PCMA

February 13th, 2024

The Honorable Donna Bailey
The Honorable Anne Perry
Members, Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station
Augusta, ME 04333

RE: LD 1793 An Act to Ensure Access to and Coverage of Low Cost Insulin; Opposed

Chair Bailey, Chair Perry, and Members of the Committee,

On behalf of the Pharmaceutical Care Management Association (PCMA), we wish to share comments related to LD 1793. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for millions of Americans with health coverage provided through large and small employers, health plans, labor unions, state, and federal employee benefit plans, and government programs.

As a result of insulin patent protection leading to limited competition and severe concentration in manufacturing, the average list price of insulin – discovered in 1921 with a patent sold for $1 – has skyrocketed, nearly doubling between 2012 and 2016 from $2,841 to $5,705 per person annually.[1],[2] Today, insulin prices in the United States can be hundreds of dollars for a one-month supply, nearly five and a half times the global median price.[3] Manufacturers are blocking competition by taking advantage of loopholes in the U.S. patent system to extend drugs' patent protection ("patent evergreening").

Uniquely, insulins have very limited generic or biosimilar competition because brand manufacturers have made incremental improvements that have kept insulin under patent from 1923 onward.[4]

- Brand manufacturers have used multi-drug combination products as an effective strategy to extend the life of older insulin brands by developing new brands (with new patent protections). Novo Nordisk's Fiasp and Fiasp Flextouch are a new combination of insulin with nicotinamide (vitamin B3) and an amino acid, which have market exclusivity (patent protection) until 2030.
- Brand manufacturers have extended patents by patenting delivery mechanisms (e.g., insulin pens, auto-injection, dose-setting limiters, etc.). 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. Rather than ending

[1] Ninety-six percent of total insulin market volume is concentrated between Eli Lilly, Novo Nordisk, and Sanofi SA

[2] Xinyang Hua, Natalie Carvalho, et al. Expenditures and Prices of Antihyperglycemic Medications in the United States: 20022013. JAMA. 2016; 315(13).

[3] Nuala Moran. Analysis by UK startup Medbelle highlights extent of drug pricing disparity. Bioworld. November 21, 2019.

[4] Jeremy A. Greene, Kevin R. Riggs. Why Is There No Generic Insulin? Historical Origins of a Modern Problem. NEJM. 2015; 372(12).

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their own anti-competitive practices, brand manufacturers are deflecting blame for skyrocketing prices by falsely claiming the high prices they themselves set are a "coverage" problem.

LD 1793 would require carriers to include on its drug formulary the insulin drug with the lowest wholesale acquisition cost for each category of insulin. PBMs are able to negotiate rebates with manufacturers for insulin, these rebates are returned to health plans and other plan sponsors, like employers, and used to lower premiums and enhance benefit designs, including cost sharing for insulin. The bill then states if a carrier submits data demonstrating another insulin drug has a lower net cost than the insulin with the lowest wholesale acquisition cost, then the carrier may elect to provide that insulin drug without any cost-sharing requirements. Yet it is unclear whether that is the lowest net cost to the plan or to the patient. In the prescription drug marketplace, carriers and PBMs use formularies and cost-sharing tiers to provide medications at various price points based on a patient's plan design. The ability of plans to negotiate the lowest net price possible for their patients is crucial, and this bill could obstruct that ability.

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. These mandates prevent payers from effectively managing high drug prices, including by encouraging the use of equally effective and lower-cost alternatives, and force the public to pay more in health premiums and overall health care costs. Capping cost-sharing shifts costs from individual patients to employers and other health plan sponsors. As plans increase premiums to reflect higher costs, all health plan enrollees pay more.

PBMs are innovating to increase affordable access to insulin. Real solutions should build on these efforts and hold brand manufacturers accountable. PBMs are innovating to reduce financial barriers for patients, in some instances outright eliminating patients' out-of-pocket costs. Mandates such as LD 1793 could interfere with a PBM's ability to drive down costs for plans and patients. Again, the private sector is working to help reduce out-of-pocket costs for patients, but manufacturers, not employers and taxpayers, must be held accountable for list prices.

PCMA appreciates your consideration of our opposition to LD 1793 regarding access and coverage of low-cost insulin to ensure that patients in Maine maintain affordable, reliable, and safe access to life-saving medications. Please do not hesitate to contact us if you have any questions or would like additional information.

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PBMs Are Innovating to Increase Affordable Access to Insulin

As a result of insulin patent protection leading to limited competition and severe concentration in manufacturing, the average list price of insulin – discovered in 1921 with a patent sold for $1 – has skyrocketed, nearly doubling between 2012 and 2016 from $2,841 to $5,705 per person annually.[i,ii] Today, insulin prices in the United States can be hundreds of dollars for a one-month supply, nearly five and a half times the global median price.[iii]

Manufacturers are blocking competition by taking advantage of loopholes in the U.S. patent system to extend drugs' patent protection ("patent evergreening").

- Uniquely, insulins have very limited generic or biosimilar competition because brand manufacturers have made incremental improvements that have kept insulin under patent from 1923 onward.[iv]
    - **Brand manufacturers have used multi-drug combination products as an effective strategy to extend the life of older insulin brands by developing new brands (with new patent protections).** Novo Nordisk's Fiasp and Fiasp Flextouch are a new combination of insulin with nicotinamide (vitamin B3) and an amino acid, which have market exclusivity (patent protection) until 2030.
    - **Brand manufacturers have extended patents by patenting *delivery mechanisms*** (e.g., insulin pens, auto-injection, dose-setting limiters, etc.). 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.
- Rather than ending their own anticompetitive practices, brand manufacturers are deflecting blame for skyrocketing prices by falsely claiming the high prices they themselves set are a "coverage" problem.

PBMs are innovating to increase affordable access to insulin. Real solutions should build on these efforts and hold brand manufacturers accountable.

- Pharmacy benefit managers (PBMs) are innovating to reduce financial barriers for patients—in some instances outright eliminating patients' out-of-pocket costs.
    - A one-month supply of insulin for one health plan's enrollees cost $41.50 on average in 2018.
    - Last year, a PBM and health plan introduced a program to cap out-of-pocket insulin costs at $25 for a one-month supply for nearly 1 million eligible health plan enrollees, lowering their monthly out-of-pocket costs by 40% or more.
    - More recently, another PBM announced it could provide access to diabetes drugs, including insulin, at no out-of-pocket costs to health plan enrollees and at a savings to plan sponsors.
- **The private sector is working to help reduce out-of-pocket costs for patients, but manufacturers, not employers and taxpayers, must be held accountable for list prices.**

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[ii] Xinyang Hua, Natalie Carvalho, et al. Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013. JAMA. 2016; 315(13).
[iii] Nuala Moran. Analysis by UK startup Medbelle highlights extent of drug pricing disparity. Bioworld. November 21, 2019.
[iv] Jeremy A. Greene, Kevin R. Riggs. Why Is There No Generic Insulin? Historical Origins of a Modern Problem. NEJM. 2015; 372(12).

Cost-sharing Caps Don't Solve the Problem of High Drug Prices

Caps on cost sharing do nothing to hold drug manufacturers accountable for ever-higher drug prices but raise costs for patients and taxpayers. Rather than ending their own anticompetitive practices, brand manufacturers are deflecting blame for skyrocketing drug prices by falsely claiming that the high prices they themselves set are a "coverage" problem that requires cost-sharing caps and other restrictions on plan design.

Cost-sharing caps are a windfall for brand manufacturers in that they discourage the availability of affordable alternatives for patients. Cost-sharing caps profit manufacturers at the expense of patients. Such caps give manufacturers a pass to continue raising their prices unencumbered.

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.

- These mandates prevent payers from effectively managing high drug prices, including by encouraging the use of equally effective and lower-cost alternatives, and force the public to pay more in health premiums and overall health care costs.
- Capping cost sharing shifts cost from individual patients to employers and other health plan sponsors. As plans increase premiums to reflect higher costs, all health plan enrollees pay more. For example:
  - The Kentucky 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.[i]
  - In Washington, an independent analysis found a $250 cost sharing cap per 30-day prescription would shift $900 million in costs to employers, health plans, and consumers over five years.[ii]

PBM tools help protect employers and consumers from ever-higher prices. The list prices of many prescription drugs have gone up drastically over the past decade. Where pharmacy benefit manager (PBM) 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. Where PBM tools are unavailable, including for the uninsured, drug costs keep rising and hurt patients' access to care.

Smart benefit design stretches the health care dollar and promotes affordability.[iii] Cost-sharing caps disrupt the sound benefit designs plans use to provide patients with access to lower-cost but equally effective alternatives, including generics. Such limits have real costs: an analysis has found prohibiting such tools would increase drug spending by 4.6% over a decade.[iv]

Health plans and PBMs are innovating to increase affordable access to pharmacy care. Real solutions should build on these efforts and hold manufacturers accountable.

- In the face of consistent drug price hikes, PBMs and health plan sponsors are innovating to better meet the needs of patients. PBMs and plans are offering low-cost-share options that work hand-in-glove with sound plan design. Those efforts – not government intervention – are part of the solution.
- **The private sector is working to help reduce out-of-pocket costs for patients, but manufacturers – not employers and taxpayers – must be held accountable for list prices.**

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[i] Kentucky Department of Insurance. 2015. https://apps.legislature.ky.gov/record/15RS/SB31/HM.pdf
[ii] Oliver Wyman. 2016.
[iii] Not all health plans are designed the same way.
[iv] Visante. Increased Costs Associated with Proposed State Legislation Impacting PBM Tools. January 2019. https://www.pcmanet.org/increased-costs-associated-with-proposed-state-legislation-impacting-pbm-tools-2/