

HB20-1198: PHARMACY BENEFITS CARRIER AND PHARMACY BENEFIT MANAGER REQUIREMENTS

Concerning requirements regarding the administration of prescription drug benefits under health benefit plans.

Details

Bill Sponsors:	House – <i>Landgraf (R) and Buckner (D)</i> Senate – <i>Fields (D) and Ginal (D)</i>
Committee:	House Health & Insurance
Bill History:	1/30/2020 – Introduced
Next Action:	Hearing in House Health & Insurance
Fiscal Note:	Not Yet Published

Bill Summary

The bill creates the “Fairness in Prescription Drug Benefits Administration Act,” which imposes requirements regarding the administration of prescription drug benefits under health plans. The bill requires an insurer to submit to the Commissioner of Insurance a list of pharmacy benefit managers (PBMs) that they use to manage/administer prescription drug benefits. Additionally, insurers and PBMs are required to submit their programs for compensating pharmacies/pharmacists and their prescription drug formularies – the Commissioner is authorized to review the programs to ensure they are fair and reasonable to provide an adequate network. The bill requires PBMs to report the amount they expect to be reimbursed from insurers for pharmacist services. Insurers and PBMs are prohibited from utilizing any untrue, deceptive or misleading ads or promotions. PBMs and insurers cannot reimburse an independent pharmacy/pharmacist less than they reimburse an affiliated pharmacy or pharmacist. The bill prohibits PBMs and insurers from modifying their prescription drug formulary at any time during the benefit year.

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, those people covered by self-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) 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

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/>

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

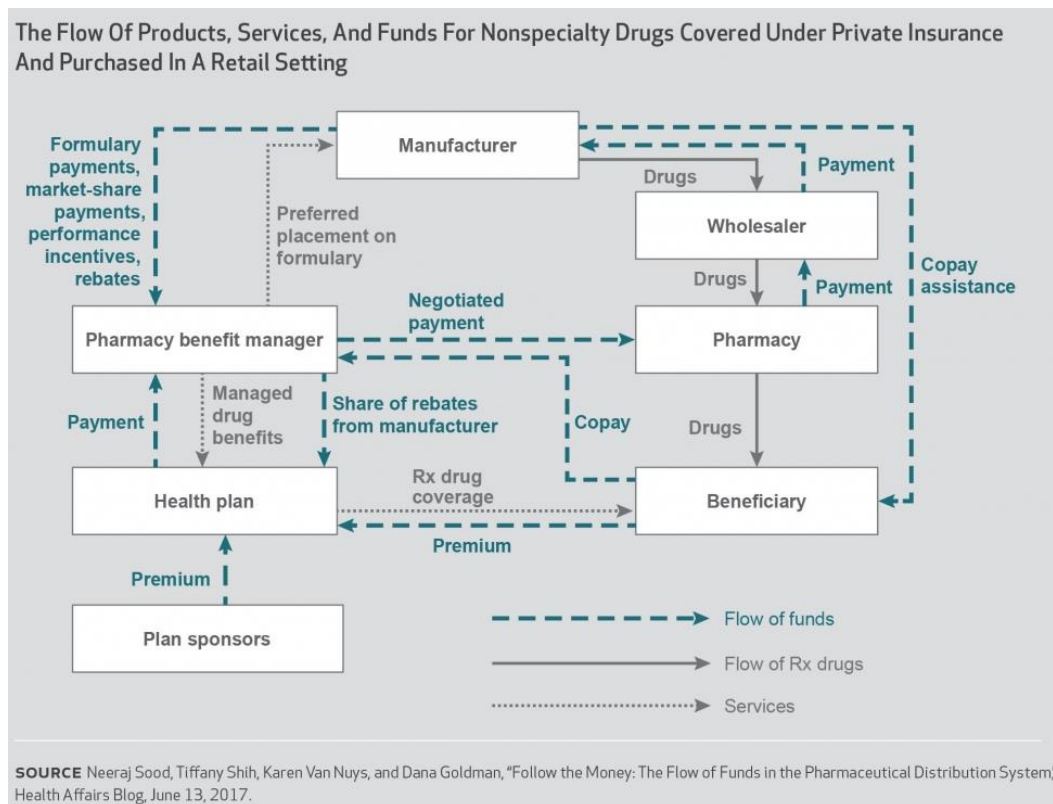
⁴ CHI (2016). *Sticker Shock: Prescription Drug Affordability in Colorado*. Retrieved from <https://www.coloradohealthinstitute.org/research/sticker-shock-prescription-drug-affordability-colorado>

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).

Supply Chain

The following graphic of the prescription drug supply chain illustrates the flow of payments and products through the system.



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 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%.

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.⁸ Additionally, PBMs may design and administer pharmacy benefits for these payers.⁹ 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.¹⁰ 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 OptumRx, control two-thirds of the market share in the U.S.¹¹ 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 2017.¹² Not only do PBMs create these relationships with manufacturers, but they also create networks of pharmacies.

PBMs typically generate revenue through five main sources: manufacturer rebates, generic pricing spreads, formulary design, fees from clients, and fees/shared savings from pharmacy networks. It is important to note that although it is difficult to analyze PBMs profitability, price negotiations are opaque by design.¹³ First, manufacturers offer rebates based on how much the PBM has the capacity to increase their market share; however, the PBM is not required to share the actual amount of these rebates with health plans.¹⁴ Therefore, the PBM can keep some or all of the funds received through rebates.¹⁵ Second, since the maximum allowable cost (MAC)¹⁶ price lists for generic medicines are a range of prices, a PBM can negotiate with manufacturers for a lower price and then use the lower MAC price to reimburse pharmacies but charge insurers the higher MAC price.¹⁷ The PBM can pocket the money from this spread in pricing. Third, PBMs can amplify the financial benefits of the previous two strategies by designing their formularies intentionally.¹⁸ Due to the previous two profit strategies, a PBM has an incentive to promote a less cost-efficient drug over another drug that is more cost-efficient because it may get a better rebate for the less cost-efficient drug.¹⁹ Fourth, PBMs receive fees from their clients for the administration of claims relating to the payer's pharmacy benefit and the dispensing of the drugs.²⁰ Finally, through the maintenance of their network of pharmacies PBMs receive fees and some of the savings that have been realized at that level.²¹

⁸ Health Affairs (Sept. 2017). *Prescription Drug Pricing: Pharmacy Benefit Managers*. Retrieved from <http://www.healthaffairs.org/healthpolicybriefs>

⁹ 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://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1045&context=annals>

¹⁰ 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

¹¹ 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

¹² 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

¹³ Health Affairs. *Prescription Drug Pricing: Pharmacy Benefit Managers*.

¹⁴ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

¹⁵ Ibid.

¹⁶ The MAC is the price list for generic drugs; there is no one standard MAC, but rather a range of acceptable prices.

¹⁷ Ibid.

¹⁸ Ibid.

¹⁹ Ibid.

²⁰ Health Affairs. *Prescription Drug Pricing: Pharmacy Benefit Managers*.

²¹ Ibid.

Many PBMs are beginning to operate their own mail-order pharmacies. For example, the mail order pharmacies for Express Scripts and CVS make up 20 percent of the market for retail pharmacies in the U.S.²² These mail-order pharmacies are an opportunity for greater revenue as it can maximize generic pricing spreads and manufacturer rebates.²³ It is estimated that in 2016, the gross profits for PBMs were \$22.6 billion.²⁴

Private Insurance Companies

A health insurance carrier or their contract PBM creates a formulary for specific health plans to detail a list of covered drugs. A formulary is a list of drugs developed by a committee within the carrier or PBM utilizing evidence-based medicine and the judgment of experts. When creating this list, the decision-making committee considers and reviews clinical literature, information from the FDA, current therapeutic use, economic data, and provider recommendations.²⁵

The primary purpose of a formulary is to encourage patients to access the most effective and affordable medications available. Frequently, this formulary is combined with a system of tiers to create incentive-based formularies.²⁶ The tier correlates to the level of coverage that will be provided. Typically, the most cost-effective or least expensive drugs are assigned to a preferred tier and have the lowest cost sharing requirements for the patient.²⁷ Most insurers place a higher copay on branded drugs in order to discourage their use and steer covered members towards purchasing a bioequivalent generic.²⁸ How the tiers are structured and whether non-preferred drugs are included in the tiers depends on the plan and the carrier. The first tier tends to be generics and possibly some select brand-name drugs, which are the least expensive drugs covered by a plan. Within the second tier are what are known as preferred drugs, or brand name drugs that have been chosen by the committee for the formulary, and tend to be a little more expensive than tier one drugs. The third tier, which may or may not be included in a plan's formulary, are the non-preferred drugs. Finally, the final tier typically includes most specialty drugs and the most expensive. Some insurers may place a drug on a high cost sharing tier to place pressure on the manufacturer to lower the cost; however this can have a financial burden on consumers, lower adherence, and penalize those that do not respond to cheaper alternatives.

A plan's formulary may change during the course of a plan year as new drugs are added, pricing fluctuates, utilization of drugs changes, or medical knowledge transforms.²⁹ These changes can include removing a drug from the formulary, increasing cost-sharing, changing the tier of the drug, or altering the utilization management criteria (i.e. prior authorizations or step therapy).³⁰ This mid-year formulary change does not initiate a special enrollment period for the consumer; therefore, they may be stuck in a health plan that no longer meets their needs.³¹ Some consumers may be able to have access to their medications through an exception process, but many consumers are not aware that this process exists and the plan may not grant an exception.³²

²² Sood, N., et al. The Flow of Money through the Pharmaceutical Distribution System.

²³ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

²⁴ Yu, N.L., et al. Spending on Prescription Drugs in the US: Where Does All the Money Go?

²⁵ Academy of Managed Care Pharmacy (Nov. 2009). *Formulary Management*. Retrieved from <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298>

²⁶ Goldman, D.P., Joyce, G.F., & Zheng, Y. (July 2007). Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health. *JAMA*, 298(1). DOI: 10.1001/jama.298.1.61

²⁷ Ibid.

²⁸ Dafny, L., et al. When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization.

²⁹ Consumer Representatives of the National Association of Insurance Commissioners [NAIC] (Aug. 2016). *Promoting Access to Affordable Prescription Drugs: Policy Analysis and Consumer Recommendations for State Policymakers, Consumer Advocates, and Health Care Stakeholders*. Retrieved from https://consumersunion.org/wp-content/uploads/2016/08/Promoting-Access-to-Affordable-Prescription-Drugs_Aug-2016.pdf

³⁰ Ibid.

³¹ Ibid.

³² Ibid.

Of the total national health expenditures on retail prescription drugs, 43 percent was by private insurance.³³ Furthermore, retail drugs comprised 21 percent of employer health benefits in 2015.³⁴ The design of pharmacy benefits is getting more complex, as illustrated by the fact that 84 percent of individuals with employer-sponsored health insurance have benefits that have three or more tiers of cost sharing.³⁵ Additionally, some employer-sponsored plans require individuals to meet a deductible before specialty drugs, such as biologics, are covered. Furthermore, the plan can require a separate deductible before any prescription drug is covered. Approximately 13 percent of covered individuals with employer-sponsored insurance have a separate annual deductible on prescription drugs, averaging at \$194.³⁶ Among employers with 1,000 or more employees that offer coverage for prescription drugs, 31 percent of those employers have reduced or zero cost sharing for maintenance drugs for chronic conditions, such as insulin for diabetes, which can reduce the cost burden for those employees.³⁷

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.³⁸ 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.³⁹ A recent PBM-sponsored study found that there is no correlation between rebates and the increase in list prices by manufacturers.⁴⁰ Some private health plans, such as UnitedHealthcare/OptumRx⁴¹ and Tufts Health Plan⁴², have opted to pass part or all of rebates on directly to consumers at the point-of-sale.

This Legislation

Definitions

The bill updates the definition of “pharmacy benefit management firm” to also include the terms “pharmacy benefit manager” and “PBM.” Additionally, the definition of the term is updated to state that it means any entity doing business in Colorado that administers or manages prescription drug benefits, including claims processing services and other prescription drug or device services, on behalf of any insurance carrier that provides prescription drug benefits to Coloradans, either by contract with the carrier or as an entity that is related/associated to or has common ownership with the carrier. A PBM does not include a CDPHE licensed/certified health facility, a provider, or a consultant who only provides advice regarding the selection or performance of a PBM.

“Claims processing services” are the administrative services performed in connection with processing and adjudicating claims related to pharmacist services, which include: receiving payments or making payments for pharmacist services. An “independent pharmacy or pharmacist” is one that is not affiliated with a PBM. “Other prescription drug or device services” means services, other than claims processing, including: negotiating rebates, discounts, or other financial incentives and arrangements with manufacturers;

³³ Kamal, R., & Cox, C. What are the recent and forecasted trends in prescription drug spending?.

³⁴ Ibid.

³⁵ Kaiser Family Foundation (Sept. 2019). *2019 Employer Health Benefits Survey: Section 9 Prescription Drug Benefits*. Retrieved from <https://www.kff.org/report-section/ehbs-2019-section-9-prescription-drug-benefits/>

³⁶ Ibid.

³⁷ Ibid.

³⁸ Meador, M. Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry through Regulation.

³⁹ 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

⁴⁰ 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>

⁴¹ 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>

⁴² Tufts Health Plan (May 2018). *Plans & Products*. Retrieved from <https://tuftshealthplan.com/documents/email/broker-email/may-2018/rx-rebates>

disbursing or distributing rebates; managing or participating in incentive programs/arrangements for pharmacist services; negotiating or entering into contracts with pharmacies/pharmacists; developing formularies; designing drug benefit programs; or advertising or promoting services. A “pharmacy benefit manager affiliate” is a pharmacy/pharmacist that directly or indirectly (through intermediaries) owns or controls or is owned or controlled by a PBM. A “pharmacy benefit manager network” is a network of pharmacies/pharmacists that are offered an agreement or contract to provide pharmacy services for a health plan. A “pharmacy services administrative organization” is an organization that helps independent pharmacies, PBMs, or third-party payers achieve administrative efficiencies, including for contracting and payment. A “prescription drug benefits plan” or “prescription drug benefit” is the component of a health plan that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services under the health plan. Finally, the bill defines a “third party” as a person, other than a PBM, that is not an enrollee or covered person under a health plan.

Fairness in Prescription Drug Benefits Administration Act

The proposed bill states that the General Assembly declares that the purpose of the bill is to create requirements for carriers and PBMs to ensure that reimbursement to pharmacies/pharmacists is fair and reasonable and that PBMs and carriers do not engage in unfair or deceptive practices in their work with pharmacies/pharmacists or impose unduly burdensome requirements on them.

Starting in 2021, each carrier is to submit to the Commissioner of Insurance, in a manner and by a date specified by rule, a list of all PBMs that carrier uses for services. The carrier is to provide the Commissioner with updated information about any change in the name or contact information of the PBM within 10 business days after the change.

Starting in 2021, each carrier and each PBM (if the carrier uses a PBM), is to submit to the Commissioner (in a manner and by date specified by the Commissioner to coincide with rate filing) its program for compensating pharmacies/pharmacists for pharmacist services under the health plan for the next benefit year and the drug formulary for the plan for the next benefit year. Additionally, the PBM is to report the amount the PBM expected to receive from the carrier for pharmacist services eligible for reimbursement under the health plan. The Commissioner can review the compensation program to ensure that reimbursement is fair and reasonable to provide an adequate provider of PBM network under the drug benefit plan.

Starting in 2021, a carrier, PBM, or representative of either entity shall not:

- Cause or permit the use of any ad, promotion, solicitation, representation, proposal, or offer that is untrue, deceptive, or misleading
- Charge a pharmacy/pharmacist a fee related to the adjudication of a pharmacist services claim including a fee for: the receipt/processing of a claim; the development/management of claims processing services in a provider or PBM network; or participation in a network
- Require pharmacy accreditation standards or certification requirements inconsistent with or more stringent than, or in addition to requirements of the Board of Pharmacy
- Reimburse an independent pharmacy/pharmacist an amount less than the amount that the carrier or PBM reimburses a PBM affiliate for providing the same service(s)
- During the benefit year, modify the drug formulary filed with the Commissioner for that benefit year. A modification includes eliminating a drug from the formulary, moving a drug to a higher cost-sharing tier, or any other modifications.

Terminating a pharmacy/pharmacist from a network does not release the carrier or PBM from the obligation to make any payment that is due for properly rendered services.

Unless the Commissioner (by rule) requires more frequent reporting, a carrier or PBM is to file an annual report with the Commissioner, in a manner and by a date specified by rule. The following information shall be included in the annual report, itemized by individual claim:

- amount the carrier or PBM actually paid or will pay to the pharmacy/pharmacist for services
- identity of the pharmacy/pharmacist actually paid or to be paid
- prescription number or other identifier of the pharmacist services
- amount the PBM received from the carrier for pharmacist services
- amount of rebates the carrier or PBM received

All of the above information must also be reported to the All-Payer Claims Database (APCD). Additionally, the reported information is considered proprietary and confidential and is not subject to the Colorado Open Records Act (CORA).

The Commissioner may adopt rules necessary to implement this section. Each carrier that uses a PBM must require its compliance with this section. The carrier must periodically audit the PBM to monitor and ensure compliance. Failure of a carrier to comply or to ensure that the PBM is complying is an unfair method of competition and an unfair or deceptive act or practice in the business of insurance. The Commissioner can use all powers conferred by law to enforce the bill. The Commissioner can examine or audit the records of a carrier or PBM and examine claims data from the APCD to determine if the entity is complying. The information gathered by the Commissioner during an examination/audit is considered proprietary and confidential and is not subject to CORA.

If passed, the bill takes effect on August 5, 2020, unless a petition is filed against the bill or part of the bill. In that case the bill or part would not take effect unless approved by the people at the November 2020 election.

Reasons to Support

There are few existing regulations for PBMs, which can contribute to higher prescription drug costs. This may beneficially impact the prices that consumers pay at the pharmacy counter. Additionally, the rising cost of prescription drugs requires some to pay exorbitant amounts of money out of pocket to receive a drug or others may opt to go without the drug if a formulary is changed in the middle of a plan year. Supporters assert that they bill could provide assurances to consumers that their health plan will maintain coverage for those drugs that they need throughout the course of the plan year.

Supporters

- Centura Health
- Colorado Community Health Network
- Colorado Consumer Health Initiative
- Colorado Cross-Disability Coalition
- Healthier Colorado
- National Multiple Sclerosis Society
- Pfizer
- Rocky Mountain Cancer Centers
- RxPlus Pharmacies

Reasons to Oppose

Allowing carriers and PBMs to make changes to the prescription drug formulary allows for accounting for drug safety or the increasing cost of some prescription drugs. Some assert that this bill is likely to result in higher health insurance premiums. Additionally, the requirements may be viewed as obstructions to developing strategies for cost-savings.

Opponents

- America's Health Insurance Plans
- Anthem Blue Cross Blue Shield
- Cigna
- Colorado Association of Health Plans

- Colorado Chamber of Commerce
- Colorado Competitive Council
- Colorado Retail Council
- CVS Health
- Pharmaceutical Care Management Association (PCMA)
- United Health

Other Considerations

The language of the bill does not expressly allow for newly FDA-approved drugs to be added to drug formularies mid-plan year. Further, the bill does not clarify that a drug may be removed from a formulary if the FDA determines there to be safety or other issues that would warrant the drug to not be provided to patients.

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.