practices do not conflict with the rights of residents with mental health and substance use challenges.

• Abuse. The guidance clarifies compliance for abuse reporting by providing sample reporting templates and providing examples of abuse at various severity levels.

• Resident rights and visitation guidelines. The guidance provides clarification and technical corrections on these issues.

• Arbitration. The guidance also clarifies existing requirements for compliance when arbitration agreements are used by LTC facilities to settle disputes, and clarifies timeliness of state investigations and communication to complainants in order to improve consistency across states.

Further information about these updates can be found in CMS QSO-22-19-NH memorandum.

Biden Administration Stresses Abortion Care in Emergency, Federal Protection for Providers

(Regulatory Intelligence) - The U.S. Dept of Health and Human Services in new guidance to healthcare providers on Monday reiterated that women must be provided with abortion care in case of a health emergency anywhere in the United States, in line with the federal emergency care statute and regardless of a state law's restrictions on abortions. [FN8]

Almost all states with abortion bans have exceptions for emergency care if the pregnant woman's life is in danger, but health experts have worried that physicians and hospitals may delay such care in states with tough legal restrictions, potentially endangering the life of the patient such as in the case of an ectopic pregnancy. States with abortion bans have largely made it a felony to perform an abortion, with penalties ranging from fines to life imprisonment.

Monday's guidance clarifies that emergency stabilizing treatment could include medical and/or surgical interventions, including abortion. If a state's law prohibits abortion without an exception for the health or life of the pregnant person or draws the exception more narrowly than the federal Emergency Medical Treatment and Active Labor Act (EMTALA) — that state law is preempted, the guidance stated.

The HHS said any physician or hospital violating this requirement may be subject to civil monetary penalties or the termination of its Medicare provider agreement, in accordance with the emergency medical act. Physicians may also be excluded from Medicare and state health care programs, the HHS said.

The EMTALA statute protects public access to emergency health stabilizing services regardless of ability to pay. Its enforcement is driven by complaints and an ensuing investigation.

President Joe Biden had directed HHS in an executive order last week to safeguard access to reproductive care for women while protecting the privacy and safety of providers and patients involved in abortion as restrictive laws mushroom across states after the Supreme Court's verdict overturning the Roe v. Wade precedent that upheld access to abortion care for women across the country.

'As frontline health care providers, the federal EMTALA statute protects your clinical judgment and the action that you take to provide stabilizing medical treatment to your pregnant patients, regardless of the restrictions in the state where you practice,” HHS Secretary Xavier Becerra wrote in a letter to healthcare providers.

'Today, in no uncertain terms, we are reinforcing that we expect providers to continue offering these services... when needed for emergency care,” Becerra said in a statement.

Ten states are already enforcing abortion bans with very limited exceptions. Arizona, West Virginia and Wisconsin have stopped offering abortion care, according to Guttmacher Institute. About 10 more states have bans being contested in court or waiting to go into effect soon, the reproductive rights advocacy organization said.

The HHS, which issued the new guidance through the Centers for Medicare & Medicaid Services (CMS), said emergency medical conditions involving pregnant patients may include ectopic pregnancy, complications of pregnancy loss, or hypertensive disorders such as preeclampsia.

'Under federal law, providers in emergency situations are required to provide stabilizing care to someone with an emergency medical condition, including abortion care if necessary, regardless of the state where they live," said CMS Administrator Chiquita Brooks-LaSure.

The EMTALA statute also requires that Medicare hospitals provide patients with medical screening, examination, stabilizing treatment, and transfer to a different facility irrespective of individual state laws or mandates.

Biden Administration Widens ACA's Nondiscrimination Clause to Include Abortions, LGBT People

(Regulatory Intelligence) - The Biden administration on Monday proposed a new rule to interpret the Affordable Care Act's healthcare nondiscrimination protections on gender more widely, to include LGBT people and to clarify that care related to pregnancies includes abortions. The proposal also, for the first time, seeks to ensure that the protections will be extended to care received via telehealth as well. The proposal seeks to both revoke Trump administration restrictions on nondiscrimination protections, as well as respond to the U.S. Supreme Court's ruling this year eliminating constitutional protections for abortion rights. The U.S. Department of Health and Human Services' (HHS) proposed rule would prohibit health-care providers and insurers from denying care or discriminating against patients based on sexual orientation, gender identity, pregnancy and abortion. In 2020, President Donald Trump's administration restricted the scope of the nondiscrimination clause to biological sex, as assigned at birth. [FN9]

The agency said the proposed requirements would apply to all health insurers that receive federal financial assistance. It also seeks to widen the net of providers that fall in that category by interpreting Medicare Part B as federal assistance. Part B of the federal Medicare program covers most physician services, even that received while in hospital, outpatient therapy and medical equipment providers.

The HHS' move to expand the scope of Section 1557, the Affordable Care Act's nondiscrimination provision, comes as several states have enacted laws restricting access to most abortions and transgender care, especially for teenagers.

'Standing with communities in need is critical, particularly given increased attacks on women, trans youth, and health care providers," HHS' Secretary Xavier Becerra said.

The health agency said the proposed protections for transgender care align with the federal court opinion in Bostock v. Clayton County case that upheld civil rights protections for the LGBT community.

The proposal also seeks to reinstate foreign language assistance requirements for communities with limited English proficiency and will require auxiliary aids and services to ensure 'effective communication and reasonable modifications" to policies and procedures for people with disabilities, the HHS said.

The Trump administration had rolled back mandatory ACA protections that provided access to interpretation and translation services for individuals with limited English proficiency, saying it would relieve costs and regulatory burden and reduce confusion.

The proposed rule now requires services to be extended in at least 15 most common languages spoken besides English, the acting Director for the HHS' Office for Civil Rights, , Melanie Rainer, said on a call with reporters. 'This work will help eliminate avoidable differences in health outcomes experienced by those who are underserved and provide the care and support that people need to thrive,' said Chiquita Brooks-LaSure, administrator for the Centers for Medicare & Medicaid Services which runs the federal government's Medicaid and Medicare program.

California AG Launches Inquiry into Bias in Healthcare Algorithms

(Regulatory Intelligence) - California Attorney General Rob Bonta sent letters to 30 hospital CEOs across the state in late August 'requesting information about how healthcare facilities and other providers are identifying and addressing racial and ethnic disparities in commercial decision-making tools.' The letters are the first step in an investigation into whether commercial healthcare algorithms have discriminatory impacts based on race and ethnicity. [FN10]

Algorithms are defined as 'mathematical formulas and models that combine different variables or factors to inform a calculation or an estimate,' often an estimate of risk. Healthcare algorithms are used across many functions in the healthcare industry from administrative work to diagnostics. They may be used to 'help providers determine a patient's medical needs,' including the need for referrals and specialty services.

However, the algorithms are 'not fully transparent to healthcare consumers' or 'healthcare providers.' As a result, although they can streamline processes and improve patient care, they can also have 'unintended negative consequences, especially for vulnerable patient groups.'

'Our health affects nearly every aspect of our lives ? from work to our relationships. That's why it's so important that everyone has equal access to quality healthcare," Attorney General Bonta said in a release. 'We know that historic biases contribute to the racial health disparities we continue to see today. It's critical that we work together to address these disparities and bring equity to our healthcare system. That's why we're launching an inquiry into healthcare algorithms and asking hospitals across the state to share information

about how they work to address racial and ethnic disparities when using software products to help make decisions about patient care or hospital administration.'

The letter asks hospitals to provide the following information:

• A list of all purchased decision-making tools, products, software systems or algorithmic methodologies currently in use for clinical decision support, population health management, care management, utilization management, operational optimization and payment management.

• The purposes for which the tools are currently used and the policies, procedures, training or protocols that apply to their use.

• The identity of the person responsible for ensuring the tools do not have a 'disparate impact based on race or other protected characteristics.'

California's investigation into potential racial bias in healthcare algorithms fits within the context of multiple recent reports of such bias.

Bias in healthcare algorithms and underlying data

In a May 2022 report on the impact of race and ethnicity in healthcare delivery, Deloitte identified the need to reevaluate 'long standing clinical algorithms' to help ensure all patients receive the care they need. Deloitte recommended forming teams to evaluate clinical algorithms, how race is used in the algorithm and whether 'race is justified.'

The Deloitte report also identified 'long-standing issues around the collection and use of race and ethnicity data in health care--due to both lack of standards and misconceptions.' The report noted Centers for Disease Control and Prevention findings that race and ethnicity data were not available 'for nearly 40% of people testing positive for COVID-19 or receiving a vaccine.' It also cited a 2019 study that found algorithmic bias in kidney function equations using a 'race-correction' coefficient that resulted in delayed treatment for Black patients with chronic kidney disease.

The Pew Charitable Trusts also reported on the U.S. Food and Drug Administration review of medical devices using artificial intelligence and the algorithms that underlay the artificial intelligence. It pointed to limitations with an algorithm to 'predict which patients at U.S. Department of Veterans Affairs hospitals were most likely to experience a decline in kidney function.' However, because 94% of the patients in the training data were men, the algorithm was less effective for women. The model was not implemented for patient care.

The Pew report identified another instance where the algorithm used to identify patients with complex healthcare needs looked not only at clinical factors but also 'used past health care costs to predict future health care needs.' As a result, the algorithm identified White patients for additional care, even though the Black patients tended to be sicker. Because Black patients 'often face greater barriers to accessing care,' they had spent less on care in the past. As a result, the algorithm perceived them as less sick.

These examples demonstrate that a lack of data or the improper weighting of data can lead to poor clinical outcomes. In some instances, the use of race or ethnicity may not be appropriate in making healthcare decisions.

Biden administration action on healthcare equity

The U.S. Agency for Healthcare Research and Quality published its research protocol on the impact of healthcare algorithms on racial and ethnic disparities in health in January 2022. The agency will identify sample algorithms that 'have the potential to impact racial/ethnic disparities in access to care, quality of care, or health outcomes.' The agency will then abstract relevant data and appraise key features of each algorithm.

The systematic review of healthcare algorithms will help the agency determine whether racial and ethnic variables are useful data or whether their 'inclusion as variables within healthcare algorithms may lead to unknown or unwanted effects, including the potential for exacerbation and/or perpetuation of health and healthcare disparities.'

The Office of the National Coordinator for Health Information Technology has been holding public events and hearings on the issue of artificial intelligence and machine learning 'to aid decision-making in health care settings.' The office notes that these predictive technologies 'may positively or negatively impact patient safety, introduce or propagate bias, and result in increased or reduced costs.' Additionally, Department of Health and Human Services Secretary Xavier Becerra has asked the office 'to take a deep look at algorithmic bias and its implications for health equity to ensure that all Americans get the benefits that modern analytic technologies can provide,' according to media reports.

A rule proposed from the Centers for Medicare and Medicaid Services that is open for comment until October 3, proposes provisions related to discrimination in the use of clinical algorithms in healthcare decision making. The clinical use of algorithms has not been addressed in previous Section 1557 rulemaking. The proposal would prohibit discrimination against any person on the basis of race, color, national origin, sex, age or disability through the use of clinical algorithms.

CDC Awards Over $3 billion to Strengthen U.S. Public Health Infrastructure

(Reuters) - The Centers for Disease Control and Prevention (CDC) said on Tuesday it is awarding more than $3 billion to help strengthen public health workforce and infrastructure across the United States after the COVID-19 pandemic put severe stress on them. [FN11]

The public health agency's funding includes $3 billion from the American Rescue Plan announced by President Joe Biden's administration last year, and would cover all state, local and territorial health departments across the country.

It also includes $140 million from a new appropriation to those jurisdictions and an award of $65 million to three public health entities to help provide training and technical assistance.

'The pandemic severely stressed (the health) agencies, which were already weakened by neglect and underinvestment,' said CDC Director Rochelle Walensky. ‘This grant gives these agencies critical funding and flexibility to build and reinforce the nation's public health workforce and infrastructure.’

II. MERGERS AND ACQUISITIONS

U.S. Sues to Stop Merger of Rhode Island Hospital Companies

(Reuters) - The U.S. Federal Trade Commission said on Thursday that it would file a lawsuit aimed at stopping the merger of Rhode Island's two largest health care providers, Lifespan Corp and Care New England Health System. [FN12]

The agency, which voted unanimously to oppose the deal, said it and the Rhode Island attorney general's office were concerned the merger would create a ‘healthcare conglomerate with outsized power.’

'This proposed merger is a bad deal for patients who are likely to see higher hospital bills, lower quality of care, and fewer cutting-edge medical services,' said FTC Bureau of Competition Director Holly Vedova in a statement.

The FTC said its complaint would allege that the deal would give the combined company at least 70 percent of the Rhode Island market for treatments that require a hospital stay and an equally high share of the market for in-patient behavioral health services.

Care New England President James Fanale said in a statement that the companies were disappointed. ‘I will say that we can truly know that we did everything we could over the past few years of hard work to get this done. We thought it was the right thing to do, but now we will need to move on to a new path forward,’ he said.

A spokeswoman for the company declined to say if a decision had been made to terminate the transaction.

Healthcare Trust of America, Healthcare Realty to Combine in Medical REIT Deal

(Reuters) - Healthcare Realty Trust Inc and Healthcare Trust of America Inc have agreed to merge, the companies said on Monday, creating the largest medical office landlord in the United States. [FN13]

The combined real estate investment trust will have 727 properties in its portfolio and a pro-forma total enterprise value of $17.6 billion as of Thursday's close.

Activist investor Elliott Investment Management had urged Healthcare Trust of America in October to explore a potential sale, saying the company's longstanding underperformance compared to its peers has stoked frustration among shareholders.

Healthcare Trust's shareholders will receive a total implied value of $35.08 per share, including a special cash dividend of $4.82 per share and a transaction exchange ratio of 1:1, the companies said.

Healthcare Trust's stock has traded between $20 and $35 since 2016, which resulted in Elliott's letter to the company.

The offer values Healthcare Trust of America at $7.75 billion, based on 220.8 million outstanding shares, according to Reuters calculations.

Healthcare Trust's shares fell nearly 4% in premarket trading on Monday, while those of Healthcare Realty tumbled 8%.

The deal is structured as a reverse merger. Healthcare Trust of America will become the corporate successor, while the company's name will be Healthcare Realty Trust Inc.

After the transaction closes, which is expected in the third quarter, Healthcare Realty shareholders will own 39% stake in the combined entity, while the remaining will be held by Healthcare Trust shareholders.

FMC's U.S. Division Health Partners in $2.4 billion Three-way Merger

(Reuters) - Dialysis provider Fresenius Medical Care has agreed to merge its U.S. unit Fresenius Health Partners with medical services groups InterWell Health and Cricket Health to expand in the care of earlier stages of kidney disease. [FN14]

FMC, the world's largest operator of dialysis centres for patients whose kidneys have failed to cleanse the blood, said in a statement on Monday the combined group would be valued at $2.4 billion with FMC owning a majority stake.

The addition of InterWell, a network of nephrology practices that FMC co-owns, and kidney care provider Cricket will help FMC to expand in the area of kidney disease patients who do not yet require dialysis.

That would increase Fresenius Medical Care's total addressable market in the U.S. from around $50 billion to around $170 billion, the statement said.

Financial terms were not disclosed. FMC expects the transaction could close in the second half of this year.

The new entity will operate under the InterWell Health brand, it added.

U.S. Hospital Association Urges Federal Agencies to Revise Merger Enforcement Guidelines

(Regulatory Intelligence) - The American Hospital Association trade group is urging federal regulators to revise guidelines governing hospital mergers amid a rise in industry acquisitions. [FN15]

The association wrote to the U.S. Federal Trade Commission and the U.S. Department of Justice federal agencies on March 30 and urged a revision to 'align with long-standing legal and economic principles and contemporary market realities.' The group was responding to a request from the FTC and the DOJ's Antitrust Division for public comment on ways to update merger guidelines 'to better detect and prevent illegal, anticompetitive deals in today's modern markets.' Hospital and health-system acquisitions have risen since 2020, raising concerns that reduced competition could lead to an increase in prices.

The hospital association said no 'major revisions' were needed, but changes in the merger evaluation process were needed to account for 'procompetitive efficiencies,' that could benefit to patients and payers. Mergers facilitate higher quality of care in a more 'cost-effective manner' due to increased scale and better standardization of care protocols, the association asserted.

The American Hospital Association represents nearly 5,000 member hospital, health systems and other health care organizations as well as more than 270,000 clinician partners and 43,000 health care leaders.

Current merger guidelines

The FTC and DOJ analyze hospital mergers using the same basic framework as they use for other mergers. The Justice Department said the process considers issues such as whether the merger is 'likely to have adverse competitive effects,' whether there are factors sufficient 'to deter or to counteract' the competitive concerns; whether there are efficiency gains; and whether, but for the merger, either entity would fail.

Although the agencies only challenged hospital mergers infrequently in the past, the increasing number of hospital systems now in highly concentrated markets and the increasing volume of mergers and acquisitions has attracted more regulatory attention, including from the White House. President Joe Biden's Executive Order on Promoting Competition in the American Economy called on the FTC and DOJ to 'review the horizontal and vertical merger guidelines' and consider whether to revise those guidelines. In the order issued July 9, 2021, Biden cited concerns that hospital mergers were resulting in 'inadequate or more expensive healthcare options' in the country. In the accompanying fact sheet, the White House noted the 'ten largest healthcare systems now control a quarter of the market' and that hospitals in consolidated markets charge 'far higher prices.'

Suggested revisions to merger guidelines

In response to the agencies' joint request for information, the American Hospital Association takes a pro-merger position that encourages the agencies to revise the merger guidelines to recognize benefits from mergers while downplaying factors that might weigh against a merger. The first revision the hospital association recommends is to correct 'defects in the economic models' the federal agencies currently use to evaluate hospital transactions. These defects result in 'inaccurate forecasts about the effects of hospital mergers on consumers,' according to the association. The association argues the FTC's demand models 'overemphasize how much value patients assign to travel times,' while ignoring other factors such as past experiences, physician admitting privileges and physician referrals.

The association also argues that the FTC's supply-side model has a flawed reliance on 'upward pricing pressure' in 'horizontal' merger guidelines. Horizontal mergers involve similar entities such as two hospitals merging together. 'Vertical' mergers, on the other hand, involve the merger of dissimilar entities such as a hospital and physician practice group.

The agencies currently use the upward pricing pressure model to measure the 'first impulse for a merged firm to raise prices.' This model does not account for a marketplace - such as hospitals - where the prices are negotiated with governments and insurers rather than set by the seller, according to the hospital association.

The association also states concerns that the FTC's models fail to consider the responses of competing hospitals or insurers to changes in merged or acquired hospital prices. It further questions the FTC's reliance on the concept of willingness to pay to 'measure how much consumers value access to a hospital.'

The second suggestion the association makes is to revise the guidelines to 'enable the antitrust agencies to account for the improved coordination of care' resulting from mergers.

Acquisitions and mergers can 'lower costs' and 'improve coordination and clinical integration,' according to the association. The association points to research, much of which it conducted, that acquisitions and mergers can 'provide measurable benefits to patients in the form of lower health care costs, improved patient care and better access to providers.'

Using existing guidelines against insurers

The hospital association also encourages federal agencies to focus on insurance companies, which are often the ultimate payer of hospital bills. The association said the agencies should use their existing authorities to 'challenge anti-competitive mergers and

deceptive conduct by insurance companies.' The association stated its support for the DOJ's recent suit to prevent UnitedHealth Group's proposed acquisition of Change Healthcare. The DOJ sued to block the deal over concerns it would result in UnitedHealth Group having access to 'access to a vast amount of its rival health insurers' competitively sensitive information' and result in an anti-competitive advantage to the insurer.

The association also encouraged the agencies to use their expanded authorities under the Competitive Health Insurance Reform Act of 2020 (CHIRA) to 'investigate and challenge anti-competitive practices' by healthcare, dental and vision insurers. The act limits the antitrust exemption available to health insurance companies under the McCarran-Ferguson Act and clarifies that, 'except for certain activities that improve health insurance services for consumers, the conduct for health insurers is subject to the federal antitrust laws.'

The hospital association points to actions by health insurers in the 'increasingly concentrated health insurance sector,' including price increases, restricted competition, inadequate networks and 'bait-and-switch tactics' that can change coverage, limit patient choice and increase out-of-pocket costs.

Impact of mergers and acquisition in healthcare

According to the KPMG 2022 Healthcare and Life Sciences Investment Outlook, hospital and health system acquisitions were up more than 26% from 2020 to 2021. KPMG notes that LifePoint Health agreed to acquire Kindred Healthcare in June 2021, resulting in a 'new company with 79 hospital campuses in 25 states.' The recently finalized merger of Spectrum Health and Beaumont Health resulted in a Michigan system with '22 hospitals, 64,000 employees and $13 billion in revenue.' The Beaumont-Spectrum merger includes Priority Health, which covers 1.2 million insureds under Spectrum Health.

KPMG expects that as smaller hospitals and health systems 'continue to struggle' as a result of staffing and revenue issues secondary to the COVID-19 pandemic, many may be 'forced to partner with, or be acquired by, larger institutions.'

Thomson Reuters contributed data to KPMG's report.

Researchers critical of the increased consolidation of hospital and health systems point to evidence that 'many hospital mergers raise prices' and state that 'concentrated markets are associated with higher prices and lower clinical quality.' They also note that 80% of hospital markets in the United States are 'highly concentrated' according to 2010 FTC and DOJ horizontal merger guidelines.

A 2020 Medicare Payment Advisory Commission (MedPAC) report to the U.S. Congress also found that by 2017, 'in most markets, a single hospital system had more than a 50 percent market share of discharges.' MedPAC also found that 'most studies find consolidation leads to higher provider prices and higher premiums for private insurance.' MedPAC is an independent congressional agency that provides advice on issues affecting the Medicare program.

U.S. Health Agency's Data Shows Nursing Home Ownership Changes Outpacing Hospitals

(Regulatory Intelligence) - The Centers for Medicare and Medicaid Services (CMS) has for the first time published data on 'mergers, acquisitions, consolidations, and changes of ownership' from hospitals and nursing homes enrolled in Medicare. The data, released on April 20 and covering the previous six years, provides information for researchers, law enforcement agencies and the public to understand the 'impacts of consolidation on health care prices and quality of care,' CMS said. [FN16]

A second, related report from the Department of Health and Human Services provides an analysis of the CMS data, examining trends in changes of ownership over the last six years. One key finding is that the pace of nursing home acquisitions has exceeded that of hospitals over the reporting period.

The new data and analysis are intended to support President Joe Biden's executive order on promoting competition in the U.S. economy. They also aim to advance the administration's goal of 'improving transparency around nursing facility ownership and enhancing nursing home safety and quality," as outlined in Biden's plan for improving nursing home care, as outlined in his State of the Union address.

'Hospital and nursing facility consolidation leaves many underserved areas with inadequate or more expensive health care options," CMS Administrator Chiquita Brooks-LaSure said in an announcement. 'This new data gives researchers, state and federal enforcement agencies, and the public new opportunities to examine how mergers, acquisitions, consolidations, and changes of ownership impact access to care, care quality, and prices as a way to enable greater transparency and insight into the hospital and nursing home industries."

According to the analysis of the new CMS data, changes in ownership have been much more common in nursing homes than hospitals over the last six years. From 2016 to 2021, 348 hospitals were sold, or nearly 10 hospitals per 1,000 per year. In contrast, 3,236 skilled nursing facilities were sold during that period or nearly 40 per 1,000 facilities per year.

Tracking ownership data can also be useful for tracking healthcare quality in skilled nursing facilities. Critics contend the role of private equity and private investment firms in the skilled nursing facility market has forced facilities to 'cut back on quality' and may have made them 'ill equipped to respond to the Covid-19 pandemic.' Academic research has also shown that private equity acquisition of skilled nursing facilities is 'associated with increases in short-term mortality and shifts in resources from patient care toward non-patient care items.'

The data also shows a wide variation in hospital ownership changes across the country during the study period. South Carolina had the highest rate with more than 19 percent of it 73 hospitals changing ownership during the six-year period. Kentucky, New Jersey and Connecticut all had rates of change above 10 percent. However, most states had rates of hospital ownership change below 4 percent.

The analysis also found that a majority (62.3%) of skilled nursing facilities that were purchased have a ‘single organizational owner,’ nearly 7%, have multiple organizational owners and 18% have only individual owners. More than 12% of facilities have both types of owners.

CMS intends to release updated change of ownership data on a quarterly basis at https://data.cms.gov/.

Amazon Strikes $3.5 billion Deal for One Medical in Long March into U.S. Healthcare

(Reuters) - Amazon.com Inc. on Thursday agreed to buy primary care provider One Medical for $3.49 billion, expanding the e-commerce giant's virtual healthcare and adding brick-and-mortar doctors' offices for the first time. [FN17]

The all-cash deal would combine two relatively small players as Amazon continues a years-long march into U.S. healthcare, seeking to grow at a faster pace.

The online retailer first piloted virtual care visits for its own staff in Seattle in 2019 before offering services to other employers under the Amazon Care brand. It likewise bought online pharmacy PillPack in 2018, underpinning a prescription delivery and price-comparison site it later launched.

'We think healthcare is high on the list of experiences that need reinvention,' said Neil Lindsay, senior vice president of Amazon Health Services.

The Seattle-based retailer has signaled its ambitions to improve and speed up care. However, a big idea akin to how Amazon has automated the role of cashiers in grocery stores has yet to emerge.

In One Medical, Amazon is acquiring a loss-making company with 767,000 members and enterprise clients such as Airbnb Inc. and Alphabet Inc.'s Google, which offer its services as a benefit to employees, according to its website and recent financial results.

Larger rival Teladoc Health Inc., by contrast, has more than 54 million paying members in the United States and double One Medical's quarterly revenue. News of the Amazon deal sent shares of Teladoc as well as drugstore retailers CVS Health Corp. and Walgreens Boots Alliance Inc. down between 0.3% and 1.8%.

The acquisition makes sense as the ‘blending of virtual and in-person care is core to both One Medical and Amazon Care's strategy,’ said Citi analyst Daniel Grosslight.

DEAL SCRUTINY EXPECTED

U.S. Senator Amy Klobuchar, who is also the Chairwoman of the Senate Judiciary Subcommittee on Competition Policy, Antitrust, and Consumer Rights on Thursday urged the Federal Trade Commission (FTC) to investigate Amazon's proposed deal, expressing concerns over the acquisition's implications for personal health data.

'Amazon has a history of engaging in business practices that raise serious anticompetitive concerns, including forcing small businesses on its site to buy its logistics services as a condition of preferred platform placement, using small businesses' non-public data to compete against them.....' the Senator added in her statement.

Amazon Care recently made its virtual care accessible nationwide and added the option for house-calls in Los Angeles, Washington, Dallas and elsewhere. The COVID-19 pandemic helped increase demand as Amazon Care started signing up clients including Hilton Worldwide Holdings Inc.

One Medical, founded in 2007, now gives Amazon 188 medical offices, its recent financial report showed.

Carlyle Group Inc., which had paid $350 million for a minority stake in One Medical in 2018, will exit its position as part of Amazon's acquisition, people familiar with the matter said.

Amazon agreed to pay $18 for each share of One Medical, a premium of 76.8% to the healthcare firm's last close. One Medical shares were trading at $17.12.

The deal is valued at $3.9 billion including One Medical's net debt.

Amazon's limited healthcare presence should minimize antitrust issues, but risks remain, analysts said.

Grosslight said Amazon ‘does seem to have a target on its back, and the DOJ (the U.S. Department of Justice) has been very aggressive in blocking deals recently.’

'That will most definitely subject this acquisition to more scrutiny than normal.'

CVS to Buy Signify Health in $8 billion Deal

(Reuters) - CVS Health Corp on Monday agreed to buy home healthcare services company Signify Health for about $8 billion in cash, a move that will enable one of the largest U.S. healthcare companies to provide further care management to patients in their homes. [FN18]

Healthcare companies like CVS have been expanding beyond managing health and pharmacy benefits with acquisitions of doctors' groups and surgical centers in recent years.

'We've been very clear about what we were looking for in expanding our health services, either be it primary care, provider enablement or in the home, and Signify Health clearly checks off two boxes: into the home and provider enablement,' CVS CEO Karen Lynch said in an interview.

Signify Health brings CVS, which runs pharmacies, pharmacy benefits and the Aetna insurance plans, a network of 10,000 clinicians who provide home-based assessments of patient health and social needs.

CVS expects the deal to close in the first half of 2023 and said that it expects the acquisition to be ‘meaningfully’ accretive to earnings.

CVS said it would pay $30.50 per share for the company, or about $7.6 billion in equity as well as about $400 million in equity appreciation rights.

Lynch said the companies would work with regulators who review deals for any antitrust issues.

'We are not competitors. We don't have any overlapping functions,' Lynch said.

Large mergers and acquisitions have come under intense antitrust scrutiny and lowering healthcare costs has been an important strategic mission for the Biden Administration.

SIGNIFY HEALTH

Signify Health serves two groups of customers: about 50 U.S. health insurance plans including CVS' Aetna division and rivals such as UnitedHealth Group Inc and groups of providers. UnitedHealth and Amazon Inc. are among companies that were interested in Signify, a source familiar with the discussions previously told Reuters.

Signify mostly serves the companies and providers associated with Medicare Advantage health plans, in which private insurers provide government-paid health benefits to people aged 65 and older. It also services Medicaid plans for people with low incomes.

The company said it expects to service 2.5 million people through annual in-person and virtual health assessments. The visits combine with technology and analytics to coordinate follow up care and social services with the goal of improving health of underserved populations and lowering health costs, Signify said.

Signify Health CEO Kyle Armbrester, who will remain as the head of the division, said the company plans to expand to commercial health plans.

The company, which went public in early 2021, has struggled since its stock market launch and had announced a restructuring earlier this summer. Talks of the sale process were first reported in August.

CVS said in a statement that the company is ‘increasingly confident’ it can achieve its long-term earnings goals. As outlined in December of 2021, that includes high single-digit year-over year growth in 2023 and low double-digit year-over-year growth in 2024.

New Mountain Capital, which owns 60% of Signify Health, said that it planned to vote for the deal. CVS and Signify Health said both boards of directors had approved the deals.

CVS was advised by Bank of America's BofA Securities and Signify Health by Goldman Sachs and Deutsche Bank.

Walmart, UnitedHealth to Offer Preventive Healthcare Program for Seniors

(Reuters) - Walmart and healthcare giant UnitedHealth Group are planning to team up to provide preventive care for people aged 65 and up, and virtual healthcare services for all age groups, the companies said on Wednesday. [FN19]

The 10-year partnership represents Walmart's latest push into healthcare and could help the retail giant better compete with CVS Health and Walgreens Boots Alliance.

Walmart's clinics could get a boost of new customers from UnitedHealth's Medicare Advantage members, while UnitedHealth gains access to the largest U.S. retailer's footprint and a venue to enroll more people, Evercore ISI analysts Mike Newshel and Elizabeth Anderson said in a research note.

Walgreens last October invested $5.2 billion in primary-care provider VillageMD, which has more than 200 locations across 15 markets.

Walmart's effort with UnitedHealth will target common ailments among aging Americans such as heart disease and diabetes.

When it gets under way in January, the collaboration is expected to initially offer seniors healthcare at 15 Walmart Health locations in Georgia and Florida. The focus will be on value-based healthcare, a model in which hospitals and doctors' offices are reimbursed for the care they provide through multiple Medicare Advantage plans.

Medicare Advantage plans are run by private insurers and are an alternative to original Medicare, the federal government's health insurance plan for seniors.

The collaboration will initially exclude coverage for members under the original Medicare.

Unlike traditional fee-for-service models, in which health insurers pay doctors a fee for each service provided, value-based health-care payments are tied to measures of a patient's health. The model typically includes dietary guides, cancer screenings and frequent doctor visits.

'We expect that through this partnership, we would grow to serve hundreds of thousands of seniors,' Dan Schumacher, UnitedHealth Group chief strategy and growth officer, said.

'Our goal is to make (healthcare) accessible and keep it affordable using these solutions, particularly in these medically underserved communities,' Dr. Cheryl Pegus, executive vice president of Health and Wellness at Walmart, said.

Walmart already provides physicians, community-health workers, behavioral-health therapists and nurse practitioners to help serve seniors who are ‘already going to buy other products' at Walmart's health facilities, she said.

Walmart's healthcare personnel will be able to use Optum, a health services company owned by UnitedHealth Group, which gives providers data analytics on patients. The collaboration also includes the expected launch of a Walmart and UnitedHealth Group co-branded Medicare Advantage plan in Georgia.

Walmart and UnitedHealth Group had partnered in January to provide free, at-home COVID-19 tests.

McKesson to Buy Pharma Tech Firm Rx Savings for up to $875 million

(Reuters) - Drug distributor McKesson Corporation said on Monday it would acquire private pharma technology firm Rx Savings Solutions for up to $875 million. [FN20]

The company helps health insurers and employers seek lower cost prescription medicines, and also provides ongoing medication reminders to help improve adherence to prescriptions.

'Rx Savings Solutions' offerings for employers and patients will strengthen McKesson's ability to help solve the most common medication challenges related to access, affordability and adherence,' McKesson Chief Executive Officer Brian Tyler said.

The transaction, which includes a $600 million upfront payment and up to $275 million contingent on Rx Savings' financial performance through 2025, is expected to close in the second half of fiscal year 2023.

Judge Denies U.S. Bid to Stop UnitedHealth Plan to Buy Change

(Reuters) - A U.S. judge on Monday denied the Justice Department's bid to stop UnitedHealth Group from buying Change Healthcare, in a blow to the U.S. administration's tougher enforcement of antitrust issues. [FN21]

Change shares rose 7% after the close of trading.

The Justice Department had filed a lawsuit in February aimed at stopping the $8 billion acquisition, saying the deal would give the largest U.S. health insurer access to its competitors' data and ultimately push up healthcare costs.

The department's top antitrust official, Jonathan Kanter, said they are ‘reviewing the opinion closely to evaluate next steps'.

UnitedHealth announced the all-cash deal in January 2021, saying it would help streamline administrative and payment processes.

Judge Carl Nichols said in a brief order on Monday that he would deny the government's request to stop the deal, and ordered the companies to go forward with an asset sale that they had proposed.

The order follows a trial in the case in August in the U.S. District Court for the District of Columbia.

UnitedHealth said it was ‘pleased with the decision’ and looked forward to combining with Change as quickly as possible.

The Justice Department had said that UnitedHealth and Change Healthcare offer competing software for processing healthcare claims and together serve 38 of the top-40 health insurers in the country.

The department argued that access to the claims would give UnitedHealth a view into rivals' health plans, including Humana Inc, Anthem Inc and others.

The loss for the Justice Department follows a recent decision by a Federal Trade Commission judge that genetic analysis equipment maker Illumina should be allowed to buy cancer detection test maker Grail - a move opposed by the agency.

The Justice Department also lost a bid to win convictions of executives at chicken processing companies that it accused of price-fixing.

But the agencies have also had wins, and successfully killed planned deals by Aon Plc and Willis Towers Watson Plc as well as Lockheed Martin's plan to buy engine maker Aerojet Rocketdyne.

Walgreens-Backed VillageMD to Buy Summit Health in $9 billion Deal

(Reuters) - Primary care provider VillageMD, which is backed by Walgreens Boots Alliance Inc, is buying urgent care provider Summit Health in a deal valued at $9 billion, as the second-largest U.S. pharmacy chain expands its healthcare footprint. [FN22]

The deal adds to the rising trend of big U.S. companies expanding into the healthcare business this year. Amazon in July announced a $3.5 billion acquisition of primary care operator 1Life Healthcare Inc (ONEM.O), while CVS Health Corp said it would buy Signify Health for $8 billion.

Private equity firm Warburg Pincus-backed Summit Health runs a physician-run medical group and operates CityMD, an alternative to hospital emergency department visits.

'For Summit, it is to accelerate their path towards value-based care and for Village to enjoy the benefit of more integrated multi-specialty care,' VillageMD Chief Executive Officer Tim Barry told Reuters in an interview.

The sector is seeing a shift towards value-based care - where healthcare providers are reimbursed based on patient outcomes instead of each test or procedure - as it helps reduce costs.

Together, VillageMD and Summit Health will operate in more than 680 locations.

The deal has an equity value of $7 billion and VillageMD will take on $1.9 billion in net debt from Summit Health.

Walgreens said on Monday it will invest $3.5 billion through an even mix of debt and equity to support the acquisition, which is expected to close in the first quarter of 2023. It will be the largest shareholder in the combined company, with an about 53% stake.

The deal will also feature investment from health insurer Cigna Corp's healthcare unit Evernorth, in exchange for a minority stake in the entity. Walgreens raised its fiscal 2025 sales goal for the U.S. healthcare business to between $14.5 billion and $16 billion, from $11 billion to $12 billion previously, to account for the deal.

The company had invested $5.2 billion last year to raise its stake in VillageMD to 63% from 30%.

III. HEALTHCARE SPENDING AND COST ISSUES

U.S. Hospital, Physician Groups Sue to Block Small Part of Surprise Billing Law

(Regulatory Intelligence) - Hospital and physician groups have sued the U.S. federal government in a late effort to prevent a part of the law banning surprise bills from going into effect next month. The lawsuit alleges the Biden administration's interpretation of the billing dispute resolution process between providers and insurers unfairly benefits insurers. [FN23]

The lawsuit brought by the American Hospital Association and American Medical Association supports the rest of the ‘No Surprises Act’ that prevents ‘surprise” bills to patients for charges not borne by insurers. The law requires providers and insurers to resolve billing disputes mutually or resort to arbiters under an independent dispute resolution (IDR) process, in the absence of an agreement.

The Biden administration's interpretation of the IDR process in its recent rule instructs the independent arbiter to take the offer closest to the median in-network rate negotiated for similar services.

The AHA, AMA and other provider groups have alleged the process tilts the negotiating process in favor of insurers who may stop contracting with higher-rate providers in order to keep the in-network median rate low for the cost of a service.

'The legal challenge became necessary because the federal regulators' interpretation upends the careful compromise Congress deliberately chose for resolving billing disputes,” the groups alleged.

The U.S. Department of Health and Human Services' proposed IDR process is ‘skewed” and will ultimately reduce access to care by discouraging meaningful contracting negotiations, reducing provider networks and encouraging unsustainable compensation for teaching hospitals, physician practices and other providers, the groups said in a statement.

Last month, a bipartisan group of 152 lawmakers also urged Secretary Xavier Becerra to fix the IDR provisions, saying the rule's approach was contrary to the statute and ‘could incentivize insurance companies to set artificially low payment rates, which would narrow provider networks and jeopardize patient access to care ? the exact opposite of the goal of the law.”

The AHA and AMA said their lawsuit will not prevent the law and its patient protections from moving forward and will not increase out-of-pocket costs to patients. ‘It seeks only to force the Administration to bring the regulations in line with the law before the dispute negotiations begin.”

The associations are joined in the suit by plaintiffs including Renown Health, UMass Memorial Health and two physicians based in North Carolina.

The No Surprises Act was supported by provider, insurer and consumer groups from the start and received bipartisan backing for seeking to end unexpected bills to patients over costs relating to out-of-network providers or the remainder of the provider's bill beyond the amount borne by the insurer.

Drugmakers Aim Big Price Hikes at U.S. Patients, Congressional Report Finds

(Reuters) - Drugmakers have targeted the U.S. market to earn outsized profits from old medicines, according to a report released on Friday by the House Oversight Committee that highlighted Eli Lilly and Co, Novo Nordisk and Sanofi, which dominate the market for insulin. [FN24]

The staff report also noted pricing and marketing tactics by Pfizer Inc that helped it earn billions of dollars from its now off-patent pain drug Lyrica.

The report, put out following a nearly three-year probe, took issue with assertions by the pharmaceutical industry that high drug prices were needed to fund innovation and research and development programs.

'The Committee's investigation also found that companies dedicated a significant portion of their R&D expenditures to research that was intended to extend market monopolies, support the companies' marketing strategies, and suppress competition,' the report said.

The report, which focused on 12 drugs made by 10 companies, said that Lilly, Novo Nordisk and Sanofi own some 90% of the market for life-sustaining insulin, which was invented in the 1920s.

A Lilly spokesperson said the company offers discounts to make its insulin affordable. A Sanofi spokesperson said the price of its insulin product Lantus had declined almost 45% since 2012. A Novo Nordisk spokesperson said the report reflected a limited picture of the company's efforts to make drugs accessible.

Medicare, the U.S. government health insurance program for those age 65 and older and the disabled, could have saved more than $16.7 billion from 2011 to 2017 on insulin purchases had it been allowed to negotiate discounts with drug companies, the report found.

'We found that drug companies target American patients for price increases, in large part because Medicare is prohibited from negotiating for lower prices. At the same time, the drug companies maintained or cut prices for the rest of the world,' Committee Chairwoman Carolyn Maloney said at a news conference on Friday.

The high prices have had human costs. More than 40% of insulin-dependent patients surveyed said they rationed their medicine in the previous year, the Colorado attorney general's office found in a 2020 report.

PRODUCT HOPPING

President Joe Biden's Build Back Better plan, which passed the House and should come before the Senate this year, includes a provision allowing Medicare to negotiate with drugmakers, although only for a small number of medicines. read more

The report also found that some pharmaceutical companies engage in what it called ‘product hopping,’ a practice of making small tweaks to formulations to get a new patent and then switching patients to the newer, more expensive version. There are bills before Congress to ban product hopping.

Among big-selling insulin products, Eli Lilly raised the price of its Humalog 1,219% per vial since it launched, Novo Nordisk raised the price of NovoLog 627% since launch and Sanofi has raised the price of Lantus 715%, the report found.

The report also found that Pfizer targeted the U.S. market for higher prices for its blockbuster Lyrica, as well as using product hopping to prevent patients from shifting to cheaper, generic versions of the medicine.

Lyrica's price had gone up 420% since it was approved in 2004, the report said. It had sales of about $2 billion in 2019.

Pfizer did not have an immediate comment.

The report also listed price hikes of 825% for Teva Pharmaceutical Industries' Copaxone, 486% for Amgen's Enbrel, 395% for Novartis' decades-old Gleevec, more than 100,000% for Mallinckrodt's Acthar, 471% for AbbVie's Humira and 82% for its Imbruvica, and 255% for Celgene's Revlimid, now owned by Bristol Myers Squibb.

Most of the drugs mentioned in the report are over a decade old.

Novartis said it invested over 18% of its global revenue into R&D. Mallinckrodt and Bristol Myers did not have an immediate comment. Amgen, AbbVie, and Teva did not respond to requests for comment.

U.S. Lawmakers Seek Answers on ‘Troubling’ Drug Price Increases

(Reuters) - Senators Elizabeth Warren and Amy Klobuchar and 11 other U.S. lawmakers pressed the president of the biggest pharmaceutical industry trade group Tuesday about what they said were ‘troubling price increases for brand name drugs' in January. [FN25]

A letter to Stephen Ubl, president of the Pharmaceutical Research and Manufacturers of America (PhRMA), was signed by 12 Democrats as well as Senator Bernie Sanders, an independent. It asks PhRMA to explain the source of the price increases, and asks for information about research costs and revenue from the medicines.

'The large, across-the-board price increases of popular, brand name prescription drugs appear to be an example of pharmaceutical companies taking advantage of their abusive market power to expand already large profits,' the lawmakers wrote.

A spokesperson for PhRMA, Brian Newell, said drug prices rose just 1.3% last year and that the letter put a ‘myopic focus' on drugmakers that fails to take into account others involved in high U.S. healthcare costs.

'This letter ignores abusive insurance practices that force patients to pay the full cost of medicines while at the same time middlemen pocket record rebates and discounts from drugmakers,' Newell said in a statement.

The lawmakers, who included Representative Katie Porter, cited two studies: one by Dr. Stephen Schondelmeyer of the University of Minnesota and another by the Johns Hopkins Drug Access and Affordability Initiative, which focused on 20 prescription medicines that the Medicare Part D program spends the most on.

Schondelmeyer's study found that drugmakers increased prices for 72% of the 100 top-selling drugs in early 2022, with 26% of brand name drugs showing higher prices.

The Johns Hopkins study found higher prices for 16 of the top 20 Medicare Part D drugs in January.

Among the widely used drugs in the Medicare program cited in the letter were Novo Nordisk's Victoza 2-Pak for type 2 diabetes, which had a price increase of 4.8% to $709.74.

Novo Nordisk spokesman Michael Bachner in a statement said that the company ‘committed in 2016 to keep annual list price increases below 10% and we have kept true to that commitment.’

Other drugs cited included AbbVie's big-selling rheumatoid arthritis treatment Humira Pen and leukemia drug Imbruvica, which saw their prices go up 7.4%. The price of Pfizer's breast cancer drug Ibrance rose 6.9%, while the price of blood clot preventer Eliquis, sold by Bristol Myers Squibb and Pfizer increased 6%, the letter said.

Representatives for other drugmakers did not comment.

Civica Aims to Launch Low-cost Insulin in U.S. by 2024

(Reuters) - Non-profit drugmaker Civica said on Thursday it expects to launch lower-cost versions of insulin in the United States by 2024, to help diabetic patients struggling with high prices for the life-sustaining medicine. [FN26]

Civica, launched in 2018 to make generic drugs, said it would produce three copycat versions of insulin, and make them available at roughly the same price for all customers, once approved by U.S. health regulators.

The company's products, which would be available as both vials and pre-filled pens, are biosmilars to Sanofi SA's Lantus, Eli Lilly and Co's Humalog and Novo Nordisk's Novolog.

The maximum price for all three of Civica's products would be no more than $30 per vial and no more than $55 for a box of five pen cartridges, the company said.

That compares with $300 per vial and $500 for five pens, which are the average wholesale prices, according to Civica.

More than 34 million people in the United States have diabetes, according to the U.S. Centers for Disease Control and Prevention (CDC).

Sanofi, Lilly and Novo Nordisk have long dominated the U.S. diabetes market, but face growing pressure from lawmakers on why the cost of the nearly 100-year-old medication had rapidly risen.

In response, Eli Lilly in 2019 launched its own cut-price versions of Humalog, while Sanofi said it would cut the cost of its insulin products for some U.S. patients. Novo also offers a generic version of Novolog at a 50% discount.

Civica, which was launched by seven health systems including HCA Healthcare and Mayo Clinic to make essential medicines available at affordable prices, is launching clinical studies for its insulins this year and expects to file for regulatory approval in 2023.

It estimates that the first product would be available for purchase by early 2024.

Arkansas Sues Drugmakers, Pharmacy Benefit Managers Over Insulin Costs

(Reuters) - Arkansas's attorney general on Wednesday accused drugmakers and pharmacy benefit managers of colluding to drive up the price of insulin drugs, the latest in a series of lawsuits to take aim at skyrocketing costs for the life-sustaining medicine. [FN27]

The lawsuit, filed in Pulaski County, Arkansas state court, targets Eli Lilly and Co, Novo Nordisk A/S and Sanofi SA, which together make the vast majority of the insulin drugs sold in the United States.

It also names the nation's leading pharmacy benefit managers (PBMs) - UnitedHealth Group Inc's Optum unit, CVS Health Corp's CVS Caremark and Cigna Corp's Express Scripts. PBMs maintain the lists of drugs covered by health insurance plans and negotiate prices with manufacturers.

Eli Lilly said in a statement that it was ‘disappointed’ by ‘inaccurate claims' in the lawsuit and that it has voluntarily taken steps to ensure that patients can get its insulin for $35 per month or less.

The other defendants did not immediately respond to requests for comment.

Around 8.4 million of the 37 million people in the United States with diabetes use insulin drugs, according to the American Diabetes Association.

Prices of top-selling insulin products have soared in recent years. According to a 2021 Congressional report, Eli Lilly had raised the price of its Humalog 1,219% per vial since it launched, Novo Nordisk raised the price of NovoLog 627% since its introduction and Sanofi has raised the price of Lantus 715%.

Arkansas Attorney General Leslie Rutledge in Wednesday's lawsuit said that the PBMs, rather than negotiating lower prices on behalf of patients, have accepted higher prices in exchange for generous rebates from the drugmakers in order to enrich themselves, violating an Arkansas law against deceptive business practices.

Rutledge in a news conference said 50,000 Arkansans with diabetes were uninsured and that many had been forced to ration insulin because of the high cost.

Similar lawsuits brought by the state of Minnesota, city of Miami and groups of drug purchasers are already pending.

Pharmacy Benefit Managers' Profits Targeted by New U.S. Bill

(Reuters) - Senators Maria Cantwell, chair of the Commerce Committee, and Chuck Grassley, the top Republican on the Judiciary Committee, introduced a bill on Tuesday that would give the U.S. Federal Trade Commission more power to rein in pharmacy benefit managers, which administer pharmaceutical plans, Cantwell's office said. [FN28]

The high cost of medical bills of all kinds, including soaring prices for older drugs like insulin, have prompted concern from lawmakers from both parties.

'The increasing cost of prescription drugs has a devastating effect on the pocketbooks of American consumers,' said Senator Cantwell in a statement. ‘PBMs are the middlemen in the prescription drug supply chain and it's time for Congress to give the FTC the ability to shine a brighter light on any deceptive and abusive practices.’

Senator Grassley said that his constituents complained regularly about drug costs.

'It is critical for Congress to direct the Federal Trade Commission to go after these arbitrary, unfair and deceptive practices,' he said in a statement.

The bill would ban unfair pricing schemes and require reports to the FTC about such things as spread pricing, when the PBM pays the pharmacy one price but charges the person's health plan a higher rate and keeps the difference.

Three PBMs control nearly 80% of the prescription drug market, according to Cantwell's office.

An aide to the senator said that they were referring to UnitedHealth Group Inc's Optum unit, CVS Health Corp's CVS Caremark and Cigna Corp's Express Scripts. PBMs maintain lists of drugs covered by health insurance plans and negotiate prices with manufacturers.

Cantwell's office cited a recent report by the Congressional Budget Office, which found that eliminating spread pricing would save Medicaid, the federal insurance program for the poor, some $900 million over 10 years.

U.S. Senate Democrats Advance Deal to Lower Drug Prices

(Reuters) - Democrats in the U.S. Senate are advancing a deal that would allow the government's Medicare health plan for older and disabled Americans to negotiate lower prescription drug prices, Senate sources said on Wednesday. [FN29]

The plan, which could potentially lower government health costs by billions of dollars, has long been a goal of President Joe Biden's Democrats and is popular with voters.

Affected drugs could include Bristol-Myers Squibb Co's top-selling cancer drug Revlimid, AbbVie Inc's rheumatoid arthritis drug Humira, and Bayer AG's blood thinner pill Xarelto, according to the Kaiser Family Foundation (KFF).

The plan has been held up by contentious intra-party negotiations on taxes, climate change and other elements of a proposed domestic policy bill.

The sources said all 50 Senate Democrats support the drug plan, including Senator Joe Manchin, who is often at odds with other members of his party.

'His support for this proposal has never been in question,' Manchin spokesperson Sam Runyon said in a statement.

A source familiar with the proposal said Senate Democrats were still working on the provisions to tackle climate change and raise taxes, which would be coupled with the Medicare proposal.

While negotiations continue, the Medicare portion was to be submitted to the Senate parliamentarian to ensure it complies with complex budget rules that would allow Democrats to bypass Republicans and pass it with a simple majority in the 100-seat chamber with Vice President Kamala Harris breaking the tie.

The Democrats' plan would allow the Medicare health program for the disabled and people aged 65 and older to negotiate discounts for some of the costliest drugs and penalize companies that raise prices faster than inflation.

It also introduces a $2,000 annual cap on out-of-pocket costs for Medicare beneficiaries.

Medicare could annually negotiate prices for 10 of the most expensive single-source drugs starting in 2026, with that number increasing to 20 drugs by 2029, according to Juliette Cubanski, a KFF analyst.

Newer drugs would not be eligible, she said.

REDUCING THE BUDGET DEFICIT

The plan would reduce the federal budget deficit by $297 billion over 10 years, according to a November report from the nonpartisan Congressional Budget Office.

AARP, an influential advocacy group for Americans over the age of 50, said it backed the plan.

But PhRMA, a lobbying group for the pharmaceutical industry, said the price controls would threaten future drug development.

The Biotechnology Innovation Organization, another industry group, also said it opposed the plan.

It was unclear when legislation bundling the three initiatives would be complete. Democrats hope to pass the legislation before the Nov. 8 midterm election, when Republicans could win control of one or both chambers of Congress.

The Senate's top Republican, Mitch McConnell, has threatened to hold other legislation hostage if the Democrats advance their package.

SCALED BACK

Biden and Democrats promised voters sweeping drug price reform but agreed in November to move ahead with a far less ambitious proposal after facing opposition in Congress.

It still allows Medicare to negotiate lower drug prices, but they would not apply to people with private health insurance, a provision included in an earlier, more ambitious, proposal. read more

It would allow the government to negotiate the price of up to 20 of the single-supplier drugs on which it spends the most, rather than the 250 drugs progressives had sought.

Other weakened provisions include an inflation cap that does not reverse previous price hikes, something the old framework would have done.

The Senate's proposed text does not include Medicare negotiation of insulin prices or a $35 monthly cap on out-of-pocket insulin costs, both present in the House version.

Democrats are proposing a separate insulin bill that would include the $35 cap.

U.S. Pharmacy Benefit Managers Face Increased Scrutiny

(Regulatory Intelligence) - The U.S. Federal Trade Commission (FTC) has put drug manufacturers and pharmacy benefit managers on notice that some fee and rebate practices could be illegal under competition and consumer protection laws. [FN30]

The commission issued the warning in an enforcement policy statement adopted on June 16, which followed the launch a week earlier of an inquiry into practices of the largest pharmacy benefit managers.

Pharmacy benefit managers (PBMs) are the intermediaries between drug manufacturers and health plans. The PBMs negotiate rebates and fees as well as developing formularies - lists of drugs the health plans will cover - and policies for the health plans.

Prescription drug prices are an ongoing concern for consumers, insurers and politicians with many pointing to PBMs as part of the reason drug prices remain high. The FTC has received complaints that drug manufacturers pay the rebates and fees to PBMs that may ‘incentivize’ them steer patients to higher-cost drugs over less expensive alternatives.' The rebates and fees may ‘shift costs and misalign incentives in a way that ultimately increases patients' costs and stifles competition from lower-cost drugs, especially when generics and biosimilars are excluded or disfavored on formularies,’ according to the enforcement policy statement.

The commission highlighted insulin as an example of a prescription drug ‘impacted by high rebates and fees' paid to PBMs. Approximately eight million Americans rely on insulin to control diabetes, according to the policy statement. The price of insulin ‘nearly tripled’ between 2009 and 2017. The increased cost has caused many patients to ration their insulin, ‘causing suffering, severe illness, and death.’

President Joe Biden has also used the high cost of insulin as an example when discussing his Build Back Better plan, stating the cost of certain types of insulin have ‘increased by 15 percent or more each year for the past decade.’ The plan would have capped patient cost-sharing costs for insulin at $35 per month.

The FTC is not concerned with negotiated ‘good-faith rebates and fees' for services that increase value to payers and patients. However, it has the ‘legal authority to investigate’ practices and take enforcement action ‘when dominant drug manufacturers or intermediaries stifle or foreclose competition from significantly less expensive generic and biosimilar alternatives.’

Vertically-integrated pharmacy benefit managers

The FTC announced on June 7 that it was launching an inquiry into vertically-integrated PBMs and was ‘requiring the six largest pharmacy benefit managers to provide information and records regarding their business practices.’ The commission is investigating the impact of vertically-integrated pharmacy benefit managers on the ‘access and affordability of prescription drugs.’

The largest pharmacy benefit managers are ‘vertically integrated with the largest health insurance companies and wholly owned mail order and specialty pharmacies. As a result of this integration, the PBMs have ‘enormous influence on which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter.’

The commission's inquiry will focus on several practices, including:

• Fees and clawbacks charged to unaffiliated pharmacies.

• Methods to steer patients towards pharmacy benefit manager-owned pharmacies.

• Potentially unfair audits of independent pharmacies.

• Complicated and opaque methods to determine pharmacy reimbursement.

• The prevalence of prior authorizations and other administrative restrictions.

• The use of specialty drug lists and surrounding specialty drug policies.

• The impact of rebates and fees from drug manufacturers on formulary design and the costs of prescription drugs to payers and patients.

• The FTC has authority to investigate these practices under Section 5 of the FTC Act, Section 3 of the Clayton Act, Section 2 of the Robinson-Patman Act as well as the Sherman Act.

Bipartisan congressional action

Senators Chuck Grassley (R-Iowa), ranking member of the Judiciary Committee, and Maria Cantwell (D-Wash.), chair of the Committee on Commerce, Science and Transportation, introduced legislation on May 24 to ‘ban deceptive unfair pricing schemes; prohibit arbitrary claw backs of payments made to pharmacies; and require PBMs to report to the FTC how much money they make through spread pricing and pharmacy fees.’ Spread pricing is the difference between how much a PBM receives from an insurer and the amount it pays to the pharmacy providing the drug.

The Pharmacy Benefit Manager Transparency Act of 2022 also emphasizes fair and transparent practices and mandates transparency. The bill would authorize the FTC and state attorneys general to enforce its provisions. It would allow civil penalties for each violations, plus an additional penalty of up to $1 million.

The bill was referred to the Senate Committee on Commerce, Science and Transportation on June 22.

'Unfortunately, S. 4293 does nothing to reduce prescription drug costs. Instead, the legislation is designed to award pharmacies and drug manufacturers an increase to their bottom lines, rather than lowering prescription drug costs for consumers,' Pharmaceutical Care Management Association (PCMA) President and CEO JC Scott said in a statement after the legislation was referred to committee. ‘In addition, the bill grants an unprecedented expansion of power and regulatory authority to the FTC, giving the agency unchecked power to intervene in private business practices, effectively granting the FTC the ability to pick winners and losers among private businesses.’

PCMA is the national association representing pharmacy benefit managers in the United States.

Newly Launched U.S. Drugs Head Toward Record-high Prices in 2022

(Reuters) - Drugmakers are launching new medicines at record-high prices this year, a Reuters analysis has found, highlighting their pricing power even as Congress moves to cut the $500 billion-plus annual bill for prescription drugs in the United States. [FN31]

At the same time, some pharmaceutical manufacturers are disclosing less information about the pricing of those treatments, which have come under greater scrutiny in recent years, Reuters found.

'In the U.S. we allow drug manufacturers to freely set prices for all brand-name drugs,' Dr. Aaron Kesselheim, professor of medicine at Harvard Medical School and Brigham and Women's Hospital, told Reuters.

The median annual price of 13 novel drugs approved for chronic conditions by the U.S. Food and Drug Administration so far this year is $257,000, Reuters found.

They were in good company: seven other newly-launched drugs were priced above $200,000. Three other drugs launched in 2022 are used only intermittently and were not included in the calculation.

Last year, the median annual price rose to $180,000 for the 30 drugs first marketed through mid-July 2021, according to a study published recently in JAMA.

While the Reuters tally does not completely replicate the work of that study, it shows that the direction of new drug prices continues to be on the rise.

The JAMA study also excluded drugs that are used intermittently. It included an adjustment for the fact that drugs for very rare diseases have higher prices, which Reuters did not.

The pharmaceutical industry says that prices for new drugs, many of which now treat rare diseases for which there are no therapies, reflect their value to patients, including the ability to prevent costly emergency room visits and hospital stays.

Drugmakers also stress that they do not determine what U.S. patients end up paying for the medicines.

'Each person's individual (health) insurer and plan will determine the out-of-pocket costs,' Eli Lilly & Co said in response to a question about the $12,700 annual price of its new diabetes drug Mounjaro, adding that the company offers savings cards to reduce those costs to as little as $25 a month.

'AN ATTEMPT TO DISTRACT'

At the same time, drug price information has become harder to confirm. Reuters requested price data from all 15 of the companies that launched new drugs this year.

Six of the manufacturers either did not respond to a request for price details or initially provided only partial information, such as a ‘per vial’ cost, rather than an annual cost based on average patient use, as they had in the past.

Sanofi said its new drug Enjaymo, used to treat a rare type of anemia, was priced at $1,800 per vial. When pressed further, the French healthcare group clarified that the typical annual price is $280,800.

Immunocore initially disclosed only a ‘per vial’ price for melanoma drug Kimmtrak, and Dermavant Sciences gave only a ‘per tube’ price for its new psoriasis cream. Bristol Myers Squibb quoted a ‘per infusion’ price for cancer treatment Opdualag. All three eventually provided annual prices.

CTI BioPharma referred Reuters to a third-party database, but later gave a monthly price for its rare anemia treatment Vonjo. Mycovia Pharmaceuticals said that ‘as a private company’ it would not provide information on the price of its antifungal drug Vivjoa.

Dr. Ameet Sarpatwari, a Harvard University professor who specializes in healthcare law, said such incomplete disclosure could be ‘an attempt to distract” from high annual costs.

Some drugmakers, in response, say treatment costs can vary depending on patient weight and other factors, complicating the estimation of prices for an average patient.

Congress last week passed the landmark $430 billion Inflation Reduction Act that includes a cap on annual drug price increases and allows the Medicare health program for seniors to negotiate prices for up to 20 of the drugs on which it spends the most.

The bill, however, does not limit what drugmakers can charge for new drugs. Some industry experts say that could leave manufacturers even more reliant on higher launch prices.

'The industry will turn to new drugs to try to use the lever that remains uncontrolled,' said Daniel Ollendorf, of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center.

The JAMA-published study on drug prices showed that between 2008 and 2021, U.S. drug launch prices grew 20% annually.

On a net basis, which accounts for volume-based rebates and other discounts that health insurers negotiate with drugmakers, prices for new drugs rose by 11% a year, according to the study led by researchers from the Boston-based Program on Regulation, Therapeutics, and Law and from Brigham and Women's Hospital.

Reuters did not calculate a comparable rise for 2022 as such discounts are not made public.

Discounts and rebates are often demanded by payers for new drugs once competing treatments become available. As patents expire, lower-cost generics also mitigate prescription drug price inflation, which in the 12 months through July has grown by 2.8%, according to the Bureau of Labor Statistics.

'The vast majority of drugs that Americans use are generics,' said Rena Conti, associate professor at Boston University's business school. Drugs for diseases with few treatment options command the highest prices, she said.

New U.S. Cancer Drug Prices Rise 53% in Five Years - Report

(Reuters) - The annual price of a newly-launched cancer drug in the United States averaged $283,000 last year, a 53% increase from 2017, according to a new report from U.S. Democratic Representative Katie Porter, a consumer bankruptcy law professor running for re-election in California. [FN32]

Cancer is the second leading cause of death in the United States, oncology treatments are nearly four times as costly as other therapies and are largely paid for by taxpayer-funded programs like the government's Medicare plan for people over age 65, the report notes.

Reuters reported in August on the record-high launch prices of new drugs in 2022 versus 2021 ? an area that has driven drugmaker profits as they limited year-over-year price increases on existing drugs due to pressure from lawmakers and the public.

This new analysis is a first look at the degree to which cancer drugmakers rely on high launch prices, an area left out of the Medicare pricing limits set out in the Inflation Reduction Act (IRA) signed by U.S. President Joe Biden in August.

The IRA focuses on Medicare price negotiation for older drugs and caps on price increases. It also limits annual out-of-pocket drug costs for beneficiaries to $2,000, which means the Medicare plan will be responsible for costs over that amount.

By law, Medicare is required to cover all cancer medications.

'Launch prices are an important issue and one that is not touched by the IRA,' Stacie Dusetzina, an associate professor of health policy at Nashville's Vanderbilt University Medical Center who studies drug costs told Reuters. ‘I do think there is a possibility we see launch prices go up,’ she said.

Porter, who championed inflation-based caps on drug prices, is calling for additional national legislation to link launch prices to how well a drug works. And, in the case of drugs approved under the Food and Drug Administration's accelerated pathway, limiting prices until there is sufficient data to show the drugs are effective.

'The trend toward ever higher launch prices is ongoing and accelerating. And I think we should expect it to continue unless we do something about it,' Porter told Reuters.

The Pharmaceutical Research and Manufacturers of America, the drug industry's main trade group, has maintained that ‘government price setting has a devastating impact on biopharmaceutical research and development and places an additional barrier between patients and innovative medicines.’

CANCER PILLS ROSE NEARLY 26% IN FIVE YEARS

Many of the newer cancer drugs are biologics that need to be given as an infusion by a healthcare professional, but an increasing number are self-administered pills or tablets.

The report found that the average launch price of a self-administered cancer drug, after adjusting for inflation, rose by nearly 26% to $238,000 between 2017 and 2021.

The analysis excluded an ultra-expensive class of treatments called CAR-T, which involve drawing white blood cells from a patient, processing them in the lab to target cancer and infusing the cells back into the patient.

In 2017, the most expensive new cancer tablet was Celgene's Idhifa at $298,465 a year. Celgene was later acquired by Bristol Myers, which said in 2020 that a study of Idhifa, approved to treat a subset of leukemia patients, failed to show that it improved survival compared to standard care.

No other new drug launched in 2017 had an annual price over $200,000.

By 2022, six out of the eight newly-launched oral cancer drugs had prices over $200,000 per year. These included lung cancer pills such as Takeda Pharmaceutical's Exkivity at $299,995, Merck KGaA's Tepmetko at $250,775 and Amgen Inc's Lumakras at $214,800.

Based on current trends, the report calculated that by 2026, when Medicare will first be able to negotiate drug prices, the average self-administered cancer drug launch price will be nearly $325,000 per year and over $525,000 for pills and biologics.

IV. OTHER BUSINESS REPORTS

Sun Pharma to Pay $485 million to Resolve Ranbaxy Antitrust Cases

(Reuters) - Sun Pharmaceutical Industries Ltd on Wednesday said it had agreed to pay $485 million to resolve class action lawsuits alleging the Indian drugmaker's subsidiary Ranbaxy engaged in an anticompetitive scheme to delay the launch of generic drugs by rivals. [FN33]

The settlement came ahead of an April 5 trial in Boston federal court over claims by generic drug buyers who said they were owed billions of dollars for being overcharged as a result of a fraud Ranbaxy Laboratories perpetrated on U.S. regulators.

Sun in a regulatory filing said it had signed a binding term sheet to resolve lawsuits by direct purchasers of the drugs, including drug wholesalers, and indirect purchasers, such as health plans, accusing Ranbaxy of racketeering and antitrust violations.

Sun, which acquired Ranbaxy in 2014 and was represented by Jay Lefkowitz of Kirkland & Ellis, said it disputes the claims and agreed to the deal to ‘avoid uncertainty.’

The deal requires the approval of U.S. District Judge Nathaniel Gorton, who has overseen the litigation since 2019. He has scheduled a status conference for Thursday.

Kristen Johnson, a lawyer for the direct purchasers at Hagens Berman Sobol Shapiro, had no comment.

In the lawsuits, drug buyers accused Ranbaxy of wrongly obtaining tentative approvals from the U.S. Food and Drug Administration in 2007 and 2008 to produce generic versions of Novartis AG's blood pressure drug Diovan, Pfizer's acid reflux medication Nexium and Genentech's antiviral drug Valcyte.

Under the federal Hatch-Waxman Act, the first company to apply to make a generic drug enjoys a 180-day period of marketing exclusivity.

But the plaintiffs said Ranbaxy locked in those exclusive periods by misleading the FDA about its compliance with current good manufacturing practices, when its processes were grossly inadequate and had suffered several failures.

The FDA granted final approval to the Diovan generic in 2014. But following regulatory scrutiny, the FDA revoked its tentative approval for the generic Nexium and Valcyte.

The plaintiffs said Ranbaxy's actions delayed the release of rivals' generic medications and caused drug buyers to sustain massive overcharges.

The direct purchasers claimed up to $7.1 billion in damages, which would be tripled under RICO and federal antitrust law, while the end payors claimed up to $3.3 billion in damages, according to court filing on Friday.

The case is In re Ranbaxy Generic Drug Application Antitrust Litigation, U.S. District Court for the District of Massachusetts, No. 19-md-02878.

COVID Vaccine Makers Shift Focus to Boosters

(Reuters) - COVID-19 vaccine makers are shifting gears and planning for a smaller, more competitive booster shot market after delivering as many doses as fast as they could over the last 18 months. [FN34]

Executives at the biggest COVID vaccine makers including Pfizer Inc and Moderna Inc said they believe most people who wanted to get vaccinated against COVID have already done so - more than 5 billion people worldwide.

In the coming year, most COVID vaccinations will be booster shots, or first inoculations for children, which are still gaining regulatory approvals around the world, they said.

Pfizer, which makes its shot with Germany's BioNTech SE, and Moderna still see a major role for themselves in the vaccine market even as overall demand declines.

Upstart U.S. vaccine maker Novavax Inc and Germany's CureVac NV, which is working with GlaxoSmithKline, are developing vaccines they hope to target at the booster market.

The roles of AstraZeneca Plc and Johnson & Johnson, whose shots have been less popular or effective, are expected to decline in this market.

'It becomes a very competitive game with companies battling it out with pricing and for market share, even for vaccines that are considered to be the best, like Pfizer and Moderna,' said Hartaj Singh, an analyst at Oppenheimer & Co.

It is not known yet how many booster doses will be needed. Second booster shots are currently recommended in some countries for only a subset of the population.

It is also unclear if vaccine makers will sell a redesigned shot this fall and each fall afterward, as flu vaccine makers do to match circulating strains, and what impact that might have on waning demand.

Pfizer Chief Executive Albert Bourla said in an interview that adults who are still unvaccinated are unlikely to seek out shots now, more than two years into the pandemic.

It will be the ‘already vaccinated” who account for demand, Bourla said.

Moderna executives recently said those who would benefit from annual boosting include people over 50 and adults with other health risk factors or high-risk occupations, including healthcare workers.

Moderna CEO Stephane Bancel estimated this population to be around 1.7 billion people, or some 21% of the global population.

Moderna and Pfizer/BioNTech, which make messenger RNA vaccines that can be updated somewhat quicker than those from competitors, said they are developing vaccines targeting the Omicron variant of the virus.

The United States and Western Europe - where about 600 million people are vaccinated - will remain important markets, but sales may be a fraction of what they have been, Cowen analyst Tyler Van Buren said.

'The low hanging fruit is that 20%-25% of people who are so-called high risk for various reasons, and I think that is the population that is most likely to get it every year,' he said.

That would be significantly less than the roughly 49% of adults in the United States and 62% of adults in Europe who have received at least one booster so far, or about 335 million people.

Analysts have forecast revenue of over $17 billion for the Pfizer/BioNTech shot and $10 billion for Moderna's in 2023, about half of the $34 billion and $23 billion they expect this year, respectively. Sales are expected to drop further from there.

THE OTHER PLAYERS

Johnson & Johnson, whose vaccine has been limited by a side effect that causes rare but sometimes fatal blood clots, declined to comment on whether it plans to push its shot as a booster in the fall. In April, the company rescinded its 2022 COVID-19 vaccine sales forecast, citing uncertainty. read more

South Africa's Aspen Pharmacare (APNJ.J), which makes J&J's shot in Africa, warned of weak demand. read more

Aspen CEO Stephen Saad in an interview said, ‘there is going to be a place for boosters ... but it is not at the volumes you had before.’

AstraZeneca CEO Pascal Soriot said in late April that its shot will still have a role in fighting the pandemic. read more

'We believe this vaccine still has a potential, it's very easy to administer and distribute,' he said. ‘The volume in the future will be less because people probably will only need one booster per year and not everybody will take it.’

Walmart, CVS to Halt Filling Prescriptions for Controlled Substances by Cerebral, Done

(Reuters) - Walmart Inc and CVS Health Corp said on Wednesday they would stop filling prescriptions for controlled substances issued by telehealth startups Cerebral Inc and Done Health. [FN35]

Cerebral and Done are known for treating patients with ADHD, prescribing stimulants such as Adderall.

Walmart confirmed the move to Reuters and said the decision was made after an audit and compliance process.

CVS said it would not accept prescriptions for controlled substances issued by the startups effective May 26, as a result of a review it conducted on the telehealth firms and after it was ‘unable to resolve concerns we have with Cerebral and Done Health.’

Cerebral had earlier this month decided to stop prescribing controlled substances and taper existing prescriptions based on the impending expiration of waivers, the company said in an emailed statement.

The company was working to ensure that existing patients with controlled substance prescriptions are able to receive their medications, while working with the pharmacies to allow sufficient time to adjust to the changes, Cerebral said.

Cerebral said it plans to continue to prescribe controlled substances to treat opioid use disorder.

Done Health also said it would continue to provide prescriptions for psychiatric chronic care management.

'We expect this situation will be quickly resolved, if provided the opportunity, so patients can access the medications they have been prescribed using evidence based medicine,' Done Health said on Thursday.

According to a Wall Street Journal report earlier this month, Cerebral had been issued a subpoena by federal prosecutors as part of an investigation into possible violations of the Controlled Substances Act.

Apple Outlines Health Technology Strategy in New Report

(Reuters) - Apple Inc. on Wednesday released a report outlining a two-pronged strategy in digital health markets, courting consumers with health and fitness features on one hand while engaging with traditional healthcare systems on the other. [FN36]

Spearheaded by Apple's chief operating officer, Jeff Williams, the report is the first time Apple has offered a comprehensive view of its approach to healthcare markets in the eight years since it began releasing health features such as a medical records storage system on iPhones. It has also started partnering with institutions such the Stanford University School of Medicine to conduct large-scale formal medical studies.

Much of the work has centered around the Apple Watch, a device that Williams played a key role in bringing to market and which contains sensors for heart health and other functions.

In the report, Apple said its focus for consumers is on providing a secure place for users to store their health and medical information on iPhones while using tools like the Apple Watch to warn and nudge users toward better health. The device can alert people to heart irregularities and detect when a person takes a hard fall to alert an emergency contact, among other features. Apple said its system can now store 150 different types of health data that is encrypted so that only users, not Apple, can access it.

The company also outlined work it is doing with medical researchers to allow them to use Apple devices to conduct studies, as well as allow patients to share and discuss data collected by Apple devices so that they can monitor their health better between doctor's visits.

Williams wrote in the report that Apple intends to keep developing health-related features for both users and the healthcare industry.

'Our vision for the future is to continue to create science-based technology that equips people with even more information and acts as an intelligent guardian for their health, so they're no longer passengers on their own health journey,' Williams wrote.

Merck Avoided Billions in U.S. Tax by Offshoring Keytruda Profits - Senator

(Reuters) - Drugmaker Merck & Co avoided billions of dollars of U.S. taxes in recent years on its top-selling cancer drug Keytruda by booking all the profits from the treatment outside of the United States, according to an ongoing investigation by Democrats on the Senate Finance Committee. [FN37]

The committee's chairman Senator Ron Wyden of Oregon sent a letter to Merck Chief Executive Robert Davis on Wednesday criticizing the drugmaker for refusing to provide all the information the committee has requested. Wyden's office provided a copy of the letter to Reuters.

Democrats on the committee have been investigating how the tax law passed by Republicans in 2017 has benefited large U.S. pharmaceutical companies such as Merck and AbbVie and whether those companies have been exploiting foreign subsidiaries to avoid taxes.

Wyden said in the letter that Merck was able to avoid U.S. taxes on Keytruda - even on sales in the United States - by holding patents in the Netherlands and manufacturing the drug in Ireland.

'Prior to today, we have received two letters from the Senate Finance Committee requesting responses to questions around our tax rate, and in each case, we have cooperated and responded with information that we believe appropriately addressed their inquiries,' Merck said in an emailed statement.

AbbVie did not immediately respond to a request for comment.

Cancer immunotherapy Keytruda is one of the world's top-selling drugs. Merck sold around $17.2 billion of it in 2021, with around $9.8 billion of those sales in the United States.

Merck's effective tax rate last year was 11%, Wyden said in his letter, just over half the current U.S. corporate tax rate of 21%.

Wyden said the $22.4 billion of sales it reported in the United States accounted for 46% of Merck's sales in 2021. Still, the company only reported $1.85 billion in pretax income in the United States for the year - less than 15% of its total pretax income.

Earlier this month, an interim report from the committee said that shifting profits overseas by AbbVie Inc resulted in ‘stunningly low effective tax rates.’

In 2018, Reuters laid out how AbbVie reported its income in lower tax jurisdictions, which was possible in part because the company parked the majority of the patents for its top-selling drug, the rheumatoid arthritis treatment Humira, in tax haven Bermuda.

'Understaffed and Overworked': Thousands of Minnesota Nurses Go on Strike

(Reuters) - Some 15,000 nurses in Minnesota walked off the job on Monday to protest hospital understaffing that their union says has harmed patient care and exhausted health workers as they negotiate a new contract with hospital executives. [FN38]

The strike, slated to last three days and described by the Minnesota Nurses Association as one of the largest in United States history, highlights nationwide health worker shortages that have been exacerbated by the COVID-19 pandemic.

The union says it has been negotiating a new agreement for more than five months, and that nurses have been working without a contract for weeks.

'Hospital executives have already driven nurses away from the bedside by their refusal to solve the crises of staffing and retention in our hospitals,' the union's negotiating team said in a statement, adding that nurses were ‘understaffed and overworked.’

The walkout was expected to affect at least 13 hospitals around Minneapolis and neighboring St. Paul. Twin Cities Hospital Group, which oversees four hospitals where nurses are striking, said it had asked the nurses' union to join them in mediation.

'A trained mediator can help parties focus on the key elements needed to move forward together. However, the nurses' union has rejected all our requests for mediation,' the group said on its website.

Allina Health, which owns four hospitals with striking nurses, said on its website it was making every effort to minimize disruptions to patient care. It said it had been planning for a strike for months.

The nurse strike has drawn support from U.S. lawmakers in Washington, including veteran Senator Bernie Sanders. ‘Nurses are the backbone of our health care system,’ Sanders wrote on Twitter, calling for fair scheduling and higher wages.

According to the U.S. Bureau of Labor Statistics (BLS), employment in healthcare across the United States is still below pre-pandemic levels. Some 37,000 fewer people work in healthcare now than in February 2020, a Sept. 2 report from BLS said.

U.S. Agencies Caution Nursing Homes and Debt Collectors on Debt Collection Practices

(Regulatory Intelligence) - The Centers for Medicare & Medicaid Services (CMS) and the Consumer Financial Protection Bureau (CFPB) issued a joint notification letter to nursing facilities and debt collectors warning against improper attempts to hold third parties responsible for residents' debts. [FN39]

Under the Nursing Home Reform Act, nursing facilities that participate in Medicare or Medicaid are prohibited from ‘requesting or requiring that a third party personally guarantee payment to the facility as a condition of a resident's admission or continued stay in the facility.’ The prohibit applies to all residents of the facility, regardless of whether they are eligible for the federal Medicare or Medicaid assistance programs.

Contract terms that conflict with the reform act are unlawful, and alleged debts resulting from those contracts are ‘invalid and unenforceable,’ according to the September 8 notification.

Some nursing facilities are attempting to evade the act's prohibition by creating admission contracts that attempt to hold third parties liable for the resident's debt, the warning said.

The agencies caution that when a nursing facility claims that a non-resident is personally financially responsible for a resident's debt and engages a third-party debt collector to collect the debt, the debt collector may violate the Fair Debt Collections Practices Act (FDCPA). The actions may also violate the Fair Credit Reporting Act (FCRA) by furnishing information regarding the invalid debts to consumer reporting agencies.

Nursing facilities that violate the Nursing Home Reform Act may be subject to enforcement by state agencies and CMS. Debt collectors that violate the FDCPA and FCRA may be subject to enforcement by the CFPB, federal and state government agencies, as well as private action by consumers.

The agencies advised nursing homes and their debt collectors to review their practices to ensure compliance with the prohibition with all three statutes.

CFPB findings

The consumer bureau issued a report on nursing home debt collection in conjunction with the agencies' letter. The agency found that there are ‘approximately 48 million family members and friends caring for adults with health or functional needs in the United States.’ Nearly one in six adults is ‘supporting the health and well-being of an older adult though illness or disability,’ according to the report.

In examining the debt collection practices of nursing homes, the bureau found that nursing homes are requiring, as a condition of a patient's admission into the facility, that a third-party caregiver sign the admission contract as a ‘responsible party’ or ‘representative.’ Based on these contract clauses, the nursing home will then seek to recover unpaid balances from third parties.

These unpaid balances can ‘range from a few thousand dollars to hundreds of thousands of dollars,’ according to the report.

If the third party fails to pay, some nursing homes hire debt collection firms, report the debt to credit reporting companies as the third party's personal debt and sue the third party. Debt collection lawsuits often result in default judgments against defendants who may lack the resources to contest the lawsuit or simply ignore it because they think it was filed in error. Once a nursing home has a judgment against the third party, they can garnish the person's wages or take other actions against their assets. This can lead to bankruptcy for the third party, the report said.

Paying for nursing home care

The issue of financial responsibility is exacerbated by the high costs of nursing home care. In 2021, the annual median cost of a single room in a nursing home was $108,405, according to the bureau. This cost ‘rose by over 60 percent, or 19 percent if adjusted for inflation’ between 2004 and 2020.

Few older adults are ‘insured against the costs of long-term care.’ Medicare only pays for nursing home care up to 100 days and only when the resident requires skilled nursing care as part of their stay. Private health plans often have similar limits. Fewer than ‘1 in 10 older adults carry long-term care insurance,’ according to the report.

As a result, it is difficult for older adults to ‘afford the out of pocket costs for long-term care without rapidly depleting their savings and accruing debt.’

Medicaid ‘acts as a safety net of last resort’ for older adults who have depleted their assets and 62% of nursing resident receive institutional Medicaid assistance, according to the report.

However, because income-eligible resident ‘must deplete their financial resources' to become Medicaid eligible, they often accrue nursing home debt while waiting for the state to process their Medicaid application. The application process can take months. If the application is denied, subsequent appeals can also ‘take several months and sometimes years to resolve.’ During this time, the resident continues to accrue debt.

This is often the time when nursing homes will begin attempt to collect the resident's debt from a third party.

Private-equity Ownership in U.S. Health Care Drives Up Pricing, May Affect Premiums - Studies

(Regulatory Intelligence) - An increase in private equity (PE) ownership of hospitals and doctors' offices has driven up health care prices and could result in higher health insurance premiums, especially in employer-sponsored coverage, according to two separate studies from a group of health insurers and a consumer advocacy organization. The organizations have sought stricter policies at the state and federal levels to encourage transparency in provider ownership and healthcare pricing practices. [FN40]

PE investments in hospitals, freestanding emergency rooms and other care providers ? especially in fee-for-service ventures such as physician offices and ambulance services ? have risen to $119.9 billion in deal values in 2019 from $41.5 billion in 2010, for a total of approximately $750 billion over the decade, according to the study from AHIP, a trade group of health insurers.

'Health care industry consolidation - particularly among hospitals - has eliminated healthy competition and led to monopolistic pricing. Consolidation has taken place without meaningful regulatory oversight or effective intervention,” the report from Families USA, a consumer advocacy organization said.

Hospital pricing has increased as much as 31 percent nationally since 2015 and now accounts for nearly one-third of U.S. healthcare spending, but healthcare outcomes in many critical areas have not improved, Families USA said. Hospital and physician care account for half of U.S. health care spending.

Healthcare-acquired infections are one of the top 10 causes of death in the country. The United States also has the lowest life expectancy, highest rates of infant mortality and the highest rates of maternal mortality among industrialized nations, the study said. These health outcomes are worse for people of color.

A separate study, from the insurance industry group AHIP, concluded, ‘The need for those PE firms to achieve high returns on investment on a fast time horizon directly conflicts with the need for lower health care costs and greater investments in quality and safety.”

Hospitals owned by PE firms bring in nearly 30 percent more income than others by cutting staffing and supplies, thereby ‘pressuring providers to bill for unnecessary services, and up-coding claims,” the insurance group added.

Insurers said PE interests in providers were responsible for the marked increase in surprise medical bills - where providers directly billed consumers for balances beyond the amount paid out by insurers ? that led to a law banning surprise bills. Insurers and providers must now settle billing disputes mutually without billing the consumer.

PE firms could acquire hospital-based physicians that have a guaranteed steady stream of patients with private insurance and take their providers out-of-network before raising claim amounts, insurers said. While providers could previously bill and sue consumers over unpaid medical bills, insurers will now have to pay more to settle provider billing disputes due to the ban on surprise bills.

A separate release from the American Hospital Association last week pointed to an analysis by healthcare consulting firm Kaufman, Hall & Associates, showing provider expenses are projected to increase by nearly $135 billion this year over 2021 levels due to the higher costs of retaining and supporting the workforce and rising expenses for supplies, drugs and equipment.

Insurers, policymakers partly to blame for higher costs

Families USA said private health insurers also bear some responsibility for rising costs, by failing to negotiate a fair price for health care services. These health plans also have a conflict of interest because the Affordable Care Act ties insurer compensation to the total amount of money paid out for health care services.

'First, insurer compensation is typically a percentage of total claims, either on a year-by-year basis or over time,” Families USA added in an email. ‘Second, many insurers face pressure from employer purchasers to retain specific health systems ? consolidated to be local near-monopolies ? in their networks. That reduces any leverage insurers might have had in rate negotiations with those health systems.” The higher costs are either absorbed by employers or transferred to employees through higher premiums and cost-sharing but go ‘hidden” because premiums are automatically deducted from paychecks and workers rarely know the total cost of health insurance.

'Each year price gouging by hospitals continues to be allowed by insurers and policymakers,” Families USA said. ‘In the end, pricing abuses in health care, including high hospital prices, cost American workers an estimated $240 billion in wasteful spending alone each year.”

Calls for more oversight over provider ownership and pricing

AHIP and Families USA both called on state and federal lawmakers to implement policy measures in addition to ongoing efforts to rein in health care costs such as hospital price transparency rules.

'Policymakers should go even further, working together to redesign the economic incentives of the health care sector to be aligned with the needs of consumers and families. The journey to fully transform our healthcare system is long, but Congress holds the power to take the next critical steps,” Families USA said in a letter to leaders of Congress.

AHIP called on policymakers to strengthen antitrust enforcement and enact policy to require public reporting of all private equity or hedge fund purchases of air or ground ambulance providers or facilities, emergency room physicians, and other specialty groups where there is evidence of high levels of concentration or low levels of network participation.

Large healthcare corporations must also be stopped from using their monopolistic position to ‘stifle negotiation and innovation through the use of all-or-nothing, anti-tiering, and other take-it-or-leave-it contract terms,” AHIP said

The AHA in turn has urged Congress to prevent further Medicare cuts from going into effect in 2023 and extend or make permanent programs that support rural hospitals and hold commercial health plans accountable for practices that increase costs and delay access to medically necessary care.

J&J Names Consumer Health Business Kenvue Ahead of Spin-off

(Reuters) - Johnson & Johnson named its consumer business Kenvue on Wednesday, moving ahead with its plans to spin-off the unit in what would be the biggest shake-up in the healthcare conglomerate's 135-year history. [FN41]

The unit has faced nearly 40,000 lawsuits alleging its baby powder and other talc products contained asbestos later linked to mesothelioma and ovarian cancer in women who used it for personal hygiene, which the company has denied.

The business also houses Band-Aid bandages and Tylenol medicines and generated revenue of $14.6 billion in 2021.

Kenvue is a combination of ‘ken’, an English word for knowledge primarily used in Scotland, and ‘vue’ a reference to sight.

Usage of the new company logo and corporate brand identity will be effective upon completion of the planned separation, which Johnson & Johnson last year said will be completed by November 2023.

U.S. Supreme Court Weighs Barring Lawsuits Against Public Nursing Homes

(Reuters) - U.S. Supreme Court justices on Tuesday signaled they were unlikely to broadly prevent people who depend on federal assistance programs including Medicaid from suing when states violate their rights even as they weighed barring a narrower class of cases concerning nursing home care. [FN42]

The justices heard arguments in an appeal by Health and Hospital Corp of Marion County, an Indiana municipal corporation, of a lower court's ruling that let the family of Gorgi Talevski, a nursing home resident diagnosed with dementia, pursue a lawsuit claiming his rights were violated while at the facility.

Public health advocates had raised alarms that the justices could use the case as a vehicle to overturn past precedents and leave tens of millions of people who receive coverage under the Medicaid health insurance program for low-income Americans powerless to sue to prevent states from denying benefits.

But the nine justices focused more narrowly on whether lawsuits filed by nursing home residents were precluded by a law called the Federal Nursing Home Reform Act of 1987 governing those facilities. That law established a ‘bill of rights' for residents of nursing homes receiving funding under the Medicare and Medicaid government health insurance programs.

Liberal Justice Ketanji Brown Jackson challenged the contention that Congress did not intend to let beneficiaries of federal spending programs bring lawsuits under a separate 19th century law giving people the power to sue when state officials violated their constitutional or statutory rights.

Talevski's family sued under a measure known as Section 1983 that was enacted as part of the Ku Klux Klan Act of 1871, a law passed in the post-Civil War Reconstruction Era to protect the rights of Black Americans.

'Congress created the right in order to allow people to go to court,' Jackson said.

But Jackson questioned whether nursing home residents' rights to sue were nonetheless preempted by a provision in the nursing home law laying out ‘comprehensive administrative processes' that could address their grievances over their care.

'What's wrong with an administrative process if it's comprehensive and works?' conservative Justice Brett Kavanaugh asked.

Talevski was admitted in 2016 to Valparaiso Care and Rehabilitation, a nursing home operated by the Health and Hospital Corp after his family determined his dementia needed professional care. In a 2019 lawsuit, his family said Talevski was subjected to harmful psychotropic drugs and unlawfully transferred to an all-male facility.

Jackson said Congress in enacting the 1871 law intended to ensure that people could go to federal court to vindicate their rights when states did not provide a proper forum to let ‘people who were terrorized’ do so.

The Supreme Court in 1987 and 1990 held that this law could be used by people to enforce rights contained in spending legislation approved by Congress setting conditions for states to receive federal money including Medicaid funds.

But Lawrence Robbins, the lawyer arguing for Health and Hospital Corp, said Congress in adopting the 1871 law could never have envisioned that individuals, rather than the U.S. government itself, could enforce rights contained in a program like Medicaid.

Liberal Justice Sonia Sotomayor asked why the court should assume that Congress wanted to take away a right under that law ‘as an additional remedy for a violation of a state obligation.’

Assistant U.S. Solicitor General Benjamin Snyder, arguing for President Joe Biden's administration, urged the justices to reject a broad limitation on lawsuits pursued under this law.

But Snyder added that the federal nursing home statute provided ‘extensive’ remedies that made a lawsuit unnecessary by exposing nursing homes that violate residents' rights to financial penalties and terminating their Medicaid funding.

Andrew Tutt, a lawyer for Talevski's family, said the 1871 law acts as ‘a life-saver for people who cannot actually make effective use of the administrative scheme.’ Tutt said Talevski's family sued only as a last resort after going through an administrative grievance process provided by Indiana that failed to rectify their concerns.

'This family was crying out for help and using every possible lever at its disposal,' Tutt added.

A ruling is due by the end of June.

V. HEALTHCARE FRAUD

U.S. Judge Bars Martin Shkreli from Drug Industry, Orders $64.6 million Payment

(Reuters) - A U.S. judge on Friday barred Martin Shkreli from the pharmaceutical industry for life and ordered him to pay $64.6 million after he famously raised the price of the drug Daraprim and fought to block generic competitors. [FN43]

U.S. District Judge Denise Cote in Manhattan ruled after a trial where the U.S. Federal Trade Commission and seven states had accused Shkreli, the founder of Vyera Pharmaceuticals, of using illegal tactics to keep Daraprim rivals out of the market.

Shkreli drew notoriety in 2015 after hiking Daraprim's price overnight to $750 per tablet from $17.50. The drug treats toxoplasmosis, a parasitic infection that threatens people with weakened immune systems.

In a 130-page decision, Cote faulted Shkreli for creating two companies, Vyera and Retrophin Inc, designed to monopolize drugs so he could profit ‘on the backs' of patients, doctors and distributors.

She said the Daraprim scheme was ‘particularly heartless and coercive,’ and a lifetime industry ban was needed because of the ‘real danger’ that Shkreli could become a repeat offender.

'Shkreli's anticompetitive conduct at the expense of the public health was flagrant and reckless,' the judge wrote. ‘He is unrepentant. Barring him from the opportunity to repeat that conduct is nothing if not in the interest of justice.’

After the ruling, FTC Chair Lina Khan tweeted the decision, calling it a ‘just outcome.’

Shkreli's lawyers did not immediately respond to a request for comment.

Shkreli is serving a seven-year prison sentence for securities fraud. He did not attend the trial held last month.

Vyera was founded in 2014 as Turing Pharmaceuticals, and acquired Daraprim from Impax Laboratories Inc in 2015.

Regulators accused Vyera of protecting its dominance of Daraprim by ensuring that generic drugmakers could not obtain samples for cheaper versions, and keeping potential rivals from buying a key ingredient.

The seven states joining the FTC case included California, Illinois, New York, North Carolina, Ohio, Pennsylvania and Virginia.

FTC Orders More Marketers to Stop Falsely Claiming Their Products Can Effectively Prevent or Treat COVID-19

The Federal Trade Commission ordered more than 20 marketers nationwide to immediately stop making baseless claims that their products and supposed therapies can treat or prevent COVID-19. In cease-and-desist demands sent to these marketers, the agency noted that violators could be hit with monetary penalties under the COVID-19 Consumer Protection Act passed by Congress last year.

The cease-and-desist demands are the latest action in the FTC's continued fight against fraudsters attempting to take advantage of ongoing coronavirus concerns, including those related to the Omicron variant.

'Americans are still suffering from the COVID-19 pandemic, and scammers are still taking advantage of them by making false claims about cures and treatments,” said Samuel Levine, Director of the FTC's Bureau of Consumer Protection. ‘Our efforts to stamp out those claims will continue in 2022, and any marketers not heeding our cease-and-desist demands can expect to face consequences, including civil penalties”

This is the eleventh set of warning letters issued by the FTC. The Commission has previously sent similar health-related letters to 405 companies and individuals. Most of the demands announced today were sent to companies using social media platforms to sell their products, and in those instances the agency also notified the platform of its demand.

Several of the letters announced today call out products and ‘treatments” the FTC has warned companies about previously, including peptide therapy, herbal remedies, ivermectin, and supplements. Others concern less-common products and therapies deceptively promoted to prevent or treat COVID-19. For example, letters went to companies claiming that ‘imprinted filtered water,” nasal irrigation, and even seaweed extract can fight coronavirus. However, currently there is no scientific evidence that any of these products can prevent or treat COVID-19 generally or any specific variant.

In the health-related letters, the FTC states that one or more of the efficacy claims made by the marketers are unsubstantiated because they are not supported by scientific evidence, and therefore violate the FTC Act. The demands order the recipients to immediately stop making all claims that their products can prevent or treat COVID-19, and to notify the Commission within 48 hours about the specific actions they have taken to address the agency's concerns.

The letters warn the recipients of the FTC's authority to seek civil penalties under the COVID-19 Consumer Protection Act. Violators who make deceptive claims related to the treatment, cure, or prevention of COVID-19 are subject to penalties of up to $43,792 per violation.

U.S. Health Agency Issues Special Fraud Alert for Telemedicine

(Regulatory Intelligence) - The U.S. Department of Health and Human Services has issued a special fraud alert for providers entering into arrangements with ‘purported telemedicine companies,’ amid a government crackdown on telemedicine fraud. The department's Office of Inspector General (OIG) issued the alert last week, on the same day the U.S. Department of Justice (DOJ) announced a major enforcement case involving $1.2 billion in fraudulent claims related to telemedicine. [FN44]

The DOJ's action resulted in the arrest of 36 defendants in 13 federal districts in alleged fraudulent schemes involving telemedicine, cardiovascular and cancer genetic testing, as well as durable medical equipment.

The investigation targeted schemes involving the payment of ' illegal kickbacks and bribes' by laboratories and others in exchange for the referral of patients by medical professionals working with fraudulent telemedicine and digital medical technology companies.

The Centers for Medicare & Medicaid Services (CMS) Center for Program Integrity also announced administrative actions against 52 providers involved in similar schemes.

Telemedicine schemes accounted for more than $1 billion of the total alleged losses associated with the enforcement actions, according to the DOJ.

Special fraud alert

Telemedicine grew rapidly during the COVID-19 pandemic, as federal regulators relaxed restrictions on the practice.

The OIG has conducted dozens of investigations into fraud schemes involving companies claiming to provide telehealth, telemedicine or telemarketing services. In some schemes, telemedicine companies paid physicians and other practitioners kickbacks to write orders or prescriptions for ‘medically unnecessary’ durable medical equipment, genetic testing, wound care items or prescription medications that resulted in the submission of fraudulent claims to federal healthcare programs.

The OIG fraud alert issued July 20 identifies the way telemedicine companies use kickbacks to ‘aggressively recruit and reward’ practitioners to order or prescribe medically unnecessary items and services. Patients are typically solicited and recruited by the telemedicine companies for the schemes. The telemedicine companies practitioners for ordering the services or prescriptions for patients ‘they never examined or meaningfully assessed,’ according to the fraud alert.

Often the amount telemedicine companies pay to the practitioner correlates with the ‘volume of federally reimbursable items or services' the practitioner orders. Not only do these volume-based fees violate the federal anti-kickback statute, they can also ‘corrupt medical decision-making, drive inappropriate utilization, and result in patient harm.’

Suspect characteristics of telemedicine arrangements

The OIG developed a list of ‘suspect characteristics' based on its experience investigating telemedicine fraud. Factors that suggest an arrangement presents a ‘heightened risk of fraud and abuse’ include:

• The patients the practitioner writes orders for were identified or recruited by the telemedicine company, telemarketing company, sales agent, call center, health fair and/or through internet, television or social media advertising for ‘free or low out-of-pocket cost items or services.’

• The practitioner lacks sufficient contact with or information from the patient to ‘meaningfully assess the medical necessity of the items or services ordered or prescribed.’

• The telemedicine company pays the practitioner based on the volume of items or services ordered or prescribed, but characterizes the payment as being based on the number of medical records the practitioner reviews.

• The telemedicine company only provides items and services to federal healthcare program beneficiaries and does not accept insurance from any other payer.

• The telemedicine company may claim to only provide items and services to individuals who are not federal healthcare program beneficiaries but actually bills federal programs.

• The telemedicine company provides only one product or type of product such that a practitioner's treat plans are predetermined.

• The telemedicine company does not expect any follow-up care with the patients after the item or service is ordered.

Practitioners entering into arrangements with telemedicine companies that exhibit one or more of these suspect characteristics may face criminal, civil or administrative liability depending on the circumstances of the case.

DOJ Announces Charges in Hacking, Fraud Schemes Targeting U.S. Health Programs and Private Insurers

(Regulatory Intelligence) - The U.S. Department of Justice (DOJ) has charged 10 people in connection with alleged computer hacking, money laundering and wire fraud schemes that resulted in more than $11 million in losses. The schemes targeted Medicare and Medicaid programs, private health insurers and other victims. [FN45]

The schemes allegedly were based on business e-mail ‘phishing’ attacks, which attempt to deceive an entity into transferring funds or disclosing sensitive information.

The schemes leading to the charges announced last week included ‘fraudulently diverted payments intended for hospitals to provide medical services to patients.’ Fraudulent emails were sent to public and private health insurance programs that requested future payment be sent to ‘new bank accounts that did not belong to the hospitals.’ The fraudulent emails were sent from ‘accounts resembling those associated with actual hospitals.’ Based on these deceptive emails, five state Medicaid programs, two Medicare

administrative contractors and two private health insurers made payments to the defendants and their co-conspirators instead of the hospitals.

The defendants and their accused co-conspirators then laundered the proceeds by withdrawing large amounts of cash and layering them through other accounts that had been opened with false or stolen identities and shell companies, transferring the money overseas as well as purchasing luxury goods and exotic automobiles.

'These defendants defrauded numerous individuals, companies, and federal programs, resulting in millions of dollars in financial losses to vital federal programs meant to provide assistance to those in need," said U.S. Attorney Ryan K. Buchanan for the Northern District of Georgia in a DOJ statement.

The Justice Department said that of the 10 peopled charged, charges against seven were unsealed last week Three others had been charged earlier and one of them has pleaded guilty and been sentences. Among those accused in the scheme:

• A Columbia, South Carolina man was charged with three counts of money laundering and one count of unlawful procurement of naturalization. He alleged used a stolen identity to open bank accounts in the name of a shell company to receive more than $1.4 million fraudulently diverted from a Medicaid program, a hospital and others. He also allegedly laundered $583,000 of the proceeds.

• An Atlanta, Georgia man was indicted on four charges of money laundering. He allegedly used false identities to open bank accounts in the names of the false identities and shell companies. He received approximately $2.4 million from Medicare and several private companies. He laundered approximately $679,000 of those proceeds.

• A woman from Atlanta was charged with three counts of wire fraud, two counts of aggravated identity theft and six counts of money laundering for using stolen and false identities to open accounts in the names of shell companies. She is alleged to have received nearly $830,000 in proceeds and to have laundered approximately $535,000 through large cash withdraws.

• A Sandy Springs, Georgia man was charged in February 2022 with conspiracy to commit money laundering and seven money laundering offenses. He allegedly used a shell company to 'receive and launder millions of dollars' from business email compromise schemes targeting a healthcare benefit program, private companies and 'individual romance scam victims.' He allegedly laundered $310,000 that he fraudulently diverted from a Medicaid program that was intended as reimbursement from a hospital. He also received $260,000 from a romance scam targeting an elderly victim that he used to purchase a Ferrari.

The charges were the result of investigations conducted by multiple state and federal enforcement agencies.

VI. DATA BREACHES & HIPAA VIOLATIONS

HHS OCR Resolves Five HIPAA Right of Access Enforcement Actions

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announced on November 30 the resolution of five investigations in its Health Insurance Portability and Accountability Act (HIPAA) Right of Access Initiative, bringing the total number of these enforcement actions to twenty-five since the initiative began. OCR created this initiative to support individuals' right to timely access their health records at a reasonable cost under the HIPAA Privacy Rule.

HIPAA gives people the right to see and get copies of their health information from their healthcare providers and health plans. After receiving a request, an entity that is regulated by HIPAA has, absent an extension, 30 days to provide an individual or their representative with their records in a timely manner.

'Timely access to your health records is a powerful tool in staying healthy, patient privacy and it is your right under law," said OCR Director Lisa J. Pino. 'OCR will continue its enforcement actions by holding covered entities responsible for their HIPAA compliance and pursue civil money penalties for violations that are not addressed."

OCR has taken the following enforcement actions that underscore the importance and necessity of compliance with the HIPAA Right of Access:

• Advanced Spine & Pain Management (ASPM), which provides management and treatment of chronic pain services in Cincinnati and Springboro, Ohio, has agreed to take corrective actions that include two years of monitoring, and has paid OCR $32,150 to settle a potential violation of the HIPAA Privacy Rule's right of access standard.

• Denver Retina Center, a provider of ophthalmological services in Denver, CO, has agreed to take corrective actions that includes one year of monitoring and has paid OCR $30,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard.

• Dr. Robert Glaser, a cardiovascular disease and internal medicine doctor in New Hyde Park, NY, did not cooperate with OCR's investigation or respond to OCR's data requests after failing to provide a patient with a copy of their medical record. Dr. Glaser waived his right to a hearing and did not contest the findings of OCR's Notice of Proposed Determination. Accordingly, OCR closed this case by issuing a civil money penalty of $100,000.

• Rainrock Treatment Center, LLC dba Monte Nido Rainrock ('Monte Nido"), a licensed provider of residential eating disorder treatment services in Eugene, OR, has taken corrective actions including one year of monitoring and has paid OCR $160,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard.

• Wake Health Medical Group, a provider of primary care and other health care services in Raleigh, NC, has agreed to take corrective actions and has paid OCR $10,000 to settle a potential violation of the HIPAA Privacy Rule's right of access standard.

U.S. Medical Body Issues Guidance on Data Collection, Governance for Health App Developers

(Regulatory Intelligence) - The American Medical Association (AMA) has released new guidance on the use of health and wellness data that is collected and shared through mobile applications. The guidance cites a need to ensure that ‘individuals understand who is collecting the data, who they are sharing it with, what will be done with it, and whose responsibility it is to protect sensitive health data.’ [FN46]

'Greater access to digital health information can have harmful consequences, whether intended or not,' according to the AMA document issued last month. This is particularly true when ‘data is used to exclude or provide substandard care for those in historically marginalized communities.’ The AMA points to health insurers that have used wearable-device data to deny claims for reimbursement, employers that have used access to health data, without employees' knowledge, to make employment decisions and even to ‘data brokers' that use the data to ‘create in-depth profiles of individuals' and limit opportunities for housing.

The AMA's guidelines for digit health data collection and equitable data governance rely on the association's Privacy Principals that were released in 2020.

Health and wellness apps

An estimated 85% of U.S. consumers own at least one smartphone, according to the AMA guidelines. There are also more than 300,000 different health and wellness apps available. Additionally, ‘at least 1 in 5 Americans use some kind of smart watch or wearable fitness tracker.’ The 21st Century Cures Act, which allows consumers to access their electronic health records, creates the opportunity for a ‘new class of apps' with access to patient records outside the umbrella of the data-privacy standards in the Health Insurance Portability and Accountability Act of 1996.

A recent Pew survey also found that patients will seek advice and recommendations from their physicians about those apps and that '90% of respondents preferred apps pre-approved by their physician.'

Risks to privacy

The AMA also identified risks[] to privacy associated with using health and wellness apps promoted by employers in ‘collaboration with their health insurance providers.’ The apps include fitness trackers, weight management apps, period tracking and conception planning. Employers often encourage the use by offering employees who use the apps subsidies on health insurance premiums or other benefits.

However, employers sometimes pay to access this information to be available for managers and human resources personnel.

In turn, ‘it's nearly impossible to ensure that such information is not used by employers to make arbitrary decisions about an employee's continued employment, salary, promotion potential and more,’ according to the AMA. For example, an employee with limited mobility who fails to meet daily exercise targets due to a disability or chronic health condition, or one who lives in an unsafe neighborhood ‘may be at greater risk of losing their job.’ This demonstrates ‘how a loss of data privacy can create or exacerbate inequities.’

The AMA also cautions that health insurers may use data collected through health apps for health-scoring and pricing decisions. Such information can be collected, without the patient's knowledge or consent, through medical devices used at home. Although such information sharing is permissible under federal law, it may result in the denial of claims.

AMA guidelines

The AMA encourages app and wearable-device companies to provide ‘clear controls and easy-to-understand terms of service.’ This will allow the companies to become ‘responsible stewards of health and wellness information while promoting equity.’ The AMA expressed concerns that consumers may not currently understand that the information collected by health and wellness apps or wearable devices may be shared among ‘data brokers, insurance companies or even social media companies.’

The AMA also encourages companies to balance ‘user wants with ethical privacy practices.’ Although patient health data is ‘useful and powerful,’ there are risks associated with personal health information ‘getting into the wrong hands or being used to deny patient treatment or make obtaining treatment more difficult.’ The AMA emphasizes that physicians will be more willing to recommend apps or devices to patients when they know the products ‘follow a comprehensive set of privacy guidelines...focused on protecting the trust at the heart of the patient-physician relationship.’

The AMA guidelines provide a list principles around individual rights, equity and entity responsibility. The guidelines for equitable use of data include:

• Privacy protections that promote equity and justice.

• Provisions to ensure awareness that accessing, processing, selling and using healthcare information ‘without the individual's best interest at heart can cause irreparable harm.’

• Protections from discrimination, stigmatization, discriminatory profiling and exploitation occurring during collection and processing of data, and resulting from use and sharing of data, with particular attention to minority and vulnerable communities.

• Privacy protections for free and purchased apps to ensure that those individuals without the resources to purchase apps are not given fewer protections.

• Requirements that law enforcement agencies requesting medical information be required to obtain a court order and show the need for information outweighs the privacy interest of the individual.

• Restrictions on employers and insurers over unconsented access to identifiable medical information, so sensitive facts are not used against individuals, such as in denying coverage for stigmatized health conditions.

The guidelines for individual rights and entity obligations are extensive. They include clear disclosures and informed consent for use of health information, continuing obligations to inform individuals about changes in the ownership or use of data, opt-in requirements where information will be used to train machines or algorithms, limitations on disclosure to law enforcement as well as prohibitions on using health data to discriminate against individuals, including the creation of risk scores for insurance.

Bipartisan Bill on Updating U.S. Health Privacy Laws Introduced in Senate

(Regulatory Intelligence) - A bipartisan duo of U.S. senators has taken an first step toward updating U.S. health privacy law, by introducing a measure aimed at producing recommendations on issues including protecting individual health data and the sharing information that could be useful to consumers. U.S. Senators Bill Cassidy, M.D. (R-LA) and Tammy Baldwin (D-WI) introduced the Health Data Use and Privacy Commission Act on February 9. The bill would form a health and privacy commission to research the issues and provide recommendations to Congress on how to modernize the use of health data and privacy laws. [FN47]

The Health Insurance Portability and Accountability Act, which sets the current health privacy standards, is more than 25 years old and fails to cover health data 'recorded on emerging technologies,' such as cell phone apps or smart watches.

'As a doctor, the potential of new technology to improve patient care seems limitless. But Americans must be able to trust that their personal health data is protected if this technology can meet its full potential," said Cassidy, a medical doctor specializing in gastroenterology. 'HIPAA must be updated for the modern day. This legislation starts this process on a pathway to make sure it is done right," he said.

Said Baldwin: 'I am excited to introduce the bipartisan Health Data Use and Privacy Commission Act to help inform how we can modernize health care privacy laws and regulations to give Americans peace of mind that their personal health information is safe, while ensuring that we have the tools we need to advance high-quality care."

The bill would establish a commission to:

• Conduct a review and comparison of existing protections of personal health information at the state and federal level, as well as current practices for health data use by the health care, insurance, financial services, consumer electronics, advertising and other industries.

• Provide recommendations to Congress on whether federal legislation is needed to modernize health data privacy, and if so, how to do it.

• Submit a report to Congress and the President six months after all members are appointed, and include 17 members to be appointed by the Comptroller General.

The commission would be charged with drafting recommendations on 8 specific areas, including:

• The potential threats posed to individual health privacy and legitimate business and policy interests.

• The purposes for which sharing health information is appropriate and beneficial to consumers and the threat to health outcomes and costs if privacy rules are too stringent.

• The effectiveness of existing statutes, regulations, private sector self-regulatory efforts, technology advances and market forces in protecting individual health privacy.

• Recommendations on whether federal legislation is necessary, and if so, specific suggestions on what should be included in that legislation.

• Analysis of whether additional regulations may impose costs or burdens, or cause unintended consequences in other policy areas, such as security, law enforcement, medical research, health care cost containment, improved patient outcomes, public health or critical infrastructure protection, and whether such costs or burdens are justified by the additional regulations or benefits to privacy.

• The cost analysis of legislative or regulatory changes proposed in the report.

• Recommendations on non-legislative solutions to individual health privacy concerns, including education, market-based measures, industry best practices and new technologies.

• Review of the effectiveness and utility of third-party statements of privacy principles and private sector self-regulatory efforts, as well as third-party certification or accreditation programs meant to ensure compliance with privacy requirements.

Several health organizations and private companies wrote a letter in support of the legislation, including: American College of Cardiology, Association for Behavioral Health and Wellness, Association of Clinical Research Organizations, athenahealth, Inc, Epic Systems Corporation, IBM, National Multiple Sclerosis Society and Teladoc Health. The organizations noted their concerns that HIPAA 'does not address the growing concerns regarding third-party applications or other technologies accessing health data that fall outside of HIPAA's reach.'

Senate bill 3620 was referred to the Committee on Health, Education, Labor, and Pensions on February 9.

Four HIPAA Enforcement Actions Hold Healthcare Providers Accountable

The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced on March 28 the resolution of three investigations and one matter before an Administration Law Judge related to compliance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Two of these cases are part of OCR's HIPAA Right of Access Initiative, bringing the total number of these enforcement actions to twenty-seven since the initiative began. OCR created this initiative to support individuals' right to timely access their health records at a reasonable cost under the HIPAA Privacy Rule. The other enforcement actions result from healthcare providers impermissibly disclosing their patients' protected health information (PHI).

'Between the rising pace of breaches of unsecured protected health information and continued cyber security threats impacting the health care industry, it is critical that covered entities take their HIPAA compliance responsibilities seriously," said OCR Director Lisa J. Pino. 'OCR will continue our steadfast commitment to protect individuals' health information privacy and security through enforcement, and we will pursue civil money penalties for violations that are not addressed."

OCR has taken the following enforcement actions that underscore the importance and necessity of compliance with the HIPAA Rules, including the foundational Right of Access provision:

• Dr. Donald Brockley, D.D.M., a solo dental practitioner in Butler, Pennsylvania, failed to provide a patient with a copy of their medical record. After being issued a Notice of Proposed Determination, Dr. Donald Brockley, D.D.M requested a hearing before an Administrative Law Judge. The litigation was resolved before the court made a determination by a settlement agreement in which Dr. Donald Brockley, D.D.M agreed to pay $30,000 and take corrective actions to comply with the HIPAA Privacy Rule's right of access standard.

• Dr. U. Phillip Igbinadolor, D.M.D. & Associates, P.A. (UPI), a dental practice with offices in Charlotte and Monroe, North Carolina, impermissibly disclosed a patient's PHI on a webpage in response to a negative online review. UPI did not respond to OCR's data request, did not respond or object to an administrative subpoena, and waived its rights to a hearing by not contesting the findings in OCR's Notice of Proposed Determination. OCR imposed a $50,000 civil money penalty.

• Jacob and Associates, a psychiatric medical services provider with two office locations in California, agreed to take corrective actions and pay OCR $28,000 to settle potential violations of the HIPAA Privacy Rule, including provisions of the right of access standard;

• Northcutt Dental-Fairhope, LLC (Northcutt Dental), a dental practice in Fairhope, Alabama, who impermissibly disclosed its patients' PHI to a campaign manager and a third-party marketing company hired to help with a state senate election campaign, agreed to take corrective action and pay $62,500 to settle potential violations of the HIPAA Privacy Rule.

Oklahoma State University Health Center Pays $875,000 to Settle Hacking Breach

Oklahoma State University ? Center for Health Sciences (OSU-CHS) has paid $875,000 to the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) and agreed to implement a corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules. OSU-CHS is a public land-grant research university which provides preventive, rehabilitative, and diagnostic care in Oklahoma.

On January 5, 2018, OSU-CHS filed a breach report stating that an unauthorized third party gained access to a web server that contained electronic protected health information (ePHI). The hacker installed malware that resulted in the disclosure of the ePHI of 279,865 individuals, including their names, Medicaid numbers, healthcare provider names, dates of service, dates of birth, addresses, and treatment information. OSU-CHS initially reported that the breach occurred on November 7, 2017, but later reported that the ePHI was first impermissibly disclosed on March 9, 2016.

OCR's investigation found potential violations of the HIPAA Rules including impermissible uses and disclosures of PHI; failure to conduct an accurate and thorough risk analysis; failure to perform an evaluation, failures to implement audit controls, security incident response and reporting, and failure to provide timely breach notification to affected individuals and HHS.

'HIPAA covered entities are vulnerable to cyber-attackers if they fail to understand where ePHI is stored in their information systems," said OCR Director Lisa J. Pino. 'Effective cybersecurity starts with an accurate and thorough risk analysis and implementing all of the Security Rule requirements."

In addition to the monetary settlement, OSU-CHS will undertake a robust corrective action plan that includes two years of monitoring.

OCR Settles Case Concerning Improper Disposal of Protected Health Information

On August 23, the Office for Civil Rights (OCR) at the Department of Health and Human Services announced a settlement with New England Dermatology P.C., d/b/a New England Dermatology and Laser Center ('NDELC"), over the improper disposal of protected health information, a potential violation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. As a result, NEDLC paid $300,640 to OCR and agreed to implement a corrective action plan to resolve this investigation. NEDLC is located in Massachusetts and provides dermatology services.

On May 11, 2021, NEDLC filed a breach report with OCR stating that empty specimen containers with protected health information on the labels were placed in a garbage bin in their parking lot. The containers' labels included patient names and dates of birth, dates of sample collection, and name of the provider who took the specimen. OCR's investigation, conducted by OCR's New England Regional Office, found potential violations of the HIPAA Privacy Rule including the impermissible use and disclosure of PHI and failure to maintain appropriate safeguards to protect the privacy of PHI.

'Improper disposal of protected health information creates an unnecessary risk to patient privacy," said Acting OCR Director Melanie Fontes Rainer. 'HIPAA regulated entities should take every step to ensure that safeguards are in place when disposing of patient information to keep it from being accessible by the public."

In addition to the monetary settlement, NEDLC will undertake a robust corrective action plan that includes two years of monitoring.

Healthcare, Financial Industries Lead in Average Cost of Data Breaches, Annual Report Finds

(Regulatory Intelligence) - The healthcare industry, followed by the financial sector, experienced the most costly data breaches of major industries in the year to March 2022, according to an annual international study for IBM Security. [FN48]

For the twelfth consecutive year, the healthcare industry had the highest average cost of a breach, averaging $10.1 million per breach. The average cost broke into double-digit millions for the first time, with a 9.4% increase of nearly $1 million over the previous year, the report said.

Across all industries, the report found data breaches cost surveyed companies an average of $4.35 million per incident, an increase of 2.6% over last year and 12.7% since the 2020 report.

The top five industries for average total cost were:

• Healthcare ($10.1 million)

• Financial ($5.97 million)

• Pharmaceuticals ($5.01 million)

• Technology ($4.97 million)

• Energy ($4.72 million)

The report recommended that firms adopt a 'zero-trust' security strategy, which assumes that every connection and endpoint for a company's network is considered a threat. It aims to protect against both external or internal security threats, and represents a shift away from relying more simply on protecting a system from intrusion.

'Businesses need to put their security defenses on the offense,' said Charles Henderson, Global Head of IBM Security X-Force in a release. IBM Security, the sponsor of the report, provides such services.

Impact of compliance failures

The report examines 28 cost factors and their impact on the mean cost of a data breach. 'Compliance failures" were one of the three factors 'associated with the highest net increase in the average cost." The other two factors were security system complexity and an occurrence when the entity was migrating to the cloud.

The report found a $2.26 million difference or 50.9% 'between high levels and low levels of compliance failures.' When a compliance failure was the 'amplifying factor,' high level compliance failures had average costs of $5.57 million while low level compliance failures had average costs of $3.31 million.

The report defined highly regulated industries to include healthcare, finance, energy, pharmaceuticals and education. In these heavily regulated industries, 'longtail costs' such as fines, penalties and legal costs following a data breach contributed to higher costs in the years following a breach.

In these highly regulated industries, an average of 24% of data breach costs 'accrued more than two years after the breach occurred.' In less regulated industries, an average of only 8% of costs accrued more than 2 years after the breach.

In 2022, the most common initial attack vectors were:

• Compromised credentials (19%)

• Phishing (16%)

• Cloud misconfiguration (15%)

• Vulnerability in third-party software (13%)

The two costliest initial attack vectors in 2022 were phishing at $4.91 million and business email compromise at $4.89 million.

Other amplifying and mitigating factors

In addition to the higher costs for heavily regulated industries, the report found a number of other factors that increased the costs for data breaches.

It took an average of 277 days to identify and contain a data breach, according to the report. This 10 days less than found in the last report. Data breaches that took longer than 200 days to identify and contain cost an average of $1.12 million more than those taking fewer than 200 days.

Predictably, mega breaches were significantly more expensive than smaller breaches. Mega breaches involve more than 1 million records. This year's report surveyed 13 companies that experienced a data breach involving 1 million to 60 million records. Mega breach costs decreased from 2021 in most size cohorts. The largest mega breaches of 50 million to 60 million records decreasing from $401 million in 2021 to $387 million in 2022. Only the cohort for 20 million to 30 million records increased with an average cost $241 million up from $230 million in 2021.

The report also identified factors that mitigated the costs of a data breach.

Organizations with ‘high levels of use of security platforms' using artificial intelligence and an average data breach cost 55.3% or $2.39 million lower than those with low levels of use of an artificial intelligence platform.

High use of an IR team had an average costs that was 44.9% or $2.12 million lower than those with a low use of an incident response team. Organizations with a high level of using an integrated development, security and operations approach had average costs that were 26.7% or $1.17 million lower than those with low use of that approach.

Research for this report was conducted by Ponemon Institute, an independent research organization specializing in information management and privacy. It was sponsored and analyzed by IBM Security. The report studied 550 organizations impacted by data breaches that occurred between March 2021 and March 2022. The breaches occurred in 17 countries and regions and 17 different industries.

FBI Warns of Cyberattack Vulnerabilities Among Medical Devices

(Regulatory Intelligence) - The U.S. Federal Bureau of Investigation (FBI) has warned the healthcare sector over cybersecurity risks to medical devices, and said attacks on such devices can endanger patient safety. The warning comes amid findings by a data privacy research organization that the vast majority of healthcare organizations have experienced a cybersecurity incident in the last year. [FN49]

The bureau on September 12 issued a so-called private industry notification warning that ‘unpatched medical devices that run on outdated software’ and devices without adequate security features are increasingly vulnerable to cyber attacks. Cyber threat actors that exploit medical device vulnerabilities ‘adversely impact healthcare facilities' operational functions, patient safety, data confidentiality, and data integrity,’ according to the FBI.

Medical devices are uniquely vulnerable to cyber attacks because the hardware can remain active for 10 to 30 years, while the software life cycle, as specified by the manufacturer, may only be a couple of months. When legacy medical devices rely on outdated software ‘because they do not receive manufacturer support for patches or updates,’ the devices are ‘especially vulnerable to cyberattacks' because cyber threat actors have time to ‘discover and exploit vulnerabilities.’

In addition to outdated or unpatched software, the FBI identified the following vulnerabilities:

• Devices used with the manufacturer's default configuration are easily exploitable.

• Devices with customized software may require special upgrading and patching that delay implementation of vulnerability patching.

• Some devices were not initially designed with security in mind because there was no perceived security threats.

Scope of medical device vulnerabilities

The FBI included data on the scope of known medical device vulnerabilities. It cited a cybersecurity firm's research report that as of January 2022, '53% of connected medical devices and other internet of things (IoT) devices in hospitals had known critical vulnerabilities.' Additionally, approximately one third of healthcare IoT devices have an ‘identified critical risk potentially implicating technical operation and functions of medical devices.’

A healthcare cybersecurity analyst's report this year cited the FBI said several medical devices are susceptible to cyber attacks. These include ‘insulin pumps, intracardiac defibrillators, mobile cardiac telemetry, pacemakers, and intrathecal pain pumps.’ Cyber attackers who compromise these devices can cause them to ‘give inaccurate readings, administer drug overdoses, or otherwise endanger patient health.’

A report from last year identified that there are an average of 6.2 vulnerabilities per medical device, the FBI said. Although recalls were issued for critical devices such as pacemakers and insulin pumps with known security issues, ‘more than 40% of medical devices at the end-of-life stage offer little to no security patches or upgrades.

FBI recommendations for medical devices

As part of its private industry letter, the FBI makes several recommendations to actively secure medical devices, identify vulnerabilities and increase employee awareness, including:

• Provide endpoint protections including antivirus software, if possible, encrypt medical device data as well as usingendpoint detection and response an extended detection and response solutions.

• Ensure default passwords are changed to secure and complex passwords specific to each medical device and limit the number of login attempts per user, if possible.

• Improve asset management protocols including the inventory of medical devices and associated software.

• Work with manufacturers to help mitigate vulnerabilities on operational medical devices.

• Conduct independent vulnerability assessments, especially prior to installing any new medical device onto an IT network.

• Implement required training for employees on how to identify and report potential threats.

These recommendations are intended to mitigate medical device vulnerabilities to cyber attacks.

Healthcare cyber attacks harm patients

A recent survey of 641 IT and IT security practitioners in healthcare organizations by the data privacy research group Ponemon Institute found 89% of the organizations ‘had at least one cyberattack’ over the previous 12 months.

Fifty percent of respondents reported an attack against their organization's supply chain, with 70% of those respondents saying ‘it disrupted patient care.’ The consequences of those disruptions included ‘an increase in the severity of an illness' (54%), ‘longer length of stay’ (51%) and an ‘increase in mortality rate’ (23%).

Sixty-seven percent of respondents said business email compromise or ransomware attack against their organizations disrupted patient care. Of those organizations experiencing business email compromise, 21% said it increased the morality rate and for ransomware attacks, 24% said it increased the mortality rate.

Ransomware attacks also caused delays in procedures or tests that resulted in poor outcomes in 64% of organizations experiencing those attacks.

The Ponemon Institute survey was sponsored by Proofpoint.

U.S. Senate Intelligence Panel Report Urges Stronger Rules on Healthcare Cybersecurity

(Regulatory Intelligence) - U.S. healthcare regulations need updating to better protect providers and patients from cybersecurity attacks that reached record levels last year, a U.S. Senate Intelligence Committee report recommended. [FN50]

'Unfortunately, the health care sector is uniquely vulnerable to cyber attacks and the transition to better cybersecurity has been painfully slow and inadequate. The federal government and the health sector must find a balanced approach to meet the dire threats, as partners with shared responsibilities,” Intelligence Committee Chairman Mark Warner wrote earlier this month in releasing white paper produced by the committee.

The report noted that cybersecurity attacks on U.S. healthcare providers ‘reached an all-time high, with one study indicating that more than 45 million people were affected by such attacks in 2021.’

This represents a 32 percent increase over 2020. Attacks on healthcare providers are increasing because personal health information ‘is more valuable on the black market’ than credit card information. Hackers can sell medical records for $10 to $1,000 per record, according to the white paper.

The paper outlines current cybersecurity threats in the healthcare sector and offers a series of government and provider policy solutions for cybersecurity in the industry.

The first section of the white paper addresses the Health Insurance Portability and Accountability Act, or HIPPA, which governs patient privacy protections at healthcare providers and related businesses. The Senate paper recommends ‘mandating a regular process to modernize HIPAA regulations to address a broader scope of cybersecurity threats.’

The paper also recommends that the National Institute of Standards and Technology provide more detailed guidance for the healthcare industry. It suggests that the Stark law governing provider conflicts of interest and anti-kickback provisions be clarified with safe harbors to ensure they do not ‘prevent stakeholders in legitimate partnerships from working together on cybersecurity improvements.’

The second section of the white paper recommends that ‘all health care organizations should be familiar with and apply certain minimum cybersecurity practices as standard operating procedure.’ This could be achieved in part by incorporating ‘some minimum level of cybersecurity hygiene practices' into provider conditions of participation for Medicare and Medicaid.

The white paper proposes providing incentives for organizations to ‘phase out legacy equipment.’ However, it also recognized that ‘larger-scale changes to product development and product procurement are needed to make these trends self-sustaining.’

Although the white paper says cybersecurity should be a ‘cost of doing business,’ it acknowledges that current Medicare payment formulas fail to account for the ‘literal costs of doing cybersecurity business' and may need to be adjusted.

Additionally, the white paper recommends streamlining how the federal government shares cybersecurity information for healthcare organizations in a way that recognizes the ‘diverse health care cybersecurity responsibilities and needs' of entities.

The third section of the white paper reports that the FBI found the healthcare sector ‘faced the most ransomware attacks in 2021 compared to other critical infrastructure sectors.’ In order to be better prepared for such attacks, the white paper recommends that the Centers for Medicare and Medicaid Services ‘better direct facilities to consider cyber attacks' in the same way they are required to approach emergency preparedness for hazards such as earthquakes or hurricanes that require a unique response.

It also proposes a ‘cyber disaster relief program’ to provide relief to victims of a cyber attack similar to the assistance provided for natural disasters.

Additionally, the white paper recommends a creating a federal reinsurance program to cover plans that require minimum cybersecurity standards, standardizing coverage elements with incentives for insurers to adopt those elements, creating a cyber insurance program similar to the Terrorism Risk Insurance Act to increase transparency around nation-state cyber attacks and mandating the reporting of cyber-insurance payouts to increase event reporting.

Increasing risks of cyber attacks in healthcare

The committee's depiction of record healthcare cyber attacks was echoed in a recent Check Point research report that shows the average weekly attacks in the healthcare industry increased 69% in the first half of 2022 over last year. Healthcare providers were among the victims of some of the more serious cyber attacks according to the recent report. Among them was a January attack on Broward Health in Florida that exposed the medical information of more than 1.3 million individuals to cyber criminals. In October, a ransomware attack hit CommonSpirit health system, which operates 142 hospitals across 21 U.S. states. The attack blocked access to the system's electronic health records and disrupted patient care.

In the third quarter, healthcare was the most targeted industry for ransomware attacks, with one in 42 entities impacted by ransomware, according to Check Point.

Last week, the Department of Health & Human Services Health Sector Cybersecurity Coordination Center warned healthcare providers that at least one U.S. healthcare entity had ‘fallen victim to Venus ransomware recently.’ The Venus ransomware has been operating since the middle of August 2022, according to the analyst note. The ransomware has breached systems worldwide.

As the threats and successful cyber attacks against healthcare entities continue to increase, providers must take measures to improve their cyber hygiene, mitigate risks and be prepared to respond to any breach.

VII. BIDEN ADMINISTRATION

Administration Awards $103 Million in American Rescue Plan Funds to Reduce Burnout in Health Care Workforce

The U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced $103 million in awards on January 20 to improve the retention of health care workers and help respond to the nation's critical staffing needs by reducing burnout and promoting mental health and wellness among the health care workforce. These awards will fund evidence-informed programs, practices and training, with a specific focus on providers in underserved and rural communities. The funds, secured through the Biden-Harris Administration's American Rescue Plan, will be disbursed to 45 grantees.

'I have traveled to many health centers across the country and know that the COVID-19 pandemic has intensified issues that have long been a source of stress for frontline health care workers — from increased patient volumes to long working hours,” said Health and Human Services Secretary Xavier Becerra. ‘This funding reflects the Biden-Harris Administration's commitment to ensuring we have enough critical frontline workers by supporting health care providers now and beyond as they face burnout and mental health challenges. We will continue to promote the well-being of those who have made so many sacrifices to keep others well.”

COVID-19 has compounded rates of depression and anxiety among health care workers. The relentless physical and emotional demands of treating patients during a pandemic have exacerbated longstanding barriers to workplace well-being. While the challenge is complex, these multi-year awards will support proven strategies for health care providers, academic institutions, and other recipients to reduce burnout and build resiliency. These strategies will include the creation of partnerships and utilization of local resources to directly support health professionals' response to workplace stressors, and provide training to help individuals manage the constantly changing, high-stress environment of health care.

'Now more than ever, it is critical to support the well-being of our health care workforce, who are working every day to protect each of us,” said HRSA Administrator Carole Johnson. ‘Today's awards will provide new tools to help support our health professionals' resilience as they continue to face the stress and challenges of responding to COVID-19 and other health care needs and provide high quality care.”

HRSA is making these awards through three programs:

• Promoting Resilience and Mental Health Among Health Professional Workforce ? HRSA is awarding $28.6 million to 10 grantees to help health care organizations establish, improve, or expand evidence-informed programs and practices to promote mental health and well-being among the health workforce, including their employees.

• Health and Public Safety Workforce Resiliency Training Program ? HRSA is awarding $68.2 million to 34 grantees to support tailored evidence-informed training development within health profession and nursing training activities. This curriculum will help reduce burnout and promote resilience among health care students, residents, health care professionals, paraprofessionals, trainees and public safety officers, such as firefighters, law enforcement officers, and ambulance crew members.

• Health and Public Safety Workforce Resiliency Technical Assistance Center ? HRSA is awarding $6 million to George Washington University to provide tailored training and technical assistance to today's awardees.

See a list of the award recipients here: https://bhw.hrsa.gov/funding/health-workforce-resiliency-awards.

HHS Distributing an Additional $413 Million in Provider Relief Fund Payments to Health Care Providers Impacted by the COVID-19 Pandemic

The Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced March 22 more than $413 million in Provider Relief Fund (PRF) payments to more than 3,600 providers across the country. This is the fourth round of PRF Phase 4 payments, totaling nearly $12 billion that has been distributed to more than 82,000 providers in all 50 states, Washington D.C., and five territories since November 2021. This is in addition to HRSA's distribution of American Rescue Plan (ARP) Rural payments totaling nearly $7.5 billion in funding to more than 44,000 providers across the country over the past four months.

'These funds have helped save lives throughout the pandemic," said HHS Secretary Xavier Becerra. 'As we continue to make progress in defeating COVID-19, it's important to keep supporting our providers with the resources they need so we can all build back better and healthier than before."

'Health care providers are doing critical work on the frontlines of the fight against COVID-19," said HRSA Administrator Carole Johnson. 'Provider Relief Fund resources are continuing to help meet these essential needs and maintain access to key health services across the country."

In September of 2021, HHS opened applications for $25.5 billion in COVID-19 provider funding. With this latest installment, more than $19 billion of this funding has been awarded. Phase 4 payments reimburse smaller providers for a higher percentage of losses during the pandemic and include bonus payments for providers who serve Medicaid, Children's Health Insurance Program (CHIP), and Medicare beneficiaries.

PRF payments received in the first half of 2022 can be used until June 30, 2023. With today's payments, approximately 89 percent of all Phase 4 applications have been processed. Remaining applications require additional manual review and HRSA is working to process them as quickly as possible.

Provider Relief Fund payments have played a key role in the nationwide response to COVID-19, helping health care providers prevent, prepare for, and respond to the coronavirus. Health care providers can use the payments to continue supporting patient care and respond to workforce challenges through recruitment and retention efforts.

Biden Administration to Evaluate Medical Debt Collection, Use in Credit Reports

(Regulatory Intelligence) - The Biden administration will evaluate illegal and harassing debt collection practices for unpaid healthcare bills and consider whether medical debt should not be included in credit reports, as part of its efforts to alleviate the burden of the high cost of healthcare in the country. [FN51]

'One in three adults in our country struggles with unpaid medical bills," Vice President Kamala Harris said in announcing the initiative this week. 'And of those adults, a disproportionate number are Black or Latino."

The federal government pays roughly $1.5 trillion a year into the health care system to provide patients with care and services, and providers receiving that funding should not subject patients to illegal and harassing debt collection practices, the White House said in a statement.

The administration also said on Monday that it will tell federal agencies to eliminate medical debt as a factor for underwriting in credit programs, while the Consumer Financial Protection Bureau (CFPB) will investigate credit reporting companies and debt collectors that violate the rights of patients and their families.

The consumer protection agency will also target credit reporting practices and determine whether unpaid medical billing data should ever be included in credit reports, according to the White House.

'Having medical debt because you were sick or injured should not lower your credit score and make it more difficult to secure the help you need to get out of debt. It's not logical," Harris said.

The U.S. Department of Health and Human Services will separately evaluate how providers' billing practices impact affordability and the accrual of medical debt by looking into the data from more than 2,000 providers on medical bill collection practices, lawsuits against patients and 3rd party contracting or debt buying practices, among other information.

The agency will use this information in its grant-making decisions for the first time, besides providing policy recommendations and ways to report potential violations, the White House said.

States including Washington, California, Maryland, Nevada and New Mexico have enacted laws with some level of consumer protection with respect to medical debt collection, credit reporting and litigation over unpaid debt. A law that went into effect in California at the start of this year prohibits hospitals from selling patient debt to a debt buyer in many circumstances and bans attempts to collect the debt less than six months from the initial billing, regardless of the patient's financial status.

Major credit bureaus Equifax, Experian and TransUnion last month said they would remove medical debt that has been paid from credit reports, in a change of policy that would eliminate up to 70 percent of a history of medical debt from credit reports. The agencies will soon start giving consumers up to one year to work with insurers and providers to address unpaid bills before adding the medical debt to their credit file.

Harris said the administration will keep an eye on the progress of these efforts.

'We're glad to see that the White House and Consumer Financial Protection Bureau will focus on the remaining 30 percent," said Chi Chi Wu, staff attorney at the National Consumer Law Center. 'No one should have trouble renting an apartment, purchasing a home, or getting a job over medical debt."

Medical debt arising from unpaid medical bills often arises from unpaid insurance claims, unforeseen medical emergencies or from treatments received by consumers dealing with chronic conditions such as cancer. This debt is recorded on credit reports, putting consumers at a disadvantage when trying to access other parts of financial systems, such as banking, mortgage, insurance, housing and sometimes employment.

CFPB research has shown $88 billion in medical debt on consumer credit records as of June 2021. The total amount of medical debt in collections in the U.S. is likely higher as not all medical debts in collections are furnished to consumer reporting companies, the agency has said.

HHS Awards Over $155 Million to Expand Training for Primary Care Residents in Underserved and Rural Communities

On July 1, the U.S. Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced over $155 million in awards for 72 teaching health centers that operate primary care medical and dental residency programs that include high need specialties such as psychiatry, as part of President Biden's Unity Agenda to address the nation's mental health crisis.

These awards ? supported by the American Rescue Plan Act of 2021 and Fiscal Year 2022 funds ? come at a significant moment when the nation's health care workforce is facing challenges, as recently highlighted in the Surgeon General's Advisory Addressing Health Worker Burnout.

'Having access to primary care and mental health support is essential to one's health and well-being," said HHS Secretary Xavier Becerra. 'Increasing the number of primary care residents training in community health centers and other outpatient community clinics is a key part of the Biden-Harris Administration's plan to address longstanding health inequities in our most vulnerable communities. We will continue to expand the primary care workforce supply line to help meet community needs."

'We are leading the effort to build a stronger primary care and mental health workforce to meet the needs of historically underserved communities by supporting primary care training programs that include psychiatry," said HRSA Administrator Carole Johnson. 'The American Rescue Plan has been a game-changer for growing this critical program and helping us build a workforce that best reflects and serves the communities that need these resources the most."

HRSA's Teaching Health Center Graduate Medical Education program focuses on supporting residents in primary care residency training programs to meet the medical and mental health care needs of rural and underserved communities. With more than 970 full-time residents, it represents an important step toward increasing much-needed access to quality health care services.

Here is a breakdown of the awards:

• $135 million in American Rescue Plan funds to support existing and new teaching health centers to support additional resident positions.

• $20 million in Fiscal Year 2022 funds to support existing Teaching Health Center Graduate Medical Education residency programs to continue resident training in the upcoming academic year.

These awards are part of the Biden-Harris Administration's work to expand and improve the distribution of the nation's primary care workforce in economically disadvantaged areas. Previous HRSA investments under the American Rescue Plan are supporting the planning and development of even more teaching health center primary care residency programs.

HHS Guidance to Retail Pharmacies on Obligations to Ensure Access to Reproductive Healthcare Services

On July 13, following President Biden's Executive Order on ensuring access to reproductive health care, the U.S. Department of Health and Human Services (HHS) is issuing guidance to roughly 60,000 U.S. retail pharmacies, reminding them of their obligations under federal civil rights laws. The guidance makes clear that as recipients of federal financial assistance, including Medicare and Medicaid payments, pharmacies are prohibited under law from discriminating based on race, color, national origin, sex, age, and disability in their programs and activities. This includes supplying prescribed medications; making determinations regarding the suitability of prescribed medications for a patient; and advising a patient about prescribed medications and how to take them. The action is the latest step in the HHS' response to protect reproductive health care.

'We are committed to ensuring that everyone can access health care, free of discrimination," said Secretary Becerra. 'This includes access to prescription medications for reproductive health and other types of care."

Under Section 1557 of the Affordable Care Act (Section 1557), 42 U.S.C. 18116, recipients of federal financial assistance cannot exclude an individual from participation in, denying them the benefits of, or otherwise subjecting them to discrimination based on sex and other bases (i.e., race, color, national origin, age, and disability) in their programs and activities. Under federal civil rights law, pregnancy discrimination includes discrimination based on current pregnancy, past pregnancy, potential or intended pregnancy, and medical conditions related to pregnancy or childbirth.

The full guidance is available here: https://www.hhs.gov/sites/default/files/pharmacies-guidance.pdf.

Biden Administration Makes More Medicare Nursing Home Ownership Data Publicly Available

On September 26, the Centers for Medicare & Medicaid Services (CMS) announced it is making additional data publicly available that provide more information about the ownership of all Medicare-certified nursing homes in order to improve nursing home transparency, safety and quality.

This data will give state licensing officials, state and federal law enforcement, researchers, and the public an enhanced ability to identify common owners of nursing homes across nursing home locations. This information can be linked to other data sources to identify the performance of facilities under common ownership, such as owners affiliated with multiple nursing homes with a record of poor performance.

The release of this new data advances the Biden-Harris Administration's goal of improving transparency of nursing home ownership outlined in President Biden's State of the Union Action Plan for Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes. It is also part of HHS and CMS's efforts to implement the President's Executive Order on Promoting Competition.

'President Biden has made clear that we must improve the quality of care in our nation's nursing homes ? and we are taking unprecedented steps to deliver on his call to action," said HHS Secretary Xavier Becerra. 'Every family deserves the peace of mind of knowing their loved ones living in nursing homes are receiving the best possible care. We are continuing to make more data publicly available than ever before to improve transparency for researchers, regulators, and loved ones."

Today's announcement builds on the historic release of nursing homes and hospitals data by CMS earlier this year following President Biden's State of the Union call to action. In April, CMS released data publicly ? for the first time ever ? on mergers, acquisitions, consolidations, and changes of ownership from 2016-2022 for hospitals and nursing homes enrolled in Medicare.

The information posted today now includes detailed information on the ownership of approximately 15,000 nursing homes certified as a Medicare Skilled Nursing Facility (SNF) ? regardless of any change in ownership, including providing more information about organizational owners of nursing homes. For example, the expanded data elements include information about each organizational owner, such as whether it's a holding company or a consulting firm. CMS has also provided key identifiers that reflect groups of nursing homes with common ownership or managerial control.

The data file on nursing home ownership will be posted to data.cms.gov and updated monthly to help researchers, states, regulators and others analyze how ownership of particular nursing homes or groups of nursing homes impacts the quality of care nursing home residents receive.

While intended primarily for researchers and state and federal agencies, the new nursing home ownership data will also be accessible to consumers through a link in the ownership section of Care Compare on the Medicare.gov website with the next update of the website on September 28th. CMS will work with consumers to obtain feedback on how best to present provider ownership information in a user-friendly way to support their health care decisions.

[FN2]

. Tom Hals, Court revives health worker COVID-19 vaccine mandate in 26 U.S. states, Reuters (December 15, 2021).

[FN3]

. Logan Mortenson, U.S. Supreme Court issues contrasting decision on vaccine mandates, Thomson Reuters Regulatory Intelligence (January 18, 2022).

[FN4]

. Kanishka Singh, Biden to extend U.S. national emergency due to COVID-19 health risk, Reuters (February 18, 2022).

[FN5]

. Antonita Madonna, Hospitals seek federal protection to curb violence against healthcare workers, Thomson Reuters Regulatory Intelligence (March 29, 2022).

[FN6]

. Ohio jury finds doctor not guilty of murder in fentanyl case - Columbus Dispatch, Reuters (April 20, 2022).

[FN7]

. Tessa Wright, U.S. health agency CMS updates long-term care facility health and safety standards, Thomson Reuters Regulatory Intelligence (July 7, 2022).

[FN8]

. Antonita Madonna, Biden administration stresses abortion care in emergency, federal protection for providers, Thomson Reuters Regulatory Intelligence (July 12, 2022).

[FN9]

. Antonita Madonna, Biden administration widens ACA's nondiscrimination clause to include abortions, LGBT people, Thomson Reuters Regulatory Intelligence (July 26, 2022).

[FN10]

. Melissa D. Berry, California AG launches inquiry into bias in healthcare algorithms, Thomson Reuters Regulatory Intelligence (September 28, 2022).

[FN11]

. Leroy Leo, CDC awards over $3 bln to strengthen U.S. public health infrastructure, Reuters (November 29, 2022).

[FN12]

. Diane Bartz, U.S. sues to stop merger of Rhode Island hospital companies, Reuters (February 17, 2022).

[FN13]

. Leroy Leo, Healthcare Trust of America, Healthcare Realty to combine in medical REIT deal, Reuters (February 28, 2022).

[FN14]

. Ludwig Burger, FMC's U.S. division Health Partners in $2.4 bln three-way merger, Reuters (March 21, 2022).

[FN15]

. Melissa D. Berry, U.S. hospital association urges federal agencies to revise merger enforcement guidelines, Thomson Reuters Regulatory Intelligence (April 11, 2022).

[FN16]

. Melissa D. Berry, U.S. health agency's data shows nursing-home ownership changes outpacing hospitals, Thomson Reuters Regulatory Intelligence (April 29, 2022).

[FN17]

. Manas Mishra and Jeffrey Dastin, Amazon strikes $3.5 bln deal for One Medical in long march into U.S. healthcare, Reuters (July 21, 2022).

[FN18]

. Caroline Humer, CVS to buy Signify Health in $8 bln deal, Reuters (September 5, 2022).

[FN19]

. Arriana McLymore, Walmart, UnitedHealth to offer preventive healthcare program for seniors, Reuters (September 7, 2022).

[FN20]

. Leroy Leo and Khushi Mandowara, McKesson to buy pharma tech firm Rx Savings for up to $875 mln, Reuters (September 19, 2022).

[FN21]

. Diane Bartz, Judge denies U.S. bid to stop UnitedHealth plan to buy Change, Reuters (September 20, 2022).

[FN22]

. Leroy Leo, Walgreens-backed VillageMD to buy Summit Health in $9 billion deal, Reuters (November 7, 2022).

[FN23]

. Antonia Madonna, U.S. hospital, physician groups sue to block small part of surprise billing law, Thomson Reuters Regulatory Intelligence (December 13, 2021).

[FN24]

. Diane Bartz, Drugmakers aim big price hikes at U.S. patients, congressional report finds, Reuters (December 10, 2021).

[FN25]

. Diane Bartz, U.S. lawmakers seek answers on ‘troubling’ drug price increases, Reuters (March 1, 2022).

[FN26]

. Amruta Khandekar and Bhanvi Satija, Civica aims to launch low-cost insulin in U.S. by 2024, Reuters (March 3, 2022).

[FN27]

. Brendan Pierson, Arkansas sues drugmakers, pharmacy benefit managers over insulin costs, Reuters (May 11, 2022).

[FN28]

. Diane Bartz, Pharmacy benefit managers' profits targeted by new U.S. bill, Reuters (May 25, 2022).

[FN29]

. Ahmed Aboulenein and Richard Cowan, U.S. Senate Democrats advance deal to lower drug prices, Reuters (July 6, 2022).

[FN30]

. Melissa D. Berry, U.S. pharmacy benefit managers face increased scrutiny, Thomson Reuters Regulatory Intelligence (July 6, 2022).

[FN31]

. Deena Beasley, Newly launched U.S. drugs head toward record-high prices in 2022, Reuters (August 16, 2022).

[FN32]

. Deena Beasley, New U.S. cancer drug prices rise 53% in five years - report, Reuters (November 2, 2022).

[FN33]

. Nate Raymond, Sun Pharma to pay $485 million to resolve Ranbaxy antitrust cases, Reuters (March 23, 2022).

[FN34]

. Michael Erman and Manas Mishra, COVID vaccine makers shift focus to boosters, Reuters (May 9, 2022).

[FN35]

. Ananya Mariam Rajesh, Juby Babu and Siddharth Cavale, Walmart, CVS to halt filling prescriptions for controlled substances by Cerebral, Done, Reuters (May 26, 2022).

[FN36]

. Stephen Nellis, Apple outlines health technology strategy in new report, Reuters (July 20, 2022).

[FN37]

. Michael Erman, Merck avoided billions in U.S. tax by offshoring Keytruda profits - senator, Reuters (July 27, 2022).

[FN38]

. Pami Ayyub, ‘Understaffed and overworked’: Thousands of Minnesota nurses go on strike, Reuters (September 13, 2022).

[FN39]

. Melissa D. Berry, U.S. agencies caution nursing homes and debt collectors on debt collection practices, Thomson Reuters Regulatory Intelligence (September 15, 2022).

[FN40]

. Antonita Madonna, Private-equity ownership in U.S. health care drives up pricing, may affect premiums -studies, Thomson Reuters Regulatory Intelligence (September 23, 2022).

[FN41]

. Mrinalika Roy, J&J names consumer health business Kenvue ahead of spin-off, Reuters (September 28, 2022).

[FN42]

. Nate Raymond and Andrew Chung, U.S. Supreme Court weighs barring lawsuits against public nursing homes, Reuters (November 8, 2022).

[FN43]

. Diane Bartz and Jonathan Stempel, U.S. judge bars Martin Shkreli from drug industry, orders $64.6 mln payment, Reuters (January 14, 2022).

[FN44]

. Melissa D. Berry, U.S. health agency issues special fraud alert for telemedicine, Thomson Reuters Regulatory Intelligence (July 27, 2022).

[FN45]

. Melissa D. Berry, DOJ announces charges in hacking, fraud schemes targeting U.S. health programs and private insurers, Thomson Reuters Regulatory Intelligence (November 22, 2023).

[FN46]

. Melissa D. Berry, U.S. medical body issues guidance on data collection, governance for health app developers, Thomson Reuters Regulatory Intelligence (January 7, 2022).

[FN47]

. Melissa D. Berry, Bipartisan bill on updating U.S. health privacy laws introduced in Senate, Thomson Reuters Regulatory Intelligence (February 16, 2022).

[FN48]

. Melissa D. Berry, Healthcare, financial industries lead in average cost of data breaches, annual report finds, Thomson Reuters Regulatory Intelligence (September 7, 2022).

[FN49]

. Melissa D. Berry, FBI warns of cyberattack vulnerabilities among medical devices, Thomson Reuters Regulatory Intelligence (September 22, 2022).

[FN50]

. Melissa D. Berry, U.S. Senate Intelligence panel report urges stronger rules on healthcare cybersecurity, Thomson Reuters Regulatory Intelligence (November 17, 2022).

[FN51]

. Antonita Madonna, Biden administration to evaluate medical debt collection, use in credit reports, Thomson Reuters Regulatory Intelligence (April 14, 2022).