

HB21-1297: PHARMACY BENEFIT MANAGER & INSURER REQUIREMENTS

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

Details

Bill Sponsors:	House – Hooton (D) Senate – Sonnenberg (R) & Buckner (D)
Committee:	House Health & Insurance
Bill History:	4/28/2021 – Introduced
Next Action:	5/11/2021- Hearing in House Health & Insurance
Fiscal Note:	<u>May 3, 2021</u> , no appropriation is required.

Bill Summary

The bill enacts the "Pharmacy Fairness Act", which imposes requirements regarding contracts between pharmacy benefit managers (PBMs) and pharmacies. The bill requires a health insurer or PBM to respond in real time to a request from an insured, their provider, or a third party acting on behalf of the insured or provider for data regarding the cost, benefits, and coverage under their plan for a particular drug. Further, the bill requires a health insurer or PBM that removes a prescription drug from the prescription drug formulary or moves it to a higher cost tier on the formulary during the benefit year to notify a covered person that is prescribed that drug at least 30 days before the action and allow the covered person to continue using the drug without prior authorization and at the same coverage level for the remainder of the benefit year, with some exceptions.

Issue Summary

Prescription Drugs

Among 11 Organization for Economic Cooperation and Development (OECD) countries, the United States (U.S.) has the highest pharmaceutical spending per capita at \$1443, well above the mean of \$749 for all 11 countries.¹ Retail pharmaceutical spending averages \$541 per capita in these OECD countries, while U.S. spending on retail pharmaceuticals is almost double, at \$1026 per capita.¹

From 2017 until 2026 prescription drug spending is anticipated to increase 6.3 percent per year.² Out-of-pocket costs for patients was \$82 billion in 2019, but each patient's exposure to these costs varied dramatically.³ For example, only 1.1%, or 69 million prescriptions, cost more than \$125 for the patient; however, these medicines bring a high burden to patients and can only be offset by coupons or vouchers in commercial plans.³ Approximately 58% of Americans report that they are currently taking at least one prescription drug while 25 percent take four or more prescription drugs.⁴

¹ Papanicolas I., Woskie L.R., & Jha AK. (2018). Health Care Spending in the United States and Other High-Income Countries. *JAMA*, 319(10):1024–1039. DOI:10.1001/jama.2018.1150

² 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

³ IQVIA Institute for Human Data Science (Aug. 2020). *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines*. Retrieved from <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

⁴ Henry J Kaiser Family Foundation (2018). *Public opinion on prescription drugs and their prices*. Retrieved from <https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/>

In 2019, 9% of all new prescriptions were abandoned at retail pharmacies.⁵ Abandonment represents patient care that is recommended by a provider but not received. Abandonment rates are less than 5% when the prescription carries no out-of-pocket cost, but it rises to 45% when the cost is over \$125 and 60% when the cost is over \$500.⁵

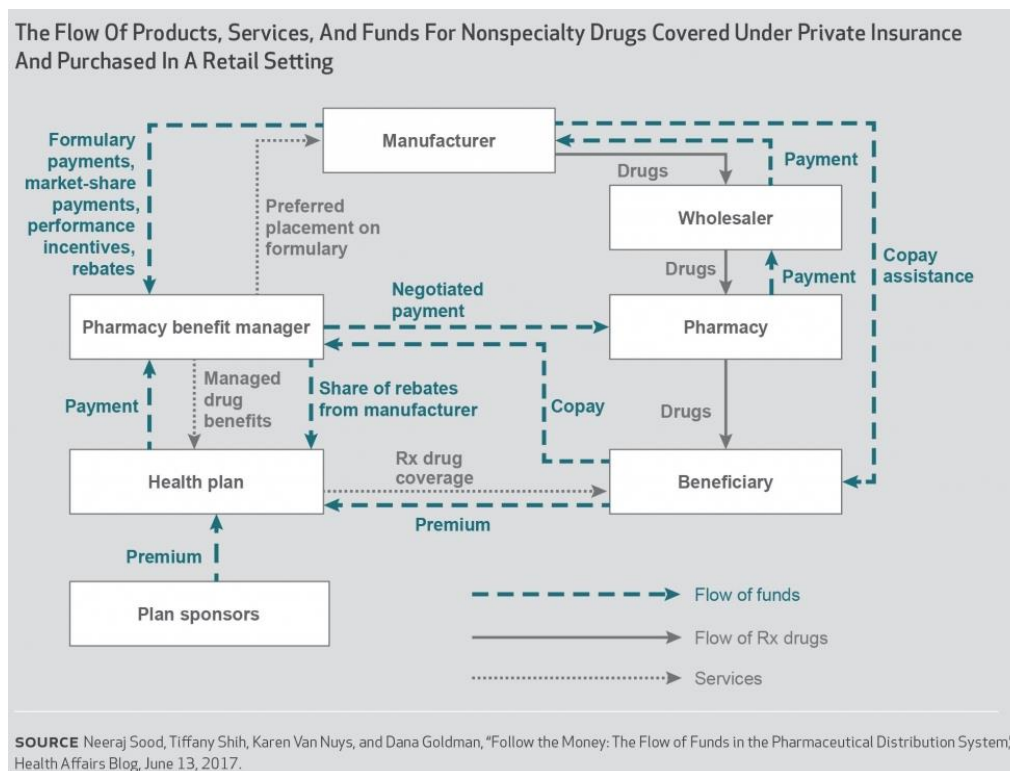
Prescription Drugs in Colorado

In 2019, more than 43.7 million prescription drugs were filled at pharmacies in Colorado, resulting in \$6.74 billion of retail sales.⁶ According to the Colorado Health Institute's (CHI) 2019 Colorado Health Access Survey, 10.8% of Coloradans cite the cost of prescription drugs as reason for not filling the medicines they are prescribed.⁷

In the 2019 Community Health Survey conducted by the Health District of Northern Larimer County, 55.1% of Larimer County residents reported taking or using more than one prescription drug at least once a week. Remaining consistent in comparison to the 2013 and 2016 Community Health Surveys, 9.7% of adult Larimer County residents reported being unable to have a prescription filled because they could not afford it during the preceding two years.⁸ This rate is much higher among those who reported being uninsured (22.1%) and those who fell between 186 and 400 percent of the Federal Poverty Level (FPL)⁹ (19.1%).

Supply Chain

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



⁵ IQVIA Institute for Human Data Science (Aug. 2020). *Medicine Spending and Affordability in the United States: Understanding Patients' Costs for Medicines*. Retrieved from <https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us>

⁶ Henry J Kaiser Family Foundation (2020). *Health Costs & Budgets Indicators*, Retrieved from <https://www.kff.org/state-category/health-costs-budgets/prescription-drugs/>

⁷ 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

⁸ With a 95% confidence interval ranging from 8% to 11.7%.

⁹ The 2018 version of the Federal Poverty Level was utilized in the survey.

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.¹⁰ Additionally, PBMs may design and administer pharmacy benefits for these payers.¹¹ 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% of the U.S. population, received their pharmacy benefits through PBMs.¹² 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.¹³ 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 2017.¹⁴ 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.¹⁵ 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.¹¹ Therefore, the PBM can keep some or all of the funds received through rebates.¹¹ 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.¹¹ 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.¹¹ 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.¹¹ 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.¹⁵ Finally, through the maintenance of their network of pharmacies PBMs receive fees and some of the savings that have been realized at that level.¹¹

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.¹³ These mail-order pharmacies are an opportunity for greater revenue as it can maximize generic pricing spreads and manufacturer rebates.¹¹ It is estimated that in 2016, the gross profits for PBMs were \$22.6 billion.¹⁷

¹⁰ Health Affairs (Sept. 2017). *Prescription Drug Pricing: Pharmacy Benefit Managers*. Retrieved from <http://www.healthaffairs.org/healthpolicybriefs>

¹¹ 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>

¹² 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

¹³ 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

¹⁴ 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

¹⁵ Health Affairs (Sept. 2017). *Prescription Drug Pricing: Pharmacy Benefit Managers*. Retrieved from <http://www.healthaffairs.org/healthpolicybriefs>

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

¹⁷ Yu, N.L., Atteberry, P., & Bach, P.B. (July 31, 2018) *Spending on Prescription Drugs in the US: Where Does All the Money Go?* Retrieved from <https://www.healthaffairs.org/doi/10.1377/hblog20180726.670593/full/>

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.¹⁸

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.¹⁹ 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.¹⁹ Most insurers place a higher copay on branded drugs in order to discourage their use and steer covered members towards purchasing a bioequivalent generic.²⁰ 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.²¹ 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).²¹ 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.²¹ 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.²¹

Of the total national health expenditures on retail prescription drugs, 42% was by private insurance.²² Furthermore, retail drugs comprised 21% of employer health benefits in 2017.²² The design of pharmacy benefits is getting more complex, as illustrated by the fact that 83% of individuals with employer-sponsored health insurance have benefits that have three or more tiers of cost sharing.²³ Among those covered workers with three or more tiers- the average copayments are \$11 for first-tier drugs, \$35 second-tier drugs, \$62 for third-tier drugs, and \$116 for fourth-tier drugs. Additionally, some employer-sponsored plans require

¹⁸ Academy of Managed Care Pharmacy (Nov. 2009). *Formulary Management*. Retrieved from <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298>

¹⁹ 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

²⁰ Dafny, L., Ody, C., & Schmitt, M. (Oct. 2016) When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. Retrieved from https://www.nber.org/system/files/working_papers/w22745/w22745.pdf

²¹ 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

²² Kamal, R., Cox, C. & McDermott, D. (Feb. 20, 2019) *What are the recent and forecasted trends in prescription drug spending?*. Retrieved from <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/>

²³ Kaiser Family Foundation (Oct. 2020). *2020 Employer Health Benefits Survey: Section 9 Prescription Drug Benefits*. Retrieved from <https://www.kff.org/report-section/ehbs-2020-section-9-prescription-drug-benefits/>

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.

This Legislation

Definitions

Pharmacy benefit management firm, pharmacy benefit manager, or PBM. 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, a consultant who only provides advice regarding the selection or performance of a PBM, or a nonprofit health maintenance organization (HMO) that offers managed care plans that provide a majority of covered professional services through a single contracted medical group and that operates its own pharmacies.

Pharmacy Fairness Act

Claims processing services. Administrative services performed in connection with processing and adjudicating claims related to pharmacist services, which includes receiving payments for pharmacist services or making payments to pharmacies or pharmacists for pharmacist services.

Other prescription drug or device services. Services, others than claims processing, provided directly or indirectly and either in connection with or separate from claims processing. These services include managing or participating in incentive programs or arrangements for pharmacist services; negotiating or entering into contractual agreements with pharmacies or pharmacists; developing formularies; designing prescription drug benefit programs, and advertising or promoting services.

PBM-affiliated pharmacy. A pharmacy or pharmacist that, either directly or indirectly through one or more intermediaries, owns or controls or is owned or controlled by a PBM.

PBM network. A network of pharmacies or pharmacists that are offered an agreement or contract to provide pharmacist services for a health plan.

Pharmacist services. Products, foods, and services provided as a part of the practice of pharmacy.²⁴ Starting in 2022, each carrier is to submit to the Commissioner of Insurance, along with its required rate filings and in a manner specified through rulemaking, a list of all PBMs that carrier uses for services. The list is considered proprietary and is not subject to disclosure under the Colorado Open Records Act (CORA).

Starting in 2022, a PBM or its representative must not preclude covered individuals from accessing prescription drug benefits under their plan at an in-network retail pharmacy unless the FDA has restricted the distribution of the drug or it requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A plan may impose a different cost sharing amount for obtaining a drug at a retail pharmacy, but all cost sharing must count towards the plan's annual out-of-pocket maximum and must be accounted for in the plan's actuarial value. A PBM or its representative shall not charge a pharmacy/pharmacist a fee related to the adjudication of a pharmacist services claim, other than a one-time reasonable fee, not to exceed the lesser of 25% of the dispensing fee or 25 cents, for receipt and processing of that claim. Additionally, the PBM shall not require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements to similarly situated PCM-affiliated pharmacies within the same network. The PBM is prohibited from failing or refusing to designate a pharmacy as 'preferred' that is located in a county with a population of 20,000 or less.

²⁴ C.R.S. § 12-280-103(39)

A PBM that administers the drug assistance program operated by the department of public health and environment is exempt from the requirements and prohibitions of the act with regard to the PBM's administration of that program only.

PBM Audit of Pharmacies

Except under certain circumstances, a PBM, carrier, or an entity acting on behalf of those entities shall not conduct an on-site audit of a pharmacy that has had an on-site audit within the immediately preceding 12 months.

Real-time Access to Benefit Information & Formularies

CMS. Federal Centers for Medicare and Medicaid Services in the U.S. Department of Health and Human Services.

Cost sharing information. The amount a covered person is required to pay for a drug that is covered under their health plan.

Covered or coverage. Health care services to which a covered person is entitled under the terms of the covered person's health plan.

Drug. Any prescription drug or medication covered under a health benefit plan, whether ordered, prescribed, or administered.

Healthcare common procedure coding system. The system developed by CMS for identifying health care services in a consistent and standardized manner.

National drug code. The unique, three-segment identifier number used by the FDA to identify drugs that are manufactured, prepared, propagated, compounded, or processed for sale in the United States.

Third party. A person other than a PBM that is not an enrollee or a covered person under a health plan.

Upon request of a covered person, their provider, or a third party on behalf of the person or provider, a carrier or their PBM must furnish the cost, benefit, and coverage data to them. The carrier or PBM must ensure that the data is current and updated no later than one business day after any change is made, provided in real time, and provided in the same format that the request was made. The person, provider, or third party shall submit the request and the carrier or PBM shall respond to it using the established industry content the transport standards published by:

- A standards-developing organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, the Accredited Standards Committee, or Health Level Seven International
- Or a relevant federal or state governing body, including the Centers for Medicare and Medicaid Services (CMS) or the Office of the National Coordinator for Health Information Technology in the U.S. Department of Health & Human Services (HHS)

A fax, proprietary payer or patient portal, or other electronic form is not an acceptable electronic format. Upon receipt of the request, the PBM or carrier must provide the following data for any covered drug for their plan:

- The person's eligibility information for the drug
- A list of any clinically appropriate alternatives to the drug that are covered
- Cost sharing information for the drug and for clinically appropriate alternatives, including a description of any variance in cost sharing based on pharmacy, whether retail or mail, or provider dispensing or administering the drug
- Any applicable utilization management requirements for the drug or alternatives, including prior authorization, step therapy, quantity limits, and site-of-service restrictions

The carrier or PBM must provide this data whether the request is made using the drug's billing code (National Drug Code or Healthcare Common Procedure Coding System code) or a descriptive term, such as the brand or generic name of the drug. Additionally, they must not restrict, prohibit, or otherwise hinder a provider from communicating or sharing with the covered person any of the requested data, any additional

information on any lower-cost or clinically appropriate alternatives or additional information that may reduce the person's out-of-pocket costs, such as cash price or patient assistance programs. PBMs and carriers cannot interfere with or materially discourage access, exchange, or use the data including: charging fees, failing to respond to a request, implement technology in nonstandard ways, substantially increase the complexity or burden of access, exchanging or using the data, or penalizing a provider for disclosing information or prescribing, administering, or ordering a clinically appropriate or lower-cost alternative.

Starting in 2022, if a carrier or a PBM during the benefit year removes coverage of a prescription drug on the formulary or moves the drug to a higher cost tier, the carrier or PBM is required to:

- Notify a person who has been prescribed the drug electronically or in writing (if requested by the covered person) and at least 30 days before removing or moving the drug in the formulary
- Allow a covered person to whom the drug has been prescribed to continue to use the drug for the remainder of the benefit year without prior authorization and at the same coverage applied before the drug was removed or moved

Nothing precludes a carrier or PBM from removing a drug from the formulary in the following circumstances:

- Due to safety issues raised by the FDA, the drug manufacturer, or the carrier/PBM
- If the manufacturer has notified the FDA of a manufacturing discontinuance or possible discontinuance
- If the manufacturer has removed the drug from the market

If a carrier or PBM removes a drug from the formulary for one of these reasons the entity must notify a covered person who has been prescribed that drug of its removal as soon as practicable after the event giving rise to the removal occurs.

Severability

If any provision of the bill is judged invalid, it does not affect the provisions that can continue to occur without the invalid provision.

Effective Date

The bill is effective upon the Governor's signature or if the Governor allows it to become law without their signature.

Fiscal Note

The bill increases workload in the Department of Regulatory Agencies and has an indeterminate, though likely minimal, impact on state agencies that work with PBMs. Local governments may experience a fiscal impact to the extent that costs for PBM contracts change.

Reasons to Support

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. The 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. The bill aims to ensure patients and providers have quick access to the cost of prescription drugs.

Supporters

- Arthritis Foundation
- Chronic Care Collaborative
- Colorado Cross-Disability Coalition
- Colorado Organization Responding to AIDS
- McKesson Corporation
- Rocky Mountain Cancer Centers

Reasons to Oppose

Allowing carriers and PBMs to make changes to the prescription drug formulary allows for them to account for the increasing cost of some prescription drugs. Some assert that this bill is likely to result in higher health insurance premiums as the carriers and PBMs would have to continue covering drugs at the same level even if there is a dramatic price increase from the manufacturer. Additionally, the requirements may be viewed as an obstruction to developing strategies for overall cost-savings.

Opponents

- America's Health Insurance Plans
- Colorado Association of Health Plans
- Colorado Competitive Council
- CVS Health

Other Considerations

How would the carrier or PBM be able to know exactly what a pharmacy would charge the patient, especially if the patient's cost sharing requirements are coinsurance and the price the patient pays is based off of the pharmacy's charges?

What does it mean that the response needs to be in the same format as the request when the bill states that "A fax, proprietary payer or patient portal, or other electronic form is not an acceptable electronic format"? Does that mean that a patient or provider cannot email the carrier/PBM and receive an email in return? Additionally, does that mean a patient couldn't use a mobile application from the carrier/PBM to request the real time information and get a response via that mobile application?

Amending Organizations

- Anthem Blue Cross Blue Shield
- Cigna
- Colorado Community Health Network

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.