Insight

Assessing the Administration's Proposal for Reducing Insulin and Epinephrine Costs

TARA O'NEILL HAYES | OCTOBER 2, 2020

Executive Summary

- Millions of Americans depend on insulin and epinephrine, and yet both of these medicines are unaffordable for many.
- In order to improve affordable access to these medications, the Trump Administration recently proposed requiring certain health centers to make these medicines available to specific individuals at the heavily discounted price offered under the 340B Drug Pricing Program—a program that allows health clinics to generate savings.
- While the proposal may offer significant savings to those who do benefit, the scope is limited, and any reduction in revenue to the health centers that may result from this policy change will reduce clinics' ability to pass those savings on to other patients.

Introduction

Insulin and epinephrine are life-saving medicines to those who need them, although both have been reported to be unaffordable for many. Of the roughly 8 million Americans who are dependent on prescription insulin, 27 percent report difficulty affording their prescription.[1] Similarly, a 2014 study estimated that at least 1.6 percent of Americans have experienced anaphylaxis and that the true prevalence is probably higher, but 52 percent had never received an epinephrine prescription and 60 percent of those with the condition did not currently have epinephrine available.[2] The price of an EpiPen, the most commonly used epinephrine autoinjector, increased so dramatically in recent years that it became the subject of a congressional oversight hearing in September 2016. While the primary epinephrine manufacturers have begun marketing "authorized generics" and a generic version from another company was approved in 2018, some still struggle to afford the medicine.[3]

In an effort to help ensure affordable access to these two life-saving medications, the Trump Administration has recently proposed requiring health centers across the country to make these products available to certain individuals at heavily discounted prices. The health centers targeted by this rule receive grants from the federal government to provide free or low-cost health services to low-income individuals. This rule could provide some savings, but the overall impact would likely be minimal.

Rule Summary

The proposed rule relates to the provision of insulin and injectable epinephrine through certain entities under the 340B Drug Pricing Discount Program, in response to an executive order signed on July 24, 2020. Under the proposal, community health centers would be required to provide insulin and epinephrine to low-income

patients at or below the 340B-acquired price if the patient is uninsured or has high cost-sharing requirements (including having a high unmet deductible).

To qualify, patients must be an established patient at the health center, not simply seeking to fill their prescription, and have annual income at or below 350 percent of the federal poverty level (FPL). High-cost sharing is defined as an amount exceeding 20 percent of the amount the health center is otherwise charging patients for the drug, while an unmet deductible means having not yet paid 80 percent of the deductible owed.

This requirement would apply to new health center grant awardees under section 330(e), including new awards to existing recipients for future program terms, and would include any subgrantees of the health center. Section 330(e) awardees provide care to medically underserved populations.

Facilities are allowed to charge a minimal administrative fee, and providers are encouraged to consider the Medicaid dispensing fees for determining what would be considered minimal and appropriate.

Points of Consideration

The Health Resources and Services Administration (HRSA) claims 2.7 million diabetes patients receive care at health centers, though it is unclear how many of them are insulin-dependent.[4] While individuals across income levels have Type 1 diabetes, numerous studies have shown a correlation between poverty and increased incidence of Type 2 diabetes, although Type 2 diabetes is much less likely to require insulin use.[5] The number of anaphylaxis individuals at risk of anaphylaxis is also unclear.

In order to qualify for grant funding through the Health Center Program, clinics must meet certain requirements, including providing free care (including prescriptions) to patients earning less than 100 percent FPL and using a sliding fee scale for individuals earning up to 200 percent FPL. According to HRSA, more than 9 out of 10 health center patients and their families have income at or below 200 percent FPL.[6] Given these existing requirements and patient characteristics, few patients are likely to benefit substantially from this policy change; those who would are most likely to be individuals and families earning between 200 and 350 percent FPL, all of whom would also be eligible for a subsidized insurance plan through the Affordable Care Act Exchanges. That said, patients who do qualify for savings may see significant cost reductions given that the 340B price is often as low as 1 cent.[7]

Grant recipients are also required to use any cost savings acquired from the spread on 340B acquisition costs relative to the payment received to provide discounts for other patients served. Reducing the margins generated by limiting what health centers are able to charge lessens the ability to spread savings to other patients. Instead, benefits will be more targeted to patients specifically in need of insulin and epinephrine–a priority of the administration.

The scope of this rule could have been much larger if other 340B entities had been included: Less than 20 percent of 340B sales (by dollar value) occur at health centers; 78 percent of sales are made at Disproportionate Share Hospitals.[8] There are more than 1,300 health centers (and 9,000 associated sites) participating in the 340B program and serving nearly 30 million patients each year.[9]

Conclusion

This proposed rule could provide lower out-of-pocket costs for certain low-income patients in need of insulin or

epinephrine. The majority of patients most likely to benefit, however, already receive significant discounts on their medications, thereby diminishing the potential impact of this change. Further, by decreasing the revenue to health centers generated by the 340B program, fewer resources will be available to spread cost savings to other patients.

[1] https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends/

[2] https://www.aafa.org/media/1597/anaphylaxis-in-america-jaci-article-2014.pdf

[3] https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-version-epipen, https://www.goodrx.com/blog/generic-epipen-is-still-expensive-heres-how-you-can-save/

[4] https://www.hrsa.gov/about/news/press-releases/proposed-rule-affordable-access-medications

[5] https://care.diabetesjournals.org/content/35/11/2286, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4021012/

[6] https://www.hrsa.gov/about/news/press-releases/proposed-rule-affordable-access-medications

[7] https://www.americanactionforum.org/research/340bmarketdistortions/

[8] http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0

[9] https://www.hrsa.gov/about/news/press-releases/proposed-rule-affordable-access-medications