

June 25, 2019

The Honorable Frank Pallone, Jr
Chair, E&C Committee
US House of Representatives
Washington, DC

The Honorable Greg Walden
Ranking Member, E&C Committee
US House of Representatives
Washington, DC

Dear Congressmen Pallone and Walden,

As the Energy & Commerce Committee continues to address the important issue of insulin affordability, I wanted to share the attached information on behalf of the Endocrine Society. I believe you will find the following helpful as you consider legislative and policy solutions:

- Increasing Insulin Affordability: An Endocrine Society Position Statement
- Testimony to the FDA on Biosimilars
- Testimony to House E&C Oversight and Investigations Subcommittee on Rising Insulin Costs by Endocrine Society Member Alvin C. Powers
- Response to HHS Rebate Proposal to Lower Drug Costs
- Comments to Administrator Seema Verma on Lowering Drug Prices
- Endocrine Society Letter to Representatives Reed and DeGette on Insulin Pricing and Formulary Switching

As you know, the cost of insulin has nearly tripled in the past fifteen years, making it difficult for many of the over 7 million people who use insulin to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary hospitalizations, complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The issue of insulin affordability is a top priority for the Endocrine Society and one we hear frequently about from our members, many of whom have conversations daily with their patients about their ability to afford their insulin. The Society represents over 18,000 basic and clinical researchers and physicians-in-practice worldwide, who take care of patients with diabetes.

We appreciate the work that the Energy & Commerce Committee has already done to better understand the drivers of high drug costs, including holding two hearings specifically on insulin prices. We realize that there is no one answer that will solve this crisis and that



all stakeholders have a role to play in making insulin more affordable.

We are eager to continue working with the Committee as it identifies potential policy solutions and welcome the opportunity to meet with you to discuss this issue. If we can be of assistance, please contact Stephanie Kutler, Director of Advocacy & Policy at skutler@endocrine.org or Meredith Dyer, Director of Health Policy at mdyer@endocrine.org.

Sincerely,

A handwritten signature in black ink that appears to read "E. Dale Abel".

E. Dale Abel, MB.BS., D.Phil. (M.D., Ph.D.)
President, Endocrine Society

Cc: Energy & Commerce Committee Members

INCREASING INSULIN AFFORDABILITY

INTRODUCTION

Insulin is a lifesaving medication for people with diabetes. However, its cost has nearly tripled in the past fifteen years making it difficult for many patients to afford this medication and effectively manage their disease.¹ This has put patient safety in jeopardy as patients opt to ration their insulin or forgo other medical care. Research indicates that a lack of transparency in the drug supply chain has made it challenging to identify the root cause of price increases. This position statement will identify barriers to accessing affordable insulin and potential policy solutions that could address this growing problem.

BACKGROUND

More than 30 million Americans have diabetes with another 84 million at risk for developing the disease.² Having diabetes increases one's risk for serious health problems including heart attack, stroke, blindness, kidney failure, amputations, and death.³ Diabetes is also the most expensive chronic condition in the United States.⁴ Average medical expenses are 2.3 times higher for people with diabetes.⁵ In 2017, the cost of diagnosed diabetes was estimated to be \$327 billion annually, with \$237 billion in direct medical costs.⁶ This equates to one-in-four health care dollars being spent on people with diagnosed diabetes.⁷ And since one-in-four are unaware they have the disease⁸, costs to the healthcare system are even higher than estimated.

Given the complex nature of diabetes, it is essential that patients adhere to their medication regimen to avoid unnecessary complications and hospitalizations. However, adherence can be difficult as people with diabetes often have co-morbidities that require them to take multiple, costly medications or they may be unable to make sustained lifestyle

changes that could improve outcomes. One study indicates that improved adherence among people with diabetes could prevent nearly 700,000 emergency department visits, 341,000 hospitalizations and save \$4.7 billion annually.⁹ Recent increases in drug costs and changes to insurance design are some of the most common reasons for poor medication adherence, particularly for patients on insulin.^{10,11}

Rising Insulin Costs

The true cost of insulin can be difficult to pinpoint because of a lack of transparency in financial agreements between stakeholders in the supply chain, geographical differences in cost, and insurance coverage.¹² From 2001-2016, the list price of Novolog, a commonly used insulin, increased by 353% per vial.¹³ Humulin U500 increased from \$170 to more than \$1,400 since 1987.¹⁴ From 2001-2015, the price of Humalog increased 585% for a vial of insulin.¹⁵ GoodRx.com, a website that aggregates claims data to estimate the average list price of medications (the price of insulin without the negotiated discounts or rebates), published cost information per vial (1000 units) for commonly prescribed insulins in August 2018. The following prices are averaged from Walgreens and CVS pharmacies:

- Lantus: \$302
- Humalog: \$322
- Novolog: \$336
- Humulin N: \$180
- Novolin N: \$155
- Basaglar: \$261*
- Levemir: \$394
- Toujeo: \$338*
- Novolin R: \$155
- Humulin 70/30: \$177
- Novolin 70/30: \$156
- Novolog 70/30: \$338
- Humalog 75/25: \$351
- Tresiba: \$388*
- Apidra: \$368
- Admelog: \$254

*cost based on conversion to 1000 units

¹Hua X, Carvalho N, Tew M, Huang ES, Herman WH, Clarke P. Expenditures and prices of antihyperglycemic medications in the United States: 2002-2013. JAMA 2016;315:1400–1402.

²Centers for Disease Control and Prevention. National Diabetes Statistics Report. <https://www.cdc.gov/diabetes/data/statistics/statistics-report.html>

³National Diabetes Prevention Program. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/prevention/prediabetes-type2/index.html>. Accessed September 1, 2018.

⁴Petersen, M. Economic Costs of Diabetes in the U.S. in 2017, Diabetes Care. American Diabetes Association. <http://care.diabetesjournals.org/content/41/5/917>. Accessed September 1, 2018.

⁵National Diabetes Prevention Program. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/prevention/prediabetes-type2/index.html>. Accessed September 1, 2018.

⁶Petersen, M. Economic Costs of Diabetes in the U.S. in 2017, Diabetes Care. American Diabetes Association. <http://care.diabetesjournals.org/content/41/5/917>. Accessed September 1, 2018.

⁷The Cost of Diabetes, American Diabetes Association. <http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html>. Accessed September 1, 2018.

⁸More than 29 million Americans have diabetes; 1 in 4 doesn't know. Centers for Disease Control and Prevention. <https://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html>. Accessed September 1, 2018.

⁹Jha, A.K., Auber, R. E., Yao, J., Teagarden, J.R., & Epstein, R.S. (2012) Greater adherence to diabetes drugs is linked to less hospital use and could save nearly \$5 billion annually. *Health Affairs*, 31 (8), 1836.

¹⁰IHS Market. Passing a Portion of Negotiated Rebates Through to Seniors with Diabetes Can Improve Adherence and Generate Savings in Medicare. May 14, 2018.

¹¹Ibid.

¹²Health Care Cost Institute. http://www.healthcostinstitute.org/healthy_bytes/price-insulin-prescription-doubled-2012-2016/. Accessed September 1, 2018.

¹³Cefalu, W. T., Dawes, D. E., Gavlak, G., Goldman, D., Herman, W. H., Nys, K. V., Yatvin, A. L. (2018). Erratum. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018;41:1299–1311. *Diabetes Care*, 41(8), 1831–1831. American Diabetes Association doi:10.2337/dc18-er08

¹⁴Good RX. Humulin R. https://www.goodrx.com/humulin-r?=form=vial&dosage=20ml-of-500-units&ml&quantity=1&days_supply=&label_override=Humulin%20R. Accessed September 1, 2018.



POSITION STATEMENT

Currently, 7.4 million Americans use insulin to treat their diabetes.¹⁶ At minimum, these patients use one vial of insulin each month. However, some patients require multiple vials of insulin or use multiple types of insulins (which necessitates multiple vials) each month. According to a survey conducted by the American Diabetes Association, 27% of respondents stated that insulin costs have affected their past year purchase or use of insulin. Thirty-four percent of families with children on insulin were impacted.¹⁷ Those affected by rising costs were more likely to experience adverse health effects than those for whom cost did not impact their purchase or use of insulin and twice as likely to experience negative emotions like stress and anxiety. Many of these patients were also forced to forgo other needs such as transportation (32%), utilities (30%), housing (27%), doctor's visits (32%), or other medications (36%)¹⁸, and were more likely to ration their insulin.

Patient Cost-Sharing

Insurance plan design directly impacts out-of-pocket costs. Patients who are uninsured pay the list price of insulin. These individuals may be eligible for a manufacturer-sponsored patient assistance program (PAP), however, these programs are restrictive, difficult to navigate, and it is unclear how many patients are able to utilize them.

Patients on some forms of commercial plans may need to pay full price, depending on the plan design, for their insulin until they meet an annual deductible and then pay a fixed co-pay. They may also be required to pay co-insurance, a percentage of the cost based on the list price of insulin that does not include rebates or discounts negotiated by the pharmacy benefit manager (PBM).

For patients with high-deductible plans (plans with a deductible greater than \$1,350 for an individual or \$2,700 for a family), out-of-pocket insulin costs are significant. Individuals must pay for the full list price of insulin until they meet their annual deductible. In 2016,

approximately 40% of Americans had a high-deductible health plan with an average annual deductible of \$4,358 for individual health plans and \$7,983 for family plans.¹⁹ In the same year, 44% reported selecting plans with annual deductibles of \$6,000 or greater in 2016.²⁰

Medicare beneficiaries with Part D coverage without a supplemental plan must also pay full price for insulin until they meet their deductible, after which point they will pay co-insurance until meeting their plan's initial coverage limit for prescription drugs (\$3,750 in 2018).²¹ At this point, they experience the Part D "donut hole", a coverage gap between the plan's initial coverage limit and when catastrophic coverage kicks in. While Medicare beneficiaries are in the donut hole, they will pay 35% of the plan's cost for covered brand-name prescription drugs until reaching their annual out-of-pocket limit of \$5,000 in true out-of-pocket spending. Catastrophic coverage will then begin, and the Medicare beneficiary will pay a small co-insurance or copayment for covered prescription drugs.²²

In some cases, purchasing medications outside of their pharmacy benefit allows patients to pay lower costs. So-called "gag rules" have prevented pharmacists from counseling patients about options to take advantage of this cost-savings and should be eliminated.

There are many stakeholders across the drug supply chain who influence rising costs, including wholesalers, PBMs, pharmacies, health plans, and employers. While manufacturers establish the list price, each of these players impact the out-of-pocket cost to a patient on insulin through a complex series of negotiations and rebates not transparent to the public. The lack of transparency makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. Research indicates that while list prices have skyrocketed, the net price increase that manufacturers earn has risen at a far slower rate (3-36% net increases).²³ Increasing transparency is critical to understand this divergence and other contributors to rising insulin costs.

¹⁶Good RX. Insulins. <https://www.goodrx.com/insulins>. Accessed September 1, 2018.

¹⁷Cefalu, W. et al. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018 May; dc180019

¹⁸American Diabetes Association. Insulin Affordability Survey 2018. American Diabetes Association. <http://www.diabetes.org/assets/pdfs/advocacy/insulin-affordability-survey.pdf>. Accessed September 1, 2018.

¹⁹Ibid.

²⁰Health Insurance Price Index Report: 2016 Open Enrollment Period. eHealth. https://news.ehealthinsurance.com/_ir/68/20169/Health%20Health%20Insurance%20Price%20Index%20Report%20for%20the%202016%20Open%20Enrollment%20Period%20-%20October%202016.pdf. Accessed September 1, 2018.

²¹Ibid.

²²Burke, V. The Medicare Part D Coverage Gap ("Donut Hole") Made Simple. Medicare.com. <https://medicare.com/medicare-part-d/coverage-gap-donut-hole-made-simple/>. Accessed September 1, 2018.

²³Medicare Part D.org. The Part D donut hole. <https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole>. Accessed October 24, 2018.

²⁴Cefalu, W. T., Dawes, D. E., Gavlik, G., Goldman, D., Herman, W. H., Nuyts, K. V., Yatvin, A. L. (2018). Erratum. Insulin Access and Affordability Working Group: Conclusions and Recommendations. *Diabetes Care* 2018;41:1299-1311. *Diabetes Care*, 41(8), 1831-1831. American Diabetes Association doi:10.2337/dc18-er08



POSITION STATEMENT

CONSIDERATIONS

Complexity of the Supply Chain

The complexity of the supply chain makes it difficult to pinpoint the drivers behind increasing insulin prices. Manufacturers set the list price for the medication and typically sell their medications to wholesalers or PBMs. The process to get the medication from the manufacturer to the patient is rather straightforward, but the flow of money and the methodology to establish the price that the patient ultimately pays is much more complex. The net price manufacturers receive is based on the list price minus any fees paid to the wholesaler, discounts paid to the pharmacy, and rebates paid to the PBMs or health plans. Financial agreements between the stakeholders are confidential. For example, manufacturers are not privy to the PBM's negotiations with the health plans.

Despite significant financial incentives negotiated between the stakeholders in the supply chain, most of these savings are never shared with the consumer. As such, an individual's cost is largely based on the list price. As list prices grow at double-digit rates, people with high-deductible plans, co-insurance, or no insurance suffer the effects.

Net Price

The process to establish the net price involves the exchange of rebates, discounts and other payments to encourage the purchase of a drug. For example, a manufacturer may offer distributor volume discounts to purchase their drug or provide financial incentives to a PBM for placement on the preferred tier of their drug formulary. Manufacturers cite these financial incentives as a major driver of high list prices; the more incentives provided to the players across the supply chain, the higher the list price must be for the manufacturer to realize any profit. In theory, the rebates offered to a PBM to place the drug on their preferred formulary tier should reduce costs for the patient. However, these rebates may be used by the employer or the health plan to reduce insurance premiums, not the cost of the drug at point-of-sale. However, due a lack of transparency, it is unclear the extent to which premiums are actually affected.

Patient Assistance Programs and Discount Cards

To address high out-of-pocket costs, manufacturers offer patient assistance programs (PAPs) that provide insulin at low or no cost to low-income patients who qualify. These requirements vary by company and patients must apply annually which can be problematic as PAPs can be difficult to navigate. Manufacturers also offer co-pay cards but these are typically used to incentivizing the use of higher cost medications and have been shown to result in overall higher medication prices.

Lower-cost Alternatives

Competition in the marketplace for both brand name and generics typically drives down prices. This has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing insulins on the market. In a true free-market economy, this should promote greater competition and drive down costs. Human insulins (i.e., NPH and regular insulins) have been available for decades, would be an effective therapy for some patients with Type 2 Diabetes, and can still be purchased at a significantly lower cost. However, most health care providers are no longer trained on how to use these.

Value-based Purchasing

Some experts believe that value-based purchasing (VBP) agreements have the potential to reduce drug costs. These agreements between manufacturers and health plans base payment on how effective a medication is at treating a disease and can be structured in different ways; if a drug does not improve outcomes or leads to poorer health among the health plan's patient population, the manufacturer will provide discounts, rebates, or refunds to the health plan. However, further research is needed to understand whether value-based purchasing agreements will reduce patient costs. Furthermore, regulatory barriers have limited the number of existing VBP contracts, thereby making it difficult to assess the real benefit of value-based purchasing on reducing drug costs.

POSITIONS

Rising costs have made access to affordable insulin far more difficult for people with diabetes, especially low-income individuals, those on high deductible health plans, Medicare beneficiaries in the Part D donut hole, or those who are uninsured. Addressing insulin affordability is critical in ensuring that patients can effectively manage their diabetes and avoid unnecessary complications and hospitalizations. For many patients with diabetes, insulin is a life-saving medication. Policymakers should address drivers of rising insulin prices and implement solutions that would reduce high out-of-pocket expenditures for patients.



POSITION STATEMENT

The Endocrine Society believes the following policy and practice changes could help expand access to lower cost insulin.

- Greater transparency is needed across the supply chain to understand rising insulin costs.
- Future list price increases should be limited and reasonable financial incentives should be pursued by all stakeholders.
- To reduce out-of-pocket expenditures, cost-sharing should be limited to a co-pay. In addition, NPH and regular insulin should be available at no cost to the patient.
- Rebates should be passed along to consumers without increasing premiums or deductibles.
- Patient Assistance Programs should less restrictive and expanded to include more accessible and easier to complete applications that can be used for multiple programs (e.g. a common application).
- Health care providers should be trained to use lower-cost human insulins (e.g., NPH and regular), so they can prescribe as appropriate.
- When clinically equivalent options are available, physicians should consider prescribing the lowest cost insulin.
- The Federal government should address regulatory barriers to create a more favorable environment for the testing of incentive programs that reduce cost and improve care (e.g. value-based purchasing agreements).
- Electronic medical records should include up-to-date formulary and price information
- Co-pay savings cards should be eliminated as they have been shown to incentivize the use of higher cost medications and raise the overall cost of drugs.
- Patients should be educated about low-income assistance programs (e.g. the Extra Help program under Medicare) and to ask their physicians about alternatives if they cannot afford their insulin.
- Gag rules, which prevent pharmacists from helping patients find less expensive ways to pay for their medications, should be eliminated.



The Future of Insulin Biosimilars: Increasing Access and Facilitating the Efficient Development of Insulin Biosimilar and Interchangeable Products

Testimony from the Endocrine Society

Docket No. FDA-2019-N1132

The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many of the over 7 million people who use insulin to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary hospitalizations, complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The issue of insulin affordability is a top priority for the Endocrine Society and one we hear frequently about from our members, many of whom have conversations daily with their patients about their ability to afford their insulin. The Society represents over 18,000 basic and clinical researchers and physicians-in-practice worldwide. We commend the FDA for holding this public hearing to ensure that the approval of insulin biosimilars considers the safety of the product as the highest priority but still allows for approval of these products in an expedited manner.

Competition from multiple medications in a class typically drives down price, but this has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple competing brands on the market. Currently, no interchangeable biosimilar version of insulin is available due to the complexity of biologically replicating a human hormone and the strict FDA review process for the approval of biosimilars. Congress recognized the need for a less arduous approval process for biosimilars with the passage of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). The abbreviated licensure pathway set to go into effect on March 23,

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2020 will allow for the development of interchangeable medications at a lower cost and will likely encourage new manufacturers to enter the insulin market.

The expectation is that availability of new biosimilar insulin products will result in cost-savings for Medicare, Medicaid, commercial insurers, and most importantly, patients. Analysis shows that new biosimilars are being introduced at an average price that is 47 percent lower than the reference biologic's list price.¹ Furthermore, cost savings may be realized from the regulation of insulin as a biologic as it will establish interchangeability with the reference product and allow for pharmacy-level substitutions. Although biosimilar drugs do not apply as great a downward pressure on drug costs as a true generic, the introduction of lower-cost insulin products is an important and meaningful step in improving the affordability of insulin. We support FDA's efforts to address the challenges of developing and approving biosimilar insulins.

In addition, it is critical that the FDA work with patients, caregivers, clinicians, pharmacists to educate and increase their awareness of biosimilars. Educating these stakeholders about the efficacy and safety of biosimilar insulins will be key to realizing the full benefit that additional insulin products can have on competition and price. A survey conducted in 2014 in the United States and European Union to understand the awareness and knowledge of biosimilars among patients, caregivers, and the general population found that general awareness was higher among patients with a diagnosed disease than the general population, and the greatest awareness was among those who were active in disease-specific advocacy groups. The study also found that those who had some familiarity with biosimilars had a more positive view of the safety and efficacy of these medications. These findings illustrate

¹ Analysis of IQVIA wholesale acquisition cost data for January 2019. The Center for Biosimilars.

<https://www.centerforbiosimilars.com/contributor/christine-simmon/2019/04/left-hand/right-hand-does-the-administration-know-that-fda-is-undermining-its-efforts-to-lower-patient-drug-costs-via-biosimilar-competition>



the importance of a comprehensive education campaign around the value of biosimilars in general and with the introduction of each new biosimilar. Partnering with disease advocacy groups may be the most effective way to create positive impressions among patients and partnering with provider advocacy groups will be important to educate the clinicians prescribing the medications. If the biosimilar product will be interchangeable with the reference product at the pharmacy, the stakeholders must understand the differences and similarities between the products and that the biosimilar product will be equally as effective at treating their disease.

The Endocrine Society is encouraged by the potentially positive effect that the introduction of biosimilar insulins will have on competition and ultimately on the ability of patients to afford their insulin. If patients no longer need to choose between taking their full dose of insulin or paying their rent, they will be able to more effectively manage their disease and avoid costly, and possibly life-threatening, complications. However, the FDA must ensure that the approval process for biosimilars establishes equal safety and efficacy as the existing reference product in order to protect patients and build stakeholder confidence in biosimilar medications.

Statement of Alvin C. Powers, MD
On Behalf of the Endocrine Society
Energy & Commerce Oversight & Investigations Subcommittee
Insulin Affordability Hearing
April 2, 2019

Thank you, Chairwoman DeGette, Ranking Member Guthrie, and members of the Oversight & Investigations Subcommittee for the opportunity to speak to you today about the rising cost of insulin and provide a physician's perspective on the scope of the problem of insulin affordability and the challenges this creates. My name is Alvin C. Powers and I am a physician-scientist. I am here representing the Endocrine Society. With over 18,000 members, the Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions like diabetes. While we hear from our members about many different clinical and research issues, one causing the greatest concern for their patients is the rising cost of insulin. We commend the subcommittee for its efforts to shed light on this important issue.

As Director of the Vanderbilt Diabetes Center and Chief of the Vanderbilt Division of Diabetes, Endocrinology, and Metabolism, our health care providers and I have many patients who struggle to afford their insulin. The need to address this growing problem is urgent. People are rationing their insulin, and forgoing other necessities, such as food and rent. This leads to serious health problems, unnecessary complications, and hospitalizations. While I live in the "Diabetes

belt” in Tennessee, the story is no different in Colorado, Kentucky, or elsewhere in the United States. The subcommittee has convened this hearing because insulin is unique in the broader context of the drug pricing debate and I want to highlight a few of the reasons why.

- First, millions of Americans take insulin to manage their diabetes. Of the more than 30 million with diabetes, more than 7 million use insulin to control their blood sugar and reduce the risk of life-altering complications such as dialysis, amputation, and heart disease. Patients with Type 1 Diabetes require insulin to survive. There is no other life-sustaining drug used by so many people who would die in a matter of days if they cannot afford it.
- Second, the price of insulin has tripled over the past 15 years. It is difficult to understand how a drug that has remained unchanged for almost two decades continues to skyrocket in price. In 2017, expenditures on insulin reached \$15 billion and three of the top ten medication costs were for different types of insulin.

What does this mean for a patient? A vial of insulin can now cost a patient more than \$300 dollars and many patients require multiple vials each month. This can mean hundreds—or thousands—of dollars in monthly out-of-pocket costs. While nearly one-quarter of individuals on insulin live below the poverty line, it is not only the low-income or those without insurance who struggle with the cost of insulin. Some of the recent, tragic

stories reported in the media involve people who are employed and have insurance, but also have high-deductible health plans and must pay the full list price for this life-saving medication. For many, this is simply not possible.

- Lastly, insulin has been around too long for this problem to be so pervasive. We are approaching the centennial of insulin's discovery in Toronto in 1921. After the scientists isolated insulin and saw its miraculous effects on individuals with type 1 diabetes, Frederick Banting, one of insulin's co-discoverers said "Insulin belongs to the world, not to me." They sold the patent for \$1 each to the University so that all patients who needed it would have access. However, exactly the opposite has happened—at least in the United States.

Patients and physicians face additional challenges because of failures to make the cost of insulin transparent, a lack of ability to know what the out-of-pocket costs will be, and limited options for low-cost solutions. I'd like to provide some context for these challenges by describing a typical patient visit. I'm seeing one of my patients who has type 1 diabetes and requires injections of a long-acting and a short-acting insulin each day. I prescribe both types of insulin but I do not know how much my patient will pay for her insulin because electronic health record systems do not provide patient-specific benefit information and I have no way of knowing what her out-of-pocket cost will be. At the pharmacy, she learns that she owes more than \$1200 for 4 vials per month. Why? Because it's January, she is on a high deductible plan, and she is now responsible for the list price of the

medication—a price she cannot afford. This scenario could be true for many working Americans and many in this room who have high-deductible health plans. In the best-case scenario, she calls my office and admits that she cannot afford her insulin. In the worst case, she rations or forgoes her insulin altogether.

My staff and I are constantly looking for options to make insulin more affordable such as patient assistance programs, but these are often restrictive, difficult to navigate for the patient and the provider, will not result in the patient going home with insulin that day, or even that week, and are not a long-term solution.

Our insulin supply system is broken, unfair, and dangerous. Our patients deserve better. Here are my thoughts about the insulin supply chain:

- Insulin is a life-saving medication that millions of our citizens must take every day.
- List prices for insulin continue to increase each year.
- No one understands the rising cost of Insulin - there is a lack of transparency in how drug prices are negotiated.
- Rebates between manufacturers, pharmacy benefit managers, and health plans are not passed along to consumers.
- Patients increasingly have high deductible health plans, dramatically increasing their out-of-pocket costs for life-saving medications like insulin.
- Patient Assistance Programs are complicated, difficult to navigate, and overly restrictive.
- Physicians are unable to access real time information about what their patients will pay for their medications like insulin.

- Thus, patients and physicians cannot have informed discussions about the cost of insulin.
- Regulatory systems and patent extensions restrict the introduction of more generics.
- And, until recently, pharmacists could not advise patients about less expensive options.

Addressing the rising cost of insulin is a priority for the Endocrine Society and are working with other organizations interested in this problem. We recently released a position statement outlining ways that stakeholders can improve its affordability. Many of our recommendations focus on opportunities to reduce out-of-pocket costs for patients while policies are formulated to lower the actual price of insulin. These recommendations include increasing transparency, limiting cost-sharing to a co-pay, integrating real time benefit information into EHRs, and ensuring rebates are passed along to patients without increasing out-of-pocket costs.

I am hopeful that by discussing the critical issue of insulin affordability, we can begin to identify additional solutions and make insulin affordable to our patients. If we can make progress on the insulin pricing and affordability, I think this can be extrapolated to other drugs. I look forward to working with the subcommittee as it moves forward in addressing this important issue.

April 8, 2019

Daniel R. Levinson
Inspector General
US Department of Health and Human Services
330 Independence Ave, SW
Washington, DC 20201

Re: Fraud and Abuse: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees; Proposed Rule [RIN 0936-AA08]

Dear Mr. Levinson,

On behalf of the Endocrine Society, I offer these comments on the Proposed Rule related to removal of safe harbor protections involving prescription medications. The Endocrine Society is the world's oldest and largest professional organization of endocrinologists, representing the interests of over 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders like diabetes, obesity, osteoporosis, thyroid disease, and infertility. Drug pricing reform is critical to us and the patients our members treat. Our member endocrinologists have difficult conversations every day with their patients who cannot afford the drugs needed to keep them alive or avoid complications of their disease.

Insulin is an important example of why drug pricing reform is needed. The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many people to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The Endocrine Society supports policy changes that provide physicians and patients with transparent information on the out-of-pocket cost of medications and lower-cost alternatives or reduces the amount that a patient must pay out-of-pocket.

The Proposed Rule would revise the discount safe harbor to explicitly exclude price reductions or other renumeration from product manufacturers to plan sponsors (Medicare Part D, Medicaid Managed Care, and Pharmacy Benefit Managers (PBMs)). It also includes two new safe harbors: (1) protecting certain point-of-sale reduction in price on prescription drugs; and (2) protecting certain PBM service fees.

In general, we support efforts to eliminate rebates that artificially inflate drug prices or policy changes that pass the rebates on to patients at point-of-sale. The current rebate system creates perverse incentives that result in manufacturers offering increasingly higher rebates in order to guarantee placement on the preferred drug tier to increase sales of their medications. While many patients see little change in their out-of-pocket expenses as these drug prices rise, those who are un- or under-



insured or who are on high-deductible health plans must pay the full list price of the medication.

While we support the proposal to eliminate rebates, we have concerns about how this change to the pricing system will impact patients and the system overall. We believe some consumer protections need to be in place to ensure assumptions about market behavior are realized. We believe the following questions must be addressed before the proposed rule is finalized:

- Without rebates or other forms of discounting, is it safe to assume that manufacturers will compete on the list price on similar medications?
- How will this policy ensure that prices of prescription drugs are reduced?
- The Proposed Rule included several estimates on the impact on premiums and out-of-pocket costs, with significant variations. Many questions remain about how premiums will be impacted. Will they increase more or less than potential out-of-pocket cost savings from drug rebates?
- Who will have oversight of PBMs and manufacturers to ensure that rebates or other discounts are not occurring?
- Will administrative fees to PBMs increase and how will that impact consumers?
- What is the incentive for PBMs to reduce costs if they receive a flat fee?
- Will local pharmacies continue to exist, or will patients be required to use PBM-based mail-order facilities?
- How will this change in Medicare Part D and Medicaid Managed Care impact the pricing system in the commercial market?
- Will it be possible for the Rule to be finalized and implemented before the proposed January 1, 2020 effective date?

Thank you again for considering our comments on the Proposed Rule. Pursuing opportunities that can make insulin affordable to all patients is a top priority of the Society and our members. If we can be of additional assistance, please contact Mila Becker, JD, Chief Policy Officer at mbecker@endocrine.org.

Sincerely,

A handwritten signature in blue ink that reads "E. Dale Abel".

E. Dale Abel, MB.BS., D.Phil. (M.D., Ph.D.)
President, Endocrine Society



January 25, 2019

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Baltimore, MD 21244

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P]

Dear Administrator Verma:

On behalf of the Endocrine Society, I offer the following comments on the Proposed Rule on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. The Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Drug pricing reform is critical to us and the patients our members treat. Our member endocrinologists have difficult conversations every day with their patients who cannot afford the drugs needed to keep them alive or avoid complications.

Insulin is an important example of why drug pricing reform is needed. The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many people to afford this medication and effectively manage their disease. This has put patient safety in jeopardy as rationing insulin may lead to unnecessary complications or death and should not be an option that people with diabetes are forced to choose. The Endocrine Society supports policy changes that provide physicians and patients with transparent information on the out-of-pocket cost of medications and lower-cost alternatives or reduces the amount that a patient must pay out-of-pocket without raising health insurance premiums.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

If finalized, the Rule would require that Part D sponsors implement a real-time benefit tool (RTBT) to convey patient-specific real-time cost or coverage data to the prescriber at the point of prescribing.

The Society strongly supports this requirement as our members consistently share their frustrations with the lack of patient-specific information available to them during a patient visit. Without this patient-specific information, physicians are unable to have informed conversations with their patients that consider cost of medication, patient cost-sharing, formulary restrictions, and lower-cost alternatives. This often means that a patient will visit the pharmacy to fill the prescription and only then learn that their share of the cost is more than they are able to afford. In these cases, the patient often must return to the physician's office to obtain a new prescription or the physician must take time away from patient care to address the issue with the pharmacy. Access to a RTBT

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would reduce the burden on patient and physician to figure out the cost of a drug and allow for informed conversations during the prescribing process.

Although there are numerous RTBTs available, most physicians either do not have access to these tools or even know of their existence. A requirement by the Federal Government would expand awareness of and access to RTBTs and likely increase their use in non-Part D plans as well. As mentioned in the Proposed Rule, no industry standard exists for integration of RTBTs into electronic medical records (EMRs), which complicates efforts to ensure that all prescribers have access to these tools. **While CMS is not requiring that an industry standard for RTBTs be developed, we urge the agency to take steps within its authority to advance the development of such a standard.** Only when RTBTs can be easily integrated into all EMRs will the benefits for price transparency and reduced prescription drug costs be realized.

Part D Explanation of Benefits

Part D sponsors are required to provide beneficiaries with an explanation of benefits (EOB) in every month in which the enrollee utilized their prescription drug benefit. CMS proposes to require Part D sponsors to include information about negotiated price changes and lower-cost therapeutic alternatives in the monthly EOB with a goal of increasing transparency and lowering drug spending. **The Society supports efforts to increase transparency in drug pricing and provide patients with information needed to make informed decisions about the best medication based on their own circumstances.**

However, until prescribers have access to RTBTs, it is important that the information provided in the EOB also be shared with them. The Proposed Rule indicates that it is CMS' hope that patients will use the information in their EOB to have a conversation with their physician about potential alternatives that have lower negotiated prices or patient cost-sharing. Patients may not be proactive in sharing this information, thereby limiting the impact that it could have on drug spending. Sending a monthly EOB to a physician whose practice included 500 Medicare patients would result in 6000 notifications each year. This would create another administrative burden on the practice, negating the benefit it would offer. **As such, providing prescription information through a monthly EOB report will not have the desired impact, which further supports the importance of implementing RTBT.**

Pharmacy Price Concessions in the Negotiated Price

CMS requests comments on whether the current definition of "negotiated price" should be deleted and instead defined as "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary." Under the current definition, the Part D sponsor must only include concessions that can be reasonably determined at the point of sale. This means that performance-based pharmacy payment adjustments, the second largest category of direct or indirect renumeration received by sponsors



and pharmacy benefits managers, are excluded from the negotiated price on the grounds that they cannot be reasonably determined at the point of sale. Although beneficiaries may benefit from these price concessions through lower premiums, they do nothing to impact the patient's out-of-pocket costs for their medications. Furthermore, the higher negotiated price results in a more rapid movement of a beneficiary through the Part D benefit phases, shifting more of the total amount spent on medications into the catastrophic phase.

The Society has identified several potential policy solutions that could impact the rising cost of insulin, including sharing more of the price concessions (rebates) with the patient at point of sale. However, lower out-of-pocket costs for medications should not come at the expense of higher insurance premiums or allow plan sponsors to force patients from higher-cost medications (for which plans currently receive higher rebates) to lower-cost alternatives that may not be as effective in treating their disease.

Thank you for considering our comments. The Endocrine Society supports policy changes that increase transparency in how drugs are priced and lower out-of-pocket costs for patients. If we can provide any additional information, please contact Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org.

Sincerely,

A handwritten signature in black ink that reads "Susan Mandel".

Susan Mandel, MD
President, Endocrine Society

October 27, 2017

The Honorable Tom Reed
US House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
US House of Representatives
Washington, DC 20515

Dear Representatives Reed and DeGette:

On behalf of the Endocrine Society, thank you for your attention to rising insulin costs and the consequent burden on patients and impact on care. Rising insulin costs and changing formularies have created a challenging environment for endocrinologists to provide optimal care and for patients to access therapies to appropriately manage their diabetes. As you have noted, average insulin prices have nearly tripled over the past 15 years and patients are becoming increasingly exposed to these costs due to high deductible plans and coinsurance. We appreciate your thoughtfulness in addressing these issues and look forward to working with you as Congress moves forward in identifying solutions to these serious problems.

The Endocrine Society is the oldest and largest global professional membership organization representing the field of endocrinology. We are dedicated to advancing hormone research and excellent care of patients with diabetes, obesity, osteoporosis, infertility, rare cancers, thyroid conditions and other endocrine disorders. Our more than 18,000 members include scientists, physicians, educators, nurses, and students, in 122 countries around the world. As diabetes experts, our members are greatly concerned about the impact of insulin costs and non-medical switching on their patients' ability to follow their treatment plan and effectively manage their disease.

In response to your request for the Society's assistance to gather more information about the cost of insulin, we conducted a series of focus groups and discussions with our members and convened a meeting with our Clinical Affairs Core Committee to address the questions posed in your September 20 letter. Participants in these discussions were endocrinologists who treat patients with diabetes in different practice settings (academic health centers, hospitals, community practices) across the United States. Below we have aggregated their responses and included a summary of recommendations our members generated that we hope you will consider as you move forward in addressing this issue.

- 1. Please describe what physicians typically take into consideration when making prescribing decisions for patients who need insulin. How do physicians choose which insulin products might work best for a particular patient?**

Our members all agreed that physician expertise and cost were the two largest drivers for making prescribing decisions for patients with diabetes. In general, endocrinologists evaluate the current medication the patient is



taking, potential or ongoing side effects, and estimate the cost of a new prescription that may be needed to address any health needs.

While endocrinologists have a variety of options from which to choose, they have found that patient adherence will decrease when prescribed a therapy that is too costly. Unfortunately, our members outlined many barriers that prevent physicians from addressing this issue at point of care. For example, physicians have no way of determining actual medication costs across the multiple insurance plans they encounter on a day-to-day basis. As a result, the therapy that is prescribed may not be an optimal choice because of cost or formulary restrictions, and this may not be known until the patient returns for their next appointment. During this time, the patient may have to choose between other life needs and paying for their medication out of pocket. Even when providers have all this information available at the point of care, patients may not feel comfortable engaging in a conversation about what they can afford.

Although there are multiple commercially-available prescribing options for managing diabetes, our members shared that choices are restricted, and care is often fragmented because of formulary changes. Our members indicated that they often are forced to change a patient's medication multiple times in a year, even when the current medication is effectively managing their disease. They described two reasons for this. First, formularies change – Medicare formularies can change twice a year and Medicaid formularies can change four times a year. Second, our members described a common scenario resulting from rising costs, which involves chasing down an affordable prescription throughout the year. For example, a patient with a high deductible plan sees the doctor in January and the physician prescribes a drug that is the least costly alternative. Three months later, the patient now gets prescribed a different drug because it is the lowest cost drug determined by the formulary. By autumn the patient has fallen into the "donut hole" and the physician provides samples or discount cards for yet another drug. This scenario is made even more challenging because physicians lack the information about the specific cost-burden of a medication for an individual patient.

The prescribing environment is exceedingly complex, with fluctuations in costs, formularies, and coinsurance often occurring in tandem. These issues create a burden on practices that are already dealing with a lack of resources and growing patient population. As a result, our members expressed significant frustration that these challenges make it difficult to provide the best care possible to their patients.

2. **Is information about how an insulin product is covered by the patient's health insurance plan typically available to physicians at the time of prescribing? Do physicians usually have a general sense of how much a particular insulin product will cost a patient when they prescribe it?**

While some physicians have access to limited insurance and formulary information in their electronic medical record, it is not always reliable or current and rarely includes specific information on drug prices. Some of our members are in practices that employ staff assigned to track information on health plans and pharmacies, but for other members this is not an option because of limited resources. Our members also



described an added complexity in determining patient costs: patients covered by the same insurance company or Medicare Advantage plan may have different benefits, and tracking individual benefit information is beyond the capabilities of most practices. When considering that these formularies may change multiple times throughout the year, this becomes even more challenging and burdensome.

While our members reported that they have a general sense of insulin costs, most agreed that they lack enough information to make appropriate, patient-centered decisions at point of care, as outlined above. This creates a cycle where the physician prescribes a therapy without knowing if the patient can afford it until the patient attempts to fill the prescription. If the patient cannot afford it, the patient either does not take the drug, returns to the physician office, or suffers a significant, unnecessary, unexpected cost burden. Our members would like to be able to discuss the cost of the medication at the time of prescribing to ensure that the patient obtains an affordable prescription option.

3. How familiar are your members with patient assistance programs or discount coupons/cards? Do your members often recommend these programs to patients as a way to reduce out-of-pocket costs? How accessible are these programs to patients?

Endocrinologists are familiar with patient assistance programs and discount coupons/cards. However, use varies.

Our members described several barriers that reduce patients' access to these programs, and limit their use. These include restrictive enrollment criteria, a complicated, time-intensive application process, and patients' need for assistance to complete the process. A major frustration is that these programs are often inaccessible or overly complicated for the patients who need them the most. For example, people with Medicare or any insurance coverage are often unable to enroll. In addition, our members noted that many of these programs communicate poorly with the patient or prescribing physician. A practice may complete the paperwork yet never hear whether the patient is accepted into the program. This is problematic because it affects prescribing decisions and requires the physician to spend additional time determining the status—time that could be used to care for their patient's chronic disease.

The use of discount coupons or cards also varies among the endocrinologists with whom we spoke. Our members noted that coupon programs benefit the patient less and the pharmaceutical company more as they often drive patients to more expensive products by masking the price.

Our members also were interested in learning more about new discount programs offered by some insulin manufacturers and PBMs, such as the Blink Health program, but expressed frustration that information about how they work and usage is not widely available.



4. What effect do marketing and other communications by pharmaceutical manufacturers have on physician prescribing decisions?

In discussing marketing and other communications by manufacturers, our members unanimously responded that there was very little or no impact on their prescribing decisions. Endocrinologists utilize their medical expertise, along with information on patient needs (including costs) and disease progression to determine their treatment approach.

5. What factors do physicians consider when deciding whether to switch a patient from one type of insulin to another? Is this a common occurrence? Are insulin cost burdens on the patient a common reason for switching insulin products?

There are several factors that contribute to an endocrinologist's decision to switch a patient from one type of insulin to another. Cost is a major driver along with blood glucose control, patient compliance, and the need to address complications or lifestyle factors. For example, a patient who has recently been diagnosed with rheumatoid arthritis or who has poor vision may benefit from using an insulin pen instead a syringe. However, most commonly, endocrinologists switch their patients from one insulin to another because of cost and formulary changes rather than medical factors.

As noted above, formularies change multiple times each year requiring physicians and practices to find the lowest cost option for their patients each time. Such changes create confusion among their patients and may require additional diabetes education depending on whether the insulin was changed to a comparable therapy or an alternative.

6. In your members' experience, what risks are associated with switching from one type of insulin to another? To what extent are studies and peer-reviewed literature available assessing these risks? Please identify any important studies we should be aware of.

In general, the risks associated with switching a patient from one brand of insulin to another comparable brand of the same type of insulin are minimal. However, it does create confusion and anxiety, increases administrative tracking, and requires subsequent education and discussion with the patient to ensure they are in compliance with their treatment. The most serious impact of switching, and our members noted this happens, is that the patient's diabetes becomes uncontrolled, which could lead to dangerous health consequences and hospitalizations.

Based on discussions with endocrinologists who treat patients with diabetes, the Society would like to offer the following recommendations to address insulin pricing and formulary switching:



1. The Centers for Medicare and Medicaid Services, along with private insurers, should work with electronic medical record vendors to provide up-to-date formulary and coverage information, including out-of-pocket costs and deductible information. Such changes would enable physicians to make appropriate prescribing decisions based on the needs of the patient.
2. Health plans should exempt insulin from coinsurance/co-pays in high-deductible plans due to its lifesaving nature and high cost.
3. Insurance companies and federal programs should maintain formularies for a minimum of one year to reduce non-medical switching; or patients who have well-controlled blood glucose levels on their current insulin should be able to stay on that insulin for at least one year.
4. Congress should consider policies that would reduce patient cost-sharing for insulin and ensure that patients benefit from rebates at point of sale.
5. Patient Assistance Programs for insulin should be less restrictive and more accessible. A first step in this accessibility could be developing a common application for all programs that can be saved for subsequent applications to the same or different programs. These programs should be expanded to include Medicare and Medicaid beneficiaries, and patients on any insurance plan.

Thank you for reaching out the Endocrine Society to discuss these important issues. We hope that there are subsequent opportunities to have our members meet with you in-person to share their experiences in more detail. Should you have any questions, please contact Mila Becker, Chief Policy Officer, at mbecker@endocrine.org or 202-971-3633.

Thank you,

A handwritten signature in black ink that reads "Lynnette Nieman".

Lynnette Nieman, M.D.
President, Endocrine Society