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July 26, 2023

RE: 340B Request for Information

Submitted via Bipartisan340BRFI@email.senate.gov

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist. Thank you for your request for information (RFI) related to the 340B drug discount program. We will focus our response on question three of the RFI: *What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?*

When it was created in the early nineties, the 340B program was intended to help uninsured and under-insured patients access medications at deeply discounted prices. However, the statute did not provide a clear definition of a qualified patient and included few provisions for oversight and reporting by the 340B covered entities with regard to how they used savings from the program. The statute also did not address contract pharmacy use. Now, about thirty years after its creation, the 340B program is not delivering the intended benefits to the intended beneficiaries: patients who need help paying for medications. Instead, the program has become a "cash cow" for major healthcare systems.

According to the Government Accountability Office, participation in the 340B Program grew to 12,700 covered entities in 2020. That same GAO report noted that the Health Resources and Services Administration (HRSA), the entity tasked with 340B oversight, "issued a total of 1,536 findings to address covered entity noncompliance found in the 1,242 finalized audits conducted from fiscal years 2012 through 2019." These noncompliance issues were spread roughly evenly across the areas of eligibility (561), diversion (546), and duplicate discounts (429).

While much criticism has been leveled at HRSA in relation to 340B, many of the issues with the program stem from a lack of statutory clarity. As noted above, the statute itself provides few parameters on the program's intent or on key aspects of the program. With regard to patient eligibility, the statute in its current form only prohibits reselling or transferring a 340B drug to someone who is not a patient of the entity. In other words, the only requirement is that there must be some ongoing relationship

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between the patient and the entity. That amounts to no meaningful limitation on eligibility at all.

The statute does, however, clearly list the types of entities eligible to benefit from the 340B program. By design, many of these entities serve narrowly defined and vulnerable patient populations, such as Native Hawaiian Health Centers or Black Lung Clinics. Based on the specific statutory listing of these entities, one can infer the patient populations intended to benefit from the program. These entities, with missions narrowly focused on unique, specific vulnerable patient populations, are not driving the current issues with 340B. To some extent, these entities have become collateral damage of the problematic behavior by one statutorily listed category of 340B entities: disproportionate share hospitals (DSH).

Unlike the other listed covered entities, DSHs do not exclusively serve a narrowly defined patient population or underserved locations. Thus, because the statute does not provide a clear definition for patient eligibility, these entities may technically be acting within the bounds of the law when they stretch the 340B program far beyond any reasonable interpretation.

Changes to DSH eligibility are not necessary to fix this issue. Rather, ***Congress must statutorily define patient eligibility for purposes of 340B.*** Although additional reforms may be needed with regard to contract pharmacies, that fix alone will help refocus the 340B program on its originally intended beneficiaries. Inaction results in a continued drain of limited Medicare resources. Covered entities can purchase drugs at deeply discounted prices and receive reimbursement by Medicare at much higher levels. That delta is the reason the program has experienced such explosive growth. However, it syphons money away from the Medicare system, which is already facing insolvency.

In closing, it is important to reiterate that the 340B program is valuable and necessary for many patient populations. However, there is an urgent problem when a hospital accesses steeply discounted drugs prices to take care of the disadvantaged, but then turns around and sues patients who cannot afford their bills or turns away low-income patients from its clinics. This crisis recently came to light in a *New York Times* investigative piece entitled "Profits Over Patients: How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits." Clear statutory boundaries, particularly related to patient eligibility, would prevent these scenarios.

On behalf of CSRO and the patients we serve, thank you for your bipartisan work on this important program. Please do not hesitate to reach out to me if CSRO can provide any additional information: info@csro.info.

Sincerely,

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs