January 11, 2021

General Phil Weiser
Colorado Attorney General
Ralph L. Carr Colorado Judicial Center
1300 Broadway
10th Floor
Denver, Colorado 80203

Delivered via email:

RE: Prescription Insulin Drug Pricing Report, Colorado Department of Law, November 2020

Dear General Weiser:

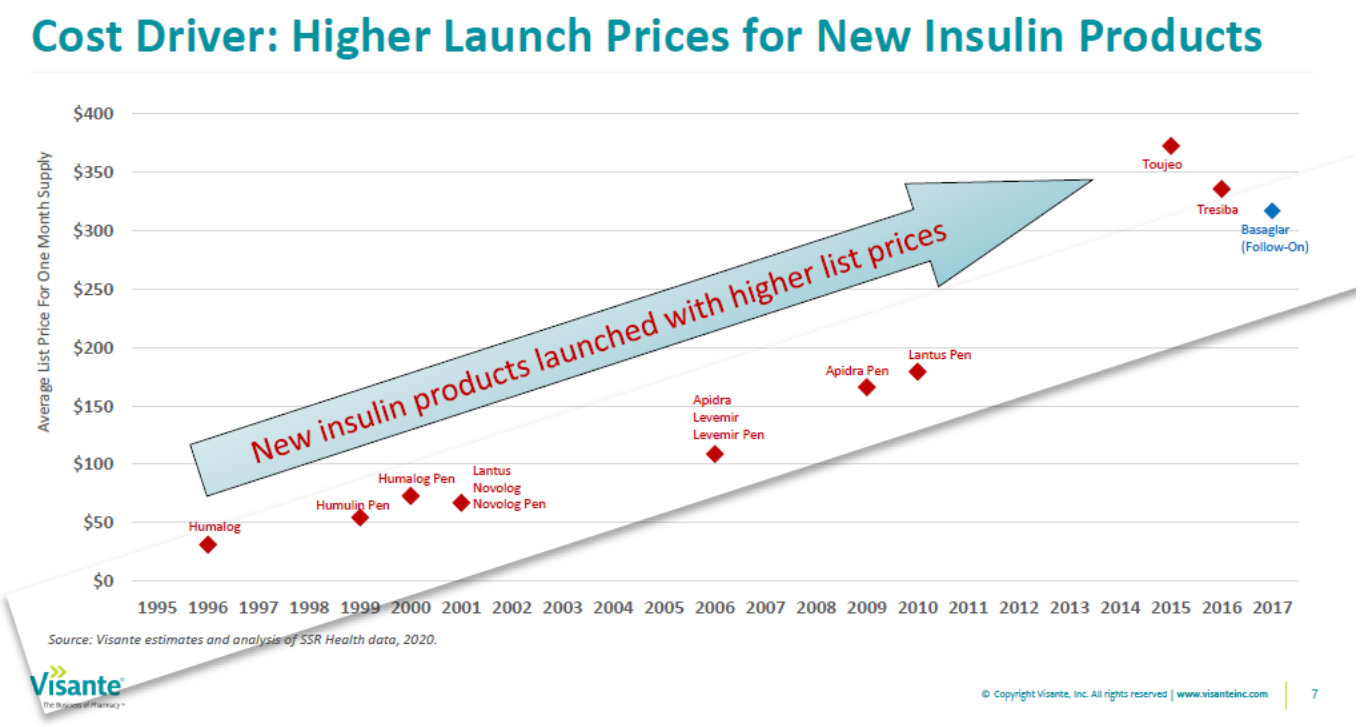
The Pharmaceutical Care Management Association (PCMA) appreciates your interest in one of the most critical issues facing policy makers today, the rising costs of prescription drugs. Please accept our response to your Prescription Insulin Drug Pricing Report[i] (report) which highlights the high costs of insulin in the U.S. and the need to increase manufacturer competition.

PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and other programs. According to researchers, PBMs, hired by plan sponsors to maximize the value of prescription drug benefits, help patients and payers save $941 per enrollee per year in prescription drug costs,[ii] equaling $654 billion over the next 10 years[iii]. Plan sponsors use these savings to benefit patients by lowering premiums or deductibles.

Lack of Manufacturer Competition Raises Prices

The CDC indicates that over 34 million Americans suffer from diabetes[iv] and although most drugs see a decrease in cost with generics and competition, insulin prices have skyrocketed over the years due to lack of competition, lack of alternative insulins, and manufacturer abuse of patent extensions. With only three drug manufacturers- Novo Nordisk, Sanofi, and Eli Lilly- controlling 96% of the U.S. market by volume and 99% by value[v], the lack of competition harms patients. Manufacturers block competition by taking advantage of loopholes in the U.S. patent system to extend their drugs' patent protection. One such loophole called "patent evergreening" allows them to extend patents by patenting delivery mechanisms. For example, Eli Lilly applied a new triple-screw thread feature to its Humalin and Humalog insulin products, which allowed for an additional 9 years

(through 2024) of market exclusivity. These anticompetitive practices spare brand manufacturers from the competition that comes from having multiple insulin manufacturers that would help lower costs for patients.



The fact is, only drug manufacturers set and raise list prices. Numerous studies continue to find large annual increases in the list prices of insulin. The current list price for a single vial of Levemir (long-acting insulin) is $308 - it was just $120 in 2012. Where pharmacy benefit manager tools, including negotiated rebates and value-based formularies, are available, they are working to keep costs stable and protect employers and patients from ever-higher prices. Manufacturers list prices rise annually. According to the American Diabetes Association (ADA), list prices for Novo Nordisk's NovoLog and NovoLog FlexPen increased 365% between 2001 and 2016.[vi] PBMs have created innovative programs that limit out-of-pocket spending to promote affordable access as well as clinical programs that improve care and patient outcomes.

PBMs Apply Downward Pressure on Drug Prices

PBMs aggregate the buying clout of millions of enrollees, enabling plan sponsors and individuals to obtain lower prices for their prescription drugs. These savings are passed along to health plans and other plan sponsors, like employers, and used to lower premiums and enhance benefit designs, including cost sharing for insulin. However, PBMs are only able to negotiate discounts for those covered by

insurance; the uninsured must pay these exorbitant list prices for live-saving insulin. The unfettered price increases of prescription drugs put patients at risk and health plan sponsors in the difficult position of either having to cut benefits or increase premiums, copays, and deductibles.

Studies have shown that negotiated discounts lower government costs and lead to lower premiums for plan enrollees.[vii] It is important to note that the report uses the terms "rebate" and "fee" synonymously, but they are not the same thing. A rebate is a negotiated discount that is tied to the utilization of medications. A fee is a payment made in exchange for a specific service. PBMs provide other services for manufacturers that are not tied to specific medications, so every financial transaction between a manufacturer and a PBM is not always a rebate.

PCMA and our member companies continue to work to reduce the costs of insulin for payers and patients, and manufacturers- not employers and taxpayers- must be held accountable for list prices. Cost is one of the biggest barriers to medication adherence and only manufacturers can lower list prices.

PBM Tools Provide Affordable Access to Effective Medications

The report offers an incomplete picture of the value of PBMs. PBMs work to keep drug costs down for consumers, increase access to medications, and improve health outcomes. Between 2016 and 2025, PBMs are positioned to save the State of Colorado $10.5 billion combined between the state Medicaid program ($865 million), Medicare Part D ($3.62 billion), and Commercial Insurance ($6.02 billion).[viii] We do this by:

- Encouraging the use of generics when available and affordable brand medications;
- Reducing waste while increasing adherence to improve health outcomes;
- Negotiating with drug makers and pharmacies;
- Tracking new outcomes evidence and updating formularies;
- Assuring patient safety by detecting contraindications;
- Running adherence programs and medication therapy management;
- Detecting and preventing fraud;
- Utilization reviews and analysis;
- Disease management and adherence initiatives;
- Creating networks of affordable, high-quality pharmacies, including offering home delivery of medications and access to high-value specialty pharmacies, which will save Colorado consumers, employers and other payers $3.6 billion over 10 years.[ix]

Specifically relative to diabetic patients, PBM tools have helped improve drug therapy and adherence for diabetic patients. These positive quality metrics have

resulted in prevention of kidney disease, heart failure, stroke, and amputations in these patients.[x]

The high cost of health care is consistently at the top of mind of many Coloradans and policy makers. Every day PBMs are working to lower those costs for employers and consumers. Utilization management tools such as formulary management through drug tiers, prior authorization, step therapy, and generic substitutions are intended to provide access to needed medications at lower costs. PBMs lower the cost of the prescription drug benefit.

PBM clients are sophisticated purchasers of healthcare. Employers, insurers, and other plan sponsors such as unions, school districts, and local and state governments are the ones best positioned to choose how to structure the coverage they provide for their enrollees. Contracts are intensely negotiated and are fully transparent between the contracting parties. This includes contracting that the report refers to as "spread pricing". A risk mitigation model (sometimes referred to as "spread pricing") provides plan sponsors with cost predictability by giving a price-certain for prescription drug benefit reimbursement to pharmacies. The report describes "spread pricing" as a secret pricing process that is "problematic". In reality, "spread pricing" is a financial arrangement for pharmacy reimbursement where the price paid to the pharmacy by the PBM may not equal the price billed to the client. In this case, the difference in the amount paid by the client to the PBM and the amount the PBM reimburses a pharmacy is how the PBM is paid for the services it provides to the client. This is not unique to PBMs, or even healthcare. It is a contracting option that clients choose because it shifts the risk of fluctuating drug costs from their bottom line onto the PBM. Many clients choose a spread pricing arrangement because it provides certainty in their pharmacy costs and allows them to budget in a more predictable manner. This contract offering is neither secret nor problematic. It is one option of many that a client can choose to structure their contracts and is not unlike pricing structures that occur in every sector of the American economy.

State Policy Recommendations

The report suggests four state policy changes including price transparency, mandatory coverage for diabetes supplies, joining a bulk purchasing plan to increase purchasing power, and passing rebates to consumers at the point of sale. Following is our response to these suggestions:

PBMs Support Increased Transparency in Prescription Drug Supply Chain
PBMs support increased transparency among all players in the drug supply chain including manufacturers and wholesalers. PBMs offer clients transparency on rebates and other price concessions as well as rights to audit PBM practices to ensure compliance. Many PBMs already use Surescripts' or other real-time benefit

tools to enable prescribers and patients to access accurate, time-of-prescribing information on the patient's benefits, formulary tiering, and cost sharing.

However, Colorado policymakers should carefully weigh the potential unintended cost impact of any state mandate to require PBMs divulge the contractual price concessions they have negotiated with drug manufacturers and pharmacies. Government agencies, including the Congressional Budget Office (CBO) and the Federal Trade Commission (FTC), have long cautioned that PBM disclosure mandates could raise costs[xi] Estimates from a Visante study specifically quantify these potential costs below for Colorado:

1. **A PBM disclosure mandate implemented by the state of Colorado would increase costs for fully insured employers and commercial health plans by $894 million over the next ten years.[xii]**
2. **A PBM disclosure mandate would impact employers and health plans that now cover some 1.5 million beneficiaries in Colorado.[xiii]**

As PBM disclosure mandates increase costs, the ability of Colorado employers to offer health insurance- would be diminished.

Mandatory Coverage Equals Higher Premiums

The report suggests capping copayments or coinsurance for diabetic supplies. State mandated cost-sharing caps shift costs and ultimately lead to higher premiums without addressing the root cause of high prices: the lack of competition. For example, in Kentucky, the Department of Insurance found that caps on cost sharing would add approximately $13.4 million to insurance premiums annually. For an average family with health coverage, caps on cost sharing would mean nearly $150 a year in higher costs through increased premiums.[xiv]

Most States Use a Rebate Pool or Bulk Purchasing Plan to Increase Purchasing Power Similar to PBMs

We agree with the report's statement that bulk purchasing gives the purchasers greater purchasing and bargaining power than they would have on their own individually. This identical concept is used by PBMs leveraging the buying clout of millions of enrollees to greatly reduce the cost of prescriptions for consumers. It is important to remember, no one is required to hire a PBM: they do so because PBMs save them money which means the consumer is ultimately the recipient of savings. PBMs combine bulk purchasing power for our enrollees with PBM tools such as claims processing, negotiated rebates for lowest net price, formulary management, drug utilization programs, mail-order and specialty pharmacy, and adherence programs to improve care management. These tools not only decrease costs but improves lives by helping patients adhere to their medications thereby reducing hospitalizations and saving on overall healthcare costs.

PCMA

New Rebate Rule Will Cost Taxpayers Billions of Dollars

Your suggestion of passing rebates through to consumers at the point of sale is a current market offering and market decision, but the offset to the rebate dollar is most often higher premiums for the other members of that plan. The U.S. Department of Health and Human Services just recently released its final rebate rule. The federal government's own estimates show Medicare Part D premiums will increase, potentially dramatically. CBO, CMS, and Avalere Health say premiums will increase from 25% to 40% under this rule.[xv] The CMS Office of the Actuary (OSCT) estimated the taxpayer cost at nearly $200 billion over 10 years,[xvi] making it one of the most expensive regulations in history.[xvii] Although this is a federal rule, mandatory point of sale rebates would similarly impact state budgets when they are already burdened by the pandemic.

While brand drug manufacturers continue to raise prices, under the rebate rule they stand to receive a windfall of $40 to $100 billion over 10 years,[xviii] due to $137 billion in new prescription drug spending.[xix] CMS' own actuarial predicts manufacturers will keep at least 15% of what they would have offered in in rebates.[xx] Taxpayers, already struggling with the effects of the coronavirus pandemic and resulting economic distress, will shoulder hundreds of billions of dollars in new costs, while brand drug manufacturers will receive a windfall.

On behalf of PCMA, I appreciate the opportunity to offer a response to the Prescription Insulin Drug Pricing Report. A copy of a relevant study prepared by Visante, "Insulins: Managing Costs With Increasing Manufacturer Prices" is attached. Should you have any questions, I can be reached at 202-893-0253 or rstivers@pcmanet.org.

Sincerely,

Regina Stivers

Regina Stivers
PCMA
Director, State Affairs

Cc: Governor Jared Polis
Chairwoman Rhonda Fields
Chairwoman Susan Lontine
Senate Health & Human Services Committee
House Health & Insurance Committee
Commissioner of Insurance, Michael Conway

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[i] Colorado Department of Law, "Prescription Insulin Drug Pricing Report" November 2020, available at https://coag.gov/insulin/

[ii] Roehrig, Charles, PhD. "The Impact of Prescription Drug Rebates on Health Plans and Consumers." April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

[iii] *Visante Inc., "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers," Prepared for PCMA,*

February 2016. https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf

[iv]CDC National Diabetes Statistics Report for 2020, https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf_

[v] ADA Statement. Insulin Access and Affordability Working Group: Conclusions and Recommendations. (June 2018)

[vi] ADA Statement. Insulin Access and Affordability Working Group: Conclusions and Recommendations. Diabetes Care 41(6). June 2018: 1299-1311. *https://care.diabetesjournals.org/content/41/6/1299*

[vii] *See* S. Gottlieb, *How Congress Can Make Drug Pricing More Rational,* FORBES (Sept. 12, 2016), https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532

[viii] Visante "Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers" 2016, available at: https://www.pcmanet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf.

[ix] Visante, analysis of savings due to the use of specialty and mail service pharmacies, prepared for PCMA. (September 2014), available at https://spcma.org/wp-content/uploads/2015/11/Visante_PCMA_Mail_and_Specialty_Savings.pdf.

[x] Visante "The Return on Investment (ROI) on PBM Services, November 2016

[xi] "Increasing transparency in the pricing of health care services and pharmaceuticals," Congressional Budget Office, June 5, 2008

[xii] "Increased Costs Associated with Proposed State Legislation Impacting PBM Tools," Visante, February 2018

[xiii] Ibid.

[xiv] Kentucky Department of Insurance. 2015. https://apps.legislature.ky.gov/record/15RS/SB31/HM.pdf

[xv] CBO, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Materials for *Updated Budget Projections: 2019 to 2029*." May 2019; and Avalere Health. "Costs for Taxpayers Could Skyrocket Under Proposed Rebate Rule." April 8, 2019. https://www.ahip.org/costs-for-taxpayers-could-skyrocket-under-proposed-rebate-rule/

[xvi] CBO, Op. Cit., CMS OACT, "Subject: Proposed Safe Harbor Regulation." (August 30, 2018), and Avalere Health, Op. Cit.

[xvii] American Action Forum. "Mandating Talking Cars: Costliest and Most Beneficial?" December 16, 2016. This article describes what were, at the time, the two costliest proposed regulations in U.S. history. The OACT cost estimate for the administration's proposal is in excess of these two. https://www.americanactionforum.org/regulation-review/mandating-talking-cars-costliest-beneficial

[xviii] OACT, Op. Cit.

[xix] OACT, Op. Cit.

[xx] OACT, Op. Cit.

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