COMMUNITY ACCESS NATIONAL NETWORK

Mailing Address:

Attn: Jen Laws
PO Box 3009
Slidell, LA 70459

Chief Executive Officer:

Jen Laws
Phone: (313) 333-8534
Fax: (646) 786-3825
Email: jen@tiicann.org

December 19, 2024

Colorado Division of Insurance
1560 Broad Way, Suite 850
Denver, CO 80202
VIA Electronic mail: Michael.conway@state.co.us

Dear Commissioner Conway,

As of current, the Colorado Department of Regulatory Affairs (DORA) has posted a webpage in anticipation of noticing a "New Rule" entitled "UPPER PAYMENT LIMITS" with an expected Colorado Register Publication date of December 25, 2024.

Request for Regulatory Analysis; 3CCR 702-9

In accordance with Colorado Article 4 Rule-making and licensing procedures by state agencies, Part 1, 24-4-103. Rule-making – procedure – definitions – statutory citation correction, paragraph 4.5, the Community Access National Network is formally requesting a regulatory analysis of the proposed rule.

The subject paragraph requires the issuing agency, in this case, the Department of Insurance, as indicated by the aforementioned webpage, provide a regulatory analysis including all of the following:

(I) A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;

(II) To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons;

(III) The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;

(IV) A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction;

(V) A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule; and

(VI) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

Background:

The Community Access National Network has been engaged with the Colorado Prescription Drug Affordability Board for the better part of the last two years. We have repeatedly requested in writing and during oral comments that DOI staff serving the Board seek certain information from potentially impacted state agencies, patients, medical providers, plans, and pharmacies, with a particular emphasis on non-chain, independent pharmacies. This information includes but is not limited to the following:

- What impact will an upper payment limit (UPL) have on the state's public health programs, including but not limited to Medicaid and SDAP (State Drug Assistance Program)?
    - In particular, because these programs generate reinvestment revenues via rebates (340B and Medicaid Drug Rebate Program), any reduction of reimbursement via UPL reduces the values of those rebate revenues, thus reducing program dollars made available to serve vulnerable Coloradans accessing these programs.
    - If a UPL were to reduce the program revenue of these public health programs, what services may need to be eliminated and/or how many fewer patients would these programs be able to serve?
- What impact will a UPL have on the state's safety-net providers, specifically those qualifying as 340B entities?
    - Similar to the state's SDAP and other public health programs like sexually transmitted infections clinics, 340B revenues are generated due to the "spread" between reimbursement and a discounted acquisition cost. Those revenues are then re-invested in the originating program in order to extend services to vulnerable Coloradans.
    - If a UPL were to reduce the program revenue of these safety-net providers, what services may need to be eliminated and/or how many fewer patients would these programs be able to serve?
- What impact will a UPL have on benefit design healthcare insurance companies and their contract pharmacy benefit managers offer?
    - According to the Federal Trade Commission's recent complaint (attached) against three large pharmacy benefit managers (PBMs), PBMs prioritize formulary placement and utilization management practices (prior authorizations, step-therapy, etc.) based upon expected revenue via rebate retention and **not** clinical care guidelines or personalized care as directed by the patient-provider relationship. Utilization management meaningfully increases administrative burden to providers and personal costs to patients.
    - Additionally, Avalere, alongside the Partnership to Fight Chronic Disease, published a survey finding of plans regarding anticipated impacts of a UPL (attached). The survey found plans expected utilization management and adverse formulary tiering. Similarly, those same **plans did not expect savings to be passed onto patients**.
- What impact will a UPL have on pharmacies with particular emphasis on economic stability for non-chain, independent pharmacies?
    - Anecdotal and system evidence exists that certain large PBMs have already been under-reimbursing pharmacies, often below acquisition costs, making the provision of certain

medications economically untenable. The closure of independent pharmacies across Colorado and the nation is a critical issue in relation to patient access to care and must be considered when implementing cost-control policies.

Data from Other States do not Favor a UPL

Given DOI staff's refusal to sufficiently inquire, CANN has turned to data gathered in another state, Oregon. In Oregon, the state's Medicaid program hired consultants to model the potential impact on the state's healthcare ecosystem. Those findings, hereafter referred to as the Stauffer-Meyer Report, were unpersuasive as to any benefit imposing a UPL might have (attached).

In addition to a paucity of potential "savings" (less than one half of one million dollars) for the Medicaid program due to loss of rebate dollar reinvestment, **the report also found an anticipated need for legislators to appropriate additional dollars for 340B covered entities in order to make them whole**.

DOI Staff Refused Cost of Implementation and Enforcement Information Request

On December 3rd, 2024, during a recorded DOI "staff hours" call with stakeholders, CANN's CEO, Jen Laws, expressed concerns regarding cost of implementing a UPL and inquired if a cost of implementation analysis would be conducted. PDAB Director and DOI staff, Lila Cummings, stated in response, "we will not be doing that".

In addition to the Colorado APA's requirement for such analysis, the PDAB and DOI cannot in any good-faith claim to "save" the state of Colorado or patients any money if the cost of implementing a UPL is not assessed.

In order to appropriately assess the cost of implementing a UPL, DOI must consider the number of full-time equivalent positions required to examine claims level data for relevant claims, establish a monitoring system to ensure patient access to care is not harmed due to a UPL, and ensure sufficient legal counsel is retained, given the expectation that various players in the drug supply chain will likely seek to prevent their data or operations from being impacted by a UPL.

Additionally, because the Board has chosen processes which have resulted in adverse selection of treatments for potentially disabling health conditions, the Board must also anticipate potential legal challenges by patients themselves, due to the discriminatory impact such selection might have.

No Other Policies Considered

As we understand it, to date, no other policy has been meaningfully considered by the PDAB or DOI staff serving the Board in any effort to save the state of Colorado, the healthcare system-writ large, or patients any money. Several alternatives have been offered throughout PDAB meetings both in written comment and oral comments, much less if there any "less costly" means to "achieve the purpose" of the proposed rule.

Costliness of Rule-Making will Compound

CANN respectfully suggests that the medications the PDAB has deemed "unaffordable" are not, due to lack of sufficient data gathered by the staff serving the PDAB. This, in essence, can be summarized as the failure to exclude Medicare recipients (the PDAB cannot impose a UPL on federally regulated plans) and the staff's

active solicitation of survey participation by out-of-state residents, among other data sufficiency issues in the survey.

Lastly, because rule-making is being done per medication determined as "unaffordable", regardless of the sufficiency of the data gathered to make such determination, we believe that in order to answer the questions asked of legislators during the December 18th, 2024 Joint Budget Committee hearing, DOI must also include the cost of multiple rule-promulgation periods.

CANN anticipates submitting an additional cost-benefit analysis request to DORA, through the proposed rule-making portal.

We thank you for your time and attention to this detailed request and look forward to DOI posting the requested regulatory analysis at least five days prior to the January 17, 2025 hearing.

Thank you,

Jen Laws
Community Access National Network

Cc VIA Electronic mail:
DORA Executive Director Patty Salazar
Lila Cummings
Department of Insurance (dora_insurance@state.co.us)
Senator Jeff Bridges
Representative Shannon Bird
Representative Judy Amabile
Senator Barbara Kirkmeyer
Representative Emily Sirota
Representative Rick Taggart

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Lina M. Khan, Chair**
Rebecca Kelly Slaughter
Alvaro M. Bedoya
Melissa Holyoak
Andrew Ferguson

In the Matter of

Caremark Rx, LLC;

Zinc Health Services, LLC;

Express Scripts, Inc.;

Evernorth Health, Inc.;

Medco Health Services, Inc.;

Ascent Health Services LLC;

OptumRx, Inc.;

OptumRx Holdings, LLC;

and

Emisar Pharma Services LLC.

Docket No. 9437

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents Caremark, ESI, and Optum (collectively "PBM Respondents"); and Zinc, Ascent, and Emisar (collectively "GPO Respondents") have engaged in conduct that violates Section 5 of the FTC Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), stating its charges as follows:

I. NATURE OF THE CASE

1. Americans pay too much for prescription drugs, including life-saving drugs like insulin. In fact, prescription drug prices in the U.S. are nearly three times higher than in other countries. In 2023, the U.S. spent over $722 billion on prescription drugs, nearly as much as the rest of the world combined. Many Americans struggle to afford the medications they need to survive.

2. This country's prescription drug affordability crisis is partly driven by Respondents' manipulation of drug price competition for their own gain. Normally, companies compete by lowering prices. And normally, insurance systems function by the healthy subsidizing the sick. Respondents' conduct has turned these basic principles on their head. This case challenges their role in designing, directing, and overseeing a drug reimbursement system, which generates billions of dollars in rebates and fees for them while incentivizing drug manufacturers to *raise* (not lower) the sticker price (i.e., list price) of their drugs. As a result, many diabetics and other sick patients are stuck paying significantly more for life-saving medications like insulin.

3. Pharmacy benefit managers (PBMs) act as middlemen, overseeing prescription drug coverage and reimbursement for health plans, health plan sponsors, and more than 200 million Americans. Through dozens of mergers, the PBMs have horizontally concentrated and vertically integrated. Three dominant pharmacy benefit managers—Caremark, ESI, and Optum—administer approximately 80% of all prescriptions in the United States.

4. Positioned at the center of the intricate and opaque pharmaceutical distribution chain, the PBM Respondents wield significant influence over which drugs patients can access, and at what price. The PBM Respondents create drug formularies, which are lists of preferred and non-preferred drugs grouped by categories. Their clients—including companies and organizations that sponsor commercial health plans—use these formularies to steer insured patients to certain prescription drugs and away from others.

5. About a decade ago, the PBM Respondents introduced restrictive formularies that completely exclude certain drugs from coverage. The introduction of these restrictive or exclusionary formularies was a game changer. Manufacturers now faced the significant risk that their products would be excluded outright from insurance coverage for tens of millions of patients. Leveraging this threat of exclusion, Respondents began demanding higher and higher rebates from drug manufacturers in exchange for placing those drugs on their restrictive formularies. In a single year, one PBM Respondent collected more than $[redacted] billion in rebates and an additional $[redacted] billion in associated fees.

6. The race for higher rebates, in principle, should have reduced drug costs for patients. For many patients, however, the reality is quite different. To satisfy the PBM Respondents' insatiable demand for larger rebates—and to preserve the manufacturers' own profits—manufacturers have steadily increased the list price of their drugs, leading to artificially inflated list prices that are disconnected from the actual cost of the drugs to insurers. Yet, many patients' out-of-pocket expenses are directly or indirectly tied to these inflated prices. For example, uninsured patients may pay the full list price, while insured patients with high

deductibles or co-insurance face costs based on these inflated list prices. As a result, as rebates and list prices rise in tandem, these groups of patients are burdened with higher out-of-pocket costs for their medications.

7. The harm caused by this broken system is far-reaching. Respondents have created an opaque drug pricing and reimbursement system, which benefits them, but which deliberately obscures the full scope of harm and financial cost from insurers and patients who may be unknowingly shouldering the burden of inflated list prices.

8. Insulin is the poster child of Respondents' broken drug pricing system. Diabetes is among the most widespread diseases in the United States, afflicting an estimated 38.4 million Americans. In 2021, diabetes was the eighth leading cause of death in the United States. And the prevalence of diabetes continues to rise. In 2023, the Centers for Disease Control and Prevention (CDC) calculated that the number of adults diagnosed with diabetes has more than doubled in the past two decades. There is no cure for diabetes, but it can be managed. For many, the only way to manage the disease is with insulin injections. Insulin was first used as medication over a century ago, and today over 8 million Americans depend on insulin for their survival.

9. For nearly 85 years, insulin medications were affordable. For example, in 1999, the average list price of Humalog, a widely used insulin, was only $21. Starting around 2012, however, the PBM Respondents began demanding increasingly higher rebates and fees from insulin manufacturers in exchange for exclusive placement on their formularies. This chase-the-rebate strategy proved highly effective (and profitable) for the PBM Respondents. Manufacturers paid rebates as steep as [redacted]% off the list price to secure exclusive formulary coverage. But this approach had a profound consequence: as the Respondents demanded more rebates, insulin manufacturers sharply inflated the list prices of their products. By 2017, Humalog's price had soared to more than $274—a staggering increase of more than 1,200%. In the past ten years alone, spending on insulin in the United States has tripled—from $8 billion in 2012 to $22.3 billion in 2022.

10. The rising list price of insulin has led to severe harm. By 2019, the PBM Respondents estimated that one out of every four insulin patients could not afford their medication. More than a million patients reported rationing their insulin, a dangerous practice that can lead to devastating health complications, including death.

11. Worse, Respondents' tactics have effects beyond insulin. The Respondents' demand for larger rebates has also inflated list prices for other critical drugs including treatments for autoimmune diseases and inflammatory conditions. Patients whose out-of-pocket costs are tied to these inflated list prices may spend hundreds of dollars per prescription. In some cases, the patient may pay more at the pharmacy counter than the actual cost to their commercial insurer. In other words, the insurer functionally makes a profit from the prescription, instead of paying its share of the cost. This turns the normal insurance model on its head with the sick subsidizing the healthy, rather than the other way around. As one PBM manager bluntly put it: "I don't see how it's justifiable to charge someone 100% of the cost of the drug (during the deductible [phase]), while you receive a rebate on the backend … I can't think of any other insurance industry that works like that[.]"

12. It is time to put an end to the Respondents' unfair and unlawful business practices and to prevent their recurrence.

II. JURISDICTION

13. Respondents are, and at all relevant times have been, corporations, as the term "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

14. Respondents' general business practices and the unfair methods of competition and unfair acts or practices alleged here are "in or affecting commerce" within the meaning of Sections 4 and 5 of the FTC Act, 15 U.S.C. §§ 44, 45.

III. RESPONDENTS

A. Caremark/Zinc Respondents

15. Respondent Caremark Rx, LLC ("Caremark") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. Caremark Rx, LLC is a wholly owned indirect subsidiary of CVS Health Corporation.

16. Caremark is engaged in the business of providing pharmacy benefit services and is the largest PBM in the United States. In 2023, Caremark administered 2.3 billion—or approximately 34%—of total prescription claims in the United States. In 2022, Caremark recorded $169.2 billion in revenue.

17. Respondent Zinc Health Services, LLC ("Zinc") is a Delaware limited liability company with its principal place of business at One CVS Drive, Woonsocket, Rhode Island. In 2020, CVS Health Corporation established Zinc as a group purchasing organization for Caremark's PBM business. CVS Health Corporation co-owns Zinc and appoints three out of the four members of Zinc's Board of Directors. Zinc negotiates rebates with drug manufacturers on behalf of Caremark's and other third parties' commercial clients.

B. Express Scripts/Ascent Respondents

18. Respondent Express Scripts, Inc. is a Delaware company with its principal place of business at One Express Way, St. Louis, Missouri. Express Scripts, Inc. is engaged in the business of providing pharmacy benefit services and is the second largest PBM in the United States. In 2023, Express Scripts, Inc. administered approximately 23% of total prescriptions in the U.S. Express Scripts, Inc. is a wholly owned direct subsidiary of Evernorth Health, Inc. and a wholly owned indirect subsidiary of Cigna Corporation.

19. Respondent Evernorth Health, Inc. ("Evernorth") is a Delaware company with its principal place of business located at One Express Way, St. Louis, Missouri. In 2022, Evernorth earned $140.3 billion in revenue, the majority of which came from ESI. Evernorth is a wholly owned direct subsidiary of Cigna Corporation. Evernorth is involved in Express Scripts, Inc.'s provision of PBM services.

20. Respondent Medco Health Services, Inc. ("Medco") is a Delaware corporation with its principal place of business at 100 Parsons Pond Drive, Franklin Lakes, New Jersey. Medco is a wholly owned indirect subsidiary of Cigna Corporation. Medco supports Cigna's PBM functions.

21. Express Scripts, Inc., Medco Health Services, Inc., and Evernorth Health, Inc. are referred to collectively as "ESI" or "ESI Respondents."

22. Ascent Health Services LLC ("Ascent") is a Delaware limited liability company with its principal place of business at Mühlentalstrasse 36, 8200 Schaffhausen, Switzerland. In 2019, ESI established Ascent as a group purchasing organization for ESI's PBM business. ESI co-owns Ascent and appoints three out of the five members of Ascent's Board of Directors. Ascent negotiates rebates with drug manufacturers on behalf of ESI's and other third parties' commercial clients.

C. Optum/Emisar Respondents

23. Respondent OptumRx, Inc. is a California corporation with its principal place of business at 11000 Optum Circle, Eden Prairie, Minnesota. OptumRx, Inc. is a wholly owned indirect subsidiary of UnitedHealth Group Inc. OptumRx, Inc. is responsible for supporting all PBM services provided by UnitedHealth Group Inc.

24. Respondent OptumRx Holdings, LLC is a Delaware corporation with its principal place of business located at 11000 Optum Circle, Eden Prairie, Minnesota. OptumRx Holdings, LLC is a wholly owned indirect subsidiary of UnitedHealth Group Inc. and the direct parent company of OptumRx, Inc.

25. OptumRx, Inc. and OptumRx Holdings, LLC are collectively referred to as "Optum" or "Optum Respondents."

26. Optum is engaged in the business of providing pharmacy benefit services and is the third largest PBM in the United States. In 2023, Optum administered approximately 22% of total prescription in the U.S. In 2022, OptumRx recorded $99.8 billion in revenue.

27. Respondent Emisar Pharma Services LLC ("Emisar") is a Delaware limited liability company with its principal place of business in Ireland. In 2021, Optum established Emisar as a group purchasing organization for Optum's PBM business. Emisar is a wholly owned indirect subsidiary of UnitedHealth Group Inc. Emisar negotiates rebates with drug manufacturers on behalf of Optum's commercial clients.

IV. BACKGROUND

A. PBMs are central actors in pharmaceutical transactions, influencing drug pricing, rebates, and sales

28. PBMs administer pharmacy benefit management services on behalf of clients. These clients are also generally known as payers, and include employers, health insurer plans, labor unions, employer coalitions, and government entities. PBMs provide various services to

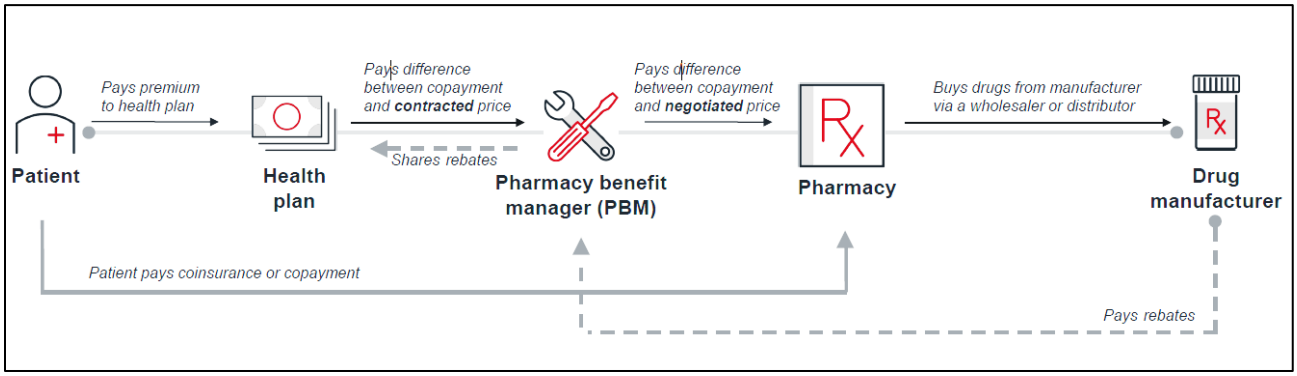
these payers including developing drug formularies, creating and managing networks of pharmacies, processing prescription drug claims, reporting drug expenditures, creating and administering clinical programs, and negotiating with pharmaceutical manufacturers for rebates on behalf of their clients.

29. PBMs began by providing claims processing and administrative services for health insurance companies in the late 1960s. Over time, however, their services expanded and PBMs began acting as intermediaries between the various segments of the pharmaceutical supply chain. Over the last 20 years, PBMs have also become increasingly concentrated. Caremark, ESI, and Optum have all gained share in the provision of PBM services through mergers and acquisitions. For example, ESI acquired Medco Health Solutions in 2012—combining the then first and third largest PBMs; Optum acquired Catamaran in 2015—combining the then third and fourth largest PBMs; and Caremark merged with Aetna (which had its own PBM) in 2018—increasing the share of the largest PBM in the U.S. today.

30. These PBMs have also become vertically integrated within large conglomerates that provide a broad range of services across the health care sector. The PBMs are integrated with private drug labelers, pharmacies, health care providers, GPOs, and insurance companies. This vertical integration has allowed the PBMs and their affiliates to leverage their power along every link in the pharmaceutical supply chain.

31. These behemoth PBMs came to exert enormous influence over drug pricing and purchasing decisions. When a patient fills a prescription at a retail pharmacy, the patient's out-of-pocket cost for the drug can vary depending on several financial arrangements within the pharmaceutical chain. Today, PBMs are at the center of these financial arrangements, contracting with drug manufacturers, health plan sponsors, and pharmacies.

Payment flow between stakeholders for pharmacy benefit drugs:



Formulary Development

32. One of the key ways PBMs exert influence over drug pricing and purchasing decisions is by creating drug formularies. A drug formulary is a list of prescription drugs covered by a health plan. Formularies often separate drugs into multiple tiers, and drugs on "preferred" tiers are typically cheaper for patients. For example, a common formulary design has three tiers: tier 1 includes mostly generic drugs and has the lowest patient out-of-pocket cost; tier 2 includes

preferred branded drugs with a higher out-of-pocket cost; and tier 3 includes non-preferred branded drugs with the highest patient out-of-pocket cost. This formulary design drives prescriptions toward the lowest tiers, including generic or preferred branded drugs.

33. Some drug formularies are more "open," meaning the formulary covers all or nearly all medications. Other formularies are relatively "closed," meaning the formulary includes only certain drugs, and excludes others, used to treat a specific condition. Generally, a health plan will not reimburse any part of the cost for an excluded drug. It follows that a physician is more likely to prescribe a drug that is covered on their patient's health plan formulary. Thus, a drug's formulary coverage dramatically impacts the drug's cost and utilization.

34. The PBM Respondents all offer several standard commercial formularies with different drug exclusion levels, ranging from open to more closed. The most-utilized commercial formularies all have a significant number of drug exclusions.

35. As of 2021, Caremark's flagship Standard Control Formulary, which excludes drugs, covered more than [redacted] million people. Caremark's more open Basic Control Formulary covered approximately [redacted] million people.

36. As of 2023, ESI's flagship National Preferred Formulary, which excludes drugs, covered approximately [redacted] million people. ESI's more open Basic Formulary covered approximately [redacted] million people.

37. As of 2023, Optum's flagship Premium Formulary, which excludes drugs, covered more than [redacted] million people. Optum's more open Select Formulary covered approximately [redacted] million people.

38. Because formularies serve a crucial role in determining patient access to prescription drugs, PBMs' central role in formulary design gives them significant leverage to extract price concessions from drug manufacturers. If a PBM excludes a drug from its formulary, the manufacturer risks losing a significant portion of sales among patients covered by that formulary. Conversely, if a PBM "preferences" or "prefers" a drug by placing it on a more favorable tier compared to competing products, it can boost the drug's sales volume and market share.

Rebate Negotiation

39. PBMs also exert influence over drug pricing and purchasing decisions by conditioning preferential treatment on their drug formularies on manufacturer rebates.

40. Drug manufacturers pay rebates that are based on a percentage of the wholesale acquisition cost (WAC) of their product. Drug manufacturers set the WAC, which is often referred to as the drug's "list price."

41. The list price of a drug minus any rebates and fees paid by the manufacturer is referred to hereinafter as the drug's "net price."

42. In recent years, each PBM Respondent has created a group purchasing organization (GPO) to negotiate commercial rebates with drug manufacturers on behalf of the PBMs. These GPOs (Respondents Zinc, Ascent, and Emisar) now perform the same commercial contracting function that the PBMs previously handled directly. In fact, many of the personnel at the GPO Respondents who negotiate or oversee commercial rebate contracts with drug manufacturers previously held the same role for the PBM Respondents. The PBM Respondents simply moved their commercial rebate contracting functions to the GPO Respondents' corporate structure. Now, the GPO Respondents enter into commercial rebate contracts with drug manufacturers, and the PBM Respondents utilize these rebate rates for their commercial clients.

43. PBM Respondents, now through GPO Respondents, solicit commercial bids from manufacturers using rebate grids. Manufacturers submit commercial bids by filling out these grids with different rebate rates for different levels of exclusivity: exclusive coverage (1 of 1 manufacturer), dual coverage with another manufacturer (1 of 2), and multiple manufacturers (1 of many).

44. Generally, manufacturers are willing to pay higher rebates for more preferential treatment of their drugs on formularies. For example, in 2022, one insulin manufacturer, Sanofi-Aventis U.S., paid Optum base rebates of [redacted]% of WAC for its insulin drug Lantus where Sanofi was the only long-acting insulin manufacturer on the formulary. In contrast, Sanofi paid Optum base rebates of only [redacted]% of WAC for Lantus where Sanofi was one of many long-acting insulin manufacturers on the formulary.

45. PBM Respondents, now through GPO Respondents, extract administrative fees from drug manufacturers as part of commercial rebate negotiations. PBMs attribute administrative fees to maintaining and overseeing the rebate program, negotiating and contracting with clients to participate in the rebate program, monitoring compliance with rebate eligibility requirements, and calculating and invoicing the rebates applicable to eligible drug utilization.

46. Administrative fees are typically calculated as a percentage of a drug's WAC, ranging from [redacted]% to [redacted]%. For example, a 2022 rebate agreement between Emisar (Optum's GPO) and Eli Lilly, another insulin manufacturer, had an administrative fee of [redacted]% of WAC. Because administrative fees are typically calculated as a percentage of WAC, the PBMs and GPOs collect higher fees on a drug with a higher WAC than a drug with a lower WAC even though the PBMs and GPOs provide the same services.

47. PBM Respondents, now through GPO Respondents, also extract data fees from manufacturers as part of their commercial rebate negotiations. Nominally, a data fee grants manufacturers access to a portal that contains utilization and other data for the manufacturer's drugs.

48. Data fees, sometimes referred to as [redacted] fees or [redacted] fees, are typically calculated as a percentage of a drug's WAC, ranging from [redacted]% to [redacted]%. For example, a 2022 rebate agreement between [redacted] GPO) and [redacted] had a data fee of [redacted]% of WAC. Because data fees are calculated as a percentage of WAC, the PBMs and

GPOs collect higher fees on a drug with a higher WAC than on a drug with a lower WAC, even though the PBMs and GPOs provide the same data services.

49. PBM Respondents, now through GPO Respondents, may also extract WAC-based fees from manufacturers in exchange [redacted] For example, a 2022 rebate agreement between [redacted] GPO) and Lilly had an [redacted] of [redacted] % of WAC depending on [redacted] And a 2022 rebate agreement between [redacted] and Sanofi had a [redacted] of [redacted] % for a particular drug [redacted]. Because these fees are typically calculated as a percentage of WAC, the PBMs and GPOs collect higher fees with a higher WAC drug than a drug with a lower WAC even though the PBMs and GPOs provide the same services.

50. PBMs implement drug formularies for their payer clients. PBMs develop standard commercial formularies, including their flagship formularies identified in paragraphs 35-37, that clients can adopt "off the shelf." Each of the three PBM Respondents, often for an extra fee, also allows clients to customize their own drug formularies. Custom formularies can range from a client making a few deviations to a standard PBM formulary to a fully customized formulary tailored to a client's specific needs. Many employers and commercial health plan sponsors lack the resources or pharmaceutical expertise necessary to develop their own formularies, so they outsource drug formulary decisions entirely to PBMs and accept the standard formularies that PBMs offer.

51. PBMs also handle the flow of rebate payments from drug manufacturers to the commercial payers. PBMs claim they pass on the vast majority of the drug rebates to their payer clients, though almost never directly to the patients.

52. In their May 2023 Congressional testimony, the PBM Respondents asserted that they pass on approximately 95% to 98% of the rebates they receive from drug manufacturers on behalf of the PBMs' clients. Industry reporting and data, however, suggest that these claims may be exaggerated, with PBMs actually retaining a larger portion of rebates and fees. According to the data that PBMs reported to the Texas Department of Insurance, fifteen PBMs collected a total of $4.39 billion in rebates, fees, and other payments from drug manufacturers in 2022 on health plans issued under Texas law. Of this, the PBMs kept $409 million—9.32%—for themselves.

53. A 2022 Drug Channels analysis of the Texas Department of Insurance data found that the data from 2016 to 2021 "tell a compelling and fairly consistent tale about what happened to the manufacturers' payments to PBMs." The Drug Channels analysis concluded that between 2016 and 2021, the PBMs retained between 7% and 21% of manufacturers' total payments, totaling hundreds of millions of dollars.

54. Payers' limited visibility into specific rebates and fees makes it difficult to verify pass-through. The formation of the GPO Respondents further exacerbated payers' ability to determine whether rebates and fees are actually being passed through, because the Respondents

do not disclose the amount of fees retained by the GPOs. Moreover, the GPO Respondents often make their rebate contracts with manufacturers available for payers' review only on-site at the GPOs' physical locations—outside the United States for two of the GPO Respondents—further obscuring payers' visibility into pass-through. A former Optum executive who helped set up Emisar, Optum's GPO, candidly explained, "The intention of the G.P.O. is to create a fee structure that can be retained and not passed on to a client."

55. Rebates that are passed on to the health plan may reduce the plan's (but not necessarily the patient's) overall net cost of a drug. Hereinafter, "net cost" refers to the actual cost to the payer, after factoring in the rebates and fees that are passed on to the payer. Payers then choose whether to retain the rebates or apply them at the point of sale (i.e., the pharmacy counter) when the patient purchases the drug that earns the rebate. According to the Texas Department of Insurance data, only 0.0002% of the collected rebates were shared directly with the patients who took the drugs.

B. Certain patients' out-of-pocket costs are tied to a drug's list price

56. Different patients may pay vastly different amounts for the very same drug. Patient cost depends on several factors, including whether the individual has health insurance, and if so, the drug benefits provided by that insurance.

57. Uninsured or cash-paying patients may pay for the prescription based on a drug's full list price.[1] Because these patients are not covered by health insurance, they do not receive rebates or other price concessions that a PBM negotiates with the manufacturer. According to the CDC National Center for Health Statistics, 8.4% or 27.6 million Americans did not have health insurance in 2022.

58. Most Americans have health insurance. But even among insured Americans, out-of-pocket costs greatly vary for the same drug. A patient's health insurance may be either commercial or government-sponsored (e.g., Medicare, Medicaid). Most Americans with commercial health insurance get coverage through their employer. According to U.S. Census Bureau data, over 183 million individuals were enrolled in employer-sponsored commercial insurance in 2019, compared to 33 million individuals with direct-purchase commercial plans and 58 million individuals enrolled in Medicare, the next largest category.

59. Employers providing health insurance may be self-insured or fully insured. Self-insured employers assume the financial risk of providing health benefits to employees. Fully insured employers, on the other hand, outsource the financial risk to the health insurance company. In 2023, approximately 65% of employees were enrolled in self-insured employer plans. PBMs administer pharmacy benefits for both self-insured and fully insured clients.

[1] The price at the pharmacy counter that is used as the basis for calculating a patient's out-of-pocket cost is generally either the drug's usual and customary price (U&C) or a discounted Average Wholesale Price (AWP), rather than WAC. However, both U&C and discounted AWP are closely correlated to and often approximate WAC for branded drugs. For simplicity, we refer to WAC and other prices based on WAC as the "list price."

60. How much an insured patient pays for a prescription is determined by the drug benefit in the patient's health plan. A patient's cost for their drug benefits includes two key components: monthly premiums and out-of-pocket expenses. A monthly insurance premium is a fixed amount the patient must pay regardless of their drug purchases. Out-of-pocket expenses are the costs the patient incurs when buying a prescription drug. Depending on the benefit design, the out-of-pocket expense may be structured as a copayment (a flat amount, e.g., $25 per drug), a coinsurance (a percentage of the total drug cost at the pharmacy, e.g., 30% of the cost), or a deductible (an amount the patient must pay before the plan begins contributing to the drug cost, e.g., $2,000).

61. When an insured patient buys a prescription drug at a pharmacy, the pharmacy charges the patient the out-of-pocket cost determined by the patient's benefit design. The pharmacy then receives reimbursement for the remainder of the drug's cost. Using a simplified example, if a drug costs $100 at the pharmacy, a patient with a $25 copay would pay $25, with the health plan (through the PBM) paying the pharmacy the remaining $75. A patient with 30% coinsurance would pay $30, with the payer covering $70, while a patient in the deductible phase of their health insurance plan would pay the full $100.

62. Patients with a copay—since they are responsible for a predetermined fixed amount—are mostly indifferent to the drug's actual list price. However, patients with coinsurance or those in the deductible phase typically have their out-of-pocket costs calculated based on the drug's list price before any rebates are applied. As a result, these patients may end up paying more out-of-pocket for drugs with higher list prices, even if the PBM and payer receive significant rebates.

63. According to KFF's (f/k/a Kaiser Family Foundation) 2023 Employer Health Benefits annual survey, at least 23% of workers with employer-based drug coverage pay coinsurance for second-tier drugs—generally, preferred branded drugs. The average coinsurance for second-tier drugs, or preferred brands, in 2023 was 26%.

64. With health insurance premiums rising far faster than inflation in recent years, patients have increasingly enrolled in high deductible health plans (HDHPs) that require them to meet a high deductible in exchange for somewhat more affordable monthly premiums. Per Internal Revenue Service guidelines, HDHPs have deductibles between $1,600 and $8,050 for self-only coverage and between $3,200 and $16,100 for family coverage in 2024. According to KFF's 2023 Employer Health Benefits annual survey, 29% of adults with employer-based health insurance were enrolled in a HDHP, up from 19% in 2012.

65. Lower-income patients are more likely to enroll in HDHPs without accompanying tax-advantaged health savings accounts. A 2017 National Health Interview Survey by the CDC found that adults in the survey's lowest income category (where income levels ranged from below the federal poverty line up to 138% of the federal poverty line) were the most likely of the income categories to have HDHPs without health savings accounts.

66. Health plans can mitigate some of their patients' exposure to high drug list prices by applying drug rebates directly at the pharmacy counter when the patient purchases the drug that earns the rebate, commonly known as a point-of-sale rebate. When all rebates from

manufacturers are applied to a drug at the point of sale, a patient's coinsurance or deductible payment for the drug is lower because it is effectively based on a measure closer to net price, rather than the list price.

67. In most cases, however, payers opt not to implement point-of-sale rebates. According to the 2023 Milliman Medical Index industry report, point-of-sale rebates are rare. Consequently, deductibles and coinsurance may shift a larger portion of the drug cost from the health plan to the patient, particularly when the manufacturer pays substantial rebates on a drug.

68. Indeed, for drugs with large rebates, a patient with out-of-pocket costs pegged to the list price may find themselves paying more at the pharmacy counter than the drug's actual net cost to the commercial payer. When a patient's out-of-pocket cost is tied to the list price, and the rebate is not passed on to the patient, the payer's "cost share" for the drug may be negative—that is, the commercial payer may functionally make money when a patient fills that prescription.

69. A simplified example illustrates this dynamic, involving a drug with a $100 list price, and a 75% rebate:

List price	$100
Rebate Rate	75%
Rebate Amount	$75
Rebated Price (net cost to the payer)	**$25**
Coinsurance Rate	30%
Coinsurance Amount (what the patient pays)	**$30**

70. In this example, despite being responsible for 30% coinsurance, the patient pays more for the drug ($30) than the rebated price ($25). Meanwhile, the commercial payer pays the pharmacy (through the PBM) the remaining $70 for the drug ($100 minus $30 coinsurance), but may ultimately receive $75 in rebates from the manufacturer (through the PBM), resulting in a $5 net gain from the prescription. With a $100 or more deductible, the cost burden may be even more pronounced, as the patient may bear the full $100 expense, while the commercial payer pays nothing and receives a rebate.

71. An insured patient's drug benefit design determines the patient's out-of-pocket cost for the drug at the pharmacy counter. The drug benefit design is largely a combination of two key components: formulary tiering and the cost-sharing between the payer and the patient associated with the tiers.

72. PBMs play a critical role in both of these components. Commercial payers frequently outsource their drug coverage decisions entirely to PBMs; PBMs create the drug formularies and place the drugs on the various formulary tiers. PBMs also heavily influence cost-sharing associated with formulary tiers. For example, PBMs often require health plans to adopt minimum copay or coinsurance differentials between formulary tiers. PBMs also offer strategy and benefit design consulting services to payers and may model the financial implications of benefit design choices. For example, according to one contract, Caremark is obligated to meet

annually with the client to "review plan strategy" and to provide "plan design modeling" that shows "cost and member impact associated with potential plan design changes."

73. PBMs may also assist in creating and distributing plan documents that describe a health plan's pharmaceutical benefit cost-sharing obligations, including whether patients are responsible for a copay, a percentage coinsurance, or a deductible.

C. Insulin is a life-saving medication for millions of diabetics

74. Naturally occurring insulin is a hormone produced by the pancreas and released into the body to turn blood sugar (or glucose) into energy. Without insulin, glucose builds up in the bloodstream leading to high blood sugar (or hyperglycemia).

75. Diabetes is a chronic health condition that occurs when a person's body cannot produce enough insulin (type 1 diabetes) or cannot use insulin properly (type 2 diabetes). Untreated diabetes can cause serious health problems, such as heart disease, stroke, kidney disease, vision loss, nerve damage, life-threatening infection, and amputations. The CDC ranked diabetes as the eighth leading cause of death in the United States in 2021, with over 100,000 deaths in which diabetes was listed as the underlying cause.

76. Diabetes is one of the most prevalent diseases in the United States. The National Diabetes Statistics Report estimated that in 2021, 29.4 million people in the United States, or 8.9% of the U.S. population, had diagnosed diabetes. The prevalence of diabetes continues to rise. In 2023, the CDC calculated that the number of adults diagnosed with diabetes has more than doubled in the past two decades.

77. There is no cure for diabetes, but diabetics can manage their blood sugar in part by taking insulin medication. Insulin medication is a biologic injectable drug made from a living organism, designed to regulate the body's blood glucose levels. Insulin was first used as a medication in 1922. According to the American Diabetes Association, in 2022, 8.4 million diabetics in the United States relied on insulin drugs to survive. All patients with type 1 diabetes take insulin, because their bodies do not produce it.

78. Four companies manufacture insulin for sale in the United States: Eli Lilly and Company ("Lilly"), Novo Nordisk Inc. ("Novo"), Sanofi-Aventis U.S. LLC ("Sanofi"), and Viatris Inc. (f/k/a Mylan). Lilly, Novo, and Sanofi have been selling insulin medications for over a century. Viatris is a far newer entrant, launching its first insulin drug, Semglee, in 2020. In 2022, Viatris Inc. sold its insulin portfolio to Biocon. Viatris and Biocon will be referred to collectively as "Viatris."

79. Most insulin products are available in both vial and pen (pre-filled syringe) dosage forms. The CDC classifies insulin types based on how fast and how long the insulin works in the body. Rapid-acting and long-acting insulins are the two main insulin categories.

80. Rapid-acting insulins lower blood sugar in approximately 15 minutes and continue to lower blood sugar for about two to four hours. Rapid-acting insulins are usually taken right before a meal to regulate the spike in blood glucose that occurs after eating. Between

2017 and 2022, rapid-acting insulins accounted for approximately 38-42% of total insulin sales in the United States.

81. Lilly sells Humalog and Lyumjev in the rapid-acting insulin category, with insulin lispro as the active ingredient.

82. Novo sells Novolog and Fiasp in the rapid-acting insulin category, with insulin aspart as the active ingredient.

83. Sanofi sells Admelog and Apidra in the rapid-acting insulin category, with insulin lispro and insulin glulisine, respectively, as the active ingredients.

84. In April 2022, the approximate shares of rapid-acting insulin commercial sales broke down as follows: Humalog (including branded and unbranded) had a [redacted]% share; Novolog (including branded and unbranded) had a [redacted]% share; Fiasp had a [redacted]% share; Lyumjev had a less than [redacted]% share; and Admelog had less than [redacted]% share. Humalog and Novolog have had a combined share of over 90% of the rapid-acting insulin sales since 2010.

85. Long-acting insulins, also known as basal insulins, lower blood sugar in approximately two hours and continue to lower blood sugar for up to 24 hours. Long-acting insulins are used to steadily regulate the body's blood glucose between mealtimes and overnight. Between 2017 and 2022, long-acting insulins accounted for approximately 46-48% of total insulin sales in the United States.

86. Lilly sells Basaglar and Rezvoglar in the long-acting insulin category, with insulin glargine as the active ingredient.

87. Novo sells Levemir and Tresiba in the long-acting insulin category, with insulin determir and insulin degludec, respectively, as the active ingredients.

88. Sanofi sells Lantus and Toujeo in the long-acting insulin category, with insulin glargine as the active ingredient.

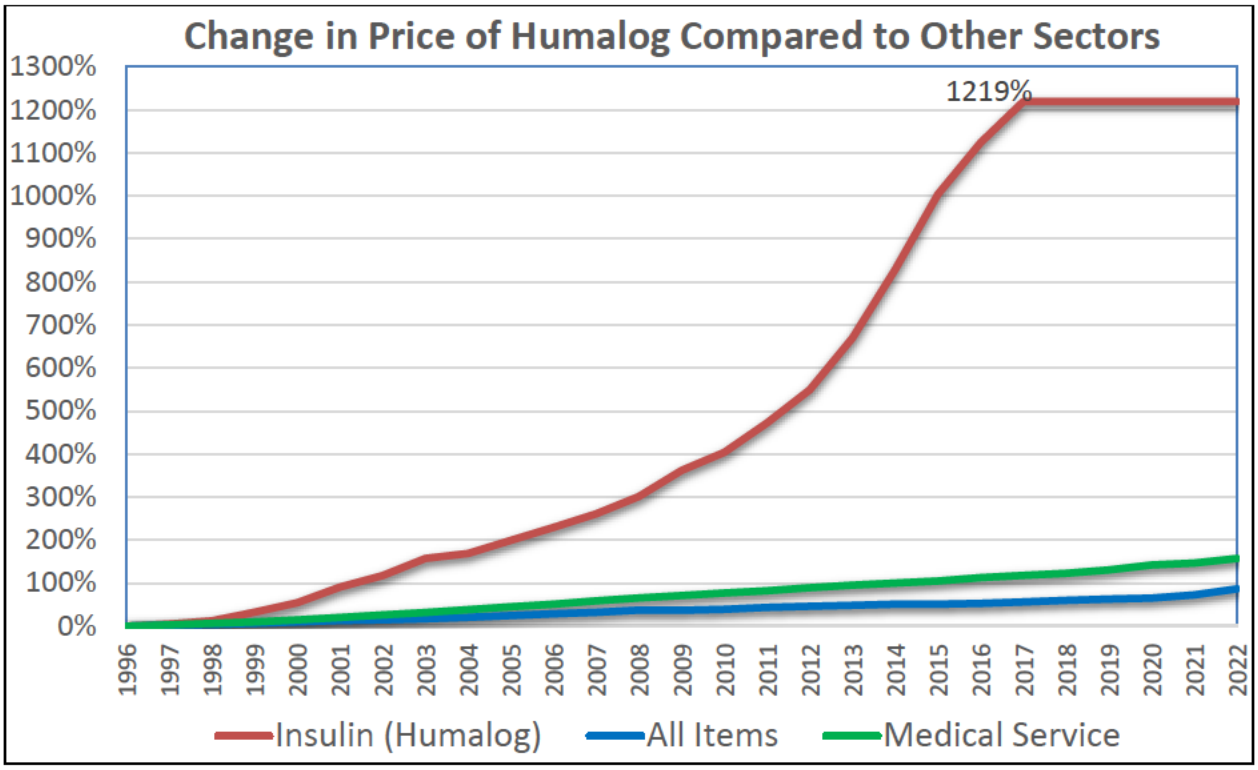
89. Viatris, and now Biocon, sells Semglee in the long-acting insulin category, with insulin glargine as the active ingredient.

90. In April 2022, the approximate shares of long-acting insulin commercial sales broke down as follows: Lantus had a [redacted]% share; Tresiba had a [redacted]% share; Basaglar had a [redacted]% share; Levemir had a [redacted]% share; Toujeo had a [redacted]% share; and Semglee had a [redacted]% share.

91. An insulin patient may take a combination of insulin drugs to regulate blood glucose levels throughout the day.

D. High list prices have made insulin drugs unaffordable for many patients

92. For nearly 85 years, insulin medication was affordable. For example, in 1999, the average list price of Humalog was $21. Over the past decade and a half, however, list price increases for insulin products have far outpaced inflation, even though the core drug has remained the same:



93. A 2022 report by the Department of Health and Human Services (HHS) found that the average list prices of insulin products nearly doubled between 2012 and 2016 alone. [redacted].

94. By comparison, between 2012 and 2018, the Consumer Price Index (CPI) rose only 9%, and the Prescription Drug CPI rose 20%.

95. These list price increases have resulted in particularly high out-of-pocket insulin costs for patients with commercial insurance and the uninsured. HHS found that in 2019, about 33% of patients using insulin had commercial health insurance. For commercially insured patients, 19% of monthly insulin prescriptions required out-of-pocket costs exceeding $70 per prescription. For uninsured patients, 27% of monthly insulin prescriptions involved costs greater than $70.

96. When patients cannot afford medication, they may be forced to ration their usage or abandon the therapy altogether. A peer-reviewed study published in the Annals of Internal Medicine found that 17% of total patients using insulin, and 18.8% of patients with commercial health insurance, reported rationing their insulin in 2021 because of its costs. Another peer-reviewed study in the Annals of Internal Medicine estimated that 1.3 million adults with diabetes in the United States rationed their use of insulin in 2021 by delaying refilling prescriptions, skipping doses, or taking smaller doses than needed. The study also found that rationing is more common among lower- and middle-income patients and among Black patients.

97. Abandoning or rationing insulin can lead to serious adverse health outcomes for patients, including death. An American Diabetes Association working group reported in 2020

that "people with high cost-sharing are less adherent to recommended dosing, which results in short- and long-term harm to their health."

98. One serious complication that can arise from rationing insulin is diabetic ketoacidosis, a condition where acids called ketones build up in the bloodstream and can cause a coma or even death. At an open meeting of the Commission in October 2021, the Commission heard directly from a mother who lost her 26-year-old son. After having difficulty affording his insulin, he tried to ration his insulin and died of diabetic ketoacidosis. The CDC reported that in 2020, 240,000 patients visited U.S. emergency rooms with diabetic ketoacidosis.

V. RESPONDENTS' UNLAWFUL CONDUCT

A. PBM Respondents developed exclusionary formularies, setting the stage for their chase-the-rebate strategy

99. Before 2012, drug formularies generally covered all approved medications. Rather than excluding clinically effective products, the PBM Respondents' formularies preferred certain products by placing them on different tiers, each with different patient out-of-pocket costs. While drug manufacturers sometimes offered modest rebates to secure a preferential tier placement, they generally did not have to worry about being completely excluded from the formulary and losing access to patients.

100. This dynamic changed around 2012 when the PBM Respondents sought ways to increase their leverage—and thus their profits—in negotiations with manufacturers. In part through a series of mergers and acquisitions, the PBM Respondents came to wield greater control over access to commercially insured patients. Accordingly, the PBM Respondents came to realize that they could extract more from manufacturers by threatening to exclude certain drugs from formularies.

101. Given that the PBM Respondents served as gatekeepers, manufacturers could not dismiss such threats lightly. If a manufacturer were excluded from a formulary that included a competitor in the same drug class, it would lose access to nearly all patients covered by that formulary, leading to significant sales losses. Consequently, the manufacturers became willing to offer higher rebates to secure preferential treatment. This shift gave rise to the exclusionary formulary.

102. The PBM Respondents began offering formularies that excluded clinically effective drugs from coverage. With these "closed" or exclusionary formularies, manufacturers faced the prospect of their product being entirely excluded. The PBM Respondents viewed these drug exclusions as "forever altering the landscape for how we negotiate with pharmaceutical manufacturers on our clients' behalf."

103. Recognizing it as a "bold move," Caremark became the first PBM to develop a commercial formulary with non-clinical drug exclusions. For example, in 2012, the predecessor to Caremark's Standard Control Formulary excluded all forms of Lilly's Humalog in favor of Novo's Novolog.

104. ESI initially thought that payers would resist Caremark's exclusion strategy as "clearly a play to obtain greater rebates[.]" A mere two years later, however, ESI introduced its own closed formulary. ESI's chief trade relations officer described the drug exclusion strategy as "a long-term game changer for rebate growth." An ESI Senior Account Executive characterized the new drug exclusions in its 2014 National Preferred Formulary—including Novolog, and Apidra—as "a great opportunity for us to increase rebates[.]"

105. In 2016, Optum introduced its own exclusionary drug formulary. As an Optum Project Manager explained to a plan's consultant, "[b]y excluding certain prescription drugs, we negotiate more aggressive discounts or higher rebates for drugs intended to treat the same condition."

106. Exclusionary formularies have expanded and now dominate the commercial space. The PBM Respondents pursue clients by guaranteeing a large portion of the rebate payments to the payers and push their standard formularies, which are based on guaranteed rebate amounts. As a result, commercial payers increasingly focus on maximizing rebates. The PBM Respondents recognize that their clients and clients' consultants "typically associate high rebate guarantees with value and do not always focus on lowest net cost[.]"

107. The PBM Respondents' most used commercial formularies all use drug exclusion strategies. Optum's Premium Formulary is "the most utilized of our standard formularies" and covers over [redacted] million people. Caremark's Standard Control Formulary covers more than [redacted] million people. ESI's National Preferred Formulary covers approximately [redacted] million people—[redacted] times as many as ESI's open Basic Formulary.

108. The PBM Respondents market these flagship formularies as providing "significant value for clients" by focusing on rebate maximization. For example, Optum presents its flagship Premium Formulary as having the "[m]ost rebates" (for payers). By comparison, Optum identifies its Select open formulary as providing the "[m]ost consumer choice" (for patients), and its Premium Value closed formulary as having the "[l]owest net spend" (for payers). Optum indicates that the Premium Value formulary, with 5-10% net spend savings over Premium, achieves this "lowest net cost" by "de-emphasizing rebates[.]"

109. Due to the presence of multiple competing manufacturers within each drug class, insulin products were a prime target for the PBM Respondents to extract rebate value from manufacturers in exchange for preferential formulary access.

110. Insulin products within the rapid-acting class are generally considered clinically substitutable. For example, in 2023, Caremark preferred Novo's rapid-acting insulins (Novolog and Fiasp) and excluded Lilly's rapid-acting insulins (Humalog and Lyumjev) from its flagship Standard Control Formulary. In the same year, ESI preferred Lilly's rapid-acting insulins (Humalog and Lyumjev) and excluded Novo's rapid-acting insulins (Novolog and Fiasp) from its flagship National Preferred Formulary.

111. Similarly, insulin products within the long-acting class are generally considered clinically interchangeable. For example, in 2023, Optum preferred Sanofi's long-acting insulins (Lantus and Toujeo) and excluded both Novo's long-acting insulins (Levemir and Tresiba) and

Lilly's long-acting insulin (Basaglar) from its flagship Premium Formulary. In the same year, though, Caremark and ESI both preferred Novo's Levemir and Tresiba and excluded Sanofi's Lantus from their flagship formularies.

B. Respondents demanded increasingly high rebates from manufacturers in exchange for favorable formulary placement

112. Insulin manufacturers need access to the PBM Respondents' formularies to effectively sell their insulin products. Novo estimated that, in 2021, [redacted]% of its entire insulin business was contracted through the PBM Respondents, with "the vast majority" of insured patients being "covered by those big three players." According to a Novo Senior Vice President responsible for strategic market access, securing coverage on the PBM Respondents' formularies was essential for reaching "large volumes of patients."

113. The PBM Respondents leveraged their size and the threat of excluding drugs from their formularies—resulting in significant sales losses—to demand higher rebates from insulin manufacturers. Indeed, when soliciting bids from manufacturers, the Respondents typically required manufacturers to maintain or increase the size of rebates or face outright rejection of the bid. Insulin manufacturers understood that "the magnitude of the rebate amount" was crucial and that they "had to compete for both net price and the amount of rebate in order to win access that PBMs prioritize." As a Novo Senior Vice President explained, "[t]he demands that PBMs have on insulin for rebates and discounts and fees have continued to increase over time." Lilly's then President of Diabetes echoed this sentiment, stating that rebates are "how you negotiate for formulary access."

114. The PBM Respondents were "[e]nacting narrow formularies so that the demands [for more insulin rebates] actually had some teeth." An internal Sanofi Market Access Background presentation highlighted that "US payers continue to use formulary placement to drive higher rebates." In just one year—from 2019 to 2020—Caremark and ESI excluded 109 and 54 more drugs, respectively. As Sanofi's Head of General Medicines Market Access explained, "the narrower the formulary, the greater that discount that can be extracted from the manufacturer."

115. To combat the "deep and real threat that [their] products would be removed from formularies at the largest PBMs," manufacturers dramatically increased the rebate rates on their insulin products.

116. In 2011, before the PBM Respondents introduced exclusionary formularies, Novo's contracted rebate rate to Caremark for Novolog was [redacted]%. In 2012, Caremark introduced the predecessor formulary to its flagship Standard Control Formulary, and preferred only Novo's insulins in the rapid-acting insulin class. In exchange for this exclusive formulary coverage, Novo [redacted] its rebate rate for Novolog to [redacted]%. By 2022, Caremark's Novolog rebate rate (negotiated by Zinc) for exclusive formulary coverage of its rapid-acting insulins had risen to [redacted]%.

117. In 2010, before the PBM Respondents introduced exclusionary formularies, ESI's contractual rebate rate for exclusive coverage of Humalog was [redacted]%. In 2014, ESI introduced

exclusions on its National Preferred Formulary, and preferred only Humalog in the rapid-acting insulin class. In exchange for this exclusionary formulary coverage, in 2015, Lilly more than [redacted] its offer for [redacted] commercial rebate rates, up to [redacted]%. By 2022, ESI's rebate rate (negotiated by Ascent) for exclusive coverage of [redacted] had risen to as high as [redacted].

118. In 2012, before the PBM Respondents introduced exclusionary formularies, Sanofi's average contractual rebate rate to Optum for Lantus was [redacted]%. In 2016, Optum introduced its Premium Formulary, and preferred only Sanofi insulins in the long-acting insulin class. In exchange for this exclusive formulary coverage, Sanofi agreed to a rebate rate of [redacted]% for Lantus. By 2022, Optum's rebate rates for Lantus had risen to as high as [redacted]%.

C. Insulin manufacturers continually raised insulin list prices to counteract increasingly higher rebate demands

119. Respondents' chase-the-rebate strategy led them to prioritize the magnitude of rebates received from drug manufacturers over lower list prices. To "offset some of the dramatic and rapid changes in the rebates" resulting from this strategy, insulin manufacturers dramatically increased list prices.

120. Lilly increased the list price for Humalog U-100 from $122.60 in 2012 to $274.70 in 2017, an increase of 124%.

121. Novo increased the list price for Novolog U-100 from $122.59 in 2012 to $289.36 in 2018, an increase of 136%.

122. Sanofi increased the list price for Lantus U-100 from $114.15 in 2012 to $283.56 in 2019, an increase of 148%.

123. Lilly's former President of Diabetes attributed these price hikes to Respondents' rebate demands, stating, "the reason you see these type[s] of price increases is as a way to compensate for the very high rebates that the company would offer."

124. By 2018, diabetes had become the top category of drug spending for traditional (non-specialty) prescription drugs, according to a Drug Channels Institute analysis. Similarly, ESI's 2017 Drug Trend Report indicated that "diabetes medications were the most expensive among traditional therapies" and "the top diabetes drugs by spend continue to be insulins." In the third quarter of 2017, insulin was [redacted] per-member spend for Optum's commercial clients.

125. Generally, competition drives down prices as sellers try to win business. However, because the Respondents prioritized negotiating rebate amounts over net prices, manufacturers were able to *increase* list prices to offer larger rebates necessary to secure formulary access. Indeed, the insulin manufacturers often raised their list prices in lockstep, and many Americans found themselves paying drastically more money for the exact same drugs.

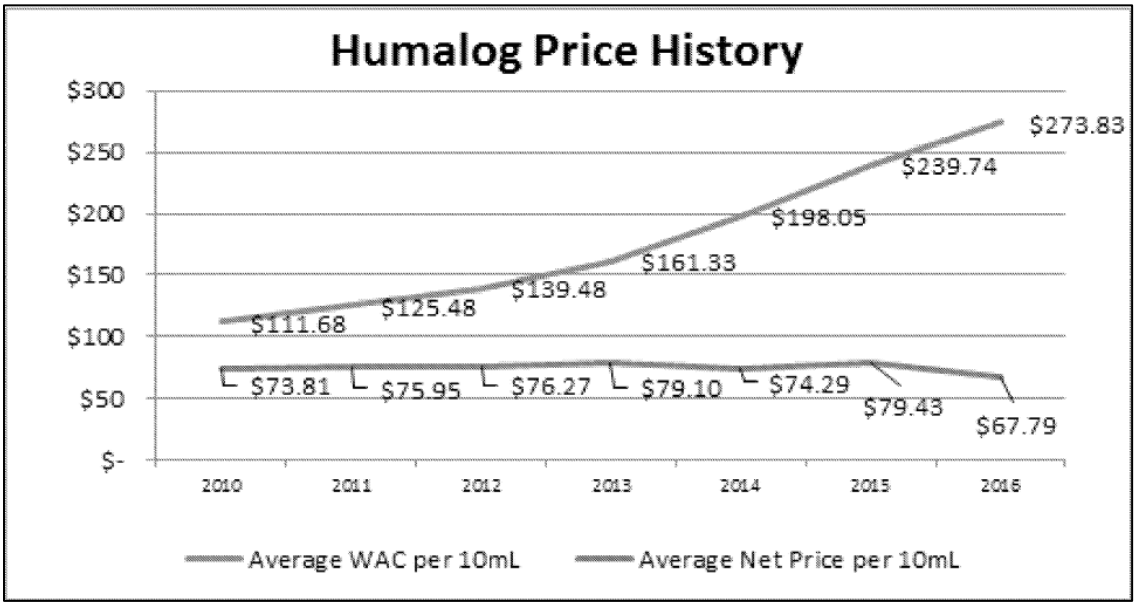
126. Lilly and Novo—the closest competitors in the rapid-acting class—specifically sought to maintain list price parity for Humalog and Novolog. Lilly's then President of Diabetes

explained that "we felt that we had to take similar price increases in order to be competitive … when Novo was taking price increases, if we didn't take similar price increases, we didn't think we could be competitive for [formulary] access."

127. Similarly, in the long-acting insulin class, Novo adjusted the list price of Levemir to match that of Sanofi's Lantus, which was its closest competitor in the long-acting insulin class.

128. Respondents' chase-the-rebate strategy meant that insulin manufacturers were not vying for favorable formulary access based on price, but instead based on higher rebates and fees paid to Respondents.

129. As list prices of insulin products continued to grow, they became wildly divergent from actual post-rebate net prices. In response to questions from Congress in 2017, Lilly charted the average list price and average net price of Humalog, revealing the growing disparity between the two.



130. Despite the growing rebates, the average net price of Humalog (after rebates and fees) continued to rise following the PBM Respondents' introduction of their exclusionary formularies—due to ever-escalating list prices. It took several years, around 2014-2015, for the net price of Humalog and other insulin products to begin to decline.

131. Although insulin net prices began to decline over time, patients whose out-of-pocket costs are tied to the artificially inflated insulin list prices continued to pay more. For example, Sanofi reported that from 2012 to 2022, "the net price in commercial and Medicare Part D plans of our most prescribed insulin, Lantus [] 100 units/mL, has fallen approximately 55%." Despite this, "average out-of-pocket costs for Lantus patients with commercial insurance and Medicare have risen approximately 45% over that same period." Sanofi highlighted that "high cost-sharing, particularly for highly rebated therapies such as insulin, creates a financial barrier for patients" to access treatments, noting that its ability to lower costs for patients was

limited because "PBMs and health plans ultimately decide what a patient pays at the pharmacy counter."

D. Rather than reduce the list prices of their insulin products and face pushback from the Respondents, manufacturers introduced identical low WAC alternatives

132. The skyrocketing insulin list prices drew significant criticism from the media, public, and Congress. Beginning in 2017, insulin manufacturers explored ways to reduce insulin list prices either by directly cutting the WAC of some of their existing insulins or by launching new, lower WAC unbranded versions of the same drugs.

133. Lilly, Novo, and Sanofi all recognized that providing patients access to insulin with lower list prices would help address affordability concerns, create "positive media attention for providing a solution," and maybe even "becom[e] a catalyst for changing the dynamics with payers."

134. Though the manufacturers considered reducing the list prices of their current insulin products, they knew that the PBM Respondents preferred to maintain competition for rebates and valued higher rebates over price cuts.

135. Novo was concerned that if it decreased the list prices of its insulin drugs, "[c]ompetitors may not follow[,] putting [Novo] at a disadvantage." Novo's Senior Vice President of Market Access explained, "[i]f we were to reduce the WAC price of our products and subsequently reduce the rebate value and administrative fee value that was being provided, we would expect, based on the conversations we had had, to receive push-back from the payers" and risk being excluded from PBM drug formularies in favor of high list price, highly rebated rivals.

136. This sentiment was shared by all three insulin manufacturers. In June 2018, Lilly executives individually met in person with representatives from each of the three PBM Respondents to present a proposal for a [redacted]% reduction in the list price of Humalog. This proposed reduction would keep the net price of Humalog the same but would reduce commercial and Medicare rebates for Humalog by an estimated $[redacted] over roughly three-and-a-half years. Unsurprisingly, Lilly received feedback that "the three PBMs were not interested in this proposal. It was that matter of fact." As Lilly's former President of Diabetes bluntly explained, if "you're cutting the rebates by [redacted] percent, we're not going to win that business." By cutting the Humalog list price, "you have … lower rebate pool, and lower admin fees, do you think that the PBM is going to choose you? … If we were to do this, we likely [redacted], so the Lilly [sales] number would be zero."

137. Caremark said something similar to Sanofi in 2019. Although Caremark professed to seek lower insulin prices for patients, it made clear that "they would be challenged" to include an insulin product on formulary if the product "had a much lower WAC with a smaller rebate." The following year, Sanofi evaluated the market prospects for a low WAC insulin product, finding a "loss of coverage with key rebate-driven customers is anticipated, as a lower WAC

price inhibits our ability to compete on rebates and increases competitors [sic] ability to create a financial upside for formulary change."

138. For the PBM Respondents, list price cuts would mean the potential loss of rebate and fee revenue. The PBMs generally guarantee rebate payments to their clients, which means that the PBMs commit to paying a fixed amount of rebate for every prescription. If list prices fell, the rebates on those prescriptions would also fall. The PBM Respondents would in turn receive less in rebates from manufacturers, but still owe their clients the same fixed amount of rebates per prescription, making it costly for the PBMs to fulfill their guarantee commitments.

139. Rather than cutting list prices on their existing insulin products and risking losing formulary access, Lilly, Novo, and Sanofi each launched new, unbranded low WAC products. These low WAC insulin versions were identical to the high WAC versions in all clinical respects. The only differences were that they did not include branding and were significantly lower list price.

140. In May 2019, Lilly launched a low WAC version of Humalog, priced 50% below the WAC of branded Humalog.

141. In January 2020, Novo launched a low WAC version of Novolog, priced 50% below the WAC of branded Novolog.

142. In June 2022, Sanofi launched a low WAC version of Lantus, priced 60% below the WAC of branded Lantus.

143. The insulin manufacturers continued to offer the high WAC, highly rebated versions while pricing their low WAC insulin at roughly "net price parity" with the branded versions. Essentially, although the low WAC version had a different list price, the smaller rebate it offered resulted in a net price roughly equivalent to that of its high WAC counterpart. Manufacturers adopted this pricing strategy "so that the payer would be neutral" or "indifferent" between the two versions.

E. Despite the entry of low WAC alternatives, PBM Respondents continued to prefer high price, highly rebated insulins on their flagship formularies

144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees.

145. In 2019, both ESI and Optum were exclusively preferring Lilly insulins in the rapid-acting insulin class on their flagship commercial formularies. In May of that year, Lilly launched low WAC Humalog. The "payer feedback [was] that this [launch] will have a negative financial impact on them" because the low WAC version would yield significantly lower rebates. Consistent with this feedback, in a monthly formulary consultant meeting, ESI explained to its client that it "will likely exclude [low WAC Humalog] on the [flagship National Preferred Formulary] due to rebate impact." In fact, both ESI and Optum kept high WAC Humalog as the

only preferred rapid-acting insulin on their flagship formularies, excluding low WAC Humalog entirely.

146. In 2020, Caremark was exclusively preferring Novo's rapid-acting insulin products (Novolog and Fiasp) on its flagship Standard Commercial Formulary. In January of that year, Novo launched low WAC Novolog. Despite this, Caremark kept high WAC Novolog and Fiasp as the only preferred rapid-acting insulins on its flagship formulary, excluding low WAC Novolog entirely.

147. In 2022, Optum was exclusively preferring Sanofi long-acting insulin products (Lantus and Toujeo) on its flagship Premium Formulary. In June of that year, Sanofi launched low WAC Lantus. Nonetheless, Optum kept high WAC Lantus and Toujeo as the only preferred long-acting insulins on its flagship formulary, excluding low WAC Lantus entirely.

148. Across the board, the PBM Respondents opted to exclude low WAC versions of insulin from their flagship formularies—even though including the low WAC versions would expand access to insulin for a swath of patients without impacting the rebate rates PBMs received for the high WAC versions. Instead, the contractual rebate rates the manufacturers offer depend on the number of manufacturers preferred on the formulary, not the number of individual insulin products. Thus, the PBM Respondents' contracts with manufacturers would allow them to include low WAC insulin versions while still receiving the same large rebate rates for the high WAC versions.

149. For example, in [redacted] 2019 rebate contract with [redacted] highest rebate rate on high WAC [redacted] for [redacted] flagship formulary was [redacted]%. This rebate rate was conditioned on [redacted] being the only preferred *manufacturer* in the [redacted] category on [redacted] flagship formulary, not on whether high WAC [redacted] was the only [redacted] *drug* in the rapid-acting drug category. In other words, under the contract, [redacted]

150. Co-preferring low WAC insulins on the formulary, however, would lead to more patients using the low WAC versions, resulting in "a huge loss in rebate $." For example, [redacted] estimated that it would lose millions in rebates and fees by co-preferring low WAC [redacted] on its flagship formulary. Indeed, the insulin manufacturers posited that the PBM Respondents were unwilling to cover the low WAC insulin products on their flagship commercial formularies due to concerns about a potential "loss of rebate stream."

151. The PBM Respondents' preference for large rebates also impeded new entry into the insulin space. In August 2020, Viatris introduced its long-acting product, Semglee. Initially, Viatris tried to market Semglee at a single discounted list price point, 65% below the list price of Lantus, the most-utilized long-acting insulin, and at least 50% below other long-acting insulins on the market. However, Viatris soon discovered that the PBM Respondents did not reward Semglee's significantly lower list price with preferred formulary placement. Instead, Semglee failed to secure formulary coverage on any of the PBM Respondents' flagship commercial

formularies precisely because its lower list price could not deliver "rebate dollars comparable to existing brands." Viatris attributed the lack of "commercial uptake" for original Semglee to the "inability to replace current Lantus rebate flow."

152. In July 2021, the Food and Drug Administration designated Semglee as interchangeable with Lantus, meaning that Semglee could be substituted for Lantus at the pharmacy without the doctor writing a new prescription. But Viatris still needed PBM formulary access to achieve sales. Having learned from the failed initial launch, Viatris introduced two versions of interchangeable Semglee: a high WAC version that could generate rebates necessary for commercial formulary coverage and a low WAC version that provided patient affordability in other, non-commercial drug channels (which did not prioritize rebate maximization).

153. Viatris introduced this high WAC version of Semglee [redacted], even though an internal model showed that [redacted], the low WAC version was [redacted] on a per unit basis. The model determined that low WAC Semglee is [redacted] to Viatris because it incurs [redacted] WAC-based fees paid into the pharmaceutical distribution chain compared to the high WAC version. According to the model, while the "payer net" (i.e., the cost to the payer) for both high WAC and low WAC Semglee was nearly identical, Viatris's net margin for low WAC Semglee pens was $[redacted], in contrast to [redacted] $[redacted] for high WAC Semglee.

154. Viatris's pivot to a high WAC Semglee yielded immediate results. In October 2021, ESI decided to include high WAC Semglee on its flagship National Preferred Formulary, while excluding low WAC Semglee. Notably, [redacted] had provided guidance to Viatris on the appropriate "rebate rate … from a competitive standpoint" but did not offer similar guidance on the appropriate "net price." ESI did not [redacted] on its flagship formulary.

155. Viatris's new entry into the insulin market had the potential to shake up market dynamics by injecting more competition, and lower prices, into the long-acting insulin space. As a Sanofi Vice President observed, however, ESI's decision to "embrac[e] the high WAC version of [Semglee]" was "a stabilizing event" that would preserve the "high WAC/high rebate market for the foreseeable future." The well-recognized sentiment that rebates drive PBM formulary decisions led one Optum employee to quip: "[A]s long as [Viatris is] keeping the lower WAC they should price Semglee at twice the price of Lantus with a huge rebate and sell it to PBMs as a product that can cover their rebate guarantees #million dollar ideas."

156. Though the high list price, highly rebated insulin versions were more lucrative for Respondents, the practical effect of the PBM Respondents' decisions to prefer the high WAC insulin, and exclude the lower list priced versions, from their flagship formularies was to deprive many patients who would have been able to better afford the low WAC insulins of that option.

157. In addition to designing standard formularies, the PBM Respondents also assisted clients with making the decision to exclude low WAC drugs from their custom formularies. For instance, one of [redacted] major custom clients, [redacted], was "very concerned about not covering" low WAC [redacted] and thought that "[f]rom a PR perspective [redacted] will likely be pushed into covering" the low WAC drug. [redacted]

prepared modeling for [redacted], demonstrating that adding low WAC [redacted] to the preferred tier could result in a loss of over $[redacted] in manufacturer rebates and administrative fees. [redacted] then "leverage[d] [redacted] talking points … to block [low WAC] [redacted]

158. Because of the PBM Respondents' systematic exclusion of low WAC insulins from their flagship commercial formularies, these products had limited uptake and "never achieved the same level of access as the branded [high WAC] version."

159. In 2022, low WAC Humalog accounted for approximately [redacted]% of total Humalog volume. Lilly estimated that "only one out of three insured patients has access to [low WAC Humalog] through their insurance."

160. Similarly, in 2022, low WAC Novolog accounted for approximately [redacted]% of total Novolog volume, and low WAC Semglee accounted for approximately [redacted]% of total Semglee volume. For low WAC Lantus, which launched in 2022, "coverage was low" and "[u]tilization was even lower."

161. The insulin manufacturers were "disappointed" with the low commercial uptake of the low WAC insulins. But as a Novo Vice President bluntly observed, "low wac/low rebate [insulins] don't stand a chance in this system."

162. Because of how the Respondents designed this system, many diabetics were left paying inflated prices for insulin.

F. Respondents financially benefit from artificially inflated list prices, rebates, and fees

163. The Respondents were focused on maximizing rebate value, not on lower list priced insulin products. Although the PBM Respondents understood that preferencing high WAC insulin products led to higher out-of-pocket costs for certain patients, the Respondents continued their chase-the-rebate strategy because it benefited them. In the words of a Novo Vice President, the Respondents, as well as commercial payers, have become "addicted to rebates."

164. The Respondents benefit from the higher rebates and fees associated with high list prices and high WAC insulin products in two primary ways: first, the PBM Respondents and GPO Respondents retain a portion of the rebates and fees; and second, the PBM Respondents use high rebate numbers to attract clients.

165. The PBM Respondents retain some of the rebates from drug manufacturers, collectively amounting to hundreds of millions of dollars per year from their commercial lines of business and billions of dollars per year in total. Additionally, the PBM Respondents and GPO Respondents retain a portion of the various WAC-based fees they charge drug manufacturers. For example, a Caremark March 2022 financial review of PBM rebates shows that Zinc retains [redacted] to [redacted]% of the combined WAC-based [redacted] fees it receives from manufacturers, amounting to nearly $[redacted] million in just one year. And some fees, such as [redacted] data fees, are retained entirely by the GPO Respondents and "are not passed back" at all.

166. As insulin list prices increased, so did the WAC-based fees that the Respondents collected for insulin products. But the Respondents did not provide drug manufacturers any additional services. As Ascent's President noted, [redacted] In other words, the Respondents extracted and pocketed hundreds of millions of dollars without providing any additional value.

167. Retention of rebates and fees from drug manufacturers is a significant "component of profitability" for the PBM Respondents and the GPO Respondents.

168. This is particularly true for insulin products, which have been among the highest rebated drugs for the Respondents. From 2017 to 2020, the long-acting insulin drug category generated the largest rebate value for [redacted]. In the third quarter of 2019, rapid-acting and long-acting insulins were the [redacted] by combined invoiced rebate dollars and administrative fees on ESI's flagship formulary. These rebates and administrative fees for insulin products totaled $[redacted] in just one quarter.

169. In 2020, rebates from insulin products comprised $[redacted] out of $[redacted]—or [redacted]%—of Optum's total commercial rebates. In 2020, Optum realized $[redacted] from insulin products. In 2021, an Optum Vice President of Industry Relations noted that [redacted], "We can still drink down the tasty Lantus rebates."

170. In addition to the higher rebates and fees Respondents retain, the PBM Respondents use the large rebates they receive from high price, highly rebated products to attract commercial payer clients. The PBM Respondents recognize that higher rebates "are [a] major point in retaining and winning clients."

171. The PBM Respondents' contract negotiations with commercial payers often focus on a guaranteed rebate amount. PBMs frequently compete for clients by trying to offer the highest minimum guaranteed rebate values. As ESI's Senior Vice President of Account Management for Commercial Accounts explained, the "minimum guarantee … is part of the RFP process based on the request of the client and the consultant. And in my experience it's used to compare across PBM[s]."

172. By offering a higher rebate guarantee, a PBM's bid is optically more attractive to a potential client. As Lilly's then President of Diabetes explained, PBMs use the rebate dollars they obtain from manufacturers "in their negotiations to get employers to choose their PBM services" and "the more … rebates they can get relative to their competitors, the more money they will have to go and win … employer's services." A [redacted] presentation on client pricing summarized: "Higher earned rebates better enable PBM to achieve rebate [guarantees] and attractive bid optics."

173. The PBM Respondents shaped competition for providing PBM services around guaranteed rebates. As a result, commercial payers prioritize the size of the rebate guarantee when selecting a PBM. [redacted]

[redacted] A [redacted] Director of [redacted] expressed concern that impacting [redacted] ability to meet rebate guarantees "will cause a lot of risk to [redacted] and could "decrease [redacted] ability to stay competitive in the market place."

174. Accordingly, commercial clients generally avoid formulary options that provide fewer rebates. Optum's Premium Value Formulary, which "de-emphasiz[es] rebates," had [redacted] clients as of 2023. ESI's Flex formulary, which "takes rebates out of the equation," covered fewer than [redacted] people in 2022.

175. Commercial payers often focus on rebate guarantees in part because the PBM Respondents typically refuse to share drug-level rebate and fee amounts or net cost information with the payers.

176. Consequently, many payers are unaware of the specific rebate amounts for individual drugs and are unable to calculate a rebated drug's true net cost. As the Department of Health and Human Services' Inspector General found, most health plans were unaware of all the contract terms that determine the rebates they receive from drug manufacturers. A [redacted] Vice President remarked in 2019 that there were "only a handful of clients that get drug level rebate reporting," and a [redacted] Director noted that those clients who did were "more sophisticated than most clients." Indeed, in April 2020, only [redacted] out of thousands of [redacted] commercial clients received specific drug-level rebate reports, which [redacted] conceded are offered to clients "as a last resort."

177. By offering rebate guarantees, the PBM Respondents lock themselves into having to generate enough rebates to meet their guaranteed minimum rebate amounts. If they are unable to meet these rebate guarantees, they might be required to cover the shortfall from their own funds. These pressures incentivize the PBM Respondents to favor high WAC insulin products on their flagship formularies, as they generate larger rebates.

178. The PBM Respondents recognized that switching to low WAC versions of insulin would result in "a major hit to overall rebates and drag on rebate [guarantees]." In evaluating the low WAC Humalog launch in 2019, [redacted] noted, "[i]nsulins earn rebates in excess of the guarantees they generate and thus a [low WAC] launch poses a risk to rebate guarantees." A [redacted] presentation from the following year, 2020, summed up the situation for the PBM Respondents: when a lower WAC product is introduced, the client [commercial payer] sees a "minimal difference in *net cost*" and members [patients] "could see a significant reduction in out of pocket costs." From the PBM's perspective, however, the "[r]eduction in rebates earned makes PBM underperform on client rebate guarantees, causing PBM to absorb losses," in other words, lose money.

179. In fact, in 2020, [redacted] was already "highly underwater" on its rebate guarantees to a large client. Even though the client was focused on lowest net cost and "[didn't] want to 'chase' rebates," [redacted] personnel decided to not bring up low WAC [redacted] with the client, because they were worried about "a drop in rebates" and "get[ting] in big trouble

if we brought the account further into the hole." [redacted] later noted in an internal presentation that this client was "[c]ritical in mitigating rebate guarantee exposure."

180. Optum conducted a financial analysis on the impact of the low WAC Humalog launch on its profit and loss statement. Optum found that if volume shifted from high WAC Humalog to low WAC Humalog, [redacted] Specifically, Optum identified a [redacted] rebate risk, with [redacted] representing a loss to Optum's profitability from retained rebates. The remaining [redacted] was [redacted], "because we're so [redacted] Humalog to [redacted]"

181. As a result, PBM Respondents largely neglected low WAC insulins in the commercial channels—even though these low WAC insulins could have meaningfully expanded drug access for diabetics. As the ESI executive who managed the company's relationship with Lilly candidly stated, "[w]e've just not discussed [low WAC Humalog] much [redacted]"

G. PBM Respondents deliberately cause the burden of inflated list prices to shift onto certain patients

182. The PBM Respondents claim to act in the best interests of patients. ESI's Vice President of Pharma Contracting and Strategy says he views his "role [a]s lowering the cost of drugs for patients and for our clients." Optum's former Market President of Health Plans described "patient affordability" as a "top organizational priority" for Optum and a "shared responsibility" between Optum and its clients. For Optum, "as a PBM – and I have said this multiple times before – our guiding principle is around doing what's best first and foremost for members, and secondly for our clients."

183. In practice, however, the PBM Respondents knowingly engage in, and incentivize, conduct that causes certain patients to bear the burden of artificially inflated drug prices.

184. The PBM Respondents are aware that commercial payers typically retain the rebates they receive, and do not pass them on directly at the point of sale to their member patients whose prescriptions generated the rebates. By retaining the rebates, the commercial payers may lower their own overall costs of covering health care benefits. This may in turn partially reduce the amount that employees have to contribute in premiums. But retaining the rebates also shifts the burden of expensive medications to chronically ill diabetics, who must pay out-of-pocket costs such as coinsurance and deductibles based on the inflated insulin list prices associated with higher rebates. As Caremark explained in internal presentations, this exploitative cost-shifting means "more members are exposed to the full cost of drugs via HDHPs and coinsurance plans" and that "[o]ut-of-pocket costs are significant for some members."

185. Typically, insurance spreads risk among the insured population, with those who do not make claims effectively subsidizing those who do. Thus, for health insurance, the healthy generally subsidize the sick or those who need medical treatment. But the strategies that have driven up list prices and rebates on insulin products, and shifted the brunt of that impact to list-

price-sensitive patients, result in the opposite dynamic: diabetics subsidizing the healthy. Indeed, a [redacted] Senior Manager criticized the payers' practice of retaining the entire rebate instead of sharing it with the patients whose prescription earned the rebate: "in the spirit of fairness, I don't see how it's justifiable to charge someone 100% of the cost of the drug (during the deductible), while you receive a rebate on the backend – even if you spread that across everyone's premiums. I can't think of any other insurance industry that works like that[.]"

186. Nonetheless, the PBM Respondents intentionally design and market formularies that enable and exacerbate this cost-shifting by excluding low WAC insulin drugs in favor of high WAC, highly rebated products. As the PBM Respondents well know, low WAC products benefit patients in deductible and coinsurance plans by helping these patients pay less out of pocket at the point of sale. A Caremark financial model vividly illustrates this point with a "cost ranking" of the options for the plan and for the member:

[redacted]

187. As this model demonstrates, excluding a low WAC drug in favor of the high WAC version is the worst option for member patients, but, according to Caremark, potentially a "huge windfall for the payer." Indeed, in the deductible phase, when the member shoulders the full list price of the drug, the payer functionally makes money off the patient's prescription because it pays nothing but collects large rebates.

188. The PBM Respondents widely recognize this phenomenon. In 2020, Caremark calculated that a patient in the deductible phase pays $[redacted] for a monthly prescription of high WAC Novolog pens—equal to [redacted]% of the net cost—while the payer pays nothing and collects $[redacted] in rebates. Even after meeting the deductible, a patient with 20% coinsurance still pays $[redacted]—the entire net cost for Novolog—out-of-pocket. The payer—who is supposed to share in drug costs—collects a rebate equal to the remaining 80% of the list price and ends up with a net cost of $0 for the Novolog prescription. In June 2019, ESI calculated that 33% of patients in HDHPs paid $[redacted] or more for a 30-day supply of insulin, and 13% of patients paid $[redacted] or more.

189. When Novo introduced an insulin affordability program that threatened to disrupt this established dynamic, Caremark expressed concerns. Though the program was designed to make insulin more affordable for many diabetics, Caremark feared it could incentivize patients to

purchase insulin outside of their insurance benefit, resulting in a "loss of value" to Caremark's payer clients, who would "miss a rebate on a claim they paid little for in [the] first place."

190. Optum's financial models show a similar troubling dynamic with Lantus. A [redacted] model created for Optum's Formulary Management Committee identifies a $462 list price for high WAC Lantus vials—[redacted] According to the model, the payer collects a $[redacted] rebate per prescription, transferring the burden of the high list price to patients with deductibles and coinsurance.

191. Not only do the PBM Respondents knowingly design formularies that can shift costs on to patients by preferring high WAC, highly rebated drugs, they also incentivize and encourage commercial payers to select these types of formularies. In 2019, Optum strategized about new formulary options for low WAC versions of drugs and modeled the "client and member financial impact" for "coinsurance versus flat copay." Though the "[low WAC] is [redacted] after rebate and Preferred Status," Optum noted that "clients with coinsurance benefits will see member cost decrease and client cost increase if the client covers [low WAC versions]." Optum posited that for clients on their flagship Premium formulary and with a coinsurance or deductible benefit design, blocking the low WAC versions was "the best financial option." It was also Optum's "default option."

192. The PBM Respondents provide modeling and consulting services to their clients showing how commercial payers can benefit from "rebate maximizing strategies," thereby incentivizing payers to adopt the exploitative cost-shifting strategies. For example, in a 2021 [redacted] outlined that the objectives of its custom client formulary consulting team include assisting with "[r]ebate modeling" to "upsell … rebate opportunities" and "[e]ncourage clients to adopt more aggressive formulary management strategies." To lure a health plan client away from [redacted], [redacted] aimed "to demonstrate to [redacted] (including their CEO) that [it] could develop a formulary for [redacted] that drives rebates at the expense of lowest net cost." In other words, [redacted] wanted to show [redacted] that it could increase total rebates, even if it also meant increasing the overall net spend.

193. The PBM Respondents could mitigate the detrimental effects of exploitative cost-shifting by requiring that rebates be shared with member patients at the point of sale, but instead use their gatekeeper role to incentivize a mode of competition that is detrimental for patients while highly lucrative for themselves. The PBM Respondents are aware that point-of-sale rebates would reduce or eliminate exploitative cost-shifting, and offer voluntary point-of-sale rebate programs that specifically "target[] … the plans with high deductible or co-insurance"—i.e., those benefit designs that most impact patients whose out-of-pocket expenditures are based on list prices. For example, the member's out-of-pocket cost for the hypothetical prescription in paragraph 186 would decline from $[redacted] to $[redacted] with point-of-sale rebates.

194. Point-of-sale rebates, however, lower patient out-of-pocket costs at the expense of the payer. As reflected in paragraph 186, point-of-sale rebates is the "[h]ighest cost" option for the payer.

195. The PBM Respondents do not require their clients to use point-of-sale rebates—in fact, the PBM Respondents' chase-the-rebate strategy disincentivizes payers from adopting them. Further, the PBM Respondents usually withhold specific drug-level rebate and net cost information that could allow payers to understand exactly how the cost-shifting is affecting their patients.

196. Consequently, payers have failed to widely adopt point-of-sale rebating practices. Optum reported "limited uptake of point of sale rebates." Caremark observed that a "majority" of its clients "opt to keep rebates at the plan level." And ESI found that "very few clients" have chosen to implement point-of-sale rebates.

197. Industry studies confirm that commercial payers tend not to pass on rebates at the point of sale and instead retain most of the rebate value. Although these rebates may reduce the plan's overall cost of providing health care benefits, they may have little impact on the patient's premium. For example, according to the 2023 Milliman Medical Index, employers allocate 70% of rebates to reduce the corporate employers' own contributions to premiums, while only dedicating 30% to reducing employees' (patients') premiums. This study observed that none of the rebates were directed towards reducing patients' out-of-pocket drug cost`s.

198. Payers have expressed concerns about the PBM Respondents' lack of transparency about drugs' true net cost, and some have specifically identified the impact on patients with high deductibles or coinsurance as a source of their concern. A 2020 internal Caremark presentation succinctly noted that according to clients and consultants, "Rebates are a black box."

199. The PBM Respondents have typically been dismissive of payers' requests for more information on rebates or the actual net costs for drugs. The PBM Respondents even rebuffed specific inquiries about lower list price options such as the low WAC insulins. For example, in 2021, [redacted] received "quite a few questions" from a large consultant asking whether the exclusion of low WAC Humalog still made sense after a recent list price cut. [redacted] internally told employees that it was "pencils down" and "less about explaining the 'math'"; instead, "the ball is in the court of the payers" to switch to [redacted] formulary, which included lower list priced products such as low WAC Humalog. [redacted] informed the consultant that [redacted] was an option for clients willing to "miss[] out on the rebate," falsely stating "these lower list price drugs like [low WAC Humalog] do not have rebates on them."

200. High out-of-pocket patient costs that result from exploitative cost-shifting can lead to lower drug adherence, higher medical costs, and adverse health outcomes. The PBM Respondents know these impacts are particularly felt with insulin. In a 2019 press release, ESI acknowledged that "1 in 4 people with diabetes who use insulin admitted to cutting back on the use of insulin because of cost." In 2023, ESI's President admitted, "[w]e do know that a lot of patients, unfortunately, don't take their drugs as prescribed because of cost concerns." Similarly, Caremark's website explains "when people can afford their medications, they are more likely to take them." Optum's website recognizes the "proven link between rising member cost share and lower medication adherence," and a UnitedHealth press release states that better adherence

"contribut[es] to better health and reduc[es] total health care costs for clients and the health system overall."

201. By denying clients access to drug net cost information, the Respondents prevent commercial payers from fully appreciating how plan designs that base patient cost-sharing on list price, such as coinsurance and deductibles, can cause this exploitative cost-shifting and harmful health effects. Payers may not realize that their patients pay out-of-pocket amounts that can exceed the entire net cost of highly rebated drugs. Respondents' lack of transparency accompanying their chase-the-rebate strategy precludes the payers' ability to make fully informed decisions and better protect their patients. This lack of transparency allows Respondents to avoid competing directly to win over clients based on the lowest net cost.

H. Even after regulatory changes forced manufacturers to lower some insulin list prices, Respondents sought to preserve the high rebates attributable to high list price insulin products

202. Despite the growing recognition of the harm to certain patients from high insulin list prices, manufacturers maintained the artificially inflated list prices of their high WAC insulins until a regulatory change forced price cuts.

203. The American Rescue Plan of 2021 repealed the Average Manufacturer Price (AMP) Cap. Under Medicaid regulations, manufacturers must pay Medicaid rebates equal to the difference between the current average price of the drug paid by retail pharmacies and wholesalers and the inflation-adjusted list price of the drug (sometimes referred to as the Medicaid inflation penalty). If a drug's list price has increased faster than inflation, the manufacturer has to rebate the difference to Medicaid. The AMP Cap, in place since 2010, had capped the Medicaid rebate at 100% of the drug's average price, even if manufacturers continued to raise list prices. The repeal of the AMP Cap, however, took away this 100% rebate maximum. Thus, beginning in 2024, insulin manufacturers who had dramatically increased list prices (exceeding the inflation rate) would be required to pay a Medicaid rebate in excess of 100% of the drug's price on every unit dispensed in Medicaid.

204. Humalog, Novolog, and Lantus, which had experienced up to sevenfold list price increases, were among the "high risk" products. The insulin manufacturers projected incurring hundreds of millions of dollars in Medicaid liability due to the AMP Cap repeal. Because of the relationship between the AMP Cap and list price, however, manufacturers could mitigate the effect of the AMP Cap repeal by lowering list price.

205. On March 1, 2023, Lilly announced that it would reduce the list price of high WAC Humalog by 70%, as well as set the price of its low WAC Humalog at $25 a vial.

206. On March 14, 2023, Novo announced that it would reduce the list price of high WAC Novolog by 75% and Levemir by 65%. Since Novo cut the list price of high WAC Novolog down to the list price of low WAC Novolog, there is no longer a low WAC/high WAC Novolog distinction.

207. On March 16, 2023, Sanofi announced that it would reduce the list price of high WAC Lantus by 78% and Apidra by 70%. Because the list price of high WAC Lantus was now lower than low WAC Lantus, Sanofi discontinued low WAC Lantus.

208. The Respondents were concerned, as a Vice President at [redacted] described, that these insulin list price cuts would "have a dramatic impact" in the commercial space, because a lower list price product "isn't changing the net, but it would change how you get to that net." In other words, a list price reduction on insulin would also reduce WAC-based rebates and WAC-based fees, as well as the PBM Respondents' and GPO Respondents' profits. The Vice President at [redacted] further explained that list price reductions were a risk to [redacted] because they could "impact rebate guarantees" and a risk to payers if they "rely[] on a certain level of rebates."

209. Optum projected that the WAC decreases on Lilly's rapid-acting insulin products would cost Optum $[redacted] in profits and $[redacted] in rebate dollars—[redacted]% of its total rebates. Optum further expected to lose another [redacted]% of rebates from anticipated list price cuts to long-acting insulins.

210. However, the PBM Respondents were determined not to give up on their high list price, high rebate strategy after the AMP Cap repeal. They realized switching to newer insulin products, which would not be affected by the AMP Cap repeal, [redacted]. For example, in May 2022, Lilly gave a presentation to Optum [redacted]. As a relatively new product that had not undergone dramatic price increases over time, the Humalog U-200 pen was not impacted by the AMP Cap repeal and thus not subject to list price cuts. Before the AMP Cap repeal, the Humalog U-100 and Humalog U-200 pens [redacted]. After Lilly cut the list price of Humalog U-100 from $530.40 to $159.12, it would generate only a $[redacted] rebate per prescription. However, the list price of Humalog U-200 would not change, leaving its $[redacted] rebate per prescription intact.

211. Caremark and ESI considered updating their flagship formularies to preference newer insulins, which had not experienced dramatic list price increases and were therefore unaffected by the AMP Cap repeal. [redacted] discussed replacing [redacted] with [redacted], a newer [redacted] insulin, in the rapid-acting category to "avoid the disruption … on the rebate." In the long-acting category, [redacted] also considered preferring high WAC [redacted], similarly not impacted by the AMP Cap repeal. [redacted] discussed replacing [redacted] with [redacted] or with a new [redacted] biosimilar entrant, which as a "brand new drug" would be priced de novo.

212. In addition, in reaction to "drug manufacturers adjusting prices in response to public policy changes and … the launch of several Humira biosimilars," Caremark created a new "Choice" Formulary for 2024 that specifically favors higher WAC products with higher rebates. Caremark explains that clients "can achieve low net cost with lower list price strategies when appropriate and applicable, or rebated product strategies with our new Choice formularies."

213. Despite the recent list price cuts on some insulin products, the Respondents are determined to continue chasing the high price, highly rebated products for their commercial formularies and their own profit.

VI. RESPONDENTS' CONDUCT RESULTED IN HARM TO CONSUMERS AND COMPETITION

214. Although the Respondents claim to prioritize patient well-being, their actions reveal a pattern of anticompetitive and unfair conduct. Respondents' practices, whether viewed individually or collectively, inflict serious harm on patients whose drug costs are calculated based on the inflated, unrebated list price and potentially on patients more broadly.

215. The Respondents' chase-the-rebate strategy has flipped healthy price competition on its head. Respondents favor high list price, highly rebated drugs over low list price alternatives at a similar net price because the PBMs and GPOs retain more rebates and fees from the higher list price drugs. The Respondents use their size, scale, and position in the prescription drug transaction chain to pressure manufacturers to secure favorable formulary placement by prioritizing the size of the rebates. Respondents push manufacturers to achieve a lower net price *with the highest rebates and fees*. As one of Viatris's head PBM negotiators testified, what matters to the PBMs and their clients is "ultimately *how* they get to the net price" (emphasis added) via "smaller rebates or larger rebates." All else equal, many prefer getting to the net cost through larger rebates.

216. The PBM Respondents' decision to prioritize highly rebated drugs on exclusionary formularies has incentivized insulin manufacturers to raise their list prices well over the rate of inflation to counteract the ever-increasing rebates and fees. A 2020 USC Schaeffer Center study found that for prescription drugs sold from 2016 to 2018, a $1 increase in rebates, on average, was associated with a $1.17 increase in WAC.

217. These artificially inflated list prices create more rebates and fees for Respondents and their clients, but do little to reduce a drug's net cost. From 2012—when Caremark introduced the first exclusionary formulary—to 2017, manufacturers more than doubled the list prices of their primary insulin drugs (Lantus, Novolog, and Humalog). Absent the PBM Respondents' chase-the-rebate strategy, the net prices of insulin products, after rebates, may have been lower.

218. The Respondents' conduct deterred insulin manufacturers from competing by lowering their list prices. Efforts to lower list prices was met with resistance by the Respondents. When manufacturers launched low WAC, low rebate versions of their insulins, the PBM Respondents systematically disadvantaged these products on formularies. Because of Respondents' conduct, many diabetics have been denied access to more affordable lower list price insulin products.

219. In response to PBM Respondents' decisions, manufacturers introduced new insulin products with a high price and a high rebate to secure placement on the PBM Respondents' flagship formularies. For instance, when Viatris launched Semglee, the first insulin biosimilar, with a lower list price than competing drugs, the PBM Respondents excluded it from

their flagship formularies. Viatris secured formulary access for Semglee only after it relaunched the product with a high list price and high rebate. Similarly, Lilly launched Lyumjev with a high list price and a rebate [redacted], because "counterintuitive[ly]," Lilly recognized that "[l]aunching at a list price discount to Humalog may present a barrier to formulary adoption."

220. On the other side of the industry, the PBM Respondents' chase-the-rebate strategy and formulary decisions also encourage commercial payers to prioritize rebates and select formularies that exclude low list price drugs. The Respondents have leveraged the murkiness of prescription drug pricing to their own advantage, by intentionally obscuring drug-level information on rebates and net costs, requiring clients to use the total guaranteed rebate value as a primary financial metric for clients selecting a PBM. The PBM Respondents' focus on enlarging and promoting aggregate rebates helps keep payers "addicted to rebates."

221. The PBM Respondents cause further harm by encouraging and incentivizing plan designs where patients' contributions are based on these inflated list prices, including coinsurance based on the unrebated price and deductibles that require payment of the full list price. As a result, a patient may end up paying more than the drug's entire net cost to the payer. This unfair and exploitative cost-shifting leads to "a windfall" for payers—at the expense of the patient who pays out of pocket based on the inflated list price. But because PBMs control the information on drug-level net costs, commercial payers—particularly smaller or less sophisticated employers—may not even realize the extent that cost-shifting is occurring.

222. Respondents' conduct causes substantial injury to insulin patients whose out-of-pocket costs are based on artificially inflated list price. This injury is not limited to the direct increase in out-of-pocket costs for their medication at the pharmacy counter. When patients cannot afford their insulin, they may skip necessary doses or stop taking the medication altogether. Patients who do not take necessary insulin face a greater risk of hospitalization and of additional medical complications, all of which can substantially increase costs for the patient and the commercial payer. It can also lead to short-term or long-term serious adverse health effects for patients, including death.

223. Patients have little ability to avoid the substantial injury incurred as a result of the PBM Respondents' anticompetitive and unfair practices. Switching plans would be ineffective as many plans are similarly affected by high list prices and high drug costs. Even if it were effective, patients cannot easily switch formularies, because the PBMs and GPOs do not contract directly with patients. Rather, patients must go through an insurer—often their employer—to benefit from the rates negotiated by the PBMs and GPOs. In at least one instance, Optum received a patient complaint from someone who had been switched from ESI to Optum but who "did not choose Optum."

224. The Respondents' actions interfere with the free exercise of consumer decision-making and hinder marketplace self-correction with respect to the exclusion of low WAC insulin products and cost-shifting of high WAC, highly rebated insulin products onto list-price-sensitive patients. Even if patients could effectively switch plans or formularies, the PBM Respondents have made the process so opaque that patients would be operating blindly. Many patients do not know what formulary undergirds their insurance options, so they cannot comparison-shop when

making decisions about their insurance coverage. Moreover, patients often do not realize the extent to which cost-shifting is occurring. Patients generally have no knowledge of the rebates and fees received by the PBM Respondents and payers; payers rarely disclose their existence in plan documents and almost never disclose the rebate and fee amounts.

225. Additionally, many plan documents are confusing, unclear, or elusive about the extent of the patient cost-sharing obligations. Thus, patients in deductible and coinsurance plans may be unaware that their "share" of the drug cost far exceeds the amount implied by their plan documents and may in fact exceed the payer's entire net cost.

226. The substantial injury to consumers is not outweighed by any countervailing benefits to consumers or to competition. The PBM Respondents' systematic practice of excluding a low WAC drug in favor of an identical high WAC alternative from the same manufacturer does not lower net prices for the high WAC drug. While some rebates may serve to lower premiums across patients in a health plan, not all rebates are used to lower patient premiums. Some rebates are retained by the PBMs and GPOs, and the majority of the remaining rebates are retained by the commercial payer. For insulin patients forced to pay coinsurance and deductible payments based on the list price, dramatically higher out-of-pocket costs for insulin are significantly more harmful than the possibility of slightly lower premiums.

227. Further, the increased risk of hospitalization and additional medical complications for patients who skip necessary insulin dosages result in higher expected costs for patients as well as commercial payers. The costs of hospitalization and further adverse health conditions are significantly greater than the cost of regularly taking insulin, and outweigh any potential small decrease in employee health premiums attributable to any rebates shared with the commercial payer.

228. The hodge-podge of affordability programs offered by PBM Respondents do not provide an adequate solution for insulin patients. Since the focus on PBM practices by Congress and other entities, the PBM Respondents have each begun offering voluntary programs designed to cap patient out-of-pocket costs, but the program designs impose costs on payers, which, in the words of [redacted], "[c]lients don't like." As a result, few commercial payers have adopted these programs, and their benefits are largely illusory. To illustrate, ESI's "Patient Assurance Program" and Optum's "Critical Drug Affordability" program both purport to cap a patient's out-of-pocket costs—at $25 and $35, respectively—but each program conditions participation on the plan capping a patient's copay and compensating for the cost. Caremark's "RxZero" program purports to lower a patient's out-of-pocket costs to nothing, except it requires plans to absorb the patient's cost of drugs in the program.

229. In 2023, Optum found that of the five drug categories in its Critical Drug Affordability offering, insulin accounted for [redacted] of the claims with greater than [redacted] patient out-of-pocket costs. In its 2023 Employer Health Benefits annual survey, KFF (f/k/a Kaiser Family Foundation) estimated that, despite these programs, only 45% of all workers with employer-sponsored health insurance had reduced or no cost-sharing for chronic condition maintenance drugs, such as insulin for diabetes.

230. Other PBM programs that claim to benefit patients are similarly illusory, as the PBM Respondents are focused on retaining payer clients. For instance, the PBM Respondents claim to encourage payers to provide point-of-sale rebates to their patients but make doing so unattractive to payers, including by sometimes charging additional fees and by obscuring the details of the cost-shifting onto list-price-sensitive patients for highly rebated products. And PBM Respondents know that a voluntary point-of-sale rebate program is unlikely to be adopted by the payer because point-of-sale rebates reduce the rebates kept by the payer.

231. There are no valid justifications for the Respondents' prioritizing of rebates over lower net prices when negotiating to secure preferred formulary placement. Offering a product with a substantially similar net price but with much higher fees and higher out-of-pocket costs to patients is not offering a better product. The chase-the-rebate strategy has resulted in reduced options for patients who can more readily afford the low WAC options that are excluded from their formularies and incentivizes manufacturers to raise list prices.

232. Although PBM Respondents and GPO Respondents collect more money from higher list price products, they do so simply because the rebates and fees are based on a percentage of list price—not because higher list price products can be administered more efficiently than lower list price products. The PBM Respondents and GPO Respondents provide no additional services to justify the higher payout on higher list price drugs from the assortment of WAC-based fees the PBM Respondents and GPO Respondents extract from manufacturers. As an Optum executive wrote, the "% basis is key" for these fees, rather than a flat fee. Similarly, ESI's Vice President of Pharma Contracting and Strategy had no justification for keeping the [redacted] fee as a percentage of WAC other than "that's how it's always been."

233. There is no justification for the PBM Respondents' using rebate value instead of net prices to attract clients. Despite the illusion of choice between different formulary options, the use of rebate value as a financial metric, coupled with the payers' incomplete information on cost, drives payers to each PBM Respondent's respective high WAC, high rebate flagship formulary. Nor does the additional rebate value on a high WAC product over a low WAC alternative with a substantially similar net price result in more efficient drug usage. For instance, when a formulary prefers high WAC Humalog over low WAC Humalog, the patient receives the exact same life-saving medication, just at a higher price.

VII. RESPONDENTS' CONDUCT IS ONGOING OR LIKELY TO RECUR

A. The list prices of some insulin products remain artificially high

234. Despite recent list price decreases on some insulin products, the list prices of other insulin products remain high. In particular, newer insulins have entered the market at, and will likely remain at, artificially inflated prices due to the Respondents' chase-the-rebate strategy.

235. Several insulin products in the long-acting category remain at artificially high prices. When Lilly launched its long-acting insulin Basaglar in 2017, Lilly specifically priced it at a "modest discount" off the list price of Sanofi's Lantus, which itself had been artificially

inflated from many years of price increases and high rebates. Lilly determined that a 10-15% discount off the Lantus price "str[uck] the optimal … balance between … meeting market expectations for list price with a modest cost reduction for some patients exposed to rising out of pocket costs" and gaining formulary access. Lilly decided against a greater discount, because "[a]t a significantly lower list price relative to Lantus, Basaglar's formulary access will likely be reduced due to PBM / Plans preference for rebate stream."

236. Despite Lantus's subsequent list price decrease, Lilly continues to sell Basaglar at an artificially inflated price.

237. When Sanofi launched its long-acting insulin Toujeo in 2015, Sanofi specifically set the list price at parity on a per unit basis with Lantus, which had an artificially inflated list price from many years of price increases and high rebates. Despite Lantus's subsequent list price decrease, Sanofi continues to sell Toujeo at an artificially inflated price.

238. When Novo launched its long-acting insulin Tresiba in 2016, Novo set the list price at a 10% premium on a per unit basis over the list price of its other long-acting insulin product, Levemir, which had been artificially inflated from many years of price increases and high rebates. Despite Levemir's subsequent list price decrease, Novo continues to sell high WAC Tresiba at an artificially inflated list price.

239. The same dynamic has occurred in the rapid-acting insulin class. When Novo launched its rapid-acting insulin Fiasp in 2017, Novo set Fiasp's list price at parity with its other rapid-acting insulin product, Novolog, which had an artificially inflated list price from many years of price increases and high rebates. Despite Novolog's subsequent list price decrease, Novo continues to sell Fiasp at an artificially inflated list price.

240. When Lilly launched its Humalog U-200 pen in 2015, Lilly set the list price at parity on a per unit basis with Humalog U-100, which had an artificially inflated list price from many years of price increases and high rebates. Despite Humalog U-100's subsequent list price decrease, Lilly continues to sell Humalog U-200 at an artificially inflated list price.

241. When Lilly launched its rapid-acting insulin Lyumjev in 2020, Lilly set the list price at parity with its other rapid-acting insulin product, Humalog, which had an artificially inflated list price from many years of price increases and high rebates. Despite Humalog U-100's subsequent list price decrease, Lilly continues to sell Lyumjev at an artificially inflated list price.

242. While the repeal of the AMP Cap thwarted the manufacturers' price inflation and by extension the Respondents' chase-the-rebate strategy on some older insulin products, current and future insulin biosimilar entrants are not affected by the repeal and can launch with high list prices and high rebates, which Novo characterized as posing "a serious threat" to its ability to compete for formulary coverage. Due to how insulin products vie for favorable formulary coverage, Novo predicted that new biosimilars staying at a high WAC was the "likely scenario." And Viatris continues to offer a higher WAC version of Semglee, which was not affected by the AMP Cap repeal.

243. The artificially inflated insulin list prices, with higher rebates and higher WAC-based fees, continue to benefit PBM Respondents and GPO Respondents, at the expense of list-price-sensitive diabetics.

B. The PBM Respondents continue to exclude low WAC insulin products in favor of their high WAC, highly rebated counterparts

244. The PBM Respondents continue to prefer some high list price insulin products that generate high rebates and fees on their flagship formularies, while excluding low WAC alternatives.

245. Caremark's 2024 flagship Standard Control Formulary prefers high WAC Tresiba and excludes low WAC Tresiba. Caremark's newly created 2024 Advanced Control Choice Formulary specifically focuses on high rebate products. It prefers high WAC Tresiba and excludes low WAC Tresiba, and prefers Fiasp and excludes the now lower-priced Novolog.

246. ESI's 2024 flagship National Preferred Formulary prefers high WAC Tresiba and high WAC Semglee, excluding the low WAC version of each product.

247. Optum's 2023 flagship Premium Formulary preferred high WAC versions of Humalog and Lantus and excluded their respective low WAC versions. While under regulatory scrutiny from the FTC's investigation, Optum changed its Premium Formulary such that its 2024 formulary now covers the low WAC versions of insulin products on the same formulary tier as the respective high WAC versions.

248. The PBM Respondents have changed their formularies at least every year, sometimes in the middle of the year, and all three PBM Respondents have the opportunity and the incentive to prefer high WAC insulins over their low WAC alternatives in the future.

C. The PBM Respondents exclude low WAC versions of other drugs from formularies

249. In addition to insulin, the PBM Respondents exclude or disadvantage low WAC versions of other drugs in favor of the high WAC versions. For example, in January 2019, Gilead Science (through a subsidiary) launched low WAC versions of its Hepatitis C medications Harvoni and Epclusa at significant discounts to the high WAC versions. Although brand companies sometimes offer low WAC versions of their drugs in response to competition from generic drugs, Gilead launched these low WAC versions unprompted by that prospect: Harvoni and Epclusa were years away from the threat of generic entry. The PBM Respondents all preferred the high WAC versions of both drugs on their 2024 flagship formularies and excluded the low WAC alternatives.

250. The PBMs' practice of excluding the low WAC products in favor of high WAC versions is likely to continue for new products. For example, in January 2023, Amgen simultaneously launched high WAC and low WAC versions of Amjevita, pricing the two drugs respectively at 5% and 55% off Humira's list price. In July 2023, Boehringer Ingelheim launched high WAC Cyltezo and, in October 2023, a low WAC version, pricing them respectively at 5% and 81% off Humira's list price. In January 2024, Optum preferred the high WAC versions of

Cyltezo and Amjevita and excluded their low WAC alternatives, and ESI preferred the high WAC version of Cyltezo and excluded the low WAC alternative, on their flagship formularies.

251. The PBM Respondents retain the same incentives and opportunities to use low WAC formulary exclusion practices with future products. The PBM Respondents' continued use of this strategy is likely to cause substantial injury to consumers whose out-of-pocket costs are based on the list prices of drugs.

D. The PBM Respondents have the opportunity and incentive to continue causing the exploitative cost-shifting onto certain consumers

252. The PBM Respondents and GPO Respondents benefit from the high rebates and high fees associated with the high list prices of pharmaceutical products. The PBM Respondents are likely to continue preferring high price, highly rebated products on their flagship formularies, and incentivizing commercial payers to shift the cost of high list price drugs onto certain patients.

253. The list prices—and rebates—associated with product categories beyond just insulin have dramatically increased in recent years. For example, Amgen increased the list price of Enbrel, a high list price and highly rebated drug used to treat inflammatory conditions, 457% between 2002 and 2020. Additionally, the list price of Lilly's immunomodulator Taltz, a high list price and highly rebated monoclonal antibody, increased 52.9% from 2016 to 2022.

254. The PBM Respondents' systematic preferencing of high price, highly rebated products incentivizes drug manufactures to compete using high list prices and high rebates and fees. It also leads to commercial payers adopting formularies preferring products with high list prices and high rebates and fees, while engaging in exploitative cost-shifting that forces list-price-sensitive patients to bear the burden of artificially inflated list prices. Respondents' continued conduct with respect to exploitative cost-shifting is likely to cause substantial injury to consumers whose out-of-pocket costs are based on the list prices of drugs.

VIII. VIOLATIONS OF THE FTC ACT

COUNT I – Unfairly Competing by Rebate Preferencing

255. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

256. The Respondents systematically prefer high list price insulin products, with high rebates and fees, over similar low list price products, with low rebates and fees, on formularies to inflate the perceived value of their commercial drug formularies and offer higher rebate guarantees. This systematic preferencing of products with a high rebate and fee value is a method of competition, not an inherent condition of the PBM or drug industry.

257. The Respondents' favoring of high list price insulin products, with high rebates and fees, while disadvantaging or excluding similar versions with a lower list price and lower rebates and fees and obscuring actual net cost, is unfair because it goes beyond competition on the merits.

258. The Respondents' conduct is coercive, exploitative, and restrictive because it (1) induces rival manufacturers to compete for formulary placement by prioritizing rebates over lower net prices; (2) exploits and abuses vulnerable patient populations by denying them access to more affordable medications; and (3) restricts commercial payers' access to information on aggregated rebate numbers rather than drugs' actual net cost.

259. The Respondents' conduct tends to negatively affect competitive conditions because (1) drug manufacturers are incentivized to compete for formulary placement by inflating list prices to counteract high rebates and fees and are deterred from lowering the artificially inflated list prices to compete with other products; (2) consumers are forced to purchase high list price products, and to pay higher out-of-pocket costs based on the artificially inflated list prices; and (3) price competition between Respondents is often limited to rebates, causing commercial payers to make decisions primarily based on the size of rebates and rebate guarantees.

260. There is no valid or cognizable justification for the Respondents' unfair method of competition.

261. The Respondents' conduct constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II – Unfair Practice of Formulary Exclusion of Low WAC Insulin Products

262. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

263. Through their development of commercial formularies, the PBM Respondents have a significant role in controlling consumers' affordable access to prescription medications. The PBM Respondents' systematic exclusion of low WAC insulin products from their most-utilized commercial formularies and custom client formularies, in favor of identical high WAC insulin products, is an unfair act or practice.

264. The PBM Respondents cause and are likely to continue to cause substantial injury to insulin consumers whose out-of-pocket costs are based on list prices. Respondents' practice limits consumers' choice, forcing them to purchase the high WAC versions of insulin products instead of the identical low WAC versions. As a result, some patients pay more for insulin than they would if the low WAC version were available on formulary. Higher prices also tend to lead to decreased adherence and adverse health outcomes for patients.

265. Insulin consumers cannot reasonably avoid the harm caused by the PBM Respondents' unfair formulary exclusion practices. Patients cannot choose to discontinue purchasing insulin and cannot reasonably switch insulin products or health plans to avoid the harm.

266. The harm to insulin consumers whose out-of-pocket costs are based on list prices is not outweighed by countervailing benefits to consumers or competition.

267. The PBM Respondents' systematic exclusion of low WAC insulin products from their most utilized commercial formularies and custom formularies constitutes an unfair act or practice in violation of Section 5(a), (n) of the FTC Act, 15 U.S.C. § 45(a), (n).

COUNT III – Unfair Practice of Exploitative Cost-Shifting

268. The allegations of paragraphs 1-254 above are incorporated by reference as though fully set forth herein.

269. The PBM Respondents unfairly create and implement the system of manufacturer rebates, construct exclusionary formularies that preference high-list priced and highly rebated insulin products, and assist in other aspects of plan design—the combined effect of which shifts the cost of high insulin prices of drugs onto certain insulin patients.

270. The PBM Respondents are aware that their rebate and formulary practices result in those patients whose out-of-pockets costs are based on the unrebated list price—rather than the significantly lower, rebated net price—paying more out-of-pocket for their insulin drugs, sometimes even more than the entire net cost of the drug.

271. The PBM Respondents' exploitative cost-shifting practices cause and are likely to continue to cause substantial injury to consumers by increasing the price of insulin products to certain patients. Higher insulin prices can also lead to decreased adherence and adverse health outcomes for patients.

272. Insulin consumers cannot reasonably avoid the harm caused by the PBM Respondents' unfair cost-shifting practices. Patients cannot choose to discontinue purchasing insulin, cannot easily switch insulin products or health plans, cannot access confidential rebates to compare the cost-sharing provisions between health plans, and cannot negotiate plans' cost-sharing terms.

273. The harm to insulin consumers whose out-of-pocket costs are based on drugs' list prices is not outweighed by countervailing benefits to consumers or competition.

274. The PBM Respondents' involvement in cost-shifting of the high insulin list prices of drugs onto certain patients constitutes an unfair act or practice in violation of Section 5(a), (n) of the FTC Act, 15 U.S.C. § 45(a), (n).

NOTICE

Notice is hereby given to the Respondents that the twenty-seventh day of August, 2025, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time provided above shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the last answering Respondent files its answer). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Respondents' conduct violates Section 5 of the Federal Trade Commission Act, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Prohibit Respondents from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary.

2. Prohibit Respondents from accepting compensation based on a drug's list price or a related benchmark.

3. Prohibit Respondents from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates.

4. Order any other relief appropriate to correct or remedy the Respondents' violations.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this twentieth day of September, 2024.

By the Commission, Commissioner Holyoak and Commissioner Ferguson recused.

SEAL:

April J. Tabor
Secretary

PUBLIC

CERTIFICATE OF SERVICE

I hereby certify that on November 26, 2024, I caused the foregoing document to be filed electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor
Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Room H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

Secretary of the Commission
Clerk of the Court

The Honorable D. Michael Chappell
Chief Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Room H-110
Washington, DC 20580
OALJ@ftc.gov

Administrative Law Judge

I also certify that I caused the foregoing document to be served via email to:

Enu Mainigi
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
emainigi@wc.com

Craig D. Singer
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
csinger@wc.com

Steven M. Pyser
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
spyser@wc.com

Mike Cowie
DECHERT LLP
1900 K Street NW
Washington, DC 20006
mike.cowie@dechert.com

Rani A. Habash

Daniel J. Howley
RULE GARZA HOWLEY
901 7th Street NW, Suite 600
Washington, DC 20006
howley@rulegarza.com

Charles F. (Rick) Rule
RULE GARZA HOWLEY
901 7th Street NW, Suite 600
Washington, DC 20006
rule@rulegarza.com

Margot Campbell
RULE GARZA HOWLEY
901 7th Street NW, Suite 600
Washington, DC 20006
campbell@rulegarza.com

Justin T. Heipp
RULE GARZA HOWLEY
901 7th Street NW, Suite 600
Washington, DC 20006
heipp@rulegarza.com

Jennifer Milici
WILMERHALE
2100 Penn. Ave. NW
Washington, DC 20037

Samuel Liversidge
GIBSON, DUNN & CRUTCHER LLP
333 South Grand Avenue
Los Angeles, CA 90071
SLiversidge@gibsodunn.com

Sophia A. Hansell
GIBSON, DUNN & CRUTCHER LLP
1700 M Street NW
Washington, DC 20036
shansell@gibsondunn.com

Michael J. Perry
GIBSON, DUNN & CRUTCHER LLP
1700 M Street NW
Washington, DC 20036
mjperry@gibsondunn.com

Matthew C. Parrott
GIBSON, DUNN & CRUTCHER LLP
1700 M Street NW
Washington, DC 20036
mparrott@gibsondunn.com

DECHERT LLP
1900 K Street NW
Washington, DC 20006
rani.habash@dechert.com

Counsel for Respondents Caremark Rx LLC; Zinc Health Services, LLC

jennifer.milici@wilmerhale.com

Perry A. Lange
WILMERHALE
2100 Penn. Ave. NW
Washington, DC 20037
perry.lange@wilmerhale.com

John W. O'Toole
WILMERHALE
2100 Penn. Ave. NW
Washington, DC 20037
john.otoole@wilmerhale.com

Counsel for Respondents Express Scripts, Inc.; Evernorth Health, Inc.; Medco Health Services, Inc.; Ascent Health Services LLC

Counsel for Respondents OptumRx, Inc.; OptumRx Holdings, LLC; Emisar Pharma Services LLC

/s/ Rebecca L. Egeland
Rebecca L. Egeland
Federal Trade Commission
Bureau of Competition
600 Pennsylvania Avenue, NW
Washington, DC 20580
(202) 326-2290
regeland@ftc.gov

Counsel Supporting the Complaint

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Health Plans Predict: Implementing Upper Payment Limits May Alter Formularies And Benefit Design But Won't Reduce Patient Costs

This report is based on research conducted by Avalere under contract to the Partnership to Fight Chronic Disease.

Overview of PDABs and UPLs

State policymakers are touting Prescription Drug Affordability Boards (PDABs) and upper payment limits (UPLs) as ways to control state spending and lower patient costs on prescription drugs in recent years. As of February 2024, eight states (Colorado, Maine, Maryland, Minnesota, New Hampshire, New Jersey, Oregon, and Washington) had enacted PDAB laws, with four states (Colorado, Maryland, Minnesota, and Washington) also authorizing UPLs. UPLs impose a limit on how much purchasers (such as health plans, pharmacy benefit managers (PBMs), or public payors) within a state may pay or reimburse for drugs found to be "unaffordable" after review by the PDAB. Products may be identified for review based on meeting certain pricing thresholds.

One of the aforementioned states, Colorado is in the process of conducting affordability reviews with Colorado's PDAB completing reviews of three drugs. Trikafta, for cystic fibrosis, and Genvoya, for HIV, were found to be "affordable" for patients in Colorado, while Enbrel, used for rheumatoid arthritis and other autoimmune conditions was found "unaffordable" and the PDAB initiated the UPL setting process.

Little is known about how states will operationalize UPLs if established. Because the laws limit "payment" as opposed to drug prices, they raise several challenges and unanswered questions which may lead to unanticipated impacts on plan benefit design and patient out-of-pocket (OOP) costs across health insurance markets. State lawmakers supporting PDABs and UPLs intend to reduce what patients pay for prescription drugs but may see the opposite happen if new access restrictions, product exclusions, or shortages appear in markets with UPLs in place.

Research Background

To better understand how payers are viewing PDABs and UPLs, including challenges to implementation and anticipated changes (e.g., plan benefit design), PFCD commissioned primary research by Avalere to gather national and regional health plan perspectives. In December 2023 and January 2024, Avalere conducted a series of double-blinded interviews with health plan representatives who (1) had current or recent experience in prescription drug benefit design, and (2) were able to speak to an organization's perception of UPLs and preparedness for implementation.

A consistent script of interview questions focused on the implementation and implications of UPLs, including payers' view of drug coverage and access changes that may result in the commercial insurance market and Medicaid.

Interview Findings

Payer Reaction to UPLs

"While well intentioned, state lawmakers did not place a ton of thought into the implementation of a UPL and how this will impact the supply chain." – CEO of Western Region, National Plan

"Lower prices may not be preferred overall since UPLs fail to consider the entirety of the drug supply chain that may be altered by a UPL, such as PBMs and distributors. Payers are not going to be the ones to make up the difference." – Chief Medical Officer of Northeast Region, National Plan

Payers were first asked what preparation they were taking in advance of UPL implementation in Colorado. All interviewees disclosed that their organizations have not spent much time contemplating potential downstream issues with PDABs and subsequent UPL implementation.

Shifts in Plan Benefit Design

"Utilization management will undoubtedly go up with UPLs, whether for the drugs subjected to them or for competition. This is going to depend on how low or high the UPLs are set at and what changes this brings to classes and volume." – Vice President of Strategic Business Operations, Regional Plan

Plan benefit designs heavily influence how patients access treatments for their health and the related costs they must pay. Payers indicated that formulary constraints are likely within a therapeutic class that has a product with a UPL. All payers interviewed noted that UPL drugs and competitors in the therapeutic class are likely to see increased utilization management (e.g., step therapy, prior authorization) should the UPL restructure new benefit designs.

Additionally, five of six payers cited in their interviews that UPL implementation would result in changes to formulary designs, such as movement up or down tiers for UPL drugs. These interviewees stated that there would likely not be significant benefit design changes, such as decreases to patient deductibles or maximum out of pocket (MOOP) limits that apply to all covered drugs. The payers indicated that plan responses would depend on where the UPL is set as well as how competitive the therapeutic class is.

Another five of the six payers interviewed noted that their respective plans were unlikely to make mid-year formulary shifts or coverage replacements mid-year; however, the same majority of payers stated that these coverage shifts would take place between six months and one year after UPL implementation.

Impact to Patient Access and Costs

"Payers will not pass their savings (if any) onto individuals. It's not realistic and somebody will need to make up the differences." –Executive Director, Health Plan Services

"UPLs will alter how formularies are determined by plans which will likely mean changes to patient copays and coinsurance amounts." – Vice President of Business Operations, Regional Plan

"*There is a good chance beneficiaries on these (UPL) drugs also have hospitalization or physician expenses that would add to OOP max, UPLs won't change that."* – CEO of Western Region, National Plan

PDABs and UPLs are being implemented by states in part with the intention to lower patient OOP costs, however most payers interviewed did not perceive this to be likely. When asked for their opinion on the impact of UPLs on patient out of pocket costs:

- Most payers (five of six) did not anticipate that UPL-related savings would be passed on to patients in the form of lower premiums, deductibles, or cost sharing.
    - Three payers noted that while patients could anticipate shifts to formulary tiering, overall changes to plan benefit design, such as premiums, deductibles, and MOOP amounts, were unlikely to decrease.
    - Two payers noted that any patients on prescription drugs subject to a UPL would likely still meet their plan's maximum out-of-pocket limits, so they would not see their overall costs reduced.

Payers did note that if a manufacturer were to stop providing drugs in a state due to the financial constraints of a UPL, the majority of payers interviewed noted that patients could cross state lines for a prescription; however, not everyone has this ability, and this could alter patient access to products.

Provider Access Issues and Site of Care

"Anything that impacts product reimbursement over time will impact patient access. Providers will not want to take financial risks regarding inadequate reimbursement under UPL." – Executive Director of Health Plan Services, National Plan

Payers expressed that UPLs may place unintended financial pressures on provider administered UPL drugs. Most payers indicated that they base commercial provider reimbursement on Average Sales Price (ASP), and if a drug were to shift to a UPL, providers may experience challenges acquiring the product at a price consistent with the UPL. Accordingly, providers may be unwilling to accept the additional financial burden and risk of inadequate reimbursement, which will limit access to medicines for those providers and their patients. One payer explained

that if a UPL is set lower than a selected drug's ASP and a provider practices buy-and-bill acquisition processes, then providers could experience financial challenges with drug acquisition from UPLs.

Conclusion

This research offers early indication that some payers in Colorado and other states with PDABs and UPLs have not prepared extensively for implementation of UPLs. States implementing and considering PDABs with UPL authority should consider potential impacts on plan benefit design and other downstream consequences for patient cost sharing, provider reimbursement, and access to care. Most importantly, states should take note that payers believe UPLs are likely to alter how patients in these states will be able to access their prescriptions and they do not believe UPLs are likely to reduce patients' costs.

Policy Changes Needed

UPLs are being pursued under the banner of promoting patient access and reducing patient costs, however, this primary research highlights that the initial processes for implementing UPLs is flawed and may decrease patient access and affordability over time. PFCD supports actions that improve access and affordability and accordingly opposes efforts to adopt PDABs. To that end, we urge policymakers to understand that:

- UPLs do not reduce costs for patients and could create additional barriers to medication access for drugs subject to UPLs and others in the same drug class.
- UPLs rely on discriminatory determinations of value that include the quality-adjusted life year (QALY), the equal value life year gained (evLYG), and other metrics that undervalue benefits to older adults, people living with disabilities, and people with chronic conditions by discounting benefits outside the health care system and the value patients place on those benefits.
- Redirecting policy efforts to the barriers to care that matter to patients will yield greater benefits: banning non-medical switching; streamlining prior authorization requirements; banning copay accumulator and maximizer and alternative funding programs are areas deserving of greater legislative and regulatory efforts.

For states implementing PDABs with UPL authority, state policymakers and regulators should:

- Consider and pursue other affordability measures with a greater impact on reducing patient costs, such as copay caps, copay accumulator and maximizer bans, and requiring rebate pass-throughs to consumers at the pharmacy counter.
- Prioritize patient engagement and testimony in UPL rulemaking and decisions, including requiring patient and care partner participation as voting members of PDABs.
- Work more closely with stakeholders that a UPL could affect, including pharmacies and providers who purchase and/or administer medications.
- Define value from a patient-focused societal perspective and include benefits relating to caregiving need, improved health status and well-being, enhanced productivity, better quality of life, increased life expectancy, and reductions in disability as well as changes in health care utilization in the short and longer term.

- Reject value measures that discriminate against people living with disabilities or chronic conditions or advanced age, including the QALY and similar measures.
- Focus affordability on patient affordability, including the availability of patient assistance programs. Payer costs should be net spending, inclusive of manufacturer rebates and discounts, instead of gross spending or list price.

As the UPL setting process is moved forward by many states, PDABs should consider the risks to patient access that UPLs could bring and work more closely with stakeholders to refine both goals and intended outcomes.

Constituent Group Engagement

As previously described, the board contracted with Myers and Stauffer to conduct constituent outreach on the board's behalf. The purpose of this outreach was to capture the perspectives of constituents throughout the pharmaceutical supply chain regarding a UPL in general, rather than targeting discussions around a particular model or approach. Seven constituent groups were identified for targeted outreach: 340B Covered Entities (CEs), carriers, hospitals, patient advocacy groups, pharmaceutical manufacturers, PBMs, and retail pharmacies. Myers and Stauffer then developed and administered an informal survey and facilitated two, one-hour virtual focus group meetings per constituent group, to identify perceptions regarding strengths, weaknesses, opportunities, and threats associated with a UPL methodology. The surveys included a series of questions and multiple response questions, as well as free-text questions to allow recipients to provide more detailed information on approaches, recommendations, or concerns. Focus group questions were organized around topics including the impact of drug affordability impact of a UPL, UPL methodologies, desired state of drug affordability, and recommendations or other strategies. The full report can be found at https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Observations

Responses to the surveys and engagement with the focus groups found that all groups were concerned about drug affordability and the impact of drug affordability on their organizations, patients and/or members. While the constituent group discussions were not intended to assess affordability reviews or the previous work of the board, participants frequently mentioned the definition of affordability and a concern about how it should be defined. Participants also struggled to assess the impact of a UPL, indicating a need to better understand how it would be developed and implemented, and reflecting a lack of experience to draw from in other states.

Key concerns centered on revenue impact, impact to patient access, and system complexity. Regarding revenue impact, pharmacies were extremely concerned that a UPL will negatively impact already thin margins and that the savings from a UPL will come from reductions in reimbursement to providers rather than being borne throughout the supply chain. 340B covered entities, particularly Federally Qualified Health Centers (FQHCs), focused on their use of 340B savings and revenue to provide additional uncompensated services and copayment support to patients, and expressed concern that a UPL would require them to reduce or eliminate services. Patient impact concerns centered on potential manufacturer withdrawal from a market in response to a UPL, an unintended impact if manufacturers chose to reduce or eliminate patient assistance programs, and responses by PBMs or payers to shift utilization into non-UPL drugs through formulary design and benefit design changes that may lead to placing UPL drugs in a non-covered or higher copayment tier. System complexity was cited as a concern, especially related to implementation, contracting and necessary system enhancements. Participants also had questions around how the UPL was intended to be implemented for patients, payers, or providers who live or conduct business in states outside of Oregon, especially bordering states, or for costly therapies that may be administered at regional centers of excellence outside of Oregon.

Recommendations

The most frequently cited recommendations are noted in Table 1. It should be noted that there are additional recommendations that could be considered from the original Constituent Group Engagement Report presented to the board in August, 2024.[41]

[41] Draft Constituent Group Engagement Report. https://dfr.oregon.gov/pdab/Documents/OR-PDAB-UPL-Report-Draft-20240821.pdf.

Table 1: Constituent Group Recommendations

Constituent Group Recommendations								
Recommendation	**340B CEs**	**Carriers**	**Hospitals**	**Patient Advocacy Groups**	**Pharmaceutical Manufacturers**	**PBMs**	**Retail Pharmacies (Ind./GPO/PSAO)**	**Retail Pharmacies (Grocery/Chain/ Wholesalers)**
Focus UPLs on drug classes, rather than individual drugs, especially those drugs without lower cost alternatives and those representing Oregonians highest percentage of spending		✓	✓	✓			✓	
Incorporate lessons learned from other state PDABs into the board's affordability reviews and UPL planning processes		✓		✓			✓	
Ensure that the UPL is enforced across the entire supply chain (i.e., that no one pays more than the UPL), that there is transparency to the process, and that savings pass-through to patients in the form of reduced premiums or reduced drug costs is demonstrated	✓	✓		✓		✓		
Ensure transparency in affordability reviews and how UPLs are established (i.e., how the board arrives at its conclusions); establish a periodic review process for UPLs to adapt to market changes, innovation, and economic conditions, ensuring they remain relevant and effective	✓	✓		✓		✓		
Pursue comprehensive PBM reform (i.e., prohibit clawbacks, spread pricing, mandatory mail order; permit pharmacy choice, including specialty pharmacies, and a shared and common definition of specialty drugs)	✓	✓	✓	✓	✓		✓	
Eliminate the use of rebates in the various levels of the supply chain	✓		✓				✓	
Ensure that pharmacies are paid no less than the UPL and separate the dispensing fee from the cost of the drug; dispensing fees should be adequate to cover the enhanced clinical services required for specialty drugs and the cost of drugs and services in pharmacies in general	✓		✓	✓	✓		✓	

Plan for Establishing an Oregon-Specific UPL

The board has engaged in an extensive and intensive process, detailed here and in other public documents, to assess the feasibility of establishing an upper payment limit in Oregon as a method for improving drug affordability. Our discussions establish the complexity of the concept, the implementation, and regulatory considerations such an approach would warrant. As has been noted in public meetings, the establishment of a UPL would require flexibility of approach and adequate, likely lengthy, time to develop and test models, assess impacts, and implement through the rulemaking process (including public comment).

Prior to establishing UPLs, the board must first determine if a drug is unaffordable through the affordability review process. The board's enabling legislation requires the board to identify nine drugs and at least one insulin product under ORS 646A.694 that may create affordability challenges for the healthcare system or high out-of-pocket costs for patients in the state.

With UPL authority, if a drug is deemed unaffordable, the board would then consider setting a UPL on the drug or its therapeutic class. There are a variety of approaches that the board may choose to leverage; it may choose one or several of the methodologies for setting a UPL or it my subsequently identify other, unique approaches that were not contemplated at the time of this report. Upon determining a UPL approach or approaches, the board would then move through the rulemaking and public comment process to establish the upper payment limit. While the affordability review process is an important step on the path to setting UPLs, not all drugs reviewed will be considered for a UPL.

UPL Potential Methodologies

There are several approaches states may leverage when setting a UPL. The board considered a number of high-level approaches (general concepts) to setting a UPL, as well as associated methodology and implementation considerations (see Table 2 below). These are intended as a framework to drive discussion about what an Oregon-specific UPL approach might look like. Ultimately, any approach to setting a product-specific UPL could involve one or more approaches, be influenced by the type of drug (e.g., specialty, physician or self-administered, etc.), market factors (e.g., level of rebates or therapeutic competition), and other strategies that have not yet been identified. As such, this should not be considered an exhaustive list of options. Alternatively, the board may determine that a particular option presented below is no longer a viable option for consideration. There is a consensus that no single methodology will work for all drug products considered for a UPL, and that multiple approaches may be considered. The board will select the best option(s) for each drug or therapeutic class.

In addition to the potential specific approach(es) to developing a UPL, there are multiple models for implementing a UPL. A rebate model implemented at the state level would offer an opportunity for the State to leverage its buying power by consolidating utilization at the state level, including utilization for uninsured and underinsured patients that are not typically included in negotiations. This model offers the advantage of increased negotiating power, but is often hampered by opacity in the process and lack of transparency in the use of savings. Additionally, leveraging a rebate model similar to that used in the Medicare Fair Price (MFP) may not be a viable approach because it would likely place administrative burdens on providers and result in payment delays that could further threaten providers' financial viability, especially for retail pharmacies. An up-front, net cost approach would likely offer the benefits of a transparent upper cost limit throughout the supply chain and reduced administrative burden,

especially on downstream members of the supply chain such as carriers and providers. It may also provide an added benefit of visibility to patients, especially those who are uninsured or who have high coinsurance obligations. These operational level details will be determined through the rulemaking and public comment process.

Table 2: UPL Approaches (General Concepts)

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
Net Cost	Establish UPL at or near the existing average net price of the drug after any rebates or discounts negotiated between the drug manufacturer and PBM. UPL then becomes the benchmark from which patient out-of-pocket costs are calculated by payers. This is particularly useful for highly rebated drugs which are generally placed on high formulary cost share tier. Consider leveraging publicly available average sales price (ASP) data for provider administered drugs to ensure that patient out-of-pocket costs are based on reimbursement rates that reflect net price.	• Option could include use of rebates negotiated at a state-wide level • Highest potential for drugs with significant rebate opportunities • Concerns include administrative complexity and concerns around a lack of transparency • Desire to ensure distribution throughout the supply chain • Requires assurances that providers are kept whole
Reference Pricing to Existing Benchmarks	Establish UPL based on prices already negotiated or set by other entities. Reduces the administrative burden of conducting independent UPL analyses, provided that the external prices are useful comparators. Most common external references include the price of drugs negotiated by other countries, Medicare MFP, and/or price negotiated by the Department of Veterans Affairs. NASHP has published a model bill leveraging MFP as the ceiling for all purchases of a referenced drug and reimbursements for a claim for a referenced drug when the drug is dispensed, delivered, or administered to a person in the state.[43]	• Use of drug prices negotiated in other countries is an option, but is controversial and would be challenging to evaluate and implement • International reference pricing carries the risk of limiting manufacturer participation in the process • Using a U.S. published reference pricing file, such as VA federal supply schedule pricing offers the benefit of being publicly available and easily accessible and could serve as a benchmark for state-level negotiations with manufacturers • Must ensure that using VA pricing as a benchmark does not create Medicaid best price implications

[42] Program on Regulation, Therapeutics, And Law (PORTAL), Determining Upper Payment Limits: Considerations for State Prescription Drug Affordability Boards (PDABs) (2024), *available at* https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf.

[43] NATIONAL ACADEMY FOR STATE HEALTH POLICY, AN ACT TO REDUCE PRESCRIPTION DRUG COSTS USING REFERENCE-BASED PRICING (2022), *available at* https://nashp.org/an-act-to-reduce-prescription-drug-costs-using-reference-based-pricing/.

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
Reference Pricing to Therapeutic Alternatives	Establish UPL based on the price of drugs that can be used in place of the selected drug. For drugs with multiple approved indications, the therapeutic alternatives may differ for each indication. In these instances, it may be necessary to only include alternatives that are approved for all of the same indications as the selected drug; or to set separate prices based on reference groups for each of the drug's indications. Where multiple alternatives exist, health plans and PBMs often select one or two "preferred" drugs within a class, which often have lower out-of-pocket costs for patients than non-preferred alternatives. Consider setting same UPL for all therapeutic alternatives, based on the lowest-priced drug of the group.	• Setting a UPL at a therapeutic class level increases the complexity of the analysis needed • This option could avoid some of the challenges noted by constituent groups that an unintended consequence of a UPL could be that an agent is moved to a non-preferred status to avoid the UPL • Long contracting runways with PBMs and carriers could be a barrier to implementation
Launch Price Indexing	Establish a UPL that uses the product launch price and indexes that price to the yearly or consolidated average CPI.	• Indexing the UPL to a launch price plus an appropriate annual CPI provides a straightforward option that may have reduced complexity at implementation • Concerns that increased or higher launch prices could be an unintended consequence of this approach • Changes to Medicare (new financial penalties for drug prices that increase faster than inflation) and Medicaid (price inflation penalties are uncapped and can exceed the WAC of a drug) make this option most applicable to drugs that have been on the market a long time with price increases before the change to Medicare and Medicaid rebates.
Percentage off of WAC	Establish a UPL that is a fixed percentage off of WAC. For brand drugs, the federal minimum Medicaid rebate is 23% of the AMP, which is confidential but, given the formula, is likely to be close to WAC. If a board is uncertain about the level of discounting in the market for first-in-class or other type of sole source products, but the drug is causing clear affordability challenges (e.g., clearly resultant premium increases, very high patient cost sharing, minimal manufacturer	• Offers a straightforward approach • Could leverage information available through a data call to determine a reasonable discounted WAC • Information is often hard to obtain • Inaccuracies in the data or inability to obtain the data could result in setting a WAC that is too low or too high

UPL Approaches (General Concepts)[42]		
Concept/Source	**Description**	**Considerations**
	patient assistance), this approach may be sufficient to induce payers to improve patient access.	
Payer Return on Investment (ROI)	For a drug that has been subject to valid pharmacoeconomic research on value/cost savings, establish an initial UPL with a minimal lower cost and assess health plan savings over a given period (e.g., 5 years). Limiting the period in which medical benefits and savings start to accrue is important, as multimillion dollar drugs that produce savings over a lifetime may not be affordable to the healthcare system for many years.	• Allows the board to assess the potential savings from a UPL along with a drug's positive impact on overall cost of therapy • A long period for assessment may limit the utility of the approach
Budget Impact-Based	Establish a UPL such that spending on the drug does not exceed a certain percentage of a given budget or have a disproportionate impact on a given budget. Could be accomplished by limiting the drug's contribution to increases in health insurance premiums (i.e., premium growth thresholds) or by leveraging a modified budget impact analysis to establish cost savings targets (i.e., assessment of costs only, rather than costs and health outcomes, as is done in cost-effectiveness analyses).	• Complex concept that requires more exploration • Assessment of the unintended consequences of the approach such as high launch prices
340B Program-Specific	Establish a UPL reimbursement adjustment for some or all 340B entities. The cost of drugs for 340B entities is approximately equal to the net cost after Medicaid rebate for the drug, although unlike Medicaid, it may not go below a penny. The 340B supply chain will continue to be discrete with much lower costs than even a UPL for a variety of programmatic reasons.[44] Regardless, profit on UPL drugs will be less than in the absence of a UPL.	• Requires an assessment of the cost to the 340B market • Recognition that the margins are important to Oregon covered entities since there is no state funding for non-grantee programs • Concern that this option doesn't fulfill the desire to ensure that all Oregonians benefit from a UPL

[44] For brand drugs, the Medicaid rebate and corresponding discounts available through the 340B program are based on 23 percent of the Average Manufacturer Price (AMP), which is roughly equivalent to federal WAC or, if greater, AMP minus the Best Price in the market to almost any entity *and* an inflation penalty rebate. A Consumer Price Index (CPI) penalty is added if/when the AMP of the drug in a given quarter exceeds CPI growth. In general, it is the CPI penalty that produces very low costs and very high rebates, and affects drugs that have been on the market many years. Best Price does *not* include the CPI penalty. Best Price may be much higher than the total 340B cost (i.e., federal rebate + CPI penalty). Under current law, a Board should avoid creating a UPL that creates a new Best Price, as it would likely automatically be extended to every state Medicaid program.

Analysis of Resources Needed by the PDAB to Implement UPL

Additional resources may be necessary to implement a UPL plan. The board must identify if the UPL shall be placed within the supply chain, as a pricing benchmark similar to WAC, rebate mechanisms, or another mechanism altogether that may be identified at a later time. Resources will be needed to support the development of a UPL, any costs or savings analysis that must be performed, and implementation support that may be required to support the board's ongoing work. Initial considerations are identified below and subsequent reports will likely result in additional recommendations. Resource requirements will be driven by the many options that are still under development not only for the UPL, but also by the stated desire to improve access to data, improve affordability review processes, and expand constituent group engagement.

- The board may need to utilize the services and expertise of the Office of Pharmacy Policy, Purchasing and Programs within OHA. This would be in lieu of creating a new government function or enlarging the PDAB to manage implementation. If needed, the Office could contract with wholesalers dedicated to supply UPL products into Oregon and work with manufacturers to prevent diversion.[45]
- The board may need to contract with the OHSU Center for Evidence-Based Policy to support the board's work. The Center provides assistance in areas such as strategic planning, training, and clinical and process consultation.
- Commercial products exist that can assist with determining the estimated impact and availability of rebates in the non-Medicaid space; if the board wishes to explore these options, separate funding will be required.
- If there is a desire to establish an advisory committee or council that includes representatives of the constituent community, including patients, providers, caregivers and other, the board may need additional staff to support the activities of this council. The number and type of staff would be determined after an assessment of current staff availability and workload.
- The Oregon Health Authority and plans administered by the Public Employees' Benefit Board and the Oregon Educators Benefit Board will be impacted by a statewide UPL.

Analysis of How UPL Would be Enforced[46]

A statewide UPL is generally intended to be self-enforcing. For example, suppliers, pharmacies, and hospitals have no incentive to buy a UPL product at a cost higher than the UPL given subsequent purchasers will not pay more than the UPL. Further, public and private health plans have no incentive to reimburse providers more than the UPL. The UPL amount will be widely known in the State, and consumers will be aware of what they should be charged when paying for a drug.

One potential enforcement challenge could be diversion. This has the potential to occur when a supplier buys a quantity of products subject to a UPL and then sells the product at market price into another state. In 2013, Congress passed the Drug Supply Chain Security Act (DSCSA), which establishes a track and trace system for prescription drugs to reduce diversion and counterfeiting of drugs.[47] Once the DSCSA is fully implemented, diversion will become less likely. A state may want to contract with a wholesaler dedicated to distribution of UPL products. The wholesaler can work with manufacturers on

[45] Horvath Health Policy, *Upper Payment Limit Operational Features*, March 2024.
[46] Horvath Health Policy, *Upper Payment Limits*, March 2024.
[47] U.S. FOOD AND DRUG ADMIN., DRUG SUPPLY CHAIN AND SECURITY ACT (DSCSA) https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

avoiding diversion. State offices that operate the federal (free) Vaccine for Children Program may also have experience to share thwarting diversion laws.[48]

Authorities Necessary for Enforcement of UPL

Leveraging UPL authority as a mechanism could improve prescription drug affordability for Oregonians; however, it also recognizes that a lengthy implementation will be required, given the effects on contractual relationships, potential procurement implications on the supply side, and a desire to ensure that implementation addresses concerns expressed by constituents. Moreover, implementation and enforcement of a UPL will require the board to conduct rulemaking through the authority granted under ORS 646A.693. The proposed list of authorities below are not considered exhaustive, and will likely require further evaluation as the board pursues its work.

- The board will require statutory authority to establish UPLs and conduct rulemaking, inclusive of a transparent public notice and comment period.
- Regulatory authority is likely required to establish an advisory council to support the board's work.
- Using a supply side or buy side approach that establishes a UPL for all transactions in the State could require regulatory authority to establish the UPL as the maximum amount to be paid throughout the supply chain.
- Regulatory authority may be required to establish a UPL at the class level, and reduce the unintended consequence of moving coverage away from a specific drug (as appropriate) in an approach that result in a situation that functions similarly to a protected class in the Medicare program.
- Regulatory authority may be required to establish an acceptable time period for implementing a UPL within systems and contracts, or to automatically apply the UPL to existing contracts without re-negotiation.
- Regulatory authority necessary to establish wholesaler relationships as needed to support the program.
- Board discussions have identified a need for improved claims data. Evaluation of recent PBM data may identify areas of improvement that will require a new or updated regulatory authority. Similarly, carrier data improvements could require updated regulatory authority to strengthen reporting requirements.
- Pharmaceutical manufacturers have indicated a willingness provide more data. Expand confidentiality protections and improve regulatory authority as needed to support these initiatives.
- Regulatory authority to establish a reporting mechanism and associated staffing to provide individuals at any level (consumers, supply chain members, etc.) with a mechanism to report noncompliance with the use of the UPL for pharmacy transactions in the state of Oregon.

Analysis of how UPLs Could be Implemented

This section will discuss the considerations for implementation for constituent groups including PEBB, OEBB, state administered health benefits, health benefit plans, and other forms of health insurance. The board's work, as described in the 2024 Annual Report, is "to consider prescription drugs that may create

[48] Horvath Health Policy, *Upper Payment Limits*, March 2024.

affordability challenges for Oregonians and the state's health care system."[49] The board work plan published on August 3, 2022, expresses an intent to study the "entire prescription drug distribution and payment system in Oregon". The discussion, which includes upper payment limits along with other options, frames the UPL as applying to "all financial transactions in this state involving a drug" and specifies that it should not "undermine the viability" of any part of the drug supply chain.[50] Throughout its deliberations, the board has consistently reiterated that an upper payment limit must not be determined to be harmful to the overall supply chain or damage an already fragile system, especially for disadvantaged populations.[51]

As described in this and other reports, the board undertook significant activities to engage constituent groups and solicit feedback on the use of a UPL, potential consequences of implementing a UPL, and alternative solutions for either developing a UPL or developing alternative or complementary strategies to improve drug affordability for all Oregonians. The board engaged consumers, pharmacy providers, PBMs, wholesalers, PSAOs and GPOs, pharmaceutical manufacturers, hospital providers, 340B covered entities, and insurance carriers licensed in the state in public comment forums. The board has also engaged with other state agencies, such as the Oregon Health Authority, to assess the impact on the state Medicaid program and on the Oregon Educators and Public Employees Benefit Boards. Each option ultimately put forth by the PDAB will be evaluated against various metrics. All metrics may not be applicable to all potential options. Generally, the approaches taken by the board will assess:

- The operational impact to constituent groups in the supply chain, including an assessment of reasonable allowances for implementation (systems, contracts and other impacts) and necessary legislative changes to ameliorate negative impacts to the greatest extent possible.
- The rulemaking necessary to ensure transparency in UPL implementation and provide financial protections for providers and consumers within the pharmaceutical supply system and ensure that providers, consumers, payers, insurance carriers, and state health authorities receive the benefit of savings generated through a UPL or other mechanisms.
- The rulemaking necessary to address the major concerns described by constituents during the forum discussions, especially:
    - Protections for the confidential and trade secret information from manufacturers, PBMs, carriers and others that is necessary to conduct affordability reviews and assess system savings and impact
    - The intersection of the use of an acquisition cost model and appropriate dispensing fee and the appropriateness of leveraging existing information from other state agencies, such as cost modeling by OEBB or PEBB or clinical reviews by the Medicaid agency, to develop Oregon-specific reimbursement models. Legislative and regulatory support will be required to appropriately gain access to the data needed to fully evaluate the impact on supply chain; for example, the impact of changes in provider reimbursement methodologies.
    - The potential to reinvest savings into the supply chain, for example, supporting changes to reimbursement models to community pharmacies or preserving access to services

[49] 2024 Report for the Oregon Legislature: Generic Drug Report Pursuant to Senate Bill 844 (2021), Oregon PDAB, https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Generic-Drug-Report-2024.pdf.
[50] Oregon PDAB Agenda, Proposed Work Plan, August 3, 2022, https://dfr.oregon.gov/pdab/Documents/20220803-PDAB-document-package.pdf.
[51] Oregon PDAB Minutes, November 16, 2022 https://dfr.oregon.gov/pdab/Documents/20221116-PDAB-approved-minutes.pdf.

provided by 340B covered entities, such as federally qualified health centers, who do not otherwise receive state funding.

As the approach to the upper payment limit is defined, the board will engage the resources needed to assess the impact of any proposed upper limit on the supply chain, including gathering input from constituent groups regarding potential areas of impact. While not an exhaustive list, this could include an estimated impact on patient copayments based upon claims provided by the carriers, an impact assessment by Medicaid to ensure there is not an unanticipated impact on best price, or impact of the UPL on net costs and copayments for the benefits provided to state employees and Oregon educators.

Current Analysis of Potential Costs and Savings

The board initially aimed to analyze and model costs associated with implementing a UPL and the resulting savings across various points within the pharmaceutical supply chain. The implementation of a UPL could potentially yield savings for the State, insurers, hospitals, pharmacies, and consumers. Myers and Stauffer elected to use a net price strategy to establish a "proxy" for determining the impact of a UPL. This approach links a UPL to the net price of a drug after accounting for rebates and discounts. Many of the products selected for initial affordability were found to be highly rebateable. Since patient copayments are generally based on the total cost of a product, reducing this cost could potentially lower patients' out of pocket expenses. The complexity of the pharmaceutical supply chain, along with the intricacies of drug reimbursement, has made this analysis challenging.

Board staff provided Myers and Stauffer with data which included insurance carrier list price concessions for specific prescriptions medications, which varied by carrier and market type. The quality and completeness of this data was higher for medications that are typically dispensed by outpatient pharmacies and self-administered by the patient. Conversely, the quality and completeness of list price concession data was more limited for medications that are typically administered to the patient by a health care provider. Using the available list price concession data, it is possible to express these concessions as a percentage of the list price. For each medication, three distinct price concession percentages were selected, either based on the data received or, in cases where data was limited, based solely on historical experience. These percentages were then applied to the current list price (WAC) of each medication, resulting in three potential UPLs for each medication. These theoretical UPLs were subsequently provided to Oregon PDAB staff for use in their modeling. The PDAB staff has tasked PEBB, OEBB, and Oregon Medicaid with modeling the costs and savings associated with these theoretical UPLs using utilization data from their plans. An overview of findings are reported below; full reports are included in the appendices.

Potential savings and costs are indeterminate at this time; savings and costs will be impacted by the drugs selected for UPL and the methodologies chosen to establish the UPL.

PEBB/OEBB Analysis

On behalf of the Oregon Health Authority (OHA), Mercer Health & Benefits LLC analyzed prescription and medical drug costs, utilization, and enrollment data for PEBB and OEBB for the period of April 1, 2023, to March 31, 2024. They calculated the impact of the proposed UPL scenarios for eight selected drugs. It was expected that the reduction in in the point of sale drug prices due to UPLs would result in lowered or eliminated rebate payments. Because this was a novel proposal, the rebates retained with UPLs in place were uncertain. To account for this uncertainty, the three different UPL scenarios were modeled with no rebates (0 percent) as well as 25 percent and 50 percent of the current rebate retained, with the most conservative estimate being that rebates for the affected drugs are eliminated upon implementation. The analysis never allowed the rebate to exceed the ingredient cost for a drug/scenario combination.

Under a scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a cost savings of $18.7 million (price reduction exceeds existing rebates) to a combined increase of $12.1 million in plan spend (where the modest price reduction is less than existing rebates). The UPL scenario prices for drugs commonly used in the medical benefit represent less of a discount from WAC than the UPL scenarios provided for drugs typically dispensed through the pharmacy benefit. As a result, there is more opportunity for savings in the pharmacy benefit than the medical benefit.

Board staff observed that the projected outcomes leading to increased program costs were based on assumptions of a modest UPL reduction from WAC and the complete elimination of all rebates. However, total loss of rebates may not be a realistic assumption. Conversely, setting a UPL close to the current net price after rebates while assuming retention of 25 to 50 percent of rebates is also unlikely. In general, if implementation a UPL results in all rebates being removed, only the more aggressive UPL scenarios result in plan savings. Board staff expect analysis of commercial plan data would have similar findings. Given the complexity of the drug supply chain, it is important to consider a range of scenarios and account for potential market shifts that could continue to offer price concessions where feasible.

Medicaid Analysis

In order to model impacts to the Oregon Medicaid program, board staff tasked OHA with modeling costs utilizing the three theoretical UPL points as above. OHA's Office of Health Analytics pulled coordinated care organization (CCO) encounter and fee-for-service (FFS) claims data for the year ending June 2024 from OHA's Decision Support and Surveillance Utilization Review System (DSSURS)/Medicaid Management Information System (MMIS) database. The Office of Actuarial and Financial Analytics (OAFA) built models for each payer and claim type, comparing actual payment levels against an estimate of payments limited by a UPL. Savings were estimated on a gross (total payments) and net (Oregon Health Plan [OHP] payments) basis. Changes to rebates were not considered in the calculation. First-dollar savings were expected to apply to OHP.

In terms of budgetary impact, the FFS costs are presumed savings, but would be offset by any reduction in pharmacy rebates. Due to timing and data constraints, OAFA did not attempt to model any rebate impacts. In assessing budgetary impact, OHA would also want to look more closely at members' category of aid to determine what proportion of the total will be state funds – 25 percent to 30 percent would be the likely proportion of state funds. In addition, there appear to be some Indian Health Care Provider claims (based on payment amounts) that should potentially be excluded from analysis. Put together, these factors suggest the $2.26 million in net FFS savings under the tightest UPL scenario might result in state budget savings of less than half a million dollars.

For CCOs, the financial impact is likely to be "absorbed" in capitation rate setting. Each year OHA tries to set capitation rates approximately 3.4 percent higher than the prior year. To the extent there are benefits or costs expansions that are not separately funded by the legislature (which happens regularly), OHA prices those into capitation rates but still fits the overall rates within the 3.4 percent budgetary increase. This process essentially subjects all other services or policy levers to a lower level of increase within the capitation rates.

In the case of the UPL application, the opposite could become true: any material expected savings to CCOs would be reflected in capitation rate development, but in absence of any direction to the contrary OHA would still target a 3.4 percent overall increase, which would leave more room for inflationary or policy increases in other areas of rate setting. However, if OHA were expecting a decrease in pharmacy rebates, the 3.4 percent target might be adjusted to offset the loss of pharmacy revenue. Therefore, unless the Legislature asks OHA to bank the savings (of which perhaps 25 percent to 30 percent would be the state's to retain), a UPL likely would not result in savings to the state but rather lead to reinvestment of the proceeds into other CCO expenditures.

For context, the CCO system is expected to incur around $6.2 billion in service costs during calendar year 2025. A savings of $56 million represents around 0.9 percent of costs, which is a significant impact in the context of rate setting. Again, offsetting for rebates foregone would reduce that potential savings/reinvestment.

Medicare Maximum Fair Price Analysis

On August 14, 2024, CMS provided an update on its progress in the Medicare Drug Pricing Negotiation Program. This program stems from the enactment of the Inflation Reduction Act of 2022, which affords CMS the "ability to directly negotiate the prices of certain high expenditure, single source drugs without generic or biosimilar competition." The CMS negotiated price for a given drug is known as the Maximum Fair Price (MFP).

As CMS continues its MFP program, Oregon's PDAB may be able to draw parallels and model similar effects if a UPL is used in the state. PDAB staff completed an analysis to examine the potential estimated savings to health plans using the recent CMS negotiated drug prices.

It is important to note this analysis was not a comprehensive comparison based on the entire Oregon pharmaceutical marketplace. The Oregon data was limited to commercial insurance carrier reporting to the Drug Price Transparency program. This only includes specific plan types (i.e., large, small and individual) while excluding groups such as Medicare, Medicaid, self-insured, PEBB, and OEBB. The analysis was only intended to model the potential savings based from the MFP negotiated pricing.

The analysis utilized carrier data and pricing from 2023 and identified potential savings per drug to be between 51 percent and 88 percent of the 2023 spend when using the MFP negotiated prices. Overall, the analysis identified approximately $37 million in savings across the 11 modeled drugs.

Future Analysis of Potential Costs and Savings

Work by Horvath Health Policy has found that upper payment limits (UPLs) will work best if the UPL applies statewide -- to all purchases, payments, billings, and reimbursements of public and private purchasers, payers, and patients. Ideally, the entire state supply of the prescription product to which a UPL is applied comes into the state at or below the UPL via wholesalers and is distributed to pharmacies, regional suppliers, and dispensing and administering providers and facilities. The product with a UPL is then available to everyone, including individuals without insurance. Under this scenario, a wholesaler negotiates with the manufacturer to buy the product at or below the UPL and the UPL replaces the wholesale acquisition cost for in-state transactions.

Once the wholesaler acquires the product, distribution (sales and acquisitions) of the product operates consistent with current practice and each participant in the supply chain realizes some margin (profit) on the product. The product (ingredient) reimbursement made by the payer is the amount of the UPL (professional fees are not part of the UPL).[52]

While Senate Bill 192 requires an analysis of the costs of implementing the plan with respect to various constituent groups, a detailed analysis is premature at this time. As specific UPL approaches are identified and finalized for specific drugs or drug classes, future analytics may be performed to estimate the cost to each of the various constituent groups. It should be noted that the discussions with specific focus groups, as detailed in other documents, provide some insight into issues or concerns that warrant additional consideration or evaluation.

Pharmacy

Assessing the impact of a UPL on pharmacies includes modeling pharmacy acquisition costs and reimbursements. With access to wholesaler drug purchasing and sales data, as well as pharmacy dispensing and reimbursement data, it would be possible to model different UPL acquisition costs and quantify savings at the pharmacy level. However, pharmacies and wholesalers are not obligated to provide

[52] Horvath Health Policy, *Upper Payment Limits*, March 2024.

drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Oregon Actual Average Drug Acquisition Cost (AAAC) and the NADAC benchmarks. Additionally, the state may not have full access to non-public payer data specific to Oregon. Modeling could potentially use data from state-administered plans and summary data from state-regulated entities. Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and State Drug Utilization Data (SDUD) for Medicaid programs (which can be obtained at the Oregon-specific level). However, data from cash payers may not be accessible. Pharmacy reimbursement data from PBMs and patients will be difficult to obtain and will vary by pharmacy organization. Aggregating pharmacy reimbursement data across different pharmacies would be necessary to project statewide effects. Projecting pharmacy acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current pharmacy acquisition costs and pharmacy reimbursements from PBMs and patients as a percentage of WAC.

Commercial Insurance Carriers

Assessing the impact of a UPL on carriers includes an analysis to quantify total gross and net prescription drug spending and the total rebates generated. Under a UPL model, total prescription drug gross spending for a specific UPL product is expected to decrease, along with a corresponding decrease in rebates generated. The overall impact on health plans will depend on the relative change in reimbursements resulting from the UPL and any reduction in rebates after UPL implementation, which may offset each other. Pharmaceutical manufacturers would likely decrease rebates in proportion to the reduction from WAC to UPL. Consequently, once a UPL is set, current claims data could be adjusted to simultaneously decrease total payments in claims to pharmacies and reduce manufacturer rebates, resulting in a net "wash" on prescription drug net spending. Claims data for Oregon State Employee Plans (OEBB and PEBB) could serve as a representative data source for commercially insured health plans. Other data, if made available from commercial health plans with members in Oregon, could also be analyzed. However, this analysis may be limited as actual claims data and rebate data correlated with the same claims are generally considered proprietary to health plans and PBMs and may be difficult to obtain.

Patient Out Of Pocket Spending

Drug affordability often centers on patient out of pocket spending. Assessing the impact of a UPL on patients could be conducted with access to detailed carrier claims data, including pharmacy reimbursement, patient out of pocket amounts, remaining deductible, and remaining out of pocket maximum for each claim. Aggregated data will not be useful in modeling changes to patient out-of-pocket spending due to the numerous variables involved in determining where a patient stands concerning their deductible and out of pocket maximums at any given time. Existing claims data could be modeled using a UPL instead of the current total reimbursement to the pharmacy, potentially lowering patient out of pocket spending and slowing progression through deductible and out of pocket maximum phases. However, the necessary claims data to fully model the effects on patient out-of-pocket spending may not be available. Deductibles and out of pocket maximums can vary from one health plan to another, so calculations based on assumptions from one health plan should not be extrapolated to others. However, the cost to patients either at the point-of-sale or through cost-sharing or coinsurance could be expected to be reduced based on the lower list price of the drug. The availability of patient assistance programs currently provided by drug manufacturers should also be considered in an assessment of UPL impacts to patient out-of-pocket spending.

Hospitals

Assessing the impact of a UPL on inpatient and outpatient hospital charges and associated reimbursements would require various data including inpatient and outpatient standard drug charges,

mark-up methodologies, and reimbursement methodologies for hospitals. The implementation of UPLs may alter the standard charges set by hospitals to the extent that UPLs are incorporated into the mark-up methodologies for setting standard charges. Reimbursements from third parties may or may not be directly impacted by UPLs, depending on the reimbursement methodologies, which will vary by hospital, third-party payer, and whether the drug was used in an inpatient or outpatient setting.
The complexity and variability in methods for setting hospital standard charges, along with the complexity and variability in inpatient and outpatient bundled payment methodologies, present significant limitations in realistically modeling the impact of UPLs on hospital charges and associated reimbursements.

Physician Offices and Clinics

A UPL could impact both pharmacy payments and payments for drugs administered in an office setting. To model any UPL impacts in this setting, the board would require detailed purchasing data from wholesalers and reimbursement data from insurance carriers. Providers and wholesalers are not obligated to provide drug purchase cost data. An estimate of pharmacy acquisition costs could be modeled using published resources such as the Average Sales Price (ASP). Additionally, the state may not have full access to non-public payer data specific to Oregon. Data from state-administered entities (e.g., Medicaid, PEBB/OEBB) could be obtained from the state. Data from state-regulated entities may be available in summary form through data calls (e.g., commercial insurance). Limited utilization data for government programs is publicly available, such as Medicare Part B and D summary data (which is national and not Oregon-specific) and SDUD for Medicaid programs (which can be obtained at the Oregon-specific level). Data from cash payers may not be available. Provider reimbursement data from carriers and patients will be difficult to obtain and will vary by provider. Aggregating reimbursement data across different provider organizations would be necessary to project statewide effects. Projecting acquisition costs in a post-UPL environment will be challenging. One approach could be to express both current provider acquisition costs and reimbursements from carriers and patients as a percentage of WAC.

340B Covered Entities

To model the effect of a UPL on a 340B covered entity, the board would need access to 340B acquisition costs, dispensing fees, prescription drug volume and costs, as well as reimbursement data from insurers. The implementation of a UPL should not affect 340B acquisition costs for covered entities. However, a UPL would decrease total payments for drugs, thereby reducing the amount of 340B savings or revenue generated from any prescription for a drug with an applied UPL. 340B acquisition costs, contract pharmacy dispensing fee information, and utilization (by NDC) could be provided by participating covered entities. However, 340B covered entities are generally reluctant to disclose this information, and there are confidentiality concerns associated with sharing their acquisition costs.

Appendices

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Legal Considerations

Federal Patent Preemption

Importantly, upper payment limits do not regulate manufacturer list pricing. Instead, a UPL is a payment rate limit on state regulated entities that buy, sell, bill or reimburse prescription drugs. The UPL does not govern a manufacturer's price, and a manufacturer can decide to forego a state's market for the product entirely. The Medicare MFP negotiation with manufacturers is also a voluntary process and federal circuits have thus far (as of the date of this document), found that manufacturer rights are not violated by voluntary government programs. . If there is a challenge to UPLs based on patent law, a state in that case should use federal healthcare/prescription laws to show that Congress does not intend that patent rights supersede the need for affordable prescription drugs.[53] Examples of Congress' intent that patent rights should not impede access to healthcare include thirty years of the 340B program and the new Medicare MFP program.[54] Both these programs would seem to indicate that when it comes to access to pharmaceuticals and affordable healthcare, patent rights are not top of mind. In fact, the new Medicare program specifically targets drugs with exceptionally extended patents and other market protections.[55]

In *Biotechnology Industry Organization v. District of Columbia*, pharmaceutical and biotechnology trade associations, PhRMA and BIO, challenged a DC law directly prohibiting drug manufacturers from selling patented prescription drugs at excessive prices in the District as unconstitutional due to federal preemption (and Dormant Commerce Clause). The Federal Circuit agreed, reasoning that the law's exclusive focus on patented drugs would penalize high prices and restrict the full exercise of patent rights. A National Academy for State Health Policy (NASHP) white paper regarding PDABs asserts that states can mitigate preemption concerns by designing PDABs to analyze and review the affordability of both patented and non-patented products, and, if necessary, impose upper payment limits on them.[56] The judge in BIO v. DC explicitly differentiated his ruling on the DC law from potential future cases involving non-patented drugs. Consequently, a UPL law encompassing both patented and non-patented products would be legally stronger.

Dormant Commerce Clause

The Federal government, by virtue of the Constitution's Commerce Clause, regulates commerce between the states.[57] States regulate in-state commerce.[58] State regulation can have ancillary out-of-state business impacts that do not reach a threshold of regulating interstate commerce.[59] State authority to regulate commerce is not written in the Constitution but state authority to regulate commerce, or the limit of that authority, has evolved over time through court decisions and is referred to as the Dormant Commerce Clause (DCC).[60] Specifically, relying on *Dep't of Revenue of Ky. v. Davis*, manufacturers may claim that states attempts to set reimbursement rates for drugs are "designed to benefit in-state economic interest

[53] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023).

[54] Id.

[55] Id.

[56] https://www.nashp.org/wp-content/uploads/2022/08/White-Paper_NASHP-Proposal-for-State-Based-PDABs_Sachs_042622.pdf

[57] Horvath Health Policy, State Prescription Drug Affordability Board and the Dormant Commerce Clause (DCC), April 2023.

[58] Id.

[59] Id.

[60] Id.

by burdening out-of-state competitors" therefore violating the DCC.[61] To further support their claim, manufacturers may point to the recent case, *Association for Accessible Medicines v. Frosh*, in which the court struck down a Maryland law that prohibited "price gouging in the sale of an essential off-patent generic drug" on the grounds that it "directly regulates transactions that take place outside of Maryland."[62] In the NASHP white paper cited above, the authors argue that there are at least two reasons that manufacturers' DCC claims are likely to fail. First, PDABs can choose to limit their UPLs to sales made or products distributed within the state thus limiting DCC concerns. Second, the Association for Accessible Medicines decision applied a more restrictive reading of the DCC than previous courts and therefore is arguably a departure from existing DCC precedent. Also, the branded drug industry operates differently than the multi-manufacturer generic drug product industry and those supply chain distribution differences are substantial. Remediation in the *Frosh* and other price gouging legislation allows a state to require a roll back of prices for multi-source generic product sold in the state at the unacceptable price as one example of a Commerce Clause question.

Medicaid "Best Price"

The Medicaid Drug Rebate Program (MDRP), authorized by Section 1927 of the Social Security Act, requires that drug manufacturers enter into a rebate agreement with the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer's drugs. The rebate formula is set in statute and is designed to ensure that the Medicaid program receives the "best price" available in the marketplace (i.e., the lowest price offered to any U.S. purchaser or payer during a rebate period) or if greater, a flat rebate percentage as specified in federal law. In effect, if a UPL is lower than the deepest price concession in the market, this would create a new national best price available to all Medicaid programs. A UPL that would create a new national Medicaid best price would likely be challenged as a dormant commerce clause violation with implications for the UPL program. A State would presumably obviate a UPL that created this situation.

ERISA Preemption

ERISA is a federal law that sets minimum standards for private, employer-sponsored retirement and health plans. ERISA preempts "any and all state laws" to the extent that they "relate to" employee benefit plans.[63] Whether state laws are preempted by ERISA has been debated by federal courts through the years, leading to a complex web of competing judicial decisions surrounding the issue.

The question of whether a UPL set by a state PDAB is preempted by ERISA has not yet been considered by the courts. Perhaps the most instructional case for how courts may rule on an ERISA challenge to a UPL methodology is *Rutledge v. Pharmaceutical Case Management Association*. In *Rutledge*, the Court held that "state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage are not preempted by ERISA."[64] As long as the state law does not bind plan administrators to any particular choice, a state law will not be preempted by ERISA. Establishing a UPL methodology is a rate setting measure, and the court in *Rutledge* held that state rate setting is not preempted by ERISA.

[61] *Dep't of Revenue of Ky. v. Davis,* 553 U.S. 328, 338 (2008) (quoting New Energy Co. of Ind. v. Limbach, 486 U.S. 269, 273-274, (1988)).

[62] *Association for Accessible Medicines v. Frosh* 887 F.3d 664 (4th Cir. 2018).

[63] 29 U.S.C. § 1001 Et. Seq.

[64] *Rutledge v. Pharmaceutical Case Management Association*, 141 S.Ct. 474 (2020).

On the other hand, a Supreme Court case from 2016, *Gobeille v. Liberty Mutual,* upheld the ERISA plan objection to reporting data to the Vermont All Payer Claims Database.[65] The Court found that the administrative burden of complying with various state claims payment, enrollee data, and other plan data reporting laws affected the heart of plan administration, and, therefore, the state law was preempted by ERISA.[66] Unlike in *Gobeille*, where the state law affecting reporting was struck down because it interfered with nationally uniform plan administration, establishing a UPL in Oregon likely will not interfere with the administration of ERISA plans. A UPL is a requirement to buy and bill at the UPL. The ERISA plan benefits and basic administrative functions are not affected.[67] Implementing a UPL using rebates to plans may be complicated by ERISA preemption.

Medicare Preemption

Recent case law has expanded interpretations of federal preemption of state laws that might affect Medicare Parts C and D plans. The preemption is arguably broader than ERISA. Regardless of preemption, a UPL is designed for the passive participation of ERISA and Medicare plans as they are billed at the UPL by pharmacies, clinics, and other providers. Presumably the UPL is less than the prevailing market rate that would otherwise be used in provider billing, so ERISA and Medicare plans have no incentive to reimburse higher, but they could. However, because the preemption is broad and can be litigated by any constituent group, such as drug manufacturers, it is best to specify in law that a UPL cannot be enforced in Medicare Part D. Medicare preemption may complicate implementing a UPL via rebates.

[65] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023). Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312 (2016).

[66] Id.

[67] Horvath Health Policy, *How US Supreme Court Decisions on ERISA and Dormant Commerce Clause Create a Path Forward for Substantive State Healthcare Financing Reforms, Notably Prescription Drug Upper Payment Limits*, (2023).