Legal Lens

Students from the Saint Louis University School of Law Center for Health Law Studies contributed the following items to this column. Amy N. Sanders, Associate Director, supervised contributions by Jessie Bekker (J.D., M.H.A. anticipated 2023) and Darian Diepholz, M.B.A., M.P.H. (J.D. anticipated 2022).

UNVACCINATED? DON'T COUNT ON LEAVING YOUR FAMILY DEATH BENEFITS

Michelle Andrews, *Kaiser Health News*, November 3, 2021. https://khn.org/news/article/unvaccinated-workers-death-benefits/

The New York Metropolitan Transportation Authority (MTA) has excluded workers who were unvaccinated and died of COVID from their death benefit policy. MTA announced the policy in June, disqualifying bereaved families of the unvaccinated from receiving a $500,000 payout. About 70% of MTA employees were vaccinated as of early November 2021. Generally, people working risky jobs, including firefighters and transit workers, are provided extra coverage for on-the-job deaths. Disease was not typically considered to be a reason for death payout, because it was presumed disease was contracted outside of working hours. Some employers are flipping the presumption when it comes to COVID. Companies are also considering limiting short-term disability benefits to unvaccinated employees.

RURAL HEALTH CARE PROVIDERS GET $7.5 BILLION IN RELIEF FUNDS

Mark Walker, *The New York Times*, November 23, 2021. https://www.nytimes.com/2021/11/23/us/politics/rural-health-care-relief-funds.html

The Department of Health and Human Services is disbursing $7.5 billion across 40,000 rural health care providers to help hospitals ravaged by the COVID-19 pandemic keep their doors open. The funding, allocated to rural providers by the American Rescue Plan, passed by Congress in March, aims to secure health care access despite the unique financial struggles rural providers faced as a result of the pandemic. Most rural providers disproportionately receive public insurance payments for patients with complex needs, thinning margins; since 2020, 21 rural hospitals have ceased operations. Providers in rural areas are eligible for payments if they serve at least one Medicare, Medicaid or Children's Health Insurance Program (CHIP) beneficiary. Payments range from $500 to $43 million, averaging around $170,000, based on the number of claims the provider submitted through 2019 up until September 2020. Providers have some discretion over how they spend funds, including coverage of labor costs, personal protective equipment, and ventilators. Vice President Kamala Harris also announced a $1.5 billion commitment to address provider shortages in both rural and urban areas.

HEALTH SPENDING GROWTH MORE THAN DOUBLED IN FIRST YEAR OF PANDEMIC

Rachael Levy, *Politico*, December 15, 2021.
https://www.politico.com/news/2021/12/15/health-care-spending-increase-pandemic-524793

By the end of 2020, the medical system accounted for almost one-fifth of the U.S. economy. Health care spending increased 9.7 percent, resulting from the federal spending to contain the spread of the COVID-19 virus. Specifically, funding for health care providers, public health programs, and Medicaid payments increased 36 percent. For example, the Provider Relief Fund and Paycheck Protection Programs were created to compensate providers for lost revenue and increased costs. Medicaid spending increased as 3.7 million people signed up for Medicaid after the pandemic struck due to reasons such as job cuts. This was the biggest rise in Medicaid enrollment since 2015. With the increased enrollment in Medicaid, program spending rose by 9.2 percent (16 percent of the U.S.'s total health care spending). Plus, Medicaid hospital spending increased by 6.7 percent. Finally, out-of-pocket spending declined by 3.7 percent for consumers due to less health care being used and little cost-sharing for COVID-19 testing and treatment.

OPIOID VERDICT PUTS HEALTH SYSTEMS NEXT IN LINE FOR LAWSUITS

Ian Lopez, *Bloomberg Law*, December 15, 2021.
https://www.bloomberglaw.com/bloomberglawnews/health-law-and-business/X4FF96S000000?bna_news_filter=health-law-and-business#jcite

Over the past four years, litigation has ensued over the opioid epidemic leading to over 800,000 overdose deaths in the U.S. These lawsuits have already moved through the drug manufacturers to distributors and recently to pharmacies. Walmart Inc., CVS Health Corp., and Walgreens Boots Alliance Inc. have joined others as the newest drug supply chains that have been blamed for fueling the opioid crises. The court found the chains failed to monitor illegitimate opioid prescriptions properly. A recent case, out of Cleveland, departed from earlier wins, as the court found the pharmacies created a public nuisance, while past judges have tossed the claims out. Such differing conclusions could lead to future forum shopping for courts likely to rule in the plaintiff's favor. Additionally, the Cleveland case could mark a shift in lawsuits, as plaintiffs start assessing other entities who may be responsible for the dispersal of opioids, such as health systems or large, managed care medical groups. David Nool, Rutgers law professor, stated that Walmart, CVS, and Walgreens were in unique situations where "robust compliance systems would have made a difference." Therefore, future litigations will be looking for similar situations of high volume and substandard compliance systems, such as hospitals with large networks. Others who may be liable include marketers for drugmakers and "data aggregators" who collect data for marketing.

MEDICARE WON'T COVER CONTROVERSIAL ALZHEIMER'S DRUG — UNLESS PATIENTS ARE IN A CLINICAL TRIAL

Katherine Ellen Foley, *Politico*, January 11, 2022.
https://www.politico.com/news/2022/01/11/medicare-alzheimers-drug-trial-526943

The Centers for Medicare and Medicaid Services (CMS) will provide coverage for a controversial Alzheimer's treatment for those enrolled in clinical trials. The drug, Aduhelm, manufactured by Biogen, "targets amyloid build-ups in the brain thought to cause the disease." While FDA approved, it is unclear whether the decrease in amyloid it causes helps patients' cognition. It is also unclear whether the drug is safe, as some clinical trial participants have experienced brain bleeding or swelling. The drug costs over $28,000 per year, though Medicare does not consider drug price when making a coverage determination. Instead, Medicare uses a cost-benefit analysis to determine whether the drug's benefits outweigh its potential harms to patient health. CMS has proposed coverage for one scan per patient to detect the proteins Aduhelm attacks. Biogen would be responsible for other clinical trial costs. Biogen's drug is the only one of its kind on the market now, though other drugs are in late-stage clinical trials and would be covered under CMS' proposal. The final coverage decision is expected by April 11.

GEORGIA BILL AIMS TO LIMIT PROFITS OF MEDICAID MANAGED-CARE COMPANIES

Andy Miller and Rebecca Grapevine, *Kaiser Health News*, January 27, 2022.
https://khn.org/news/article/georgia-legislation-limit-profits-medicaid-managed-care-companies/

Georgia's Medicaid managed care programs may be required to spend a certain amount on medical care or repay millions of dollars should a bipartisan bill pass. The House of Representatives is weighing a mental health parity act, within which is a provision that would require Medicaid managed care companies in the state to spend more on medical care and quality improvements or send its unspent dollars back to the state. On average, the state's managed care insurers pocket $189 million in profits. Of the 40 state Medicaid programs which contract with managed care companies to insure the state's Medicaid beneficiaries, 36 and the District of Columbia mandate a minimum threshold of dollars spent on medical care. Six, including Georgia, do not. If the bill becomes law, mandatory spending limits would begin in 2023. The state Department of Community Health, which runs the Medicaid program, did not comment on the legislation.

NURSES MADE $1.5 MILLION SELLING FAKE VACCINATION CARDS, PROSECUTORS SAY

Hannah Knowles, *The Washington Post*, January 30, 2022. https://www.washingtonpost.com/health/2022/01/30/nurses-fake-vaccination-cards-long-island/

Julie DeVuono, a pediatric nurse who for years taught "vaccine exemption workshops," was arrested in January, along with an employee, for allegedly selling falsified COVID vaccine cards. In about three months, DeVuono, 49, and Marissa Urraro, 44, raked in $1.5 million in profits. Both were charged with forgery, and DeVuono was also accused of knowingly providing false information to a public office, or offering a false instrument for filing under New York law. They are accused of providing false information to the state through New York's immunization information system. Both have pleaded not guilty. Across the country, cases alleging illegal attempts at dodging COVID vaccination requirements are surfacing. A paramedic in Delaware and a woman in New Jersey were accused of selling fraudulent or blank COVID vaccination documents, respectively.

MENTAL HEALTH THERAPISTS SEEK EXEMPTION FROM PART OF LAW TO BAN SURPRISE BILLING

Julie Appleby, *Kaiser Health News*, February 3, 2022. https://khn.org/news/article/surprise-billing-mental-health-therapists-exemption-no-surprises-act/

Mental health therapists are worried about the price transparency provision of the No Surprises Act, which requires licensed medical practitioners to provide detailed upfront cost estimates. These estimates include information on the length of a course of treatment. Therapists are concerned because diagnoses take time and can change. If they over estimate by at least $400, the law allows uninsured or self-pay patients to challenge the bill in arbitration. Mental health providers sent a letter on January 25, 2022, to the Department of Health and Human Services seeking exemption from these "good faith" estimates. The therapists claim requiring billing codes in the estimates before ever seeing a new patient is unethical, and tallying up months of treatment costs could discourage patients from seeking care. They fear insurers could also use estimates to limit treatment for those insured or to negotiate pay. The Center for Medicare & Medicaid Services says mental health providers are not exempt but are working on technical assistance for mental health providers. Additionally, in an email to KHN, CMS noted that mental health providers could provide an estimated cost for screening and follow-up with future estimates after a diagnosis is made.

BILL SEEKS TO LIMIT OUT-OF-POCKET SPENDING ON INSULIN

Steve LeBlanc, *AP News*, February 10, 2022. https://apnews.com/article/health-business-massachusetts-medication-prescription-drugs-bb30f93e339efb00474e485523fbac63

The Massachusetts Senate approved a bill in February 2022 that addresses the rise in prescription drug costs. The bill proposes to eliminate deductibles and coinsurance, plus cap co-pays at $25 for a 30-day supply of insulin. Supporters of the bill point to the out-of-pocket costs for insulin reaching over $1,000 a year for some patients. Beyond insulin, the bill

would direct the Massachusetts Health Policy Commission to create a process for finding other drugs with a price threshold that could pose a public health risk. The Commission could recommend pricing to increase access and manufacturers that do not comply would have to pay a fee towards new drug cost assistance programs to support patients, specifically communities of color and low-income disproportionately harmed. Additionally, the bill would provide easier access to mail-order prescriptions and allow patients to choose their pharmacy by new specialty drug licensing for pharmacists. Finally, pharmacy benefit managers would have more oversite with the bill, and pharmaceutical companies would be required to alert the state of new drugs coming to market and significant prices increases of current drugs. The bill is now headed to the House for review.