STATE PRESCRIPTION DRUG AFFORDABILITY BOARDS: A ROAD OF GOOD INTENTIONS PAVED WITH PRICE CONTROLS & CONTRACT IMPAIRMENT

Contributed by
William G. Schiffbauer, Esq.

To date, eight states have enacted laws empowered to establish the upper payment limit amounts allowed to be paid by health insurance plans for certain prescription drugs. As a government "knows best" effort to reduce prescription drug prices for citizen patients and payers of health benefits, the road of good intentions will inevitably run roughshod over hundreds of thousands of contractual agreements between drug manufacturers, wholesalers, pharmacy benefit managers (PBMs), health insurers, group health plans, and retail pharmacies.

Each state will likely set a different upper limit. As more states enact these boards the businesses operating in several states will face different price caps for the same drugs. Will counties and cities follow suit with their own boards seeking even lower price caps? Drug development will likely halt as manufacturers try to determine if costs can be recovered and a profit realized. The distribution system will be disrupted as wholesalers, pharmacy benefit managers, health insurers, group health plans, and retail pharmacies will be divorced from the pricing and payment process and will no longer be able to guarantee access.

Enacting states have seen legal roadblocks based on various challenges such as patent-related preemption arguments, dormant commerce clause issues, and ERISA preemption. Litigation over the past several years seems to have given state legislators a clear roadmap to take over the commercial market's decades of experience in pricing and negotiating prescription drug costs. However, around the next curve in the middle of the road sits Article I, Section 10, Clause 1 of the U.S. Constitution: no State shall pass "any" Law impairing the Obligation of Contract.

Basics of a Typical State Prescription Drug Affordability Board

Anxious to assume the role of drug price controller, states establish the board as an independent unit of state government. Generally, it is a five-member board that is appointed by the Governor. Members must have expertise in health policy, health care economics, or clinical medicine. To sustain its functions the board can often assess a fee on the very private entities that are already performing this function through hundreds of thousands of contract arrangements - manufacturers, health plans, pharmacy benefit managers, and pharmacy wholesale distributors.

The board is typically authorized to identify and select prescription drugs for price control review that have a wholesale acquisition cost above a specified amount and that have increased in cost by a specified percentage during a set time period. The board would obtain information to make this determination and judgment based on: average cost, market competition, revenue projections, and estimates of cost-effectiveness, off-label use, development and manufacturing costs, publicly available pricing information from manufacturers and even foreign countries.

To determine whether the drugs under review are "affordable" the board could employ a variety of criteria such as: wholesale acquisition cost, discounts, rebates, and other price concessions, patient co-pays and cost-sharing, effect of price on consumer access in that state, availability to underserved communities in that state, patient assistance programs, therapeutic alternatives, average cost in that state, market competition, projected manufacturer revenue, off-label use, and other factors determined as relevant by the board.

To exercise its price control role, the board would be empowered to set an upper payment limit for the specified drugs that are judged to be unaffordable. The board may be required to take into account various factors when setting an upper limit: cost of administering the drug, cost of delivering the drug to patients, any shortage situation, any differential in price between the drug in that state and in other foreign countries, and any other criteria decided by the board to be relevant to set an upper payment limit.

Once the board sets an upper payment limit, that limit would apply to all purchases of the prescription drug and any reimbursements for a claim for the drug when it is dispensed or administered to an individual in that state. This established upper limit would apply to all purchases, contracts, and plans after a specified effective date. All of the affected health plans in that state would be required to submit reports to the board every year describing the savings achieved by applying the upper payment limits.

Enforcing the upper payment limits on the vast array of players in the prescription drug market is less certain. First of all, the board must "police" the upper limit as it might apply to manufacturers, wholesalers, pharmacy benefit managers, health benefit plans, health insurance issuers, and retail pharmacies. A board could be authorized to impose financial penalties or assess civil penalties on noncomplying entities, further compounding the unintended costs and consequences of a government price controlled system. The state attorney general would likely be authorized to investigate and bring a civil action against any entity for noncompliance.

Obvious Legal Challenges to State Laws Controlling Drug Prices - to Date

Prescription drug manufacturers have had initial successful challenges to aspects of some state drug price setting efforts. PhRMA and BIO successfully challenged a District of Columbia law that capped "excessive" wholesale drug prices when the price was 30% higher than the comparable price in specified foreign countries. The Fifth Circuit Court of Appeals ruled that the law was preempted by federal patent law by undercutting a company's ability to set prices for patented products. See *BIO v. District of Columbia* (2007).

In 2017, the State of Maryland enacted a first-of-a-kind law prohibiting "price gouging" for certain prescription drugs. The law authorized the Attorney General to bring a civil action when a price increase for certain drugs was determined to be "unjustified" and "unconscionable" based upon the discretion of the Attorney General. The Fourth Circuit Court of Appeals ruled the law unconstitutional under the "dormant" Commerce Clause because it regulated commercial activity outside of the state. See *Association for Affordable Medicines v, Frosh* (2018).

A similar "price gouging" law enacted in Kentucky was upheld because the Sixth Circuit Court of Appeals found that the law only applied to consumers in the state and only had an indirect impact on out-of-state commerce. See *Online Merchants Guild v. Cameron* (2021). Most recently, the U.S. Supreme Court ruled that the dormant Commerce Clause prohibits economic protectionism by a state using measures "designed" to benefit in-state economic interests by burdening out-of-state competitors. See *National Pork Producers Council v. Ross* (2023).

In August 2023, the State of Colorado enacted a law setting a co-pay limitation of $60 for epi-pens injectors based on the legislature's finding that many individuals are unable to afford the co-pay required under their health plan. The law has been challenged by Teva Pharmaceuticals as an unconstitutional "taking" because the law requires the company to send a pharmacy a free replacement by reimbursing the pharmacy the full retail price paid rather than the wholesale price. See *Teva Pharmaceuticals v. Michael Conway* (U.S. Dist. Ct. Colorado, 2023).

So far, there has been no challenge based on ERISA preemption, in part, due to the states becoming more attuned in their legislative drafting to the reach and possible limits of ERISA section 514. States know full well that any law that reaches into an ERISA-governed health benefit plan to control prescription drug prices paid by the plan would be preempted. States are exploring the reach of the Supreme Court's opinion in *Rutledge v. Pharmaceutical Care Management Association* (2020) in the manner of the blind men and the elephant parable.

More recently, the Tenth Circuit Court of Appeals struck down an Oklahoma pharmacy benefit management law on the basis that it was preempted by ERISA and Medicare Part D. See *Pharmaceutical Care Management Association v. Mulready* (2023). On December 12, 2023, the court denied a petition for a rehearing en banc.

Hiding in Plain View - the Contract Clause Expressly Limits State Laws

The Contract Clause provides that "No State…shall pass any law impairing the Obligation of Contract..." The U.S. Supreme Court's views on the level of protection that the Contract Clause provides for contract rights have shifted over time. In the early years of the nation, it became the primary vehicle for federal judicial review of state legislation before the adoption of the Fourteenth Amendment. The Contract Clause was one of the most litigated provisions of the Constitution throughout the nineteenth century. See *The Constitution of the United States of America: Analysis and Interpretation,* Sen. Doc. 12, 117th Cong. 2d at 581 (2022).

The Court's reliance on the Contract Clause fell into disuse with the ratification of the Fourteenth Amendment and the imposition of limits on state power in the Amendment's Due Process Clause. The Court's view underwent major changes in the New Deal Era when in the depths of the nation's depression the Court became more supportive of a state's use of its police powers to regulate contracts in a manner to protect homeowners from foreclosure, for example. See *Home Building & Loan Association v. Blaisdell* (1934).

Recently, however, the Supreme Court's view on the Contract Clause has seen a reawakening in several cases. The Court found that a Minnesota law requiring employers to pay a pension funding charge if they terminated a plan or closed an office violated the Contract Clause. The Court reasoned that the employer had a Contract with its employees that permitted termination of the plan; however, the state law overrode this provision forcing the company to continue to make pension payments. See *Allied Structural Steel Co. v. Spannus* (1978).

The Court's opinion in *Spannus* characterized the Contract Clause as perhaps the strongest single constitutional check on state legislation. In walking back some of the Court's New Deal opinions that weakened the force of the Contract Clause, the *Spannus* opinion went on to note that "if the Contract Clause is to retain any meaning at all…it must be understood to impose some limits upon the power of a State to abridge existing contractual relationships, even in the exercise of its otherwise legitimate policy power".

The *Spannus* opinion was viewed as something of a retreat from the erosion of the Contract Clause that had become overshadowed by the more frequent reliance on the Fourteenth Amendment and the New Deal Court's more solicitous view of the states' exercise of police power during the Great Depression era. Commentary on the *Spannus* opinion concluded that the Supreme Court revitalized the Contract Clause showing that it retains "potency" and broadened the scope and application of the prohibition. See "The Contract Clause: A Constitutional Basis for Invalidating State Legislation", *Loyola of Los Angeles Law Review* (1979).

The Supreme Court reviewed another Minnesota law that revoked a beneficiary designation that an individual may have made with respect to his or her spouse if the marriage becomes dissolved or annulled. The law assumed that the policyholder would have supported the revocation of an ex-spouse. The law also allowed the policyholder to reinstate the ex-spouse as the beneficiary at any time. Although the Court of Appeals held that this violated the Contract Clause, however, a majority of the Supreme Court upheld the state law. See *Sveen v. Melin* (2018).

Justice Gorsuch dissented from the majority opinion in Merlin, emphasizing that the Contract Clause categorically prohibits states from passing "any" law impairing the obligation of contract. Criticizing the majority's gerrymandered "no substantial impairment" analysis, he pointed out that the framers knew how to impose more nuanced limits on state power, pointed to the same section of the Contract Clause, and noted permissions allowing states to take otherwise unconstitutional action when absolutely necessary.

Justice Gorsuch observed that in the Contract Clause the framers were absolute. Citing the Court's early Contract Clause opinions, he stated that treating existing contract as "inviolable" would benefit society by ensuring that all persons could count on the ability to enforce promises lawfully made to them, even if they or their agreements later prove unpopular with some passing majority; and that any legislative deviation, however minute, or apparently immaterial, violates the Constitution. See *Sturges v. Crowninshield* (1819), and *Green v. Biddle* (1823).

Gorsuch concluded that it seems hard to square this balancing test with the Constitution's original meaning. After all, he noted, the Constitution does not speak of "substantial impairments" - it bars "any" impairment he emphasized. Such a balancing test, he observed, would reduce the Contract Clause's protection to the Court's judgment about the reasonableness of the state legislation in question, and would not let people know whether their lawful contract will be enforced tomorrow or be undone by a legislative majority with different sympathies.

Recent commentary notes that the Contract Clause has been employed in challenges to the extraordinary measures state governments undertook to combat the COVID-19 pandemic. In New York, a landlord challenged the state's "Guaranty Law" as impairing the landlord's Contract rights and the Second Circuit Court of Appeals agreed. See *Melendez v. City of New York* (2021). See also, "The Contract Clause: Reawakened in the Age of COVID-19", *Harvard Law Review* (2023) (quoting Shakespeare that the Contract Clause "hath not been dead, but it hath slept").

Conclusion - What is Past is Prologue for the Contract Clause

State laws establishing prescription drug affordability boards may unconstitutionally impair hundreds of thousands of contract agreements that exist between drug manufacturers, wholesalers, pharmacy benefit managers, health insurers, group health plans, and retail pharmacies. When a prescription drug affordability board sets an upper payment limit it undermines contracts in which a price has already been negotiated, agreed to, and relied upon by the parties. The proliferation of such boards in all fifty states - and perhaps even counties and cities competing for the lowest price caps - will undermine contract pricing, and disrupt prescription drug distribution and access nationwide for the very citizen patients that these boards are intending to protect.