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The Long, Winding Road of Drug Pricing

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Author profile image

Brian Allen

VP of Government Affairs, Enlyte Pharmacy Solutions

One of the most persistent and complex challenges facing workers' compensation claims administrators and insurers is managing prescription drug costs. The problems around prescription drugs are pervasive throughout the health care industry, have been around for over a century, and cover a wide range of issues including accessibility, efficacy and cost. For workers' compensation payors, cost has been the most challenging issue.

Annual price increases for half the drugs covered by Medicare outpaced inflation in 2019 and 2020. In 2021, ASH Clinical news reported that the median wholesale price for 645 brand name drugs increased 4.8%, just slightly above the reported average inflation rate for 2021. According to a Kaiser Health Network Morning Briefing, more than 450 drugs saw price increases of 5% or more at the beginning 2022. In 2020, the Kaiser Family Foundation reported that drug price increases outpaced inflation for half of the drugs covered by Medicare. JAMA, the Journal of the American Medical Association, published a study documenting brand name drug price increases over a ten-year period. The study noted, "Using 2007-2018 net pricing data on branded pharmaceutical products in the US, list prices increased by 159% and net prices increased by 60%". Those increases amount to three and one-half times the annual inflation for the same period.

Generic drugs are not immune to their own unique pricing challenges. While not impacted by inflation as heavily and broadly, market competition in the generic space that would tend to reduce costs over time has been inhibited by alleged anti-competitive behavior among generic manufacturers. Led by the Attorney General in Connecticut, 46 states, the District of Columbia and three U.S. territories, filed suit in June of 2020 against 26 generic manufacturers alleging a wide-spread and coordinated effort to interfere with competition and drive up the cost of generic drugs. As quoted in the referenced article, "Through phone calls, text messages, emails, corporate conventions, and cozy dinner parties, generic pharmaceutical executives were in constant communication, colluding to fix prices and restrain competition." Further, Connecticut Attorney General William Tong said, "They took steps to evade accountability."

This is not a new problem in the prescription drug world. One of the first cases of drug price fixing was alleged in 1941. Twenty years after the discovery of insulin, three companies, Eli Lilly & Company, Sharpe & Dohme,

and E. R. Squibb were indicted on charges of violating an anti-trust law by "unlawfully combin[ing] and conspir[ing] to bring about arbitrary, uniform and non-competitive prices for insulin and to prevent free and normal competition in its sale throughout the United States."

The researchers who developed the first insulin were more interested in helping humankind than profiteering. In 1923, three of the researchers who discovered insulin assigned their U.S. patents for the insulin formula to the University of Toronto for $1.00 each (equates to about $16 today). Yet, insulin prices remain problematic. Today, most state legislatures across the country have filed bills to reduce the out-of-pocket cost for health care consumers who use insulin. Prices have remained so persistently and inexplicably high that non-profit drug manufacturers are hoping to spur competition within the insulin market. CivicaRx, a newly formed, non-profit drug manufacturer based in Utah, publicly announced in early March of this year, that they have begun the process to begin manufacturing insulin that they hope to bring to market in 2024 with a list price up to 80% less than current insulin products currently being sold.

Another area of concern, not limited to the workers' compensation market but more persistent as a percentage of claims, is high-cost topical creams and topical compounds. Upon review of our internal Mitchell Pharmacy Solutions data, payors in the workers' compensation system frequently see topical and compounded creams that are not FDA-approved but are billed at amounts that often exceed $2,000 for a 30-day supply. Based on recent reported action by the US Department of Justice, it appears they are working to eradicate and prosecute purveyors of these creams in the federal workers' compensation and health care systems. On July 31, 2020, the US Department of Justice (USDOJ) Eastern District of Tennessee announced the sentencing of five individuals convicted of multiple counts of fraud in a compound cream scheme that cost the U.S. Tricare system, private insurers and self-insured employers more than 30 million dollars. In July of 2021, the USDOJ Western District of Arkansas, announced a Louisiana doctor pleaded guilty to workers' compensation fraud for a topical patch and compounded pain cream scheme that netted over 1 million dollars. Additionally, the USDOJ Southern District of Texas released a statement on June 17, 2021, announcing the indictment of seven individuals in a compounding drug scheme. The indictment claims the defendants defrauded federal government programs of over 110 million dollars.

States are starting to take action against these abusive practices. The Arkansas Board of Pharmacy revoked the license of a pharmacy involved in a topical pain cream fraud. Other states workers' compensation programs have or are enacting strict fee schedules on topical creams and patches, including compounded creams. Colorado was the first to enact a specific fee schedule for topicals. South Carolina will become the latest with the adopting of its new fee schedule effective April 1, 2022.

Over the last several years there has been a lot of legislative activity around drug price transparency and rebates. The efforts are primarily directed at Pharmacy Benefit Manager (PBM) services within the commercial and government health care markets, but in some states, workers' compensation PBMs are also subject to the regulation. Unfortunately, most state laws only target the PBMs and wholesalers but fail to require accountability from manufacturers and dispensers. Price transparency could be a useful tool if the entire supply chain was subject to the same transparency rules, but most of the laws are only getting half the picture. Rebate reporting is generally a part of these transparency reports. Rebates are offered by manufacturers to health plans to encourage the plan to include a particular brand drug on their formulary. The rebate practice, in theory, should reduce costs when brand manufacturers with drugs that treat the same condition will offer discounts to get on a formulary. However, workers' compensation programs mandate the use of generic medications and if there is a formulary, the formulary is chosen by the state and not by the payor. In non-formulary states, the workers' compensation PBM develops a formulary based on treatment guidelines, medical necessity, and lower-cost generic medications as mandated. In the instances where a doctor prescribes a medically necessary brand name medication, a workers' compensation PBM may receive a rebate, but the rebate is driven by the actions and

decisions of a physician and not anything controlled by the workers' compensation PBM.

There is also some legitimate question as to whether or not rebates are increasing drug costs. A recent study by Matrix Global Advisors, as reported by the Coalition for Affordable Drugs, found the price increases from 2018 to 2021 for rebated drugs and non-rebated drugs were similar. The study concluded, "The market-based strategies most likely to constrain prices are robust competition among drug manufacturers and insurance-design mechanisms that incentivize cost-effective treatments." This is an important point to consider. In a state where an injured worker has the choice of pharmacy provider, there are no market forces at play since the injured worker has no financial stake in the cost of the care and no incentive to shop around for the most affordable option. In fact, the inverse is true. The injured worker's right to choose may ultimately increase costs.

In the workers' compensation pharmacy world, robust competition does exist among the various PBMs providing pharmacy benefit services for injured workers and decreasing costs for payors. That competition works best when states allow employers to direct the pharmacy care to contracted pharmacies. Most workers' compensation pharmacy networks include 90% or more of the local pharmacies in a given state. Injured workers benefit from convenient access to care while the payors and the workers' compensation system enjoy fiercely competitive pricing on drugs. Additionally, network pharmacies can help guide adherence to generic mandates, drug formularies and treatment guidelines at the point of dispensing. The pharmacy networks can also control areas of potential fraud and abuse around compounded creams and topicals. The PBM can screen medications for efficacy, medical necessity and can contract for reasonable, market-based pricing.

While there has been some political reticence to embrace direction of pharmacy care for injured workers, the benefits of managed care and the resultant improvement in care and control of costs, fraud and abuse, may outweigh the potential inconvenience of an injured worker having 10% or less fewer pharmacies to choose from. It has been a long and winding road that got us to where we are today in pharmacy care for injured workers, but a systemic, managed and directed approach to providing pharmacy care to injured workers may increase market competition, increase adherence to state formularies and treatment guidelines, has the potential to reduce fraud and abuse and improve overall outcomes for injured workers by increasing the efficacy of the pharmacy care they receive.

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