

Secondary Purchases In Pharmacy & 340B

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1

Learning Objectives

- Define what a secondary purchase is and the different considerations such purchases may require
- Outline expectations to maintain 340B compliance when making secondary purchases
- Discuss best practices for loading contracts to secondary accounts
- Assess potential compliance pitfalls and best practices


2

CE Question

True/False:

Secondary purchases do **NOT** have to follow the same 340B compliance requirements as primary purchases because of the heavy operational burden to covered entities.

☐ True
☐ False



3

Primary vs. Secondary Purchasing

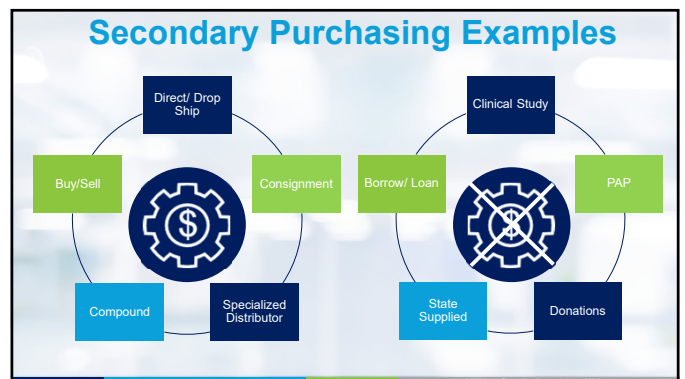
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4

Primary vs. Secondary Purchasing

Primary	Secondary
<ul style="list-style-type: none"> • Majority of purchases from primary wholesaler • Ordered electronically • Utilizes split billing software for replenishment 	<ul style="list-style-type: none"> • Requires different ordering method(s) <ul style="list-style-type: none"> – Phone, manufacturer website, email, etc. • Manual process • Does not incorporate split billing software

5



6

Why Secondary Purchases Exist



- Shortages
- LDD models
- Allocation enforcement
- Delivery interruptions
- Unexpected care scenarios
- REMS program

7


Secondary Order Workflow



Best Practice
Check available accumulations prior to placing an order.

8

What is your biggest struggle with secondary purchases?

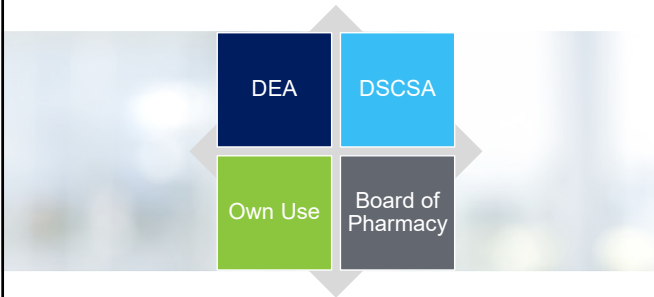


9

Purchasing Compliance

10

Compliance Expectations



11

Compliance Expectations—340B Sites



12

Compliance—Diversion



- Diversion occurs when a covered entity resells or otherwise transfers a 340B drug to a person who is not an eligible patient of that entity.
 - The act of just “dispensing a drug” does not confer eligibility
 - Applies to all drugs purchased at 340B, not just the drugs an entity charges for
 - In-house or clinic-administered drugs are given to patients with an outpatient status at the time of dispense; inpatients are not eligible
 - Risks include findings during a HRSA audit and/or repayment of improper purchases to manufacturers

13

Compliance—Duplicate Discounts



- Duplicate discounts are prohibited by the 340B Program statute.
- The easiest way to understand the meaning of a duplicate discount is to imagine yourself as a drug manufacturer:
 - As a drug manufacturer, if you sell your drug to covered entities at a steeply reduced 340B price AND you also pay the state a Medicaid rebate on that same drug, it will result in giving **two** discounts for the same product.



14

Compliance—Duplicate Discounts (continued)



- Medicaid status would be “carve-in.”
- In contrast, if that site chooses not to bill Medicaid for 340B drugs, then its Medicaid status would be “carve-out.”
 - Find or create a list of sites that carve out Medicaid; ensure that these sites have a non-340B account available to purchase drugs for Medicaid outpatients.



15

Compliance—GPO Prohibition



- The GPO Prohibition applies to covered outpatient drugs (CODs) based on the covered outpatient drug definition in the Social Security Act, section 1927(k).
 - Check for COD purchases **outside** the pharmacy department (e.g., materials management, clinic ordering)
- Review your policies and procedures for drugs that do not meet the COD definition; includes vaccines and supplies



16

Compliance—Orphan Drug Rule



- A drug that is designated as “a drug for a rare disease or condition” is referred to as an orphan drug, as defined by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act
- Are not considered CODs for free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals (CAN/RRC/SCH/CAH)
- Manufacturers are not required to provide these hospitals orphan drugs at a 340B price; voluntary discounts may be available. Review the HRSA orphan drug list at:
<http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html>



17

What is one thing you
do at your entity to
remain compliant with
secondary purchases?



18

Contract Load Options

PVP Contract Types

- **Sub-WAC Pricing**
 - Contract pricing below the wholesale acquisition cost (WAC) and made available to PVP participants that are subject to the GPO Prohibition
- **Sub-340B Pricing**
 - Contracted pricing below the statutory 340B ceiling price and made available to all PVP participants
- **Value-Added Products (VAPs)**
 - Contracted pricing for products that do not meet the definition of a COD, made available to all PVP participants (e.g., vaccines or blood glucose monitoring supplies)

Supplier Account Setup: DSH/PED/CAN

Account 1	Account 2	Account 3
GPO	340B	Non-GPO/Non-340B
Inpatient	Outpatient	
<ul style="list-style-type: none"> • GPO contracts • Optional contract loads: <ul style="list-style-type: none"> • DSH inpatient contracts (DSH only) • GPO or Wholesaler Generic Source Program • Individual CE: MFR Agreements** 	<ul style="list-style-type: none"> • PHS/340B contracts • Optional contract loads: <ul style="list-style-type: none"> • PVP Sub-340B* • PVP Value-Added* • Individual CE: MFR Agreements** 	<ul style="list-style-type: none"> • WAC pricing by default • Optional contract loads: <ul style="list-style-type: none"> • PVP Sub-WAC* • PVP Value-Added* • Individual CE: MFR Agreements**

* = if enrolled in PVP

** = single covered entity agreement with manufacturer

Supplier Account Setup: NOT DSH/PED/CAN

Account 1	Account 2	Account 3
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Contract Indicators

Contract Indicator	Account	Description	Contract Indicator	Account	Description
PHSB	340B	PHS Contract - Ceiling price	PHSB	340B	PHS Contract - Ceiling price
APXV	340B	Prime Vendor Contract - Sub-340B, Value Add Program and Apexus Generic Portfolio	APXV	340B	Prime Vendor Contract - Sub-340B and Value Add
APXV	WAC	Prime Vendor Contract - Sub-WAC and Value Add Program	APXV	WAC	Prime Vendor Contract - Sub WAC and Value Add
AGPP	WAC	Prime Vendor Contract - Apexus Generic Portfolio	APXV	340B	Prime Vendor Contract - Apexus Generic Portfolio
ASDS	340B	PHS and/or Prime Vendor Contract - ASD 340B Pass Through	SPDAPX	340B	PHS Contract - Ceiling price (Specialty Pharma Division)
INDV	All	Individual Agreement Contract	SPDAPX	340B	Prime Vendor Contract - Sub-340B and Value Add (Specialty)
P	340B	PHS Contract - Ceiling price	SPDAPX	WAC	Prime Vendor Contract - Sub-WAC and Value Add (Specialty)
V	340B/WAC	Prime Vendor Contract - Sub-340B, Sub-WAC & Value Add Program	INDV	All	Individual Agreement Contract
M	340B/WAC	Prime Vendor Contract - Sub-340B, Sub-WAC & Value Add Program	PHS	340B	PHS Contract - Ceiling price
A	340B/WAC	ADAP Contracts - Apexus Generic Portfolio	PVP	340B/WAC	Prime Vendor Contract - Sub-340B, Sub-WAC & Value Add
I	All	Individual Agreement Contract	AGPP	340B/WAC	Prime Vendor Contract - Apexus Generic Portfolio
			IND	All	Individual Agreement Contract

* Contract indicators are based on wholesaler preference.

Can you get contract pricing on secondary purchases?



Compliance Pitfalls & Best Practices

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25

Direct Manufacturer Purchases

Can cause compliance risks

Diversion

- 340B purchase with no accumulations available
- 340B purchase is not updated (decremented) in accumulator, causing additional, improper purchases on 340B

GPO Prohibition

- Manufacturer has only GPO account available for direct purchases
- GPO contracts loaded to retail or WAC account

Best Practices

- Ensure non-GPO/WAC account available
- Designate non-GPO/WAC for purchase when accumulations insufficient
- Verify and decrement accumulations for direct purchases
- Conduct self-audits

26

Consignment

Can cause compliance risks

Diversion

- An order is placed on 340B without proper accumulations available
- 340B purchase is not updated (decremented) in accumulator, causing additional, improper purchases on 340B

GPO Prohibition

- Consigner has only GPO account available for direct purchases
- GPO contracts loaded to retail or WAC account

Best Practices

- Develop a process for determining patient status
- Inform vendor of appropriate account(s) for purchase
- Verify/decrement from accumulations
- Identify/train staff for consignment process
- Conduct self-audits

27

Patient Assistance Programs & Donations

Can cause compliance risks

Diversion

- Accumulations used from the 340B account in split-billing software

GPO Prohibition

- Accumulate to the GPO account in split-billing software

Best Practices

- Track quantities received
- Block or deduct accumulations
- Outline compliant process in P&Ps
- Conduct self-audits

28

Who uses a consignment program in their pharmacy?



29

Takeaways

- Be mindful when you are making secondary purchases
- Understand and follow all purchasing compliance expectations
- Review the contract types that can be used and loaded to which accounts to maintain program compliance
- Be aware of the possible compliance scenarios that can occur and enact the appropriate processes to prevent them

30

CE Question

True/False:

Secondary purchases do **NOT** have to follow the same 340B compliance requirements as primary purchases, because of the heavy operational burden to covered entities.

- ☐ True
- ☐ False



31

CE Question & Answer

True/False:

Secondary purchases do **NOT** have to follow the same 340B compliance requirements as primary purchases, because of the heavy operational burden to covered entities.

- ☐ True
- ☒ False

False — **ALL** 340B purchases made by covered entities are required to follow all 340B Program regulations.

This includes preventing diversion, GPO Prohibition violation, and duplicate discounts from occurring.

32



Questions

33



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34