Medicare 340B Drug Changes Effective 1/1/18

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Statement of Conflicts of Interest

PAUL HERNANDEZ HAS NO ACTUAL OR POTENTIAL CONFLICT OF INTEREST IN RELATION TO THIS PRESENTATION.

- Overview of the 340B program
- Exempt facilities
- Drugs impacted by the reduction
- Modifiers distinguishing reduced drugs and exempt drugs
- Impact these changes will have on the revenue cycle
- Other items to review

AGENDA

What is 340B Drug Discount Program?

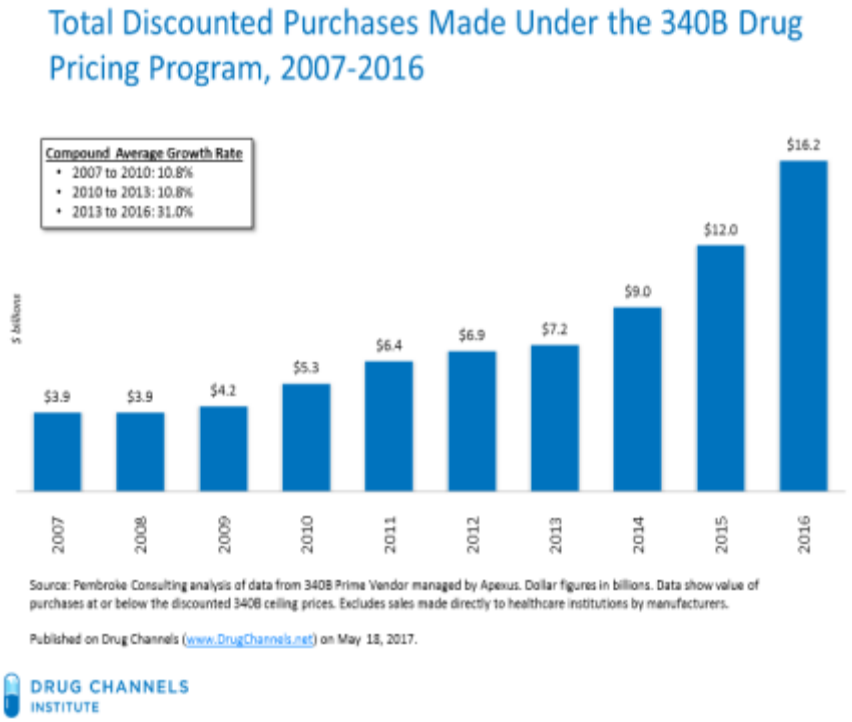
The **340B** Drug Discount Program is a federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.

It was in part a reactive policy to address rising drug prices caused by the Medicaid Drug Rebate Program that was enacted by Congress in 1990

Additional History of Program

As of 2016:

- Covered entities' spending on 340B drug purchases was estimated to be about $16.2 billion annually
- Pharmaceuticals purchased at 340B pricing accounted for 5% percent of all medicines purchased in the United States



Source: Drug Channels Institute - analysis, *The 340B Program Hits $16.2 Billion in 2016; Now 5% of U.S. Drug Market*
http://www.drugchannels.net/2017/05/exclusive-340b-program-hits-162-billion.html

Eligible 340B “Hospital” Entities

- Critical Access Hospitals (CAHs)
- Maryland Waiver Hospital
- Children’s Hospitals
- Free Standing Cancer Hospitals
- Disproportionate Share Hospitals (DSH)
- Medicare Dependent Hospital
- Rural Referral Centers
- Sole Community Hospitals
  - Rural
  - Non Rural

Entities “Excepted” from new Reimbursement Policy

- Critical Access Hospitals (Optional Reporting)
- Maryland Waiver hospitals (Optional reporting)
- Children’s Hospitals
- PPS-exempt cancer hospitals
- Rural Sole Community Hospitals

Drugs Impacted

Reimbursement for “Excepted” Facilities only on Separately Payable drugs including:

- Non-Pass-Through Drugs, Biologicals
- Brachytherapy Sources
- Blood and Blood Products

Separately Payable drugs are classified with a status indicator K

Drugs Impacted (continued)

All other participating facilities* are required to apply informational modifiers to:

- Separately Payable Drugs (status indicator K)
- Pass through Drugs (status indicator G)

Up to date lists of each drug type is kept current on the CMS website here:

* Maryland Waiver and Critical Access Hospitals are not required to report any modifier

Modifiers

- Modifier JG applied to drugs receiving the reduction
  - 106% of Average Sales Price (ASP)
  - The 22.5% reduction is applied to the 106% ASP Rate.
  - Non pass-through drugs
  - Non exempted facilities
- Modifier TB is an informational modifier
  - Non-excepted off-campus provider-based departments
  - Facilities exempt from the reduction
  - Pass-through and non pass-through drugs

340B Modifier Guide

Hospital Type (determined by CMS)	Separately Payable Drug (SI "K")	Pass-through Drug (SI "G")	Packaged Drug (SI "N")	Vaccine (SI "F" "L" or
Not Paid Under OPPS				
CAH	TB, Optional	TB, Optional	TB or JG, Optional	N/A
Maryland Waiver Hospital	TB, Optional	TB, Optional	TB or JG, Optional	N/A
Non-Excepted Off-Campus PBD	TB	TB	TB or JG, Optional	N/A
Paid Under OPPS, Excepted from the 340B Payment Adjustment for 2018				
Children's Hospital	TB	TB	TB or JG, Optional	N/A
PPS-Exempt Cancer Hospital	TB	TB	TB or JG, Optional	N/A
Rural Sole Community Hospital	TB	TB	TB or JG, Optional	N/A
Paid under the OPPS, Subject to the 340B Payment Adjustment				
DSH Hospital	JG	TB	TB or JG, Optional	N/A
Medicare Dependent Hospital	JG	TB	TB or JG, Optional	N/A
Rural Referral Center	JG	TB	TB or JG, Optional	N/A
Non-Rural Sole Community Hospital	JG	TB	TB or JG, Optional	N/A

Legend

- Triggers reduction in reimburesment
- Informational Only (Required)
- Informational Only (Optional)

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Impact on Patient Liabilities

- Part B prescription drugs that are administered via doctor's office or pharmacy will see a reduction
  - RE: After meeting their Part B deductible patients pay a 20% copay
- Part B prescription drugs that are administered in a hospital OP setting will not see any impact
  - RE: Part B recipients pay a copay which is fixed
- Part D recipients
  - Impact will vary depending on the plan selected by the recipient

Impact on Billing Processes

- Assess documentation and record management (EMR/EHR) and reporting systems to ensure that National Drug Code (NDC) specific 340B drug purchases can be traced from order placement/receipt to patient administration/dispensing and eventual billing/reimbursement.
  - RE: Billing systems may not have the ability or readily capture info needed to identify when to apply modifiers
  - May require coordination with Pharmacy or Purchasing/Inventory Management groups to ensure controls and processes in place capture necessary details for compliant billing
  - Biggest chance for disconnect occurs between pharmacy inventory management software systems and the (EMR/EHR) record management systems
- Review Billing controls and systems to ensure compliance with changes
  - RE: Even if system can identify when 340B drugs are administered a review of billing system edits should be performed to confirm changes to program billing requirements are made and in place by policy deadlines

Strengthen Program Integrity

- Covered entities that participate in the 340B Drug Pricing Program must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements.
- Develop appropriate tracking systems to ensure that covered outpatient drugs purchased through the 340B Program are not used for hospital inpatients. It is the responsibility of the hospital to ensure appropriate safeguards are in place to protect against diversion. If a hospital is unable to implement an effective tracking system, it should not use the 340B Program in that setting.
- This is usually the responsibility of Compliance or Internal Audit teams but will require involvement across multiple departments (e.g. IT, Pharmacy, Business Office, Internal Audit)
- The complex nature of tracking inventory and application of discounted drugs should be understood by the business owners responsible for responding to audits or defending erroneous reductions in payments

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QUESTIONS


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