



AstraZeneca 340B Contract Pharmacy Policy

A Review and Response Options

August 19, 2020

To: Selected Clients

From: Devon Seibert-Bailey, Senior Vice President
Paul Lee, Senior Partner

Pharmaceutical manufacturer Astra Zeneca announced through a [letter](#) sent to providers and wholesale pharmacy contacts earlier this week 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 is the latest drug manufacturer to look at 340B contract pharmacies – and most all-encompassing policy – following Eli Lilly who stopped distributing three formulations of Cialis to 340B contract pharmacies, and Novartis, Merck, and Sanofi who are collecting and analyzing 340B covered entities’ contract pharmacy claims data to mitigate duplicate 340B drug discounts and “ineligible rebates.”

Astra Zeneca Policy

While the letter is limited on details, here is our understanding –

- Each parent entity, along with all child sites connected to that parent, will only provide 340B pricing to one pharmacy. This could be either on-site (contract or run by the entity itself) or a separate off-site contract pharmacy. Only one pharmacy for each parent entity and all of its child sites.
- A hospital system may have multiple “parent entities” or hospitals that also have multiple “child sites” or outpatient clinics and the like. For each one of those parent entities, one pharmacy may be chosen. Another way to look at it, a system has three parent entities, may therefore choose three pharmacies.
 - If a hospital has a child site that is a cancer clinic, dialysis center, or hemophilia clinic with a separate contract pharmacy, that pharmacy will no longer be able to receive the 340B price as the on-site pharmacy to the hospital would be the only pharmacy eligible for any AstraZeneca drug.

Response

When contacted by groups in July following the Eli Lilly notice, HRSA stated only that it “strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements.”

There has been discussion among associations that a lawsuit may be necessary to force a reversal of the policies limiting contract pharmacy access to 340B pricing.

Legal Issues

Contract pharmacies were established through a HRSA guidance document ([61 FR 43549, August 23, 1996](#)) allowing for covered entities “participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity’s patients.

HRSA further clarified the guidance a few times 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.”

It is important to note that 340B contract pharmacies do not exist under either statute or regulations, and it is often said that guidance documents will not hold up in the Courts.

Strategies

Assuming hospital/system opposition to the AstraZeneca policy change (and perhaps opposition to the actions of the other pharma companies), we should consider the following actions.

Short Term

- Hospital system letter, signed by as many systems as possible within a week, to HHS Secretary Azar calling out these policy changes that are not supported by agency guidance. Urging action that these pharma companies reverse their policies that “violate the spirit and intent” of the 340B program as outlined in HRSA policies.
- This same letter could also be sent to congressional leaders, i.e. chairs of committees of jurisdiction.
- Develop congressional sign on letter led by members of the committees of jurisdiction (E&C, HELP) to HHS Secretary urging action against the pharma companies.
- Health systems urge their associations in Washington to engage by
 - Sending joint letters to pharma, HHS, Congress raising objections and seeking relief
 - Considering legal action against pharma companies
 - (These associations include: AHA, AEH, 340B Health – and others as appropriate. These associations have pursued a “lawsuit only” strategy against HHS 340B cuts to date. Unfortunately, they have been less than enthusiastic about engaging Congress, which may make their engagement on this issue more difficult to achieve in the short term.

Long Term

- Develop legislation to be introduced this year that would achieve all of the desired policy objectives. This would build on the legislative initiative started by U.S. Rep. David McKinley (R-WV) about two years ago.
 - While such legislation would unlikely pass this year, it could more easily pass next year – especially if the Democrats take control of the White House and Senate.