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April 19, 2022

The Honorable Jeanne Shaheen
United States Senate
Washington, D.C. 20510

The Honorable Susan Collins
United States Senate
Washington, D.C. 20510

Via email to insulin@shaheen.senate.gov

Dear Senators Shaheen and Collins,

Thank you for the opportunity to provide input on your proposal to reduce insulin costs.

Civica is a non-profit, non-stock generic drug company established by U.S. health systems and three philanthropic organizations to reduce chronic drug shortages and ensure a safe and stable supply of essential medicines to U.S. patients. Through our CivicaScript initiative, we are also focused on lower drug costs for patients.

Civica recently announced that it is developing affordable biosimilar versions of three major insulin products–glargine, lispro and aspart (biologics corresponding to, and interchangeable with, Lantus, Humalog and Novolog, respectively)–each of which will be available both in vials and prefilled pens. These products will be available to patients for not more than $30 per vial and $55 for 5 pens – a roughly 90% reduction from today's list prices for the reference products. Civica will makes its insulin available to any purchaser at a single, low, transparent price, without the high list prices and large rebates typical for many insulin products available today.

We applaud your commitment to addressing the cost of insulin for U.S. patients, and make the following observations on the legislative outline you have offered for comment:

1. **Out-of-pocket caps**. A $35 monthly cap on out-of-pocket costs would provide meaningful savings for some insulin users in covered plans. However, much greater savings for consumers could be achieved by ensuring out-of-pocket costs are indexed to true net prices. For example, recent Senate and House measures would limit out-of-pocket costs to the *lower of* $35 per month or 25 percent of net cost.
2. **Effect on uninsured individuals**. If insulin makers lowered their list prices to 2006 levels, it could reduce costs for uninsured and underinsured individuals whose costs today are based on list or "usual and customary" pricing. However, even at 2006 list-price levels of approximately $75 for common brand insulins, insulin may remain unaffordable for many uninsured consumers and families.
3. **Total insulin spending**. Under this framework, manufacturers would have an incentive to lower their prices to 2006 list price levels, but little incentive to lower prices further or to compete on price. For many insulin products, 2006 list prices were higher than today's net prices, meaning total insulin spending could rise.
4. **Utilization management limits**. The legislative outline appears to limit the ability of health plans to use utilization management tools to achieve savings on insulin. We are

concerned that this approach would prevent plans from achieving the potential cost savings from biosimilar insulins. Plans should be able to prefer an insulin that costs $21 over an identical product that costs $75.

5. **Viability of voluntary model.** The proposed legislation appears to rely on manufacturers voluntarily reducing their list prices to 2006 levels in exchange for certain benefits (i.e. elimination of rebates, preferred formulary placement, lack of U.M.). However, it seems distinctly possible that manufacturers with preferred formulary status and established market share may prefer to retain the status quo, rather than opting into a new system. If this occurs, any potential benefits from this framework wouldn't be achieved.
6. **Potential unintended consequences**. If insulin manufacturers opt in to this framework by reverting to 2006 prices, they are likely to be in a position of actively fighting for market share. A variety of tools are available, including use of non-rebate price concessions to PBMs and pharmacies, direct "detailing" of physicians to influence prescribing choices, and direct to consumer advertising. In contrast with true competition based on price, none of these tactics is likely to generate net savings for patients or reduce health costs as a whole.

Suggestions

1. Enable price competition in the insulin market by allowing insurers to prefer a lower-cost product over a higher-cost product. Ensure that limits on utilization management do not prevent plans from actively preferring lower cost insulin products.
2. Adopt measures that will facilitate competition based on price, rather than inhibiting it. For example, plans should be able to offer lower copays for preferred insulins.
3. Consider incentives for manufacturers to set prices below 2006 levels. For example, require plans to cover the lowest cost version of any insulin product at the lowest tier and/or to cover insulin products at the lowest tier if they are available below a specific benchmark, such as $4/mL, indexed to inflation.
4. Ensure that limits on out-of-pocket costs allow consumers to benefit from truly low-cost insulin products by setting out-of-pocket maximums to the *lower* of $35 per month or 25 percent of net cost.

Thank you for commitment to managing the cost of insulin for Americans. We look forward to working with you on this legislation,

Sincerely,

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