

340B GPO PROHIBITION AND WHOLESALE WAC ACCOUNT LOAD OPTIONS

A Feb. 7, 2013 HRSA Policy Release provided clarification for hospitals subject to the Group Purchasing Organization (GPO) Prohibition. Apexus is providing this document to facilitate 340B compliance in the marketplace; the information contained in this document is not legal advice.

KEY MESSAGES

1. Establishing an outpatient non-GPO/WAC (i.e., PVP Non-340B) account provides a compliant method for obtaining covered outpatient drugs for 340B ineligible outpatients of these hospitals. Such an account is useful if the hospital elects to carve-out Medicaid or uses replenishment in mixed-use areas.
2. For entities using a replenishment model, replenishment orders may result in a physical inventory in the mixed-use area that is composed of a variety of contract purchases. The following should be met:
 - 340B accumulation occurs only for 340B eligible patients;
 - 340B ineligible outpatients generate accumulation only for orders on an outpatient non-GPO/WAC account and
 - Hospitals maintain auditable records of policies, procedures, and transactions.
3. HRSA expects hospitals to establish compliant practices in accordance with the GPO Policy Release by August 7, 2013:
 - Hospitals may use up existing GPO inventory.
 - If the hospital is unable to establish compliant practices in accordance with the GPO Prohibition, the hospital should self-report to HRSA.
 - No new inventory for ineligible 340B outpatients should be purchased through a GPO.

TO BRING VALUE TO HOSPITALS SUBJECT TO THE GPO PROHIBITION, APEXUS OFFERS THE FOLLOWING CONTRACTS.

Outpatient Contracts or Pricing	Definition	Account Load Options	
		Wholesaler Account 340B Primary	Wholesaler Account Non GPO/WAC
340B/PHS	Manufacturer calculates prices for 340B covered outpatient drugs according to the 340B statutory formula.	YES	NO
Apexus PVP Sub-340B	Reflects pricing that is negotiated with branded and/or generic manufacturers offering sub-340B pricing.	YES	NO
Apexus PVP Sub-WAC	Apexus PVP sub-WAC contracted pricing allows entities to order covered outpatient drugs in situations that would otherwise require the entity to purchase at WAC pricing. This pricing is negotiated without regard to 340B pricing; use of this pricing is GPO Prohibition compliant. Pricing is negotiated for outpatient covered drugs at sub-WAC or GPO-similar.	NO	YES
Apexus Value-Added	Other value-added contracts are for non-covered drugs such as vaccines, blood glucose monitoring supplies, prescription vials and labels, discounts on service contracts such as pharmacy automation hardware and software.	YES	YES
Apexus Generics Portfolio (AGP)	Apexus subcontracts to wholesalers to extend generic source pricing to Apexus participants. AGP pricing in the non-GPO/WAC account can be used on 340B ineligible patients while AGP pricing in the PHS account may be used on 340B eligible patients.	YES	YES
Individual Hospital Agreement	A hospital obtains discounts based on the individual hospital's negotiation with a manufacturer (single entity contract).	YES	YES
GPO Non-Acute	GPOs obtain discounts from vendors on outpatient drugs based on the collective buying power of the GPO members.	NO	NO
GPO or Wholesaler Generic Source	GPOs and wholesalers obtain discounts from manufacturers based on the collective buying power of the GPO or wholesaler members/customers.	NO	NO

QUICK GPO SELF-ASSESSMENT

Our hospital should be able to answer NO to all of the following:

1. Use GPO purchased covered outpatient drugs for 340B ineligible outpatients in OPA-registered participating clinics?
2. Have systems (or vendor systems) set up to use GPO purchased covered outpatient drugs for 340B ineligible outpatients?

This information is provided only as a reference to encourage 340B program integrity. This information has not been endorsed by the HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.