

HB19-1296: PRESCRIPTION DRUG COST REDUCTION MEASURES

Concerning measures to reduce prescription drug costs, and, in connection therewith, creating the "Colorado prescription drug cost reduction act of 2019" 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; to direct the commissioner to analyze the information and submit a report regarding the effects of prescription drug costs on health insurance premiums; to preclude pharmacy benefit management firms from retroactively reducing payments to pharmacies; and to require carriers to reduce consumer cost sharing for prescription drugs to reflect rebates the carrier or pharmacy benefit management firm received.

Details

Bill Sponsors:	House – <i>Jackson (D) and Jaquez Lewis (D)</i> , Roberts (D) Senate – <i>Ginal (D) and Donovan (D)</i>
Committee:	House Health & Insurance House Appropriations House Finance
Bill History:	3/29/2019- Introduced in House 4/3/2019- House Health & Insurance Refer Amended to Finance 4/11/2019- House Finance Refer Amended to Appropriations
Next Action:	Hearing in House Appropriations Committee
Fiscal Note:	<u>4/18/2019 Version</u>

Bill Summary

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. 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 2017, more than 45.9 million prescription drugs were filled at pharmacies in Colorado, resulting in \$6.28 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-

¹ Henry J Kaiser Family Foundation (2018). *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/>

insured employer plans, and those covered under Federal programs like TRICARE, Indian Health Services, or Veterans Affairs (VA). According to the Colorado Health Institute's (CHI) 2017 Colorado Health Access Survey, 10.7 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. 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

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.⁶ 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.⁷ 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.⁸ 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.⁹ 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.¹⁰ The list price (wholesale acquisition cost [WAC]) of the average brand-name drug increased from \$308.77 in 2013 to \$415.78 in 2017. However, the average out-of-pocket costs for patients only rose twelve cents to \$30.33. As stated earlier, these averages do not portray the true picture as there are individuals and families that must pay extensively more out-of-pocket for prescription drugs.

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

³ Colorado Health Institute [CHI] (2017). *Colorado's New Normal: Findings from the 2017 Colorado Health Access Survey*. Retrieved from https://www.coloradohealthinstitute.org/sites/default/files/file_attachments/2017%20CHAS%20DESIGN%20FINAL%20for%20Web.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 Quinoy). Retrieved from http://www.healthcarevaluehub.org/files/3214/4969/6175/Consumers_Union_Drug_Prices_Testimony.pdf

⁶ With a 95% confidence interval ranging from 7.3% to 10.0%.

⁷ U.S. Food and Drug Administration [FDA] (Jan. 2018). *Development & Approval Process (Drugs)*. Retrieved from <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm>

⁸ 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.jacbts.2016.03.002>

⁹ 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

¹⁰ 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>

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.¹⁹ Additionally, PBMs may design and administer pharmacy benefits for these payers.²⁰ 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.

In 2016, more than 266 million individuals, approximately 82 percent of the U.S. population, received their pharmacy benefits through PBMs.²¹ 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.²² 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 2017.²³ 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.²⁴ Therefore, the PBM or insurer can keep some or all of the funds received through rebates.

In May 2018, the Trump Administration proposed in “American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” requiring Part D plans to pass on to beneficiaries at least one-third of the rebates and price concessions from manufacturers.²⁵ It is estimated that this would actually increase federal spending by approximately \$43.4 billion for 10 years as it would increase premium subsidies since plans would not be able to use those rebates to reduce total costs.²⁶ On January 31, 2019 the Department of Health and Human Services’ (HHS) Office of Inspector General (OIG) issued a proposed rule that would ban rebate arrangements under Medicaid Part D and Medicaid managed care organizations that it believes are harmful, while protecting discount and service arrangements it

¹⁹ Health Affairs (Sept. 2017). *Prescription Drug Pricing: Pharmacy Benefit Managers*. Retrieved from <http://www.healthaffairs.org/healthpolicybriefs>

²⁰ 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>

²¹ 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>

²² 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

²³ 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

²⁴ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

²⁵ U.S. Department of Health and Human Services [HHS] (May 11, 2018). *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. Retrieved from <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

²⁶ Cubanski, J. (June 2018). What’s in the Administration’s 5-Part Plan for Medicare Part D and What Would it Mean for Beneficiaries and Program Savings. *Henry J Kaiser Family Foundation*. Retrieved from <http://files.kff.org/attachment/Issue-Brief-Whats-in-Administrations-5-Part-Plan-for-Medicare-Part-D>

believes are beneficial.²⁷ The goal of this approach is that consumers would see those rebates or discounts reflected at the pharmacy counter.

Some private health plans, such as UnitedHealthcare/OptumRx²⁸ and Tufts Health Plan²⁹, have opted to pass part or all of rebates on directly to consumers at the point-of-sale.

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.³⁰ 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 purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price.”³¹ The WAC serves as a basis for negotiations between entities in the supply chain.

Retroactive Reduction of Payments

Pharmacies may encounter PBMs’ requirement that they pay “direct and indirect remuneration” (DIR) fees, which are imposed after sale in an unpredictable manner.³² Pharmacies do not know when they will be charged these fees and how high they will be, with pharmacy owners reporting that DIR fees make cash flow unpredictable (78 percent) and inflate patient cost-sharing levels (69 percent).³³ Some assert that the DIR fee has become a “catch-all” term and are a means for PBMs to “clawback” funds from pharmacies for medications that have been dispensed. Typically, when a commercially insured individual’s copayments exceed the total cost of the drug to their insurer/PBM it is a prescription drug overpayment, known as a “clawback.”³⁴

At the federal level a bill was introduced in 2017, “Improving Transparency and Accuracy in Medicare Part D Drug Spending Act” (H.R. 1038 and S. 413), which provides that after a pharmacy submits a receipt for Medicare Part D, the PBM “may not retroactively reduce payment.” Neither bill was passed or enacted.

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 for drug pricing. The General Assembly further declares that this is intended to

²⁷ Alston, M., Bazell, C. & Mike, D.R. (Feb. 8, 2019). Changing the rebate game: A primer on the HHS proposed rule to shift drug rebates to POS. *Milliman*. Retrieved from <http://us.milliman.com/insight/2019/Changing-the-rebate-game-A-primer-on-the-HHS-proposed-rule-to-shift-drug-rebates-to-POS/>

²⁸ 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>

²⁹ Tufts Health Plan (May 2018). *Plans & Products*. Retrieved from <https://tuftshealthplan.com/documents/email/broker-email/may-2018/rx-rebates>

³⁰ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

³¹ 42 USC § 1395w-3a(c)(6)(B)

³² Carrier, M. (Aug. 30, 2018). A Six-Step Solution To The PBM Problem. *Health Affairs Blog*, DOI: 10.1377/hblog20180823.383881. Retrieved from <https://www.healthaffairs.org/doi/10.1377/hblog20180823.383881/full/>

³³ National Community Pharmacists Association (Feb. 9, 2018). *NCPA Survey: Pharmacy DIR Fees Plague Both Community Pharmacies and Their Patients*. Retrieved from <https://www.ncpanet.org/newsroom/news-releases/2018/02/09/ncpa-survey-pharmacy-dir-fees-plague-both-community-pharmacies-and-their-patients>

³⁴ Van Nuys, K., Joyce, G., Ribero, R., & Goldman, D.P. (Mar. 2018). Overpaying for Prescription Drugs: The Copay Clawback Phenomenon. *USC Leonard D. Schaeffer Center for Health Policy & Economics*. Retrieved from http://healthpolicy.usc.edu/documents/2018.03_Overpaying%20for%20Prescription%20Drugs_White%20Paper_v.1.pdf

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

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 label 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. An “essential drug” is a prescription drug included on the most current version of the World Health Organization’s (WHO) “Model List of Essential Medicines.” 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 2020, health insurers³⁵ 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 for outpatient use and paid for by the insurer in the previous calendar year, the insurer’s report should include the following information:

- 25 prescription drugs that the health insurer paid for the most frequently
- 25 most costly prescription drugs by total annual drug spend
- 25 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
- 25 outpatient drugs that the insurer paid for the most frequently and for which the insurer received from the manufacturer(s) a rebate, discount, or other source of revenue that reduced the cost to acquire the drug

Each insurer is to submit a written certification, with supporting documentation, that certifies that the insurer accounted for all rebates and discounts, other than rebates used to reduce cost-sharing, which reduced the cost to acquire a drug in calculating the insurer’s plan premiums. Additionally, the insurer must submit to the Commissioner a list of all PBM firms that the insurer contracts with. After a change in contracted PBMs, the insurer shall provide, within 10 business days, the updated information about the contracted 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.

Drug Manufacturer Notices

This section of the bill applies to a manufacturer of a prescription drug that is purchased or reimbursed by any of the following entities:

- Department of Health Care Policy and Financing (HCPF)
- Department of Corrections (DOC)
- Department of Human Services (DHS)
- Any other Colorado agency that purchases a drug on behalf of the state, or entity that is acting on behalf of a department, including a PBM
- Health insurer
- PBM that has contracted with an insurer

³⁵ As defined in C.R.S. 10-16-102(8).

The manufacturer of a drug with a price of more than \$100 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, 2020 if:

- The increase in the price is 10 percent or more over the previous 12 months or 16 percent or more over the previous 24 months
- Or the drug is an essential drug and the increase in the price is 10 percent or more over the previous 12 months, 16 percent or more over the previous 24 months, or 20 percent or more over the previous 36 months

The manufacturer will provide the notice in writing at least 30 days 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, 2020 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 to notification pending FDA approval if the market availability of the drug is expected within three days after approval.

The Commissioner is to make a list of purchasers to whom the notices are to be sent available to the manufacturers.

Drug Manufacturer Reports

On or after January 1, 2020, 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
- A description of the specific financial and nonfinancial factors (i.e. shadow pricing, 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 five immediately preceding 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 drug³⁶, noninnovator multiple source drug³⁷, or single source drug³⁸ 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

³⁶ A brand name drug that has generic competitors.

³⁷ A generic drug.

³⁸ A brand name drug that has market exclusivity.

- Name of any generic version of the drug that is available on the market
- Direct costs incurred by the manufacturer to research and develop, manufacture, market, distribute, and for ongoing safety and effectiveness research
- Manufacturer's profit attributable to the drug during the prior year
- 10 highest 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
- Documentation necessary to support all of this information

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

The manufacturer must also include information about each patient assistance program offered by the manufacturer to Colorado residents. This information must include:

- Number of consumers who participated
- Total value of the coupons, discounts, copayment assistance, or other reductions in costs provided to Colorado consumers
- For each drug, the number of refills that qualify for the program
- If the program expires after a specified period, and the period the program is available to consumers
- Eligibility criteria and how eligibility is verified for accuracy

On or after January 1, 2020, 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
- 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 additional documentation and for manufacturers to respond, including extensions. The Division of Insurance (DOI) is to make available, through phone and internet, a process for consumers to notify the DOI about a price increase.

Pharmacy Benefit Manager Reports

Starting in 2020, insurers and contracted PBMs are to report information required by the bill by a date specified by the Commissioner that coincides with insurer rate filing. For all prescription drugs paid for in the prior calendar year, the PBM or insurer are to report:

- Aggregate amount of all rebates and discounts that reduce the cost to acquire prescription drugs that the insurer or PBM received from manufactures during the prior year
- Aggregate amount of all rebates and discounts that reduce the cost to acquire all prescription drugs retained by the insurer or PBM
- Aggregate amount of administrative fees the PBM received from the manufacturers and insurers for all prescription drugs
- Aggregate annual payments, including reimbursements and fees, paid to Colorado pharmacies for dispensing drugs, identifying:
 - Aggregate amount attributable to dispensing fees

- Aggregate amount attributable service or administrative fees
- Explanation of all other services offered by the insurer or PBM, excluding proprietary and client-specific information

Each insurer that contracts with a PBM to manage or administer prescription drug benefits must include in a new or renewed contract with the PBM a requirement that the PBM complies with the reporting. The health insurer is to periodically audit the PBM to monitor and ensure compliance. If an insurer fails to ensure that the contracted PBM is complying it is deemed an unfair method of competition and unfair or deceptive act or practice.

Nonprofit Organization Reports

This section of the bill applies to any nonprofit organization that:

- Has a budget over \$50,000
- Advocates on behalf of patients regarding pharmaceutical treatment
- 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

By April 1, 2020, and each April 1 thereafter, 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, and insurer
- Percentage of the nonprofit organization's total gross income attributable to payments, donations, subsidies, or other things of value received 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 by the Executive Director or Chief Operating Officer or by the board of directors or any member of the board. A nonprofit organization that is subject to these reporting requirements but fails to comply is subject to a fine of up to \$1,000.

Commissioner of Insurance Reports

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

- The information reported by health insurers
- The following specific information reported by manufacturers:
 - List of prescription drugs that were reported for price increases or being a new specialty drug, as well as the manufacturers of those drugs
 - Information reported to the Commissioner regarding the price increases and bringing a specialty drug to market
 - Written requests by the Commissioner to manufacturer(s) for supporting documentation or additional information
- The combined aggregate information reported by all insurers and PBMs that is required under the PBM reporting section
- The 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 redact specific items of proprietary information from what is posted on the DOI's website. This information shall not disclose the information 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, discounts, and other sources of revenue that reduce the cost to acquire a drug in calculating premiums for a plan issued or renewed during that year
- A statement disclosing whether insurers made these rebates and discounts available to the covered person at the point-of-sale during the year
- Any other manner where the insurers applied rebates, discounts, or other sources of revenue that reduce the cost to acquire a prescription drug
- Other information that the Commissioner deems relevant

If an insurer, manufacturer, PBM, or nonprofit organization claims that information in a submitted report is proprietary, the Commissioner is to redact specific items of proprietary information 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.

At least 30 days before the Commissioner publishes and submits the reports, they are to provide the insurers, manufacturers, and PBMs that reported information an explanation and description of the information released in the report and an opportunity to object the release of claimed proprietary information. If an insurer, PBM, or manufacturer objects, it must submit the objection and information demonstrating that the information is proprietary no later than 15 days after receiving the explanation from the Commissioner. If the Commissioner finds in favor of the objecting party, they shall remove that proprietary information before publishing the report. The determination of the Commissioner is final and not subject to review.

By December 1, 2020, 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. By December 1, 2020, and by each December 1 thereafter, the Commissioner shall 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 Act³⁹ hearing prior to each legislative session, starting prior to the 2021 session.

The Commissioner, in consultation with HCPF, DHS, and any other state department that purchases or reimburses the cost of prescription drugs, shall include in the report any legislative policy 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 reporting sections of this bill. In adopting these rules, the Commissioner can consult the Board of Pharmacy, Secretary of State, HCPF, DOC, DHS, Department of Personnel, and any other relevant state department.

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

³⁹ "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.

PBM Retroactive Reduction of Payments

In this section, “clean claim” is defined as a claim that has no defect, impropriety, including any lack of required substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment from being made on the claim.

A contract between a pharmacy and PBM must include that after the date the PBM receives a clean claim from a pharmacy the PBM cannot retroactively reduce (directly or indirectly) payment on the claim, unless during an audit it is determined that it is not a clean claim. This does not prohibit a PBM from retroactively increasing payment to a pharmacy pursuant to a written agreement between the two entities. Each insurer that contracts with a PBM is to include in their contract a requirement that the PBM comply with this condition. The insurer’s failure to comply or ensure that the PBM complies is an unfair method of competition and an unfair or deceptive act or practice.

Prescription Drug Cost Sharing & Rebates

The bill defines “cost sharing” as a deductible payment, copayment, or coinsurance amount imposed on a covered person for a covered prescription drug in accordance with the terms and conditions of the person’s health coverage plan. A “rebate” is defined as a price concession given by a manufacturer directly to a carrier or PBM that reduces the carrier’s drug costs for the benefit year.

For each of an insurer’s plans issued or renewed on or after January 1, 2021, the insurer is to reduce the amount of cost sharing that it would otherwise charge a covered person for a prescription drug by an amount equal to 100% of the estimated rebate per prescription that the insurer received. This is calculated based on the rebates received for that drug during the previous quarter; the amount cannot exceed the cost sharing amount that would otherwise be charged for the dispensed drug. The covered person and insurer are not responsible for any difference between the estimated and actual rebate amount that the insurer receives. This does not prevent an insurer from reducing a person’s cost sharing by an amount greater than that would occur under this requirement. The Commissioner is to adopt rules, as necessary, including ensuring rebates are applied in a manner to provide a price reduction for covered persons who have not reached their annual cost sharing limit and to limit the effect on premiums. In order to enforce this section, the Commissioner can utilize any of their enforcement powers.

Unprofessional Conduct & Disciplinary Action

The bill adds failing to comply with PBM required reports and PBM reduction in payments as unfair methods of competition and unfair/deceptive acts or practices in the business of insurance. The Colorado Board of Pharmacy can suspend, revoke, refuse to renew, or otherwise discipline manufacturers that fail to notify purchasers, report required information, or pay required filing fees. In addition to any other penalty the Board of Pharmacy may impose, it may fine a manufacturer for failing to notify purchasers or report information up to \$10,000 per day that it fails to comply.

Effective Dates

The bill takes effect on July 1, 2019. If HB19-1172 becomes law, the section regarding the Board of Pharmacy and unprofessional conduct as well as disciplinary action takes effect October 1, 2019.

Fiscal Note

For state fiscal year 2019-2020, the bill requires an appropriation of \$166,539 to the Department of Regulatory Agencies, which houses the Division of Insurance, from the DOI Cash Fund, which holds the revenues from the required filing fees. The majority of these appropriated funds would come from the DOI Cash Fund, through the required filing fees. The fiscal note estimates that the filing fee for fiscal year 2019-2020 will be \$353, affecting at least 530 entities, for a total of approximately \$187,151. It is assumed that the DOI will utilize these funds for computer programming and maintenance, enforcement activities, as well as legal services to review the confidentiality requirements.

Reasons to Support

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 WACs 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. Requiring the sharing of rebates with patients may save Colorado consumers money at the pharmacy counter while possibly minimally increasing premiums.⁴⁰ Prohibiting retroactive reduction of payments for clean claims may further the intent of a bill passed during the 2018 legislative session, HB18-1284⁴¹, that aimed to prohibit “clawbacks.”

Supporters

- Colorado Consumer Health Initiative
- Colorado Medical Society
- National Multiple Sclerosis Society
- RxPlus Pharmacies

Reasons to Oppose

Some assert that the WAC transparency that is mandated by the bill is not effective as it is mandating transparency of something that is already transparent. A drug’s WAC is already publicly available from manufacturers or services that track prices. Furthermore, the mandate to notify purchasers of increases in WAC is not useful as it is not the list price of the drug. Therefore, there could be an increase in the WAC but the PBMs or carriers may not pay more than they did previously. Additionally, 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. The advanced notice could allow wholesalers and distributors to buy up supplies of the drug at the lower price, and then after the price increase, sell the product for a large profit. Additionally, economic studies have consistently demonstrated that advanced price notice of this

⁴⁰ PhRMA (Feb. 25, 2019). *Point of Sale Rebate Analysis in the Commercial Market*. Retrieved from <https://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market>

⁴¹ The Health District Board of Directors voted to Support the bill.

kind facilities greater industry coordination.⁴² 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.

Opponents

- Amgen
- Bristol-Myers Squibb
- Novo Nordisk
- Otsuka America Pharmaceuticals
- Pfizer
- Pharmaceutical Research Manufacturers of America (PhRMA)
- Vertex Pharmaceuticals

Other Considerations

Shifting rebates and other negotiated discounts from the insurers and PBMs to the point of sale is a new proposed policy that is currently being discussed on the federal level in regards to Medicare Part D. As this experiment has been limited to willing insurers/PBMs in the market, it is unknown how such a change would exactly effect the market, industries, or consumers. Therefore, it could be useful to evaluate the effect of this policy.

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 summary or the Health District, please contact Alyson Williams, Policy Coordinator, at (970) 224-5209, or e-mail at awilliams@healthdistrict.org.

⁴² 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>