

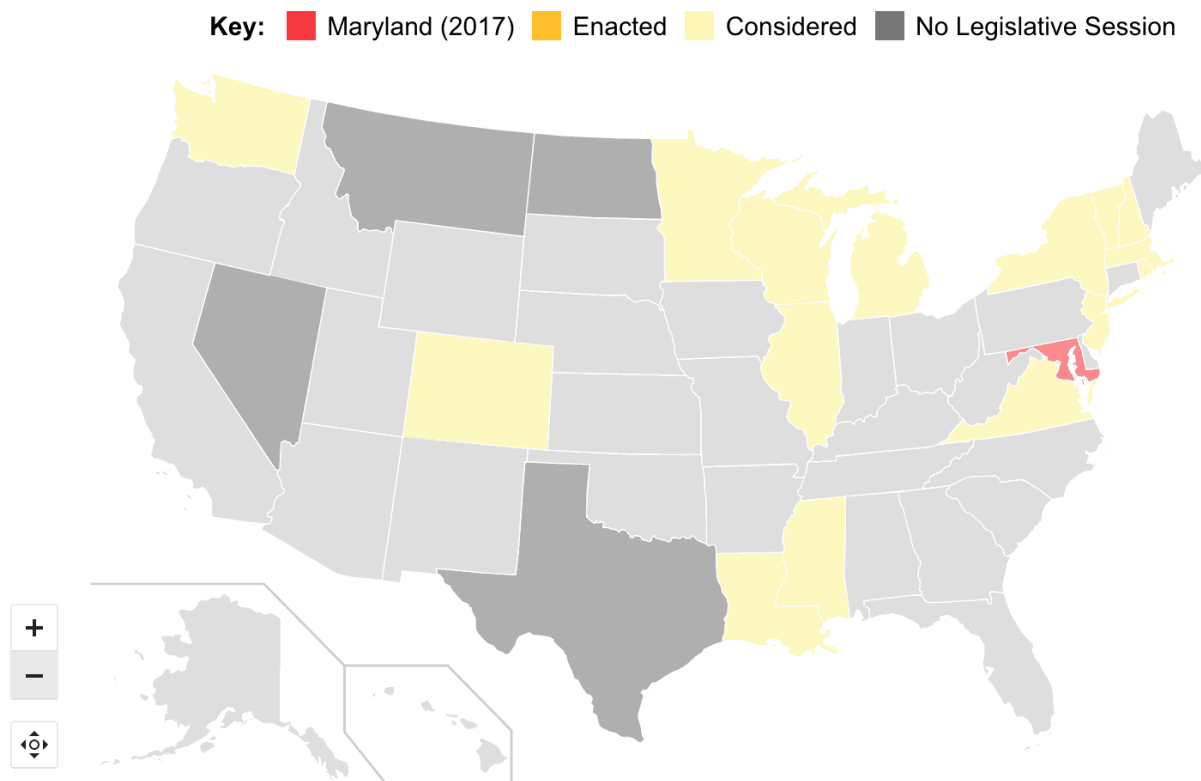
Spotlight on 2018 State Drug Legislation: Part 4 - Price Gouging Prohibitions

**Update: This post was written before the end of the 2018 legislative session. For the most recent count of states that passed these legislation, see the [Spotlight on 2018 State Drug Legislation Summary: The Year in Review](#) or download our [Summary Chart](#).*

In this installment of The Source's Spotlight on State Drug Legislation, we focus on price gouging prohibitions. In 2017, Maryland became a pioneer among states addressing rising drug costs when it passed the first law ([HB 631](#)) to prevent price gouging in the pharmaceutical market. At the start of 2018, fifteen states were poised to follow in Maryland's footsteps and adopt new or strengthen existing price gouging laws to include pharmaceuticals (see Map and Table 1). In April 2018, however, the 4th Circuit Court of Appeals declared Maryland's law unconstitutional, and following that decision, no state passed pharmaceutical price gouging bills. In this post, we discuss pharmaceutical anti-price gouging legislation and why the Source expects the case to be appealed to the Supreme Court.

Price Gouging Prohibition

Price gouging prohibitions typically empower the state Attorney General to act if the price of a drug is raised above a threshold. Click on highlighted states to see legislation considered in the 2018 session. See the Source Spotlight on 2018 State Drug Laws Part 4 for more information.



Existing Anti-Price Gouging Law and Inclusion of Pharmaceuticals

Eighteen states already have laws that ban “unconscionable” price increases for commodities, household essentials, rent, etc. following a natural disaster or emergency.[\[1\]](#) For example, Maine prohibits selling “necessities at an unconscionable price” when there is an abnormal market disruption.[\[2\]](#) Idaho’s anti-price gouging law already prohibits “selling or offering to sell... fuel or food, *pharmaceuticals*, or water... at an exorbitant or excessive price” following the declaration of an emergency (emphasis added).[\[3\]](#) Some states, like California and Arkansas, have laws that ban a price increase of more than 10% after a declared emergency.[\[4\]](#) As of 2012, thirty-three states have laws banning some form of price gouging, but nearly all require a declaration of an emergency and many only apply to petroleum.[\[5\]](#) These price gouging laws demonstrate that states have the ability to regulate prices to ensure public health and safety in times of emergency.[\[6\]](#) In 2018, both Rhode Island and New York considered bills that prevent pharmaceutical price gouging in declared emergencies or when the Food and Drug Administration (FDA) or state governor reports that the drug is experiencing a market shortage. These bills, like existing price gouging laws, likely fall within the police powers of

the states.

Maryland's Price Gouging Law

The price gouging law that Maryland passed in 2017, [HB 631](#), however, went further. The law did not require a declared state of emergency like other price gouging laws. Rather, the law allowed the Attorney General to bring a civil lawsuit when a price increase for an essential off-patent or generic medication is “unjustified” and “unconscionable”. The law does not set a threshold price or price increase above which the law deems it price gouging, rather if the Attorney General believes a price increase amounts to price gouging, he must argue to a judge that the price increase reaches the level of “unconscionability,” and the manufacturer has the opportunity to argue that the price increase was justified. The law also provides that if the increased price was due to increased costs of production or expanded access to the drug, the increase in price is not price gouging.

The concept of an “unconscionable” price is a high bar. The Maryland bill defines an unconscionable increase as one that “is excessive and not justified by the cost of producing the drug or the cost of appropriate expansion of access to the drug to promote public health AND results in consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price.”[\[7\]](#) In addition, the concept of unconscionability is defined in contract law to include “terms so egregiously unjust and so clearly tilted toward the party with superior bargaining power that no reasonable person would freely agree to them.” Case law has further refined the concept of unconscionability to include cases in which the seller vastly inflates the price of goods. For example, in *Williams v. Walker-Thomas Furniture Co.* (1965),[\[8\]](#) the court held that the contract that allowed the Walker-Thomas Furniture company to repossess all of the furniture a customer purchased over a 5-year period after missing a single layaway payment would be unenforceable if elements of “unconscionability” existed when the contract was signed. In another example, *People v. Beach Boys Equipment Company* (2000),[\[9\]](#) the court held that a retailer who doubled the price of generators following an ice storm charged unconscionably excessive prices. Recently a few

class action lawsuits have been filed on behalf of uninsured patients who were billed chargemaster rates after visiting an emergency room, but so far, no court has found for the patients.[\[10\]](#)

When Maryland passed its pharmaceutical price gouging law, it attempted to expand the idea of “unconscionable” prices to drugs. While the law would likely not prevent manufacturers from raising the price of a drug over time, it would target manufacturers of generic medications that exploit market inefficiencies to raise prices without justification.[\[11\]](#) In a now classic example of a price increase that Maryland’s law seems intended to prevent, Martin Shkreli, former CEO of Turing Pharmaceuticals, raised the price of Daraprim, a drug that treats rare toxoplasmosis and cystoisosporiasis infections, from \$13.50 to \$750 per pill overnight.[\[12\]](#) While these cases may be relatively rare, patients and providers are essentially helpless in these situations – the patients need the drug because there are no real therapeutic alternatives and the conditions are serious so there is no option to delay treatment. Situations like these, where one party (the manufacturer) has such a dominant bargaining position that the other party (the patient) is forced to accept terms (prices) that no reasonable person would accept if they had any alternatives, are critically in need of intervention by the government to protect consumers.

The 4th Circuit Court of Appeals Found Maryland’s Law Unconstitutional

The Maryland law, however, was not allowed to take effect. In April 2018, the 4th Circuit Court of Appeals held that Maryland’s law was unconstitutional because it violated the dormant commerce clause. The court found that the law could affect commerce that never took place in Maryland because it applies to any drug “offered for sale” in Maryland, not just drugs actually sold in the state. The court further explained that even when the drugs are actually sold in Maryland, they are typically first sold between out-of-state manufacturers and out-of-state wholesalers. Finally, the court held that even if the law were changed to apply only to drugs actually sold in the state, it would still violate the dormant commerce clause because it targets the price set by the manufacturer at the initial sale of the drug, not at the point of sale in Maryland.[\[13\]](#)

A three-judge panel of the 4th Circuit heard the case and Judge Wynn issued a dissent arguing that the Maryland law applies equally to in-state and out-of-state manufacturers and, therefore, does not violate the Supreme Court's precedent concerning the dormant commerce clause. In writing the dissent, Judge Wynn argues "HB 631 does not favor in-state interests at the expense of out-of-state interests... [and] HB 631 does not discriminate against interstate commerce—manufacturers and distributors remain free to engage in interstate commerce, they just may not charge unconscionable prices for essential generic drugs later sold to Maryland consumers. [As a result,] the majority opinion's expansive interpretation of the extraterritoriality doctrine substantially intrudes on the States' reserved powers to legislate to protect the health, safety, and welfare of their citizens."[\[14\]](#) The 4th Circuit denied Maryland's petition for rehearing *en banc* (that is, by the full court),[\[15\]](#) but Judge Wynn again dissented from the denial, demonstrating that there is disagreement among legal experts about whether the law should be allowed to stand.

What Does the Ruling Mean for Price Gouging Statutes for Pharmaceuticals

After the 4th Circuit ruling, no other state passed pharmaceutical price gouging legislation. As a result, no court in any other Circuit will decide whether similar price gouging laws violate the dormant commerce clause in the near future. With the well-reasoned dissent of Judge Wynn, other states should consider passing similar laws with the hope that another federal court would reach a different conclusion – that the dormant commerce clause does not render their law unconstitutional. If the Circuit Courts have differing opinions or if Maryland appeals the 4th Circuit decision, the Supreme Court may clarify whether "excessive prices" for drugs can fall within a state's ability to ensure public health and safety.

Like [drug importation](#) and [gag-clause prohibitions](#) laws, these price gouging laws address a specific market inefficiency, but don't directly target prices. Maryland's price gouging law, and nearly all of the price gouging bills considered in 2018, target generic drugs with little to no competition that experience an

“unconscionably” large price increase. These drugs may seem like a small part of the pharmaceutical market, but the Government Accountability Office studied generic drugs covered by the Medicare Part D program and reported that “[m]ore than 300 of the established generic drugs analyzed had at least one extraordinary price increase of 100% or more between first quarter 2010 and first quarter 2015”.[\[16\]](#) As the drugs with extraordinary price increases were not typically among the top 100 most utilized generic drugs in Medicare Part D[\[17\]](#) and account for a small percentage of the total spending on drugs, these price gouging prohibitions may not move the needle on overall drug spending. Nonetheless, they would protect patients with no treatment options from experiencing excessive price increases. Furthermore, they represent an important device in the toolbox of legislators seeking to prevent anticompetitive behavior by pharmaceutical companies and, as a result, may help leverage other laws to control drug prices.

Table 1: States Considering Pharmaceutical Price Gouging Laws in 2018

State	Bill	Description
Colorado	SB 152	Uses definition of “unconscionable increase” similar to MD HB 631
Illinois	HB 4900	Defines “unconscionable increase” as an increase in the wholesale acquisition cost of the essential off-patent or generic drug of 30% or more within the preceding year, 50% or more within the preceding 3 years, or 75% or more within the preceding 5 years; or (2) is otherwise excessive and unduly burdens consumers because of the importance of the essential off-patent or generic drug to their health and because of insufficient competition in the marketplace
Louisiana	HB 243 and HB 710	Uses definition of “unconscionable increase” similar to MD HB 631

Massachusetts	<u>S 652</u>	Provides that the attorney general may promulgate regulations to define when prescription drug prices excessively higher than justified as an “unfair practice”.
Michigan	<u>SB 900/HB 5690</u>	New consumer protection law that includes provisions for prescription drugs that uses definition of “unconscionable increase” similar to MD HB 631 also prohibits “excessive prices” which it defines as “a price that is grossly in excess of the price at which similar property or services are sold.”
Minnesota	<u>SF 2841/HF 3131</u>	Uses definition of “unconscionable increase” similar to MD HB 631
Mississippi	<u>HB 137</u>	Uses definition of “unconscionable increase” similar to MD HB 631
New Hampshire	<u>HB 1780</u>	Uses definition of “unconscionable increase” similar to MD HB 631
New Jersey	<u>S 1590/A 3987</u>	Uses definition of “unconscionable increase” similar to MD HB 631

New York	S 5262/A 7087 S 2544/A 5733	<p>Prohibits price gouging for medications that the FDA reports as being subject to a shortage. Provides that no party within the chain of distribution of and drug subject to a shortage shall sell or offer to sell that drug for an amount which represents and unconscionably excessive price. Provides that “unconscionably excessive” is a question of law for the courts.</p> <p>Applies to both branded and generic drugs. Creates a Drug Utilization Board to review when it determines a price increase to be excessive. Provides that the Attorney General can bring a price gouging suit against a manufacturer after the Board determines there was an excessive price increase. Provides that whether a price is unconscionably and unjustifiably excessive is a question of law for the court.</p>
Rhode Island	H 7022	<p>Only applies in declarations of market emergencies and compares prices before and after the declaration to determine price gouging. The governor may declare a market emergency or shortage for a vital drug for a period of no more than 6 months.</p>
Vermont	H 713	<p>Uses definition of “unconscionable increase” similar to MD HB 631</p>
Virginia	SB 223	<p>Uses definition of “unconscionable increase” similar to MD HB 631 with slight modification in language</p>

Washington	SB 5995/HB 2556	Requires manufacturers to report price increases of more than 100% in a year to the insurance commissioner for review by the prescription drug program, which determines if the price increase instituted by the drug manufacturer is excessive. Provides that a price increase instituted by a drug manufacturer that is determined to be excessive is not reasonable in relation to the development and preservation of business and is injurious to the public interest for the purpose of the attorney general's application of the consumer protection act.
Wisconsin	SB 874/AB 1046	Uses definition of "unconscionable increase" similar to MD HB 631

[1] See list in <https://knowledgeproblem.com/2012/11/03/list-of-price-gouging-laws/> and Emily Bae, *Are Anti-Price Gouging Legislations Effective Against Sellers During Disasters?*, 4 **Entrepreneurial Bus. L.J.** 79, 85 (2009). See e.g. South Carolina Code §39-5-145(5), Virginia Code [§59.1-527](#).

[2] Maine Revised Statutes Title 10, §1105.

[3] Idaho Code [§48-603\(19\)](#).

[4] California Penal Code [§396](#), Arkansas Code [§4-88-303](#).

[5] Michigan does not require an emergency declaration, but prohibits "[c]harging the consumer a price that is grossly in excess of the price at which similar property or services are sold." Mich. Stat. Ann. § 445.903(1)(z). Maine's price gouging law does not require a declared emergency, but only applies to abnormal market disruptions "caused by an event such as a natural or man-made emergency or disaster, whether local or remote." Me. Rev. Stat. tit. 10, § 1105.

[6] Christopher Lea Lockwood, *Biotechnology Industry Organization v. District of*

Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals, 19 **Alb. L.J. Sci. & Tech.** 143, 156 (2009).

[7] Maryland [HB 631](#) (2017).

[8] *Williams v. Walker-Thomas Furniture Co.*, 350 F.2d 445 D.C. Cir. (1965).

[9] *People ex rel. Vacco v. Beach Boys Equip. Co.*, 273 A.D.2d 850, 851, 709 N.Y.S.2d 729, 730 (2000).

[10] See e.g., *Solorio v. Fresno Cmty. Hosp. & Med. Ctr.*, No. F073953, 2018 WL 3373411 (Cal. Ct. App. July 11, 2018), as modified on denial of reh'g (July 31, 2018), review filed (Aug. 13, 2018); *Kendall v. Scripps Health*, 16 Cal. App. 5th 553, 224 Cal. Rptr. 3d 446 (Ct. App. 2017), review denied (Jan. 31, 2018); *Caudle v. Northbay Healthcare Grp.*, No. A148912, 2017 WL 6546377, at *1 (Cal. Ct. App. Dec. 22, 2017), reh'g denied (Jan. 12, 2018), review denied (Mar. 14, 2018).

[11] For more details about the market inefficiencies that allow these price increases see previous blog posts on the Source: [Drug Money \(Part 1\): What Limits Competition in the Pharmaceutical Market?](#) or [Drug Money Part 4 - The Return of the CREATES Act: Fourth Time's a Charm?](#)

[12] Pollack A. **Drug Goes From \$13.50 a Tablet to \$750, Overnight.** *The New York Times*. Published September 20, 2015. https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0.

[13] *Ass'n for Accessible Medicines v. Frosh*, 887 F.3d 664 (4th Cir. 2018)

[14] *Id* at 686.

[15] *Ass'n for Accessible Medicines v. Frosh*, No. 17-2166, 2018 WL 3574755, at *1 (4th Cir. July 24, 2018).

[16] United States Government Accountability Office, Report to Congressional Requesters. **Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases.** GAO-16-706.

August 2016. Available from: <https://www.gao.gov/assets/680/679022.pdf>.

[17] From first quarter 2013 to first quarter 2014, 4 of the 91 extraordinary price increases were for drugs that were among the 100 most utilized. In all other periods, no more than 1 drug of the 100 most utilized generic drugs in Medicare Part D experienced an extraordinary price increase.