

HB20-1160: DRUG PRICE TRANSPARENCY INSURANCE PREMIUM REDUCTIONS

Concerning measures to reduce health care costs related to prescription drug prices, and, in connection therewith, creating the "Colorado Prescription Drug Price Transparency Act of 2020" to require health insurers, prescription drug manufacturers, pharmacy benefit management firms, and nonprofit organizations to report specified information about the costs of prescription drugs to the commissioner of insurance and to direct the commissioner to analyze the information and submit a report regarding the effects of prescription drug costs on health insurance premiums; and requiring health insurers to reduce insurance premiums to adjust for rebates the insurers receive for prescription drugs.

Details

Bill Sponsors:	House – <i>Jackson (D) and Roberts (D)</i> , Buckner (D), Caraveo (D), Coleman (D), Cutter (D), Froelich (D), Hooton (D), Kennedy (D), McCluskie (D), Melton (D), Melton (D), Mullica (D), Singer (D), Titone (D) Senate – <i>Ginal (D) and Donovan (D)</i>
Committee:	House Health & Insurance
Bill History:	1/21/2020- Introduced
Next Action:	2/12/2020- Hearing in House Health & Insurance
Fiscal Note:	Not Yet Published

Bill Summary

The bill establishes the "Colorado Prescription Drug Price Transparency Act of 2020." The bill requires reporting on prescription drugs by manufacturers, insurers, pharmacy benefit managers (PBMs), and certain nonprofit organizations with the intent of promoting cost reduction. Drug manufacturers are to provide one day advance notice to purchasers when drug prices are increasing beyond a specified threshold. The Commissioner of Insurance is required to post this information on the Division of Insurance's (DOI's) website, excluding any information that is proprietary. Further, the DOI is to conduct an analysis utilizing the reported information. PBMs are prohibited from retroactively reducing the payment provided on a clean claim submitted by a pharmacy unless the PBM determines, through an audit conducted in accordance with state law, that the claim was not a clean claim. Health insurers are required to reduce the cost sharing a covered person is required to pay for prescription drugs by an amount related to the average aggregate rebates received by the insurer.

Issue Summary

Prescription Drugs in Colorado

In 2018, nearly 42.5 million prescription drugs were filled at pharmacies in Colorado, resulting in \$6.02 billion of retail sales.¹ On average, there are approximately 10.8 medications dispensed per year per person in Colorado; of those, 8.7 are generic medications.² This approximation utilizes data from the Center for Improving Value in Health Care (CIVHC), which does not reflect the uninsured, some people covered by self-insured employer plans, and those covered under Federal programs like TRICARE, Indian Health Services, or

¹ Henry J Kaiser Family Foundation (2019). *Health Costs & Budgets Indicators*, Retrieved from <https://www.kff.org/state-category/health-costs-budgets/prescription-drugs/>

² Center for Improving Value in Health Care (n.d.) *Utilization*. Retrieved from <http://www.civhc.org/get-data/interactive-data/statewide-metrics/utilization/>

Veterans Affairs (VA). According to the Colorado Health Institute's (CHI) 2019 Colorado Health Access Survey, 10.8 percent of Coloradans cite the cost of prescription drugs as reason for not filling the medicines they are prescribed.³ Another study by CHI found that in 2015 the median out-of-pocket expenditures on prescription drugs was \$149 per year.⁴ However, average prices do not tell the whole story; some individuals and families can have high cost burdens for out-of-pocket costs for prescriptions, in some cases ranging into the thousands of dollars per year. What an individual pays for medications is dependent on factors like their condition, type of insurance, and cost sharing requirements. A 2015 Consumer Reports poll found that 30 percent of people who take at least one prescription drug a month had unexpected spikes in the out-of-pocket cost of their drug(s) in the past year.⁵ A majority, 82 percent, of Colorado voters think that the cost of prescription drugs are too high.⁶ The same survey also showed that 89 percent of respondents agreed with the statement, "The public should have the right to know the costs that are factored into the price of prescription drugs and medications to ensure fair and ethical business practices." Additionally, as drug prices continue to increase for insurers, those costs may be passed along to employers and consumers in the rates of premiums, copays, coinsurance, and deductibles.

In the 2016 Community Health Survey conducted by the Health District of Northern Larimer County, 8.6 percent of adult residents within the Health District reported being unable to have a prescription filled because they could not afford it during the preceding two years.⁷ This rate is much higher among those who reported being uninsured (28 percent).

Brand-Name Drugs

The FDA utilizes a structured framework for the approval all new brand-name drugs. To grant approval, the agency conducts an analysis of the target condition and other treatments in the market for the condition, assesses the benefits and risks of the drug, and evaluates risk-management strategies.⁸ From preclinical testing to approval the average length of time for a new drug is 12 years, this time may be quicker due to the various designations and programs.⁹ An analysis by IQVIA found that the increase in spending on drugs during 2016 was mainly driven by new brands and price increases for those drugs that are still under patent protection.¹⁰ Brand-name drug prices nearly doubled in price from 2008-2016. However, in 2017 brand-name net prices increased by an average of 1.9 percent, which is below the rate of inflation.¹¹ The list price per course of treatment (wholesale acquisition cost [WAC]) of the average brand-name drug increased from \$308.77 in 2013 to \$415.78 in 2017. The average final out-of-pocket costs, including after the use of manufacturers coupons to offset the cost, was \$42 per brand prescription in 2018.¹² In the same year, 19 percent of patients on commercial insurance used coupons to reduce their out-of-pocket costs.

³ Colorado Health Institute [CHI] (2017). *Colorado Health Access Survey 2019: State of Colorado*. Retrieved from https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/State%20of%20Colorado_0.pdf

⁴ CHI (2016). *Sticker Shock: Prescription Drug Affordability in Colorado*. Retrieved from <https://www.coloradohealthinstitute.org/research/sticker-shock-prescription-drug-affordability-colorado>

⁵ *Impact of Surging Drug Prices on Consumers: Hearings before the Democratic Steering and Policy Committee*, House, 114th Congress (2015) (Testimony of Lynn Quinicy). Retrieved from http://www.healthcarevaluehub.org/files/3214/4969/6175/Consumers_Union_Drug_Prices_Testimony.pdf

⁶ Keating Research (Dec. 4, 2019) *Healthier Colorado Poll-November 2019-Key Findings*. Retrieved from <https://healthiercolorado.org/wp-content/uploads/2019/12/Memo-Poll-Xtabs.pdf>

⁷ With a 95% confidence interval ranging from 7.3% to 10.0%.

⁸ U.S. Food and Drug Administration [FDA] (Jan. 2018). *Development & Approval Process (Drugs)*. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm>

⁹ Van Norman, G.A. (Apr. 2016). *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, *JACC Basic to Translational Science*, 3(1). DOI: <https://doi.org/10.1016/j.jacbs.2016.03.002>

¹⁰ Kamal, R., & Cox, C. (2017). *What are the recent and forecasted trends in prescription drug spending?*. *Peterson-Kaiser Health Systems Tracker*. Retrieved from https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-growth-prescription-spending-slowed-2016-increasing-rapidly-2014-2015_2017

¹¹ IQVIA Institute (Apr. 19, 2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*. Retrieved from <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>

¹² IQVIA Institute (May 2019). *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*. Retrieved from <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>

Generic Drugs

Generic drugs are identical to their brand-name counterparts and work in the same manner. These generics must be approved by the FDA and can only go to market after the patents and regulatory exclusivities have expired for the brand-name drug. In 2017, approximately 90 percent of retail prescription drugs filled were generics.¹³ Also, they were dispensed 97 percent of the time it was possible to do so.¹⁴ Generics are typically sold at prices that are 80 to 85 percent less than the cost of a brand-name drug.¹⁵

Specialty Drugs

The definition of a specialty drug is highly dependent on the entity utilizing the phrase, thus the definition can vary widely. One organization, IQVIA, defines it as a drug that treats a complex, chronic, or rare disease, and has at least four of the following characteristics: list price over \$6,000 per year, maintained by a specialist medical provider, not self-administered, requires special handling in supply chain, requires patient payment assistance, distributed through non-traditional channels, and/or has significant side effects that require patient monitoring.¹⁶ For 2019, Medicare defines a specialty tier drug as one that costs more than \$670 per month.¹⁷ The anticipated growth in prescription drug spending over the next decade is largely attributable to a larger percentage of that spending on specialty drugs.¹⁸ Specialty drug spending was \$87 billion in 2012, representing 25 percent of total drug spending and 3.1 percent of total health care spending in the U.S.¹⁹ Specialty drugs accounted for 46.5 percent of drug spending in 2017, a dramatic increase from 2012.²⁰ In 2017, spending has shifted greatly to specialty medicines, driving nearly 82 percent of the net growth of new brands on the market. The use of specialty medicines grew by 5 percent in 2018, more than double the rate of other drugs.²¹

Pharmacy Benefit Managers (PBMs)

Pharmacy benefit managers (PBMs) can represent a variety of different types of health plans (i.e. private carriers, self-insured employers, union health plans, or government purchasers) in both the purchasing and distribution of pharmaceutical products.²² Additionally, PBMs may design and administer pharmacy benefits for these payers.²³ PBMs can influence what products are utilized and set the rates that pharmacies are reimbursed for their services in the supply chain. Essentially, PBMs are the broker between the payers, drug manufacturers, and pharmacies. Due to the variety of roles PBMs perform, these entities play a central role in the pharmaceutical market.

¹³ IQVIA Institute. *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*.

¹⁴ Lupkin, S. (May 23, 2018). Drugmakers Blamed for Blocking Generics Have Jacked Up Prices and Cost U.S. Billions, *Kaiser Health News*. Retrieved from <https://khn.org/news/drugmakers-blamed-for-blocking-generics-have-milked-prices-and-cost-u-s-billions/>

¹⁵ FDA (Jan. 2018). *Generic Drugs: Questions & Answers*. Retrieved from <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm#g4>

¹⁶ IQVIA Institute (Oct. 2017). *Orphan Drugs in the United States: Providing Context for Use and Cost*. Retrieved from <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/orphan-drugs-in-the-united-states.pdf>

¹⁷ Cubanski, J., Koma, W., & Neuman, T. (Feb. 1, 2019). Specialty Drugs in Medicare Part D in 2019. *Kaiser Family Foundation*. Retrieved from <https://www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/>

¹⁸ Cuckler, G.A. et al. (2018). National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs*, 37(3). DOI: 10.1377/hlthaff.2017.1655

¹⁹ Kleinke, J.D., & McGee, N. (2015). Breaking the Bank: Three Financing Models for Addressing the Drug Innovation Cost Crisis. *American Health & Drug Benefits*, 8(3). Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4467013/>

²⁰ IQVIA Institute (Apr. 19, 2018). *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022*. Retrieved from <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>

²¹ IQVIA Institute (May 2019). *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023*. Retrieved from <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-use-and-spending-in-the-us-a-review-of-2018-and-outlook-to-2023>

²² Health Affairs (Sept. 2017). *Prescription Drug Pricing: Pharmacy Benefit Managers*. Retrieved from <http://www.healthaffairs.org/healthpolicybriefs>

²³ Meador, M. (2011). Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation, *Annals of Health Law*, 20(1). Retrieved from <https://lawcommons.luc.edu/cgi/viewcontent.cgi?article=1045&context=annals>

In 2016, more than 266 million individuals, approximately 82 percent of the U.S. population, received their pharmacy benefits through PBMs.²⁴ With the volume of the clients they serve, they can leverage those numbers to negotiate rebates and other discounts from manufacturers. Three PBMs, Express Scripts, CVS Health, and Optum Rx, control two-thirds of the market share in the U.S.²⁵ Rebates to PBMs from manufacturers have increased in previous years and are estimated to have contributed to lower net prices for drugs and decreased expected drug spending growth in 2017.²⁶ Not only do PBMs create these relationships with manufacturers, but they also create networks of pharmacies.

Rebates

Manufacturers offer rebates based on how much the PBM or insurer has the capacity to increase their market share; however, PBMs are not required to share the actual amount of these rebates with health plans and plans are not required to share with consumers.²⁷ Therefore, the PBM or insurer can keep some or all of the funds received through rebates. The majority of manufacturers use rebates to get insurers to get the drug placed favorably on the formulary in order to boost overall sales.²⁸ A recent PBM-sponsored study found that there is no correlation between rebates and the increase in list prices by manufacturers.²⁹ Some private health plans, such as UnitedHealthcare/OptumRx³⁰ and Tufts Health Plan³¹, have opted to pass part or all of rebates on directly to consumers at the point-of-sale.

Average Wholesale Price (AWP)

Although the name leads one to believe that this is the average price to wholesalers, it is actually an industry-wide published list of prices typically for wholesalers selling to pharmacies.³² However, it is not the price that pharmacies pay but rather is used as a benchmark for negotiations for pharmacies in determining the price charged to pharmacy benefit managers (PBMs), health plans, and government purchasers.³³ This price is not defined in federal statute and entities have moved away from using it after litigation regarding inflated AWP.³⁴ The AWP for drugs are reported by the manufacturers and published in clearinghouses (i.e. Redbook or Medi-Span).³⁵ The AWP is sometimes described as the “sticker price.”³⁶

Wholesale Acquisition Cost (WAC)

Also known as list price, the wholesale acquisition cost (WAC) is similar to a suggested retail price created by the manufacturers for wholesalers or direct purchasers and is only occasionally relevant to the pricing of both generic and brand-name drugs.³⁷ Thus, the WAC is not based on any actual sales of a drug. It is defined in federal Medicaid statute as “the manufacturer’s list price for the drug or biological to wholesalers or direct

²⁴ Pharmaceutical Care Management Association (May 18, 2018). Pharmacy Benefit Managers (PBMs). *Presentation to National Conference of State Legislatures*. Retrieved from http://www.ncsl.org/Portals/1/Documents/Taskforces/PharmacyCostsPBMs-PCMA_Presentation_31397.pdf

²⁵ Sood, N., Shih, T., Van Nuys, K., & Goldman, D. (June 2017). The Flow of Money through the Pharmaceutical Distribution System. *USC Leonard D. Schaeffer Center for Health Policy & Economics*. Retrieved from http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf

²⁶ Cuckler, G.A. et al. (2018). National Health Expenditure Projections, 2017-26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. *Health Affairs*, 37(3). DOI: 10.1377/hlthaff.2017.1655

²⁷ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

²⁸ Roehrig, C. (April 2018). *The Impact of Prescription Drug Rebates on Health Plans and Consumers*. Altarum. Retrieved from https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

²⁹ Pharmaceutical Care Management Association [PCMA] (June 2017). *Increasing Prices Set By Drugmakers Not Correlated with Rebates*. Visante. Retrieved from <https://www.pcmnet.org/wp-content/uploads/2017/06/Visante-Study-on-Prices-vs.-Rebates-FINAL.pdf>

³⁰ UnitedHealth Group (March 12, 2019). *Successful Prescription Drug Discount Program Expands to Benefit More Consumers at Point of Sale*. Retrieved from <https://www.unitedhealthgroup.com/newsroom/2019/2019-03-12-prescription-drug-program-expands-to-benefit-consumers-point-of-sale.html>

³¹ Tufts Health Plan (May 2018). *Plans & Products*. Retrieved from <https://tuftshealthplan.com/documents/email/broker-email/may-2018/rx-rebates>

³² Young, K. & Garfield, R. Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control.

³³ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation,

³⁴ Young, K. & Garfield, R. Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control.

³⁵ Medicaid and CHIP Payment and Access Commission [MACPAC] (May 2018). *Medicaid Payment for Outpatient Prescription Drugs*. Retrieved from <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>

³⁶ Pew Charitable Trusts. *Drug Spending Glossary*.

³⁷ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.”³⁸ The WAC serves as a basis for negotiations between entities in the supply chain.

This Legislation

Legislative Declaration

The General Assembly declares that Colorado has a substantial public interest in the price and cost of prescription drugs because the state is a major purchaser of drugs through public health care programs, state agencies, and state employee group benefit plans. The intent of the reporting requirements of the bill is to provide notice and disclosure of information relating to the cost and pricing of drugs in order to provide accountability to the state and all Coloradans for drug pricing. The General Assembly further declares that this is intended to create transparency in prescription drug pricing. It does not preclude a manufacturer from making pricing decisions regarding its drug products, including price increases. Further, it does not preclude public and private purchasers and pharmacy benefit managers (PBMs) from negotiating discounts and rebates consistent with state and federal law.

Definitions

“Average wholesale price” is defined in the bill as the average wholesale price of a prescription drug, as determined and published by a nationally recognized drug compendium. The bill defines “course of therapy” as either the recommended daily dosage units of a drug for a 30-day treatment pursuant to the drug’s package insert, as approved by the FDA, or the recommended daily dosage units of a drug for a normal course of treatment that is less than thirty days, as approved by the FDA. A “disinterested third party” is an entity that has no financial interest in, is not employed/funded by, or otherwise connected with an insurer, manufacturer, PBM, or nonprofit organization that is required to submit reports under this bill. A “line extension” is defined as a new or an additional formulation of the prescription drug, such as an extended release formulation. “Price” is defined as the wholesale acquisition cost, “the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.”³⁹ The bill defines purchasers as: Department of Health Care Policy and Financing (HCPF), Department of Corrections (DOC), Department of Human Services (DHS), any other agency or contractor of an agency that purchases prescription drugs, health insurers, PBMs, pharmacies or hospitals. “Rebates” are a rebate, discount, market share allowance, remuneration, compensation, or other payment or price concession provided by a manufacturer to a PBM or insurer. The bill defines a “specialty drug” as a prescription drug that exceeds the threshold for a specialty drug under the Medicare Part D program.

Health Insurer Annual Reports

Beginning in 2021, health insurers must report to the Commissioner of Insurance, at the same time as its annual rate filing, certain mandated information. For all covered prescription drugs, including generics, brand-name, and specialty drugs, which are dispensed at a pharmacy and paid for by the insurer in the previous calendar year, each insurer’s report should include the following information:

- Top 50 drugs by volume (calculated by unit)
- 50 most costly prescription drugs, by total annual plan spending
- 50 drugs paid for by the insurer that accounted for the highest increase in total annual plan spending when compared with the total annual plan spending for the same drugs in the year prior
- 50 drugs that caused the greatest increase in the insurer’s premiums
- 50 drugs that the insurer paid for most frequently and also received a rebate from manufacturers
- 50 drugs that the insurer received the highest rebate, as a percentage of the price of the drug
- 50 drugs that the insurer received the highest rebates for

³⁸ 42 USC § 1395w-3a(c)(6)(B)

³⁹ 42 USC § 1395w-3a(c)(6)(B)

Through rulemaking, the Commissioner can change the number of prescription drugs that the insurer is required to report on, except that it cannot be fewer than 25. Each insurer is to submit a written certification, with supporting documentation, which certifies that the insurer accounted for all rebates in calculating plan premiums that were issued or renewed during that year and how the insurer accounted for those rebates. Additionally, the insurer must submit to the Commissioner a list of all PBM firms that the insurer utilizes. After a change in PBMs, the insurer shall provide, within 10 business days, the updated information of the PBM, including any change in the name or contact information of the PBM firm.

An insurer that fails to comply with these requirements is subject to a fine of up to \$10,000 per day that it fails to comply. Any money gathered pursuant to these fines by the Commissioner is to be transferred to the General Fund. An employer or third-party administrator of a self-insured employer that is not subject to the DOI's jurisdiction is encouraged, but not required, to submit the information regarding prescription drug spending and rebates.

Drug Manufacturer Notices

This section of the bill applies to a manufacturer of a prescription drug that is purchased or reimbursed by a purchaser.⁴⁰

The manufacturer of a drug with a price of more than \$50 for a course of therapy is to notify the Commissioner and each purchaser of an increase in the price of the drug that will be implemented on or after January 1, 2021 if the increase in price is:

- 10 percent or more over the previous 12 months or
- 16 percent or more over the previous 24 months or
- 20 percent or more over the previous 36 months

For calendar year 2022, and each year after, the Commissioner shall adjust the threshold by rule, using the Consumer Price Index for Denver-Aurora-Lakewood. The manufacturer will provide the notice in writing to the DOI and each registered purchaser at least 1 day before the planned effective date of the increase in the price. The notice must include the date of the increase, the current price of the drug, and the dollar amount of the future price increase. Additionally, it must include a statement whether a change or improvement in the drug necessitates the price increase, if so, it is to include a description of the change or improvement.

On or after January 1, 2021, a manufacturer that introduces a new specialty drug to the market is to notify, in writing, the Commissioner and each purchaser within three days after the drug's release. The manufacturer may make the notification pending FDA approval if the market availability of the drug is expected within three days after approval.

To receive these notices, a purchaser must register with a DOI. Before registering the purchaser the DOI must verify that the entity qualifies. The DOI is to maintain a list of registered purchasers and make the list available to manufacturers. A fee to register as a purchaser may be imposed to offset the cost to the DOI in registering and maintaining the list.

Drug Manufacturer Reports

On or after January 1, 2021, within 15 days after the end of each calendar quarter, a manufacturer is to report to the Commissioner the following information for each prescription drug for which the manufacturer was required to notify purchasers in the prior quarter:

- Name and price of the drug as well as the increase, as a percentage, in the price over the course of the previous year
- Length of time the drug has been on the market

⁴⁰ Defined in previous "definitions" section.

- A description of the specific financial and nonfinancial factors (i.e. off-label use, changes in FDA policy, cost of current treatments, etc.) used to make the decision to increase the price of the drug
- Amount of the price increase, including an explanation of how the financial and nonfinancial factors drive the increase
- Introductory price of the drug when approved for marketing by the FDA
- Net yearly price increase, listed by calendar year, during the five immediately preceding years
- If the drug was acquired by the manufacturer within the previous five years:
 - Price at the time of acquisition and the year prior to acquisition
 - Name of the company from which the drug was acquired, the date acquired, and purchase price
 - Year the drug was introduced to the market and price on introduction
- Patent expiration date of the drug, if under patent
- Whether the drug is an innovator multiple source drug⁴¹, noninnovator multiple source drug⁴², or single source drug⁴³ or has a line extension
- Description of any change or improvement in the drug that necessitates the increase
- Total gross revenues from sales of the drug in Colorado for the immediately preceding calendar year
- Name of any generic version of the drug that is available on the market
- 10 highest prices and 10 lowest prices paid for the drug during the prior year in any country other than the U.S.
- Any other information that the manufacturer deems relevant to the price increase
- Documentation necessary to support all of this information

The Commissioner may request and use any drug price information they deem appropriate to verify that manufacturers have properly reported price increases.

On or after January 1, 2021, within 15 days after the end of each calendar quarter, a manufacturer is to report to the Commissioner the following information for each new specialty drug introduced to the market during the prior quarter:

- Description of the marketing and pricing plans used in the launch of the drug in Colorado and all associated costs of those plans
- Estimated number of patients in Colorado that might be prescribed the drug for its FDA-approved use
- Whether the specialty drug was granted breakthrough therapy designation or priority review by the FDA
- Date and price of acquisition if the drug was not developed by the manufacturer

After receiving either of these reports, the Commissioner can request that a manufacturer provide supporting documentation or additional information. The Commissioner is to prescribe by rulemaking the time periods for requesting addition documentation and for manufacturers to respond, including extensions.

Pharmacy Benefit Manager & Insurer Reports

Starting in 2021, insurers and contracted PBM firms are to report information required by the bill by a date specified by the Commissioner that coincides with insurer rate filing, but in a form and manner that is separated from the filing process. For all prescription drugs that the PBM/insurer received a notice from a manufacturer for in the prior calendar year, the PBM or insurer are to report:

- Total amount of all rebates received

⁴¹ A brand name drug that has generic competitors.

⁴² A generic drug.

⁴³ A brand name drug that has market exclusivity.

- Total amount of administrative fees the PBMs received from insurers and manufacturers for the drug
- Total annual payments, including reimbursements and fees, paid to Colorado pharmacies for dispensing drugs, identifying:
 - Amount attributable to dispensing fees
 - Amount attributable service or administrative fees
- Explanation of all other services offered by the insurer or PBM, excluding proprietary and client-specific information

Additionally, insurers and PBMs are to report the AWP paid for the following categories of prescription drugs:

- Brand name drugs purchased at retail pharmacy
- Generic drugs purchased at retail pharmacy
- Brand name drugs purchased from mail-order pharmacy
- Generic drugs purchased from mail-order pharmacy
- Prescription drugs dispensed by a practitioner
- Specialty drugs administered in inpatient hospital setting
- Specialty drugs administered in outpatient hospital

The insurer or PBM are to report the AWP for the above drugs paid by each market sector enrolled in its health plan or drug benefit. The market sectors are specified as individuals, small employers, large employers of 100-500 eligible employees, large employers of 501-5000 eligible employees, and large employers with more than 5000 eligible employees.

Each insurer that uses a PBM is to require the PBM's compliance with these reports. The insurer must periodically audit the PBM to ensure compliance. Failure of the insurer to comply with the reports or to ensure PBM compliance is an unfair method of competition and an unfair or deceptive act in the business of insurance.

Nonprofit Organization Reports

This section of the bill applies to nonprofit organizations that:

- Have a mission focusing on issues regarding pharmaceutical treatment for Coloradans
- And has received a payment, donation, subsidy, or thing of value that exceeds \$1,000 in value during the prior year from a manufacturer, PBM, insurer, or trade association representing any of those industries

Starting in 2021, the nonprofit organization is to compile and submit a report to the Commissioner a report that includes:

- Amount of each payment, donation, subsidy, or thing of value received directly or indirectly from each manufacturer, PBM, insurer, and trade association
- Percentage of the nonprofit organization's total gross income attributable to payments, donations, subsidies, or other things of value received directly or indirectly from each manufacturer, PBM, and insurer in the prior year

The nonprofit organization shall include in the report the above information for any payment, donation, subsidy, or thing of value that exceeds \$1,000 in value that is received directly or indirectly by an officer, employee or member of the board of directors of the organization. A nonprofit organization that is subject to these reporting requirements but fails to comply is subject to a fine of up to \$10,000.

Commissioner of Insurance to Publish Reports

The Commissioner is to post on the DOI's website the following:

- Information reported by health insurers

- Information in the manufacturer notices
- Information reported by the manufacturers, specifically listing the drugs information was reported on and the names of the manufacturers of those drugs
- Information reported by all insurers and PBMs
- Information reported by nonprofit organizations

If an insurer, manufacturer, PBM, or nonprofit organization claims that information in a submitted report is proprietary, the Commissioner is to review and redact specific items of proprietary information from what is posted on the DOI's website. The reporting entity bears the burden to prove that the information is proprietary. This redacted information shall not be disclosed to the public or any person outside the DOI, except for a disinterested party that is contracted to perform an analysis of the information.

The Commissioner, or a contractor, is to analyze the data reported by the insurers, manufacturers, PBMs, nonprofits, insurers' rate filings, and any other information that is relevant to determine the overall effect of drug costs on premiums. The Commissioner is to issue a report that analyzes the drug cost data and effect of drug costs on premiums. The report, using information reported by insurers, is to describe the rebate practices of insurers, including:

- An explanation of the manner in which insurers accounted for rebates in calculating premiums for plans issued or renewed during that year
- Any other manner where the insurers applied rebates
- Other information that the Commissioner deems relevant for this report

If an insurer, manufacturer, PBM, or nonprofit organization claims that information in a submitted report is proprietary, the Commissioner is to review and exclude specific items from the report. If the DOI contracts with a party to analyze the data, the contractor shall not disclose the proprietary information to the public or any person outside of the DOI. The reporting entity bears the burden to prove that the information is proprietary.

By December 1, 2021, and by each December 1 thereafter, the Commissioner shall publish the report on the DOI's website, which details information that was received from entities through July of calendar year in which the report is published. The Commissioner shall also submit the report to the Governor, Senate Health and Human Services Committee, House Health and Insurance Committee and House Public Health Care and Human Services Committee. The report is to be presented during a SMART Act⁴⁴ hearing prior to each legislative session, starting prior to the 2022 session.

The Commissioner, in consultation with HCPF, DOC, DHS, and any other state department that purchases or reimburses the cost of prescription drugs, shall include in the report any legislative recommendations to contain the costs of prescription drugs and reduce the effects of price increases on consumers, HCPF, DHS, DOC, other state departments, commercial health insurance premiums, and premiums for the state group benefit plans.

Rules and Enforcement

The Commissioner can adopt rules as necessary. This includes rules that specify the form and manner that insurers, manufacturers, PBMs, and nonprofit organizations are to report information. Additionally, the rules should establish filing fees to be paid by insurers, manufacturers, and PBMs, which fees must be used solely to pay for the DOI's costs in administering the bill. In adopting these rules, the Commissioner can consult the Board of Pharmacy, Secretary of State, Attorney General, and any department that is considered a purchaser.

A manufacturer engages in unprofessional conduct and is subject to discipline and penalties if it:

⁴⁴ "State Measurement for Accountable, Responsive, and Transparent (SMART) Government Act"

- Fails to notify purchasers of a prescription drug price increase or new specialty drug introduced to the market
- Fails to report required information to the Commissioner
- Fails to pay filing fees

Any violation shall be reported by the Commissioner to the Board of Pharmacy. The Board may impose an administrative fine up to \$10,000 per day it fails to comply.

It is an unfair method of competition and unfair or deceptive acts or practices in the business of insurance for an insurer to not comply with the reporting requirements and/or not ensure that a contracted PBM is complying.

Prescription Drug Cost Sharing & Rebates

For each health plan issued or renewed on or after January 1, 2022, an insurer is to reduce the premiums for that plan by an amount equal to 100 percent of the estimated rebates for prescription drugs that the insurer received for that plan in the previous plan year. The Commissioner is to adopt rules to maximize the reduction in premiums. Additionally, the Commissioner can use any of the office's enforcement powers to obtain insurer compliance.

The bill takes effect July 1, 2020.

Reasons to Support

Although only one day, the advanced notice could inform and aid purchasers. The notice could also provide assistance in scaling back potential WAC price increases, which tend to increase the prices down the line in the supply chain. Proponents claim that the notifications and reports could provide insight to policymakers in order to identify strategies to ensure the continued access to life-saving and life-improving pharmaceutical products at prices that are beneficial to consumers and manufacturers. Furthermore, the public notice could create a public relations backlash or shame that the companies would respond to by not increasing the prices as often or as dramatically.

Legislation such as this is considered to be a way for policymakers and the public to vent their frustrations with and continue to shine the spotlight on the pricing practices of the industry. If this bill was to pass, proponents believe it would signal to the industry that they do not have power over the legislation that travels through state legislatures. Requiring more than just manufacturers to report information will allow for a more complete view of the supply chain and how drugs are priced.

By including the provision that requires insurers to use rebates to directly reduce consumer premiums, it could provide more immediate relief for Coloradans struggling to afford health insurance.

Supporters

- | | |
|---------------------------------------|---------------------------------------|
| • AARP | • Healthier Colorado |
| • Colorado Center on Law and Policy | • National Multiple Sclerosis Society |
| • Colorado Community Health Network | • RxPlus Pharmacies |
| • Colorado Consumer Health Initiative | • Small Business Majority |
| • Colorado Cross-Disability Coalition | |

Reasons to Oppose

Supporters claim that the advanced notice of the purchasers could help them push back against price increases but others claim that it is unknown what additional leverage the purchasers would have beyond the normal negotiating tactics they utilize to receive rebates.

The bill could have negative consequences. Economic studies have consistently demonstrated that advanced price notice facilitates greater industry coordination.⁴⁵ Industry coordination can lead to higher prices as the manufacturers can create a market average and not have low-lying outliers that sell the product at a lower price.

Trade associations, including PhRMA and the Biotechnology Innovation Organization (BIO), have filed legal action in most of the states where similar bills have passed the legislature. If this legislation is passed, a lawsuit may be expected. The cost of this action could require both monetary resources and staffing to defend the law in court.

Some may say that this transparency reporting mandate would require additional resources for manufacturers, insurers, and PBMs. Some may assert that these additional required resources to remain in compliance could add costs to the drug products and premiums.

Opponents

- Amgen
- America's Health Insurance Plans
- Bristol-Myers Squibb
- Cigna
- Colorado BioScience Association
- Colorado Competitive Council
- CVS Health
- Denver Metro Chamber of Commerce
- Genentech
- GlaxoSmithKline
- Johnson & Johnson
- Pharmaceutical Care Management Association (PCMA)
- Pharmaceutical Research Manufacturers of America (PhRMA)
- United Health

About this Analysis

This analysis was prepared by Health District of Northern Larimer County staff to assist the Health District Board of Directors in determining whether to take an official stand on various health-related issues. The Health District is a special district of the northern two-thirds of Larimer County, Colorado, supported by local property tax dollars and governed by a publicly elected five-member board. The Health District provides medical, mental health, dental, preventive and health planning services to the communities it serves. This analysis is accurate to staff knowledge as of date printed. For more information about this analysis or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.

⁴⁵ Werden, G. (2004). Economic Evidence on the Existence of Collusion: Reconciling Antitrust Law with Oligopoly Theory. *Antitrust Law Journal*, 71(3), 719-800. Retrieved from <http://www.jstor.org/stable/40843604>