The Source Roundup: March 2018 Edition

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Happy March! In this edition of the Source Roundup, we cover four academic articles and reports from January and February. The topics this month include: (1) recent state solutions to reduce prescription drug costs, (2) legal challenges to Maryland and Nevada's prescription drug laws, (3) how the CVS-Aetna deal could reduce healthcare costs, and 4) economic and demographic trends behind increasing healthcare spending.

Recent State Solutions Aimed at Reducing Prescription Drug Costs

Medicaid spending on outpatient drugs increased 25%, from $22.4 billion in 2013 to $28 billion in 2014, and another 13% in 2015 to $31.7 billion. Medicaid has a higher spending growth rate for prescription drugs than any other healthcare payer. In the paper titled "Snapshots of Recent State Initiative in Medicaid Prescription Drug Cost Control," published by the Kaiser Family Foundation, authors Katherine Young and Rachel Garfield explore recent state policy solutions aimed at lowering Medicaid prescription drug costs. To account for large spending growth in Medicaid, states have previously tried to control drug costs by implementing prescription limits, negotiating supplemental rebates, requiring prior authorizations, and using state Maximum Allowable Cost programs. Such actions have slowed in recent years because economic conditions have improved, allowing states to increase their utilization review limits. Recently, states have shifted their strategies by focusing on solutions that obtain greater supplemental rebates from manufacturers.

The article provides a number of ways that states have been trying to reach this new goal. One method creates drug growth caps. For example, New York passed a law in 2017 utilizing this method to target prescription prices. Under New York's drug cap law, if total Medicaid drug spending in a year is projected to exceed the growth target, the state Commissioner of Health may identify specific drugs for referral to a Drug Utilization Review Board. In another method, states have opted to create closed formularies where only specific drugs in each therapeutic class are covered. This strategy allows states to negotiate greater rebates, because each manufacturer strives to include their drug as one of the few drugs for the therapeutic class. In addition to the strategies mentioned above, states are undertaking broader efforts that are not specific to Medicaid, but would still affect Medicaid spending. These tactics include promoting low price generic drugs|implementing limits on generic price increases (see "Legal Challenges to State Drug Pricing Laws" discussed below)|decreasing regulation on biosimilars to allow more drugs to enter the market|and increasing transparency. Transparency regulations include price transparency laws, which tend to mandate public reporting as a component in prescription initiatives|manufacturer transparency laws, which focus on making public information about Wholesale Acquisition Costs|and Pharmacy Benefit Manager transparency laws, which focus on making PBM rebates publically available. While some actions may be feasible for states to take on individually, some actions, such as urging certain types of federal action, may be more effective if coming from a coalition of states.

Legal Challenges to Maryland and Nevada's 2017 Prescription Drug Laws

As mentioned in the article above, some state efforts to reduce prescription drug prices have focused on placing limits on price increases and promoting pharmaceutical benefit

manufacture transparency. In the JAMA article titled "Legal Challenges to State Drug Pricing Laws", Theodore Lee, Aaron Kesselheim and Amy Kapczynski review two pieces of legislation relating to these strategies and the resulting legal challenges. In 2017, Maryland passed the nation's first anti-price gouging law that prohibits certain price increases for generic off-patent drugs. Under the law, manufactures must justify price increases of over 50% in a one-year period to the state's attorney general. Nevada's 2017 law used a different tactic by imposing reporting requirements on certain manufacturers of diabetes drugs. The law also directs the state to publish an annual report based on the information disclosed.

The lawsuits brought by the pharmaceutical and biomedical industries challenge these two laws on similar claims. In both lawsuits, the industry has invoked the dormant commerce clause, which is a constitutional doctrine that prohibits states from engaging in economic protectionism. Under the dormant commerce clause, states cannot unduly burden nor discriminate against interstate commerce. This article argues that the Maryland law does not violate the dormant commerce clause because the law does not allow Maryland to formally set prices in other states – and therefore does not impose an undue burden on prescription prices in other states. The trial court adopted this argument and upheld the Maryland law in September 2017. Similarly, the authors argue that the Nevada law does not violate the dormant commerce clause because the state is only requiring transparency and is not directing pricing requirements.

Two other legal challenges have also been brought. First, plaintiffs in Maryland and Nevada have asserted that state laws that affect the prices of patented drugs conflict with federal law. The Maryland trial court held that the law does not target patent holders in a way that interferes with their abilities to make maximal use of their federal patent rights.

In similar fashion, the authors predict that the court will uphold the Nevada law because it only requires disclosure of information, not curbs on prices. With the Maryland trial court decision awaiting appellate review, it is unclear how its fate will unfold. However, these authors make compelling arguments that there are strong reasons to believe the law will survive. The second challenge pertains to trade secrecy and was brought against the Nevada law. Pharmaceutical and biotech industry associations have argued the Nevada law conflicts with trade secret law – laws that protect company trade secrets from competitors. Because Nevada's transparency law can be construed to have little or no influence on genuine trade secrets, and because there are significant public interests served by disclosing prices, production costs, rebates, and similar information, the law is likely to be upheld. While a trial court decision has not been reached in the challenge of the Nevada law, it is a less controversial law than the Maryland law. The fact that the law only regulates price transparency and does not directly control prices makes it a harder case for plaintiffs.

How the CVS-Aetna Merger Could Reduce Healthcare Costs

On December 3, 2017, healthcare powerhouses CVS and Aetna announced their plan to merge to create a new healthcare company. This proposed $70 billion merger marks the largest deal ever in the history of healthcare. In the article published by the New England Journal of Medicine titled "Does CVS-Aetna Spell the End of Business as Usual," author Leemore Dafny explores what it means for our healthcare delivery system. In short, the merger combines a health insurer (Aetna) with a pharmacy benefit manager (CVS Caremark) and a retail pharmacy and provider chain (CVS stores). This merger is largely vertical, meaning the new company is consolidating up and down the value chain. When the deal was announced, the companies proclaimed they seek to be a "new front door to

healthcare" by expanding to provide the scope of services supplied in its in-store Minute Clinics. Minute Clinics differ from other healthcare delivery systems in that they only provide a limited array of acute care services, usually at prices below outpatient clinics, urgent care facilities, and emergency departments. Dafny suggests that the company may achieve lower healthcare spending rates by "redirecting patients to lower cost sites for certain services…|using its physical convenience and non-visit care technologies to maintain contact with patients requiring closer monitoring…|and combin[ing] medical and pharmacy spending." The integration of medical and prescription drug insurance may also yield total cost savings and better health.

Despite these feats, uncertainty remains as to whether this business model will actually reduce health care costs. Dafny suggests there is no evidence supporting the idea that retail clinics reduce short term healthcare spending. Additionally, consumers and competitors have expressed concerns that the new entity will try to change and expand the provider's business, potentially at the expense of rivals. On the other side of the equation, antitrust enforcers are looking to whether CVS-Aetna could foreclose rivals by refusing to offer PBM services to other insurers or declining contracts to fill prescriptions for other insures' enrollees. If so, the merger may be closed under antitrust law. For this effort to achieve the companies' objective, their method must be better than what existing providers currently offer. If CVS-Aetna are successful in luring patients away from higher priced and more inconvenient services, some other company will surely follow suit.

Economic and Demographic Trends Explain Increasing Healthcare Spending

In "National Health Expenditure Projections, 2017-2026: Despite Uncertainty, Fundamentals Primarily Drive Spending

Growth," a report released by the Centers for Medicare and Medicaid Services (CMS) and published in Health Affairs, the CMS' Office of the Actuary (Gigi Cuckler et al.) projects that national health expenditure growth will rise 5.5 percent annually from 2017-2026. The authors attribute this rising growth in healthcare spending to four primary factors: 1) increases in the use and intensity of care in Medicare|2) growing costs for medical goods and services|3) projection of fastest average annual growth for prescription drug spending|and 4) decreased number of people with health insurance after the passage of the 2018 Tax Cures and Jobs Act. Specifically, the first factor leads to higher healthcare costs because as Medicare enrollment increases, so does the amount spent on Medicare. The second factor increases healthcare spending simply because prices for healthcare goods and services are expected to rise by 2.2 percent beginning in 2018. The increasing trends in the volume of users for these goods and services also contribute to increases in spending. The third factor contributes to higher spending because fewer drugs are coming off brand, meaning less generics are entering the market. To make matters worse, more expensive specialty drugs are entering the market. Finally, the fourth factor increases health spending because without the individual mandate, which was eliminated by the 2018 Tax Cures and Jobs Act, some people will choose to forego insurance. In summary, the authors claim that under current law, demographic and economic trends are the main reasons for the 5.5 increase in healthcare spending over the next eight years. This growth rate is more rapid than the growth rate experienced from 2008-2016. Unless serious changes are made, the proportion of GPD spending attributable to healthcare will continue to grow.

That's all for this month's Roundup. As always, if you find articles or reports that you think should be included in the monthly Roundup, please send them our way. Enjoy your reading!