

Maryland Is First to Ban “Price Gouging” on Generic Drugs, but Other State and Federal Initiatives May Soon Follow

By Helaine I. Fingold

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Executive Summary

Going back a number of years, federal and state policymakers have discussed various mechanisms to address the increasing costs of certain prescription drugs in the United States. This issue gained particular notice with the 2014 release of several costly medications to treat Hepatitis C. Increases in the price of certain generic drugs have raised more recent concerns. As the Trump administration, Congress, and state legislatures seek ways to respond to these price increases and the concerns that they raise for payers, consumers, and other stakeholders, Maryland has stepped out as a state leader in enacting a landmark law to address what it calls “price gouging.” Whether this state law can withstand legal challenges is unclear. Nevertheless, there is drug-pricing activity at the state level that should be monitored in addition to federal activity, which often gets more visibility.

This Client Alert describes the provisions of Maryland’s landmark law, summarizes similar efforts in other states as well as discussions at the national level to address price concerns, and examines recent efforts occurring in the private sector to highlight pricing issues, facilitate state communications on related initiatives, and influence the state and national debate on this topic.

Provisions of the Maryland Law

On May 26, 2017, Maryland became the first state to ban pharmaceutical “price gouging” on certain prescription drugs made available for sale in the state.¹ Amidst overwhelming bipartisan support from both the House of Delegates (137-2-2) and the State Senate (38-7-2),² Maryland Governor Larry Hogan allowed House Bill 631, also

¹ H.B. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017).

² General Assembly of Maryland, *Public Health - Essential Off-Patent or Generic Drugs - Price Gouging – Prohibition: Documents* (last visited June 12, 2017),

known as the “Prohibition Against Price Gouging for Essential Off-Patent or Generic Drugs” (“Act”), to become law without his signature. The Act, which takes effect on October 1, 2017, has two key provisions: (1) a prohibition on price gouging on certain drugs and (2) the authorization of administrative and legal action by the Maryland Attorney General (“MD AG”) to enforce this new law.³

The first key provision of the Act (to be codified in Maryland Code Health-General as Section 2-802) prohibits manufacturers and wholesale distributors from engaging in “price gouging” when selling “essential off-patent or generic drug[s].”⁴ An “essential off-patent or generic drug” is any drug or drug-device combination that (1) is not subject to exclusive marketing rights, (2) is listed on the most recent World Health Organization Model List of Essential Medicines or indicated by the Maryland Secretary of Health and Mental Hygiene, (3) is actively manufactured and marketed in the United States by fewer than three manufacturers, and (4) is made available for sale in Maryland.⁵

According to the Act, “price gouging” is an “unconscionable increase in the price of a prescription drug.”⁶ An “unconscionable increase” is defined as an increase that is “excessive and not justified” by costs associated with production or access to the drug for public health promotion and results in prescribed consumers lacking “meaningful choice” due to personal necessity and inadequate competition in the market.⁷

The second key provision of the Act (Section 2-803) authorizes the Maryland Medicaid Program to notify the MD AG when (1) over the previous one-year period, a 50 percent increase in either the wholesale acquisition cost (“WAC”) or price paid by the Maryland Medicaid Program for the drug occurs and (2) the WAC for either a “full course of treatment” or a 30-day supply exceeds \$80.⁸ Under this provision, the MD AG also may compel a potential justification disclosure statement from the manufacturer of the drug identified by the Maryland Medicaid Program.⁹ If requested by the MD AG, the manufacturer has 45 days to provide a statement that includes an itemized list of production costs and the potential justification for the drug price increase.¹⁰ In addition, the MD AG may compel a manufacturer or wholesale distributor to produce any records or documents relevant to a determination of whether the price increase violates the first provision of the Act that prohibits price gouging.¹¹

<http://mgaleg.maryland.gov/webmga/frmMain.aspx?pid=billpage&stab=02&id=HB0631&tab=subject3&ys=2017>
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³ H.B. 631, 437th Gen. Assemb., Reg. Sess. (Md. 2017).

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ The Act specifically requires manufacturers to identify any “circumstances and timing” for increases in materials and manufacturing costs and expenditures related to expanded access and promoting public health.

Id.

¹¹ *Id.*

In addition, the MD AG may seek a court order for the following remedies: (1) compelling the manufacturer or wholesale distributor to provide the disclosure statement and supporting records and documents, (2) restraining or enjoining violations of the Act, (3) obtaining monetary relief for consumers, (4) requiring the manufacturer or wholesale distributor to sell the essential off-patent or generic drug to Maryland state health plans for up to one year at the drug's price prior to the price-gouging violation, and (5) imposing civil penalties up to \$10,000 per violation.¹²

Although the Act will take effect on October 1, 2017, Governor Hogan withheld his signature, expressing concern that this new legislation was unconstitutional based on the dormant commerce clause and with ambiguity of the key term “unconscionable increase.”¹³

Parallel and Related Efforts in Other States and at the National Level

While other states are working on initiatives to address pharmaceutical price increases, none of them have yet succeeded in enacting legislation as aggressive as the Act.¹⁴ At least three states (New York, Oregon, and Massachusetts), however, currently have pending legislation similar to the Act, and there have been discussions at the national level to address price concerns:

New York. Two bills filed in the New York State Senate—S2402 and S2544 (identical to A5733, filed in the New York State Assembly)—also would prohibit price gouging. Bill S2402, which has a much broader reach than the Act, would ban manufacturers and wholesalers from selling “any compound manufactured for sale as a medicinal drug” at “unconscionably excessive price[s],” a question of law determined by a court based on enumerated factors.¹⁵ Bill S2544 would require manufacturers of brand or generic drugs to notify the New York Commissioner of Health of WAC increases greater than or equal to 100 percent over a span of one year.¹⁶ A “drug utilization review board” would then make a determination of whether the increase was excessive based on a justification provided by the manufacturer.¹⁷ Under both bills, the New York Attorney General would be given authority to take action against “unconscionable” and “unjustifiably excessive” price increases.¹⁸

¹² *Id.*

¹³ Letter from Larry Hogan, Governor, to Michael E. Busch, Maryland House Speaker, on HB 631 (May 26, 2016),

https://content.govdelivery.com/attachments/MDGOV/2017/05/26/file_attachments/822635/HB631Letter.pdf.

¹⁴ Some states even sought information from Maryland's legislators who debated HB631. Jeremy A. Greene, M.D., Ph.D., and William V. Padula, Ph.D., *Targeting Unconscionable Prescription-Drug Prices — Maryland's Anti-Price-Gouging Law*, NEW ENG. J. MED 1–3, 2 (2017) (online only), <http://www.nejm.org/doi/full/10.1056/NEJMp1704907>.

¹⁵ S.B. 2402, 202nd State Assemb., Reg. Sess. (N.Y. 2017).

¹⁶ S.B. 2544 and A.B. 5733, 202nd State Leg., Reg. Sess. (N.Y. 2017).

¹⁷ *Id.*

¹⁸ S.B. 2402, 202nd State Assemb., Reg. Sess. (N.Y. 2017); S.B. 2544 and A.B. 5733, 202nd State Leg., Reg. Sess. (N.Y. 2017).

Oregon. SB793 is broad reaching, much like the New York proposal. This bill, if enacted, would require manufacturers of prescription drugs sold in Oregon to report pricing data to the Oregon Department of Consumer Business Services (“DCBS”).¹⁹ Prescription drugs affected would include both brand and generic, including those that are used as a component of another drug.²⁰ “Excessive price increases,” prescription drugs increasing more than 3.4 percent within one year and not justified according by the DCBS according to specified factors, would impel the DCBS to order the drug manufacturer to refund these excessive increases.²¹ The DCBS would have authority to subpoena witnesses, documents, and records and compel testimony under SB793.²²

Massachusetts. Bill S.652, scheduled for hearing on July 11, 2017, would require pharmacy benefit managers (“PBMs”), manufacturers, and insurers to report cost data to the state government.²³ Manufacturers of identified drugs²⁴—including those “whose [WAC] has increased by 50% or more within the past five years or by 15% or more within the past one year”—would be required to provide the state government with detailed reports to justify the cost increase.²⁵ The Massachusetts Attorney General would have broad authority under the bill to review data, compel information from prescription drug parties (PBMs, insurers, manufacturers, providers, etc.), and promulgate regulations to define prescription drug prices “excessively higher than justified.”²⁶ Should the Massachusetts “health policy commission” deem the prescription drug’s cost to be “excessively higher than justified,” the bill would enable the commission to enlist the Attorney General to bring further legal action.²⁷ The bill would also impose a reporting requirement for PBMs, manufacturers, and insurers to “promote price transparency,” another common and related movement among the states.²⁸

National level. Options for controlling pharmaceutical drug pricing are being discussed by the federal government, as well. Reports have been published stating that the Trump administration is preparing an executive order that reportedly will instruct executive

¹⁹ S.B. 793, 79th Leg. Assemb., Reg. Sess. (Or. 2017).

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ S.652, 190th Gen. Court, Reg. Sess. (Ma. 2017).

²⁴ Identified drugs are also based on the overall highest prices, the highest increase in price, new drugs to the U.S. market with a WAC of \$10,000, etc. *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ According to the National Conference of State Legislatures, since 2015 (and as of March 2017):

- fourteen states have filed legislation that would require PBMs to disclose detailed cost data to their state government agency (four states enacted),
- seventeen states filed legislation that would require manufacturers to disclose cost data (two enacted), and
- seven states have proposals that require insurers to disclose cost data (three enacted).

agencies to utilize value-based pricing in drug-purchasing contracts²⁹ and will seek to ease regulatory burdens on manufacturers.³⁰

Stakeholder Initiatives

Private stakeholders also are analyzing and highlighting prescription drug price increases in order to affect the policy debate. The National Association for State Health Policy (“NASHP”) recently announced its establishment of the Center for State Rx Drug Pricing (“Center”), funded by the Laura and John Arnold Foundation (“Arnold Foundation”). The Center will “provide technical and strategic assistance to states,” convene a workgroup of state regulators “to address policy and strategic issues,” work with state organizations “to advance the states’ drug price policy agenda,” and “disseminate learnings – successes and challenges – among states,” among other things.³¹ The Center grew out of a 2016 NASHP initiative, the Pharmacy Price Work Group, also funded in part by the Arnold Foundation, to develop new policies and revise others in an effort to constrain prescription drug price increases.

The Arnold Foundation, established by a former hedge fund executive, has funded a number of projects addressing prescription drug pricing through a targeted initiative launched in 2016.³² Funded projects include support (1) for *Kaiser Health News* for its coverage of prescription drug development, costs, and pricing;³³ (2) to Johns Hopkins University to look at “policy options that maximize access to and affordability of prescription drugs”;³⁴ and (3) to Memorial Sloan Kettering Cancer Center to further research and testing of alternative value-based payment structures for specialty drugs.³⁵ Other national foundations are funding similarly targeted efforts.³⁶ Health care providers also are taking action. The American Medical Association recently approved resolutions addressing extreme price escalation, including mandating that drug companies list the

²⁹ P&T Community, *Trump White House Prepares Executive Order on Drug Pricing* (June 14, 2017), <https://www.ptcommunity.com/news/20170614/trump-white-house-prepares-executive-order-drug-pricing>.

³⁰ Sheila Kaplan and Katie Thomas, *New York Times*, *Draft Order on Drug Prices Proposes Easing Regulations* (June 20, 2017), <https://www.nytimes.com/2017/06/20/health/draft-order-on-drug-prices-proposes-easing-regulations.html>.

³¹ See NASHP Center for State Drug Rx Pricing website, at <http://nashp.org/center-for-state-drug-rx-pricing/> (June 21, 2017, 01:30 P.M.).

³² Laura and John Arnold Foundation, *Laura and John Arnold Foundation announces \$7.2 million in grants to address the rising cost of pharmaceutical drugs*, Press Release (February 17, 2016), <http://www.arnoldfoundation.org/laura-and-john-arnold-foundation-announces-7-2-million-in-grants-to-address-the-rising-cost-of-pharmaceutical-drugs/>.

³³ The Foundation awarded \$1.3 million to the Henry J. Kaiser Family Foundation “to support Kaiser Health News in providing independent reporting on pharmaceutical drug development and pricing,” <http://www.arnoldfoundation.org/grants/#grant-15683> (June 21, 2017, 01:38 P.M.).

³⁴ The Foundation awarded \$3.6 million to Johns Hopkins University “[t]o develop research on policy options that maximize access to and affordability of prescription drugs,” <http://www.arnoldfoundation.org/grants/#grant-15690> (June 21, 2017, 01:52 P.M.).

³⁵ See *supra* note 31.

³⁶ See, e.g., The Pew Charitable Trusts’ drug spending research initiative, <http://www.pewtrusts.org/en/projects/drug-spending-research-initiative> (June 21, 2017, 02:10 P.M.).

retail prices of their drugs on television commercials and supporting expedited review of generic drug applications during drug shortages.³⁷

Potential Impact of These Laws on Prescription Drug Pricing and Coverage

It is uncertain whether or how the Act and similar laws or policy initiatives will affect certain drug price increases or access. Nevertheless, what is clear is that ongoing pressure from providers, consumers, and other stakeholders will keep this issue at the top of legislators' agendas. Manufacturers, distributors, payers, providers, and consumers should monitor legislative initiatives in states of interest, as aggressive state legislation to limit drug price increases could impact drug demand and availability.

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This Client Alert was authored by Helaine I. Fingold. Matthew Sprankle, a Summer Associate (not admitted to the practice of law) in Epstein Becker Green's Washington, DC, office, contributed significantly to the preparation of this Client Alert. For additional information about the issues discussed in this Client Alert, please contact the author or the Epstein Becker Green attorney who regularly handles your legal matters.

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³⁷ Stephen Joyce, Bloomberg BNA – BNA's Health Care Daily Report, *Doctors OK Policies to Fight Skyrocketing Drug Costs* (June 14, 2017, 01:57 P.M.).