

To: Michigan Members, U.S. House and Senate

From: Michigan 340B Hospitals

Date: September 16, 2020

Subject: Pharmaceutical manufacturers undermining 340B drug pricing

Several of you recently joined a Dear Colleague letter to Health and Human Services (HHS) Secretary Alex Azar regarding the actions taken in recent weeks by pharmaceutical manufacturers toward hospitals, negatively impacting their 340B programs. The aggressive actions of the manufacturers will limit 340B arrangements with contract pharmacies within the 340B Drug Pricing Program. We are writing en masse to inform you that the pharmaceutical manufacturers' move to limit payment to contract pharmacies, and the other actions underway, are a significant detriment to the 340B hospitals of Michigan and the services we can provide to eligible patients because of the 340B Program.

The 340B Program provides much needed savings that enable 340B hospitals and other qualifying entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. In 1996, the Health Resources and Services Administration (HRSA) set forth guidance that created contract pharmacies (61 FR 43549, August 23, 1996) specifically to allow covered entities "participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity's patients." The HRSA further clarified the guidance most recently in 2010 (75 Fed. Reg. 10272, March 5, 2010), stating, "Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition."

In the past few weeks, several pharmaceutical manufacturers notified covered entities of various policy changes that would impact their usage of contract pharmacies under the program. Most recently, Astra Zeneca announced to providers and wholesale pharmacy contact partners that, effective Oct. 1, it "only will process 340B pricing through a single contract pharmacy site for those covered entities that do not maintain their own on-site dispensing pharmacy." This follows the policy change by Eli Lilly, which will stop distributing three formulations of Cialis to 340B contract pharmacies, as well as Novartis, Merck and Sanofi, which intend to collect and analyze 340B covered entities' contract pharmacy claims data to mitigate duplicate 340B drug discounts and "ineligible rebates." These actions are in direct violation of either the HRSA guidance and/or the various 340B entity contracts.

Overall, these policies are counter to the intention of the 340B Program as well as the governing policies of the program. Even worse, these policies have severe financial implications to Michigan 340B hospitals and our patients, just as we are working to survive the financial distress of the COVID-19 pandemic. Both the financial and clinical impact of the pharmaceutical manufacturers' actions vary by hospital, by system and by region. 340B supports patients who cannot afford the usual price of prescription drugs and other community-based assistance for patients who have needs beyond their own means. To learn more about the impact on the 340B hospitals in your congressional district, please contact us at the facilities identified below.

Again, we appreciate the effort of the Michigan delegation to deliver this message to HHS Secretary Azar. Please continue to partner with us to resolve this newest challenge to the 340B program.

Thank you.

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