NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Submitted via email alex.azar@hhs.gov

August 19, 2020

Alex M. Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Thomas Engels
Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

RE: Recent Announcements from Major Pharmaceutical Companies Impacting Contract Pharmacy Participation in the 340B Program

Dear Secretary Azar and Administrator Engels:

On behalf of chain pharmacies, the National Association of Chain Drug Stores (NACDS) is writing to express our concerns with recent announcements from major pharmaceutical companies that indicate the companies will no longer provide 340B pricing on some drugs to covered entities utilizing contract pharmacies, or will require covered entities to submit contract pharmacy claims data for certain drugs to pharmaceutical manufacturers.[1] Specifically, NACDS is concerned that these recent announcements will undermine contract pharmacy participation in the 340B program, which could reduce essential access to medications by beneficiaries. What's more, these recent announcements may signal a broader trend by manufacturers to undermine the 340B program.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. Chain pharmacies represent almost two-thirds of all contract pharmacies participating in the 340B program.

[1] *See* HRSA, Notice: Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf (filing from Elli Lilly on the limited distribution of Cialis, effective July 1, 2020). As early as this week, media reports have indicated that AstraZeneca will only process 340B pricing at a single contract pharmacy site for covered entities that do not maintain their own on-site dispensing pharmacy. Further, NACDS understands that Merck and Sanofi have communicated their requests regarding pharmacy claims data directly to covered entities. The communications explain that the intent of these requests is to investigate duplicate discounts.

Many of our members have a major presence in medically underserved neighborhoods across the nation and play a critical role in bringing pharmacy-led health and wellness services to struggling patients in these communities. As part of this commitment, our members have served as contract pharmacies on behalf of eligible covered entities under the federal government's 340B program. Along with providing a vital local access point to medications and clinical pharmacy services such as medication counseling and medication therapy management, contract pharmacies provide a wide range of administrative support services to many 340B-covered entities, allowing them to operate with transparency, efficiency, and accountability. These services benefit the program, covered entities, and most important, patients, helping to ensure they benefit from drug discounts. Having access to lower cost pharmaceuticals provides vulnerable patients the opportunity to be more compliant with their physician's prescribed therapy.

As described herein, we urge HRSA to take swift action to enforce the clear meaning of the 340B statute, which has provided the avenue for contract pharmacy participation in the 340B program. In the alternative, we urge HRSA to adopt its 2010 guidance through the rulemaking process as a means to formally express HRSA's ten-year policy that covered entities may contract with multiple pharmacies "as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition."[2]

HRSA must ensure that manufacturers provide 340B pricing to covered entities

The purpose of the 340B program is to allow safety-net providers "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] In doing so, statute requires pharmaceutical manufacturers, who wish to participate in the Medicaid and Medicare Part B programs, to enter into an agreement with the government that stipulates the manufactures will offer 340B covered entities drugs to be purchased at or below the applicable ceiling price "if such drug is made available to any other purchaser at any price."[4] HRSA has spent considerable effort on ensuring that manufacturers are prohibited from knowingly and intentionally charging 340B covered entities for covered outpatient drugs more than the statutory ceiling price.[5]

A recent manufacturer's announcement to no longer provide 304B pricing on Cialis to covered entities who ship the discounted drug to contract pharmacies or to no longer honor contract pharmacies' orders for the drug is tantamount to those manufacturers refusing to offer 340B drugs to 340B covered entities. This action is a clear violation of the 340B statute. Contract pharmacies operate in the 340B program in a manner as their name implies; they contract with covered entities to act as a pharmacy/dispensing location for those entities, often times in rural areas and to underserved populations. The manner with which covered entities should supply discounted drugs at a contract pharmacy, either by shipping the drugs to a pharmacy or permitting pharmacies to directly order the discounted drugs from manufacturers, should have no bearing on whether manufacturers must continue to offer discounted prices to covered entities. Thus, we urge HRSA,

[2] 75 Fed. Reg. 10272, 10273 (Mar. 5, 2010).
[3] HRSA, 340B Drug Pricing Program, *available at* https://www.hrsa.gov/opa/index.html.
[4] 42 U.S.C. § 256b.
[5] *See* 83 Fed. Reg. 61563 (Nov. 30, 2018).

as a matter of law, to ensure manufacturers provide 340B pricing to covered entities, including through their contract pharmacies.

Furthermore, HRSA should enforce the clear meaning of the 340B statute, which allows for covered entities to use contract pharmacies. NACDS highlights that some manufacturers' announcements to limit distribution may be an attempt to cut out contract pharmacies completely from the 340B program. To wit, NACDS contends that a specific manufacturer may be using the drug Cialis as a test case to gauge HRSA's enforcement of the 340B statute and may signal plans to expand limited distribution to several drugs in the near future. We urge HRSA to ensure this manufacturer's announcement does not become a larger trend by this and other manufacturers to cut out contract pharmacies in the 340B program. If necessary, we encourage HRSA to formally adopt its 2010 guidance,[6] which offered guardrails for covered entities who choose to utilize more than one contract pharmacy to dispense its 340B drugs.

HRSA must ensure that manufacturers do not impose requirements outside of the 340B statute and HRSA rules

The 340B statute permits a manufacturer to conduct an audit of a covered entity should there be a question of the covered entity's compliance with the 340B program (i.e. duplicate discounts). Furthermore, under HRSA guidelines and the informal dispute resolution process, a manufacturer may make a good-faith inquiry into a covered entity regarding compliance concerns prior to initiating an audit.[7] Outside of these processes, manufacturers do not appear to have an additional avenue to request information from covered entities.

The recent announcements that some manufacturers will require covered entities to report to the manufacturer all contract pharmacy claims data to address compliance concerns is overly broad and burdensome on covered entities and contracted pharmacies. These requests fail to pass the "good-faith" standard outlined in long-standing HRSA guidelines. Thus, HRSA should have an interest in addressing these requests as they appear to set up barriers for participation in the 340B program outside of federal laws and rules.

We appreciate the opportunity to share our concerns with your agency. Should you have any questions, please contact Kala Shankle at kshankle@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer

Cc: Krista Pedley

[6] 75 Fed. Reg. 10272 (Mar. 5, 2020), *available at* https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf.

[7] 61 Fed. Reg. 65406 (Dec. 12, 1996). HRSA continues to review this process. For example, last year HRSA issued a request for information regarding guidelines for the Office of Pharmacy Affair's (OPA) informal dispute resolution process that resolves disputes between manufacturers and covered entities.