

United States Senate
WASHINGTON, DC 20510

May 2, 2022

Christi A. Grimm
Inspector General
Department of Health & Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Grimm,

The 340B Drug Pricing Program (340B Program) helps maintain health care access for low-income patients. In 2020, the Trump administration’s Department of Health & Human Services (HHS) established the 340B Administrative Dispute Resolution (ADR) Board that outlines a process to settle disputes between drug companies and covered entities.¹ The HHS Office of the General Counsel released an advisory opinion concluding “that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.”² This advisory opinion was withdrawn by the Biden administration “in the interest of avoiding confusion and unnecessary litigation.”³ The Biden administration appointed new board members to the ADR Board.⁴

In May 2021, the Health Resources & Services Administration (HRSA) reviewed policies in place by six drug manufacturers who placed “restrictions on 340B pricing to covered entities that dispense medication through pharmacies.”⁵ HRSA sent letters to those six drug manufacturers determining their “actions have resulted in overcharges and are in direct violation of the 340B statute.”⁶ In September 2021, HRSA referred the matter to your office, the HHS

¹ 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80632-80646. <https://www.federalregister.gov/documents/2020/12/14/2020-27440/340b-drug-pricing-program-administrative-dispute-resolution-regulation>.

² HHS – Office of the General Counsel, “Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program December 30, 2020,” https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

³ HHS – Office of the General Counsel, “Notice of Withdrawal,” June 18, 2021, <https://www.hhs.gov/sites/default/files/notice-of-withdrawal-of-ao-20-06-6-18-21.pdf>.

⁴ Appointment of Administrative Dispute Resolution Board Members, 86 Fed. Reg. 33317. <https://www.federalregister.gov/documents/2021/06/24/2021-13461/appointment-of-administrative-dispute-resolution-board-members>.

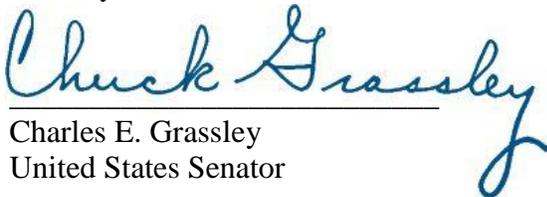
⁵ HRSA Correspondence to Stakeholders, HRSA Letters to United Therapeutics Corporation, Sanofi, Novo Nordisk, Novartis Pharmaceuticals Corporation, Eli Lilly and Company, and AstraZeneca Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, May 17, 2021, <https://www.hrsa.gov/opa/program-integrity/index.html>.

⁶ *Id.*

Office of the Inspector General (HHS-OIG).⁷ Since the September 2021 referral, HRSA has referred an additional drug manufacturer to your office.⁸ At the timing of this letter, HHS-OIG has not taken enforcement action related to these referrals. I am requesting an update on HHS-OIG's work and if it plans to take enforcement action against these drug manufacturers.

I remain committed to passing the bipartisan and negotiated Prescription Drug Pricing Reduction Act (PDPRA). This legislation meaningfully lowers prescription drug costs and results in savings for seniors and taxpayers.⁹ It also brings more sunshine and accountability into the prescription drug industry while promoting competition and innovation. Additionally, I have consistently supported more transparency into the 340B Program. I will never stop working to advance bipartisan legislation that lowers prescription drug costs and promotes accountability, competition, and innovation.

Sincerely,


Charles E. Grassley
United States Senator

⁷ HRSA Correspondence to Stakeholders, Updated HRSA Letters to United Therapeutics Corporation, Sanofi, Novo Nordisk, Novartis Pharmaceuticals Corporation, Eli Lilly and Company, and AstraZeneca Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, September 22, 2021, <https://www.hrsa.gov/opa/program-integrity/index.html>.

⁸ HRSA Correspondence to Stakeholders, Updated HRSA Letter to Boehringer Ingelheim Pharmaceuticals Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, March 29, 2022, <https://www.hrsa.gov/opa/program-integrity/index.html>.

⁹ Office of Senator Chuck Grassley, "Grassley Introduces the Updated Prescription Drug Pricing Reduction Act of 2020," press release, July 2, 2020, <https://www.grassley.senate.gov/news/news-releases/grassley-introduces-updated-prescription-drug-pricing-reduction-act-2020>.