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FDA Approves First Oral Postpartum Depression Drug

- On August 4, the FDA granted approval to Zurzuvae, manufactured by Sage Therapeutics and Biogen Inc., to treat Post-Partum Depression (PDD). The treatment is a 14-day oral drug that can show results in as few as 3 days with long-lasting effects, compared to the only other option for new mothers of an IV injection provided in a healthcare facility. The manufacturer has not yet disclosed the launch price of the drug which will determine insurers' coverage guidelines. The oral treatment will likely be more accessible than the current injection which costs $34,000 and must be administered in a facility over multiple days. Postpartum depression affects 1 in 7 new mothers and can account for about 20% of postpartum deaths as a result of suicide, making it the leading cause of maternal mortality in the U.S. However, clinical trials completed earlier this year for general treatment of depression had mixed results and only measured short-term outcomes. Therefore, Sage Therapeutics did not receive FDA approval for broader use of major depressive disorder in addition to PPD.

CMS Suspends Surprise Billing Arbitration Following Court Decision

- On August 3, a District Court sided with the Texas Medical Association (TMA) on surprise billing regulatory requirements, striking down portions of the regulatory process. In response, CMS closed the arbitration portal for physician and insurer disputes over payments for emergency department services and other surprise billing claims. The TMA has brought multiple lawsuits against regulatory aspects of the arbitration process, this time successfully arguing that changes made to increase administrative fees and grouping together claims in a single batch were not made with the proper notice and comment period. Providers have not been able to "batch" claims together even though different services are typically performed in a single patient visit and were required to be filed in separate Independent Dispute Resolutions (IDRs). Previous court rulings have made forced small changes to the arbitration process but have not satisfied providers who say that the starting point for negotiations, the qualifying payment amount, which is calculated as a median reimbursement amount for negotiated services, is not reflective of the true market value of a procedure. Providers have also faced difficulties with enforcement of the law and insurers arguing that many arbitration payment decisions are not enforceable or binding. Insurers say that services are being improperly grouped together and largely unnecessary disputes are resulting in missing information and delaying payments. Going forward, government agencies will revise current regulations and work through the backlog of cases while providers and insurers continue open negotiations.

Department of Labor Sues UHC Subsidiary for Claims Denials

- On July 31, the government sued UMR, a large third-party administrator for UHC, based on information that they had improperly denied thousands of emergency department and drug screening claims between 2015 and 2018 in violation of ERISA and ACA coverage standards. The suit alleges that ER claims were denied solely on diagnosis code lists without further review and not on the merit of whether a layperson would make the same decision, the current standard for whether a claim should be approved or denied. Additionally, nearly all urinary drug screening

claims were denied outright, and patients were given limited information about their denials and the appeals process for overturning those decisions. While these policies were changed in 2018, UHC and other insurers have been accused in other lawsuits of using algorithms to improperly deny care based only on diagnosis codes and using automated tools.

White House and Federal Agencies Announce Mental Health Parity Rules

- On July 25, the departments of Labor, Health and Human Services, and the Treasure jointly announced a proposed rule to strengthen access to mental health and substance use disorder treatment in line with the Mental Health Parity and Addiction Equity Act of 2008. The rule would create new regulations for comparing Non-Quantitative Treatment Limitations (NQTLs) against insurers' medical benefits when evaluating access to mental health services. NQTL measures include provider networks, payments to out-of-network providers, and utilization management. Insurers would be required to collect, evaluate, and publish analyses on these measures of access in addition to enhancing network requirements. The rule would also close a loophole for self-funded, non-federal government health plans (e.g., state health plans) to opt out of compliance requirements as a result of recent legislation. The White House released a related press release outlining the difficulties Americans face with finding mental health providers accepting new patients, scheduling appointments, and affording coverage. Comments on the rule and other ways to improve mental health coverage and benefits are open through October 2.

FTC and DOJ Seek Comment on Merger Guidelines

- On July 19, the Federal Trade Commission (FTC) and Department of Justice (DOJ) released a highly anticipated draft of guidelines used when considering business mergers in order to increase transparency of antitrust enforcement and decision-making. The update was part of an ongoing public comment process and combines aspects of both Horizontal and Vertical Merger Guidelines. This will very likely result in more mergers and acquisitions being challenged by regulatory authorities. The new guidelines identify key principles for mergers to avoid increasing market concentration, eliminating competition, and the tendency to create a monopoly, among other issues. Stakeholder comments are open through September 18.

Other Policy News:

- UnitedHealth Group and other health systems report Q2 2023 revenues
- Analysis of healthcare bankruptcies in 2023 shows higher rates than 2022, especially for senior care and pharmaceutical businesses due to consolidation and difficult market conditions
- FDA requests comments on Canadian drug importation, possibly signaling a decision on pending state proposals
- New study finds that hospital prices for commercial plans taken from healthcare transparency data are double those for Medicare Advantage plans despite being negotiated by the same insurer