



October 17, 2022

Emeka Egwim, PharmD
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Dear Dr. Egwim:

We write to draw your attention to recent and very concerning actions taken by pharmaceutical manufacturers that we believe are jeopardizing access to 340B discounted medications. An increasing number of pharmaceutical manufacturers are requiring that 340B eligible entities submit patient prescription data via a technology platform, known as 340B ESP, as a condition to receiving their statutorily mandated 340B drug discounts.

There is no statutory basis whatsoever for manufacturers to require the submission of these data. Further, manufacturer imposition of this requirement is in direct conflict with manufacturers' obligations under the statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall...offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." As HRSA has previously indicated, "nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data.¹"

Despite HRSA's prior statements prohibiting manufacturer-imposed requirements to produce claims data, manufacturers nevertheless continue to condition access to discounted medications on covered entity submission of prescription data via 340B ESP.

Accordingly, we ask that HRSA take urgent action to:

1. Inform manufacturers that they may not impose additional requirements on eligible entities beyond those identified in the statute. We ask that HRSA specifically inform manufacturers that they have no authority to require eligible entities to submit patient prescription information to manufacturers via the shared platform known as 340B ESP, and may not condition provision of 340B discounts or discounted products on submission of such data via this platform.
2. Communicate to eligible entities that they are under no obligation to submit data to 340B ESP in order to receive discounted medications, and that manufacturers cannot condition access to discounted medications on the submission of such data.

We thank you for your consideration of this important issue.

Sincerely,

ASHP (American Society of Health-System Pharmacists)

¹ May 6, 2022 warning letter to Merck & Co regarding manufacturer-imposed requirement to submit claims data via a third-party technology platform.