Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"
April 10, 2019

Mr. Thomas Moriarty, Executive Vice President,
Chief Policy and External Affairs Officer, and General Counsel
CVS Health

The Honorable Joseph P. Kennedy III (D-MA)

1. Last year, CVS Caremark sent a letter regarding the 340B program to various pharmacies in Massachusetts stating that CVS Caremark would be reducing reimbursement rates. Please provide a list of all pharmacies to which CVS Caremark sent this letter.

Our intent was to bring reimbursement at pharmacies owned by 340B covered entities in line with the rest of our network. In all, the pharmacies that received that notification represented less than 2.5 percent of our total pharmacy network and was based on their own self-identification in their reporting to us.

Certain pharmacies that participate in CVS Caremark's pharmacy network are also participants in the federal government's 340B Drug Pricing Program, which is a program that requires pharmaceutical manufactures to provide significant discounts on prescription drugs to providers who serve low-income and vulnerable patient populations. As such, pharmacies that are owned by a 340B covered entity and serve 340B-eligible patients are able to acquire their products at very deep discounts through the program. Participation in this program creates unique financial implications for payors (including governmental and non-governmental payors). Most importantly, due to these large discounts manufacturers must provide to these pharmacies, the manufacturers will typically not pay rebates on claims for drugs purchased under the 340B program. Because payors do not receive rebates for these claims, they represent a much higher net cost than traditionally purchased drugs.

2. It is my understanding CVS Caremark has since rescinded its proposal to reduce reimbursement rates to pharmacies owned by safety net providers. What caused CVS Caremark to change course? Will CVS Caremark commit to refrain from similar anticompetitive tactics undermining the 340B program in the future?

After careful review, CVS Caremark decided not to implement commercial reimbursement rate changes for 340B covered entity-owned pharmacies that were scheduled to become effective on April 1, 2019 (with an original effective of February 1, 2019). CVS Caremark made this decision after speaking to many of the pharmacies and trade associations who would be impacted by this change, and took into consideration the feedback they provided.

3. How would the reduction in reimbursement rates affect medication adherence for diabetic patients if CVS Caremark put it in place? How would the reduction in reimbursement rates affect access to insulin?

The proposed change would have only applied to pharmacy reimbursement, and would have had limited effect on patient cost sharing. In limited instances where cost share may have been affected, we believe it may have lowered patient out-of-pocket costs.

The Honorable Brett Guthrie (R-KY)

1. In December 2018, CVS Health announced that it was introducing a new approach to pricing of pharmacy benefit management services, referred to the Guaranteed Net Cost Model. Will the Guaranteed Net Cost Model apply to all insulin products?

Yes, the Guaranteed Net Cost model applies to all prescription drugs. The Guaranteed Net Cost model guarantees the client's average spend per prescription, after rebates and discounts, across each distribution channel – retail, mail order and specialty pharmacy. The model focuses on a simple concept – net cost per claim. Under the new model, CVS Caremark will pass through 100 percent of rebates to plan sponsors and take accountability for the impact of drug price inflation and shifts in drug mix. With the Guaranteed Net Cost model, clients continue to have the option to implement point-of-sale rebates to reduce cost-sharing for plan members.

a. What percentage of CVS Caremark's clients have chosen to adopt the new model? What is CVS Caremark doing, if anything, to incentivize clients to adopt this model?

Although a limited number of clients have chosen to adopt the new model since it was announced six months ago, we have provided approximately 70 pricing quotes to current and prospective clients thus far who are considering moving to Guaranteed Net Cost.

b. According to press releases, CVS Health will pass through 100 percent of rebates in the Guaranteed Net Cost Model. Why under the traditional rebate model does CVS Health only pass through 98 percent of the rebates? How will CVS Health be compensated under the Guaranteed Net Cost model? Will the amount CVS Health receives be a fixed fee or will it vary depending on different factors?

As a whole, we are currently only retaining two percent of rebates, while the rest are passed along to our clients. In Part D, we effectively pass along 100 percent of the rebates to the Part D plans, which use them, in general, to lower premiums. Two main items determine the share of rebates we retain. First, we may guarantee a certain level of rebates to a client. If we exceed the guarantee level, we may keep all or some of those rebates above the guarantee. Second, a client may choose to compensate us for our services by allowing us to retain some or all rebates.

In the Guaranteed Net Cost model, CVS Caremark will be compensated by the difference between the client's performance versus our cost of the products and dispensing. If the client elects to pay CVS Health an upfront administrative fee in lieu of making a differential between

client price and pharmacy reimbursement, that is another option of how CVS Caremark would be compensated.

c. One article notes that a CVS spokesperson said that "the company does not expect CVS Health's profitability to increase or decrease as a result of the shift to 100% pass-through rebates."[1] Is this correct? If so, please explain why a shift to 100 percent pass-through of rebates will not impact CVS Health's profitability.

The majority of our clients today receive 100% pass-through of rebates (as previously stated our average pass-through rate across our book of business is 98%), so we do not expect a noticeable profitability change as clients move to the Guaranteed Net Cost Model.

d. Under the Guaranteed Net Cost Model, will CVS Health share information about the price of the medicine paid by CVS Health to obtain a medicine such as insulin with its clients?

All clients receive disclosure of rebates and fees received from manufacturers and all clients have audit rights covering our contracts with manufacturers and the amount of rebates or fees collected from manufacturers. We do not, however, typically provide product specific rebate levels outside of an audit.

e. What impact, if any, will the Guaranteed Net Cost Model have on the out-of-pocket costs for a patient at the pharmacy counter—especially those patients that are in the deductible phase of a high deductible health plan or that have coinsurance for their insulin?

The Guaranteed Net Cost model is a model offered to health plan sponsors in how to structure their overall prescription drug benefit costs. It does not necessarily have any impact on patient out-of-pocket costs at the pharmacy counter, which are determined by how the plan sponsor decides to set up their plan's benefit design. We offer our clients the option of doing point-of-sale rebates to lower drug costs at the pharmacy counter and if the client is using a high deductible health plan with an HSA, the option of using a preventive drug list to provide coverage for preventive medications, like insulin, prior to satisfaction of the deductible.

The Honorable Michael C. Burgess (R-TX)

1. One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?

[1] Evan Sweeney, *CVS Caremark shifts PBM model to 100% pass-through pricing and focus on net cost*, FIERCE HEALTHCARE (Dec. 5, 2018), *available at* https://www.fiercehealthcare.com/payer/cvs-caremark-launches-guaranteed-pbm-model-100-pass-through-pricing.

High-deductible plans have been growing in popularity for the last fifteen years. According to one Kaiser Family Foundation survey, enrollment among covered employees in high-deductible plans grew from 4% in 2005 to approximately 29% in 2018.[2]

2. As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.

    a. What kinds of drugs are commonly included on preventive drug lists?

In accordance with IRS guidance, preventive drug lists generally include drugs intended to prevent a disease that has not yet manifested itself or prevent the reoccurrence of a disease from which a person has recovered. These can include cholesterol-lowering drugs, smoking deterrents, anti-asthmatics, blood pressure medications, and insulins and other anti-diabetic drugs. We include all covered insulins on our preventive list.

3. One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?

We provide for our own employees and also recommend that our clients adopt a $0 copay for preventive drugs. When our clients combine a $0 copay preventive drug list with point of sale rebates they can drive member OOP to zero dollars and still save money through medical savings, gaps in care closure, productivity gains, and better adherence and improved outcomes.

Clients can save up to $3 million per 100,000 lives as a result of using a preventive drug list with $0 copays and POS rebates, despite a slight increase in pharmacy costs due to greater adherence. Patients on such plan have no out-of-pocket costs for insulin.

    a. CVS told the Committee that you encourage clients who use health savings accounts (HSAs) to cover preventive drugs with a $0 copay and prior to satisfaction of the deductible. Additionally, since CVS Health provides its employees with an HSA plan, CVS said it covers certain preventive drugs and supplies with a $0 copay and prior to satisfaction of the deductible. Does CVS provide insulin to its employees with an HSA plan with a $0 copay and prior to satisfaction of the deductible? Why or why not?

[2] *2018 Employer Health Benefits* Survey at https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-8-high-deductible-health-plans-with-savings-option/.

Yes, CVS Health provides insulin for its employees with an HSA plan with a $0 copay prior to satisfaction of the deductible. This allows the plan to reduce patient out-of-pocket costs and improve adherence.

i. We've heard that some plans have the option of taking insulin out of the deductible entirely for enrollees in a high deductible health plan. Do you offer this to your clients and, if so, do you recommend that your clients include insulin on their preventive drug lists for high deductible health plans?

Yes, we recommend this option to our clients.

ii. How long have you recommended that your clients include insulin on their preventive drug list?

We have included insulin on our template HDHP/HSA preventive drug list and recommended that clients do the same for over a decade.

iii. Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?

Of the HDHP clients that have adopted our template HDHP/HSA preventive drug list (in whole or in part), 95% include insulin.

iv. How many covered lives does that translate to?

Seven million HDHP lives have implemented our standard template HDHP/HSA preventive drug list.

4. What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?

We provide our plans with a wide range of benefit plan design options. Including a preventive drug list, $0 copays, and point-of-sale rebates may increase a plan's pharmacy spending and increase premiums. We give our clients the option to balance a variety of options so they can manage both premiums and member out-of-pocket.

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi

noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

So, which is it? Is there innovation in the insulin market or not?

It is true that manufacturers have introduced a number novel insulin products onto the market in the past years. While many of these products can help limited populations, we have also found that a variety of legacy products are just as efficacious for many patients. As an example, most Type 2 diabetes patients who require insulin can remain stable on older human insulins, rather than newer analog products. We design our clinical programs to strive to get patient the most efficacious, cost-effective treatment.

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

The regulatory status of insulins is certainly complex. FDA has recently finalized a rule redesignating insulin as a biologic rather than a traditional small molecule drug as it has been historically. The existence of patents on newer products also increases the cost of development for generic manufacturers who must go through expensive patent litigation to bring a product to market. The longer these patents keep competitors off the market, the longer the brand has to increase prices. Commissioner Gottlieb himself recognized the challenges in bringing substitutable insulin to the market, and expressed hope that the new regulatory regime will lead to competition in the future.[3]

3. As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it

[3] *Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's continued efforts to bring competition to the insulin market to lower prices and expand access* available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-continued-efforts-bring-competition-insulin

provides the company that made the drug an economic advantage by avoiding more competition entering the market.

In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

CVSH believes that patent evergreening is a problem generally in the pharmaceutical industry. For that reason we have recently endorsed a bill introduced by Senators Cornyn and Blumenthal, the *Affordable Prescriptions for Patients Act*, which would give FTC the authority to review pharmaceutical patenting practices.

a. If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it difficult for them to create the generic alternative if there are only patents remaining on the delivery device?

We cannot speak to the drug development or commercialization process, as CVSH does not develop or commercialize prescription drugs. However, recent regulatory uncertainty around the status of insulin products may have discouraged development of follow-on products. We are grateful for FDA for finalizing guidance that will clarify this for biosimilar developers going forward. Additionally, follow-on developers face costly litigation from brand products looking to delay competition.

b. If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?

We cannot comment on the decision making process employed by generic pharmaceutical manufacturers