



The 340B Drug Pricing Program

Presentation at Alliance of Community Health Plans
Medical Directors and Pharmacy Directors Meeting
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Avalere Health LLC

Avalere Health, LLC

- Avalere Health delivers research, analysis, insight & strategy to leaders in healthcare policy and business
- 170+ policy and industry experts with backgrounds in government, academia and research organizations, managed care, industry and healthcare delivery, financial services and professional societies
- Capabilities in policy analysis, modeling & scoring, evidence reviews, data analytics, due diligence, qualitative research and market strategy
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Eric Hammelman

- Eric Hammelman, CFA, Vice President, provides data-driven analysis of the impact of payment policies on healthcare patterns. He helps clients across multiple sectors understand how data can better inform their business strategies, including responding to emerging trends such as medical homes and Accountable Care Organizations, or shaping new payment policies including payment bundles.
 - Eric has experience working with a wide range of datasets to understand the best option for each particular assignment, including Medicare, Medicaid, commercial, or other survey-based data. He has a special interest in provider payment, and is a regular speaker at provider conferences to discuss how payment reform may impact provider performance in the years to come.
 - Prior to joining Avalere, Eric was an Associate Analyst with JPMorgan, where he analyzed healthcare service companies and provided investment advice to institutional investors. He also analyzed payment policies for each of these areas, including Medicare, Medicaid, and private payers.
 - Eric has a Bachelors of Music Performance from the University of Illinois at Urbana-Champaign. He also earned an M.B.A. from the Marshall School of Business (University of Southern California), as well as a Masters of Music Performance from the Mannes College of Music in New York, N.Y. Eric is a CFA charterholder.
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340B Program Overview



The intersection of business
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The 340B Drug Pricing Program has Been Providing Safety-Net Providers With Access to Discounted Drugs for 20 Years

- Section 340B of the Public Health Service Act mandates manufacturer discounts on outpatient drugs for certain safety-net providers
 - » Since 1992 all manufacturers participating in Medicaid and/or Medicare Part B have been required to offer 340B discounts
 - » Facilities that qualify for discounts are called ‘covered entities’
 - » On average, covered entities can save 20% to 50% on the cost of outpatient drugs
 - » Program is administered by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA)
- Drugs purchased under 340B are intended only for ‘patients’ of the covered entity
- Entities without an in-house pharmacy of their own may:
 - » Use outside contract pharmacies as a dispensing agents (“ship to / bill to”) and/or
 - » Pay manufacturers directly

The entity is eligible for 340B discounts rather than the patient. Entities may access 340B pricing on outpatient drugs for all their patients, regardless of their insurance status*

* For Medicaid there is a prohibition against double rebates, i.e., the drug may not be subject to 340B pricing and a Medicaid rebate

A Variety of Health Facilities Qualify for the 340B Program

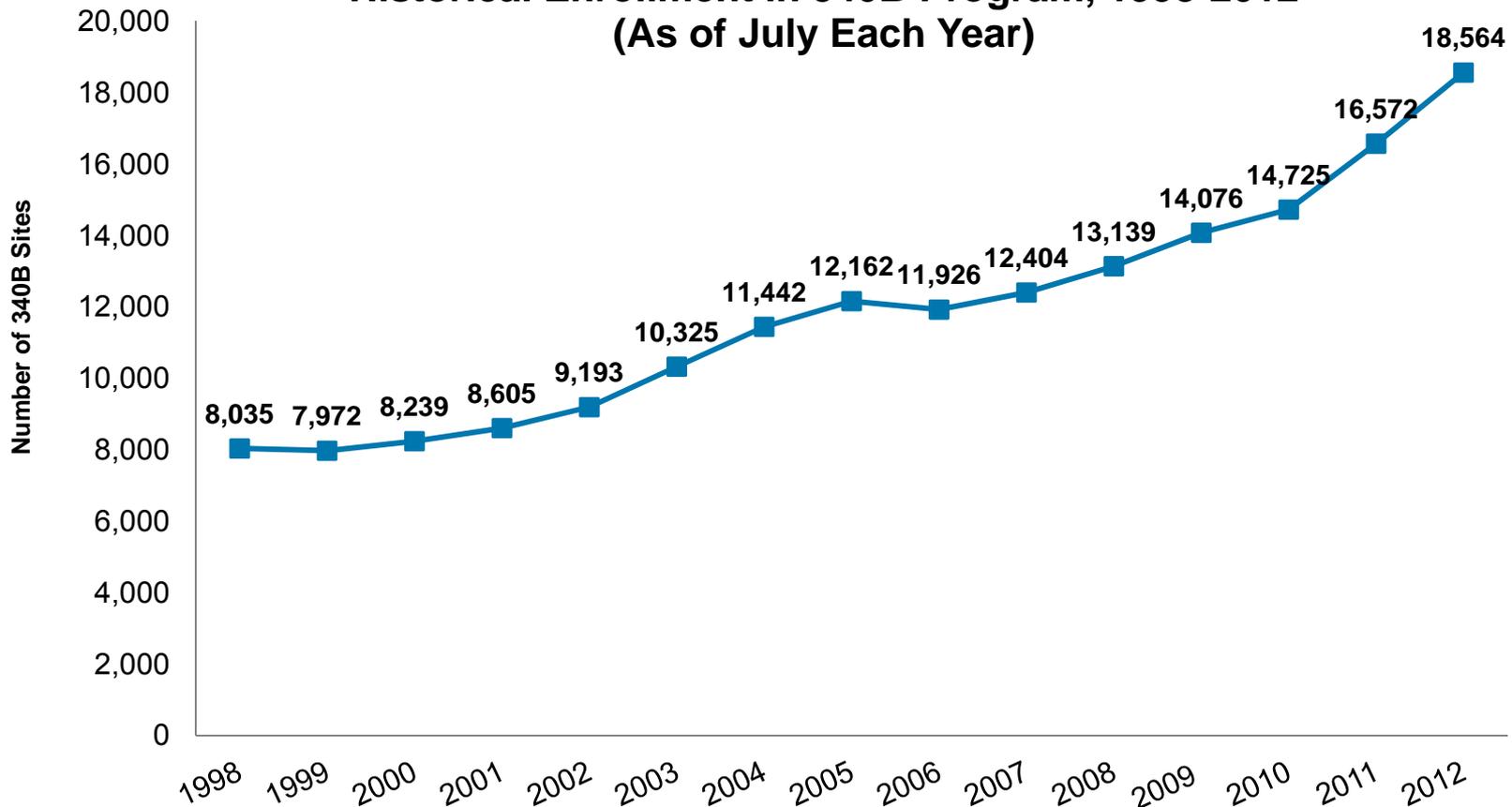
- 340B covered entities include:
 - » Certain Disproportionate Share Hospitals (DSH)
 - Must be either: government owned/operated, non-profits granted governmental powers, or non-profits with contract with state or local government to provide care to low-income people who are not Medicare or Medicaid beneficiaries; and
 - Must have a DSH adjustment >11.75% of the population the facility treats
 - » Federally-qualified health centers and “look-alikes”
 - » Family planning/STD clinics
 - » Ryan White Care Act grantees
 - » State-operated AIDS drug assistance programs
 - » Black lung and tuberculosis clinics
 - » Urban Indian clinics
 - » Native Hawaiian health centers
 - The 340B statute defines all qualifying entity types in a precise manner, with specific criteria that apply to each category of covered entity
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The Affordable Care Act Made new Categories of Hospitals Eligible for 340B Discounts

- Effective January 1, 2010, the Affordable Care Act (ACA) expanded 340B eligibility to additional categories of hospitals, including:
 - » Children's hospitals (DSH >11.75%)
 - Children's hospitals were previously included under the Deficit Reduction Act of 2005 (DRA); ACA clarified eligibility
 - » Freestanding cancer hospitals (DSH >11.75%)
 - » Sole community hospitals (DSH >8%)
 - » Rural referral centers (DSH >8%)
 - » Critical access hospitals (No DSH requirement)
- Orphan drugs are excluded from 340B discounts for those new hospital categories
 - » In May 2011, HRSA released the proposed rule that allows new categories of eligible entities to buy orphan drugs at 340B prices but only for non-orphan uses
 - » Comments to the rule were due July 2011; release date of the final rule is unknown

340B Enrollment Grew Steadily Before the ACA and Accelerated After the Legislation Was Passed

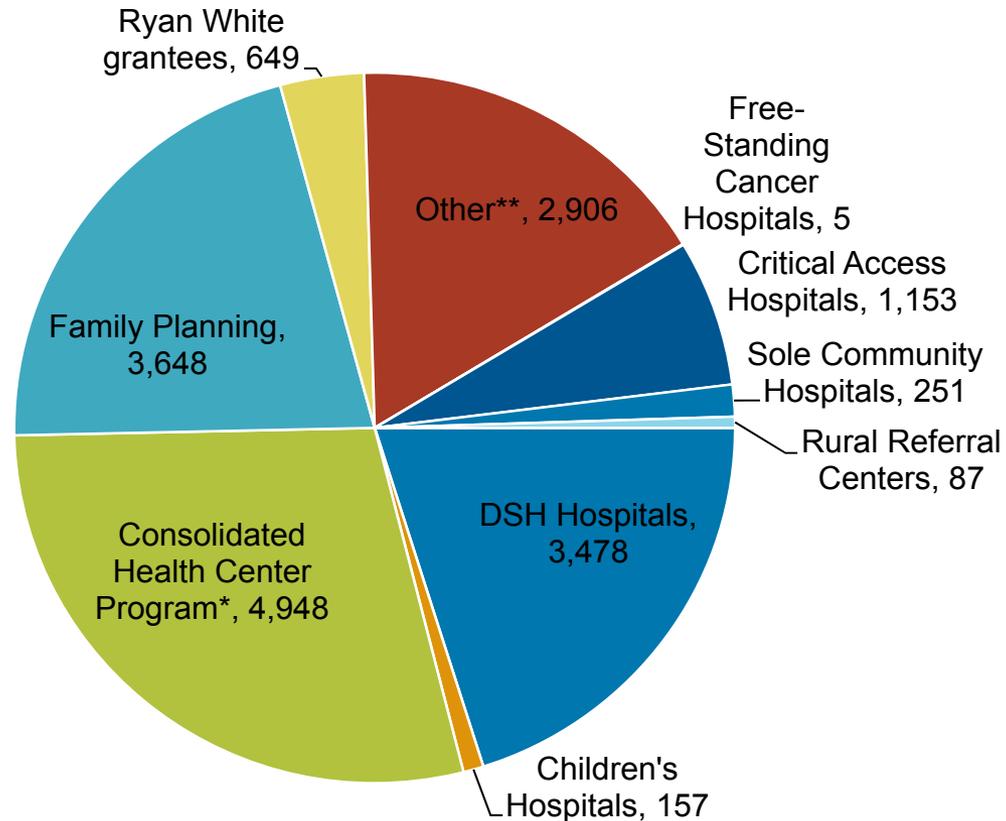
**Historical Enrollment in 340B Program, 1998-2012
(As of July Each Year)**



Source: Avalere analysis of 340B Database of Covered Entities from the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA).



More Than 18,000 Locations Are Enrolled in 340B; Growing Enrollment Has Generated Interest in Program Operations



* Includes FQHC look-alikes, Tribal Care organizations, Community Health Centers, School Based Programs, Health Care for the Homeless Programs, Migrant Health Programs, and Public Housing Primary Care Programs entities.

** Includes black lung clinics, HIV clinics, hemophilia centers, etc.

Source: Avalere analysis of 340B Database of Covered Entities from the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA).

340B Entities Save on Average 20-50 Percent on Outpatient Drug Costs

- Entities participating in 340B purchase drugs at or below a ceiling price defined in the 340B statute
- The ceiling price equals the net Medicaid price which is the lower of:
 - » Average Manufacturer Price (AMP) minus 23.1% for brand name drugs (13% for generic and over-the-counter drugs)*
 - » Manufacturer's best price - the lowest price available to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or the government
- The amount owed by manufacturers due to the Medicaid inflation penalty, if AMP has increased over the consumer price index, is subtracted from the ceiling price
- The Prime Vendor Program (PVP) managed by Apexus helps 340B entities improve access to affordable medications by negotiating sub-ceiling prices with manufacturers
 - » The PVP is free and majority of covered entities participate in the program
 - » The PVP reports offering drugs at prices about 12 percent below the ceiling price (resulting in a 340B price of 35 percent below the AMP)**

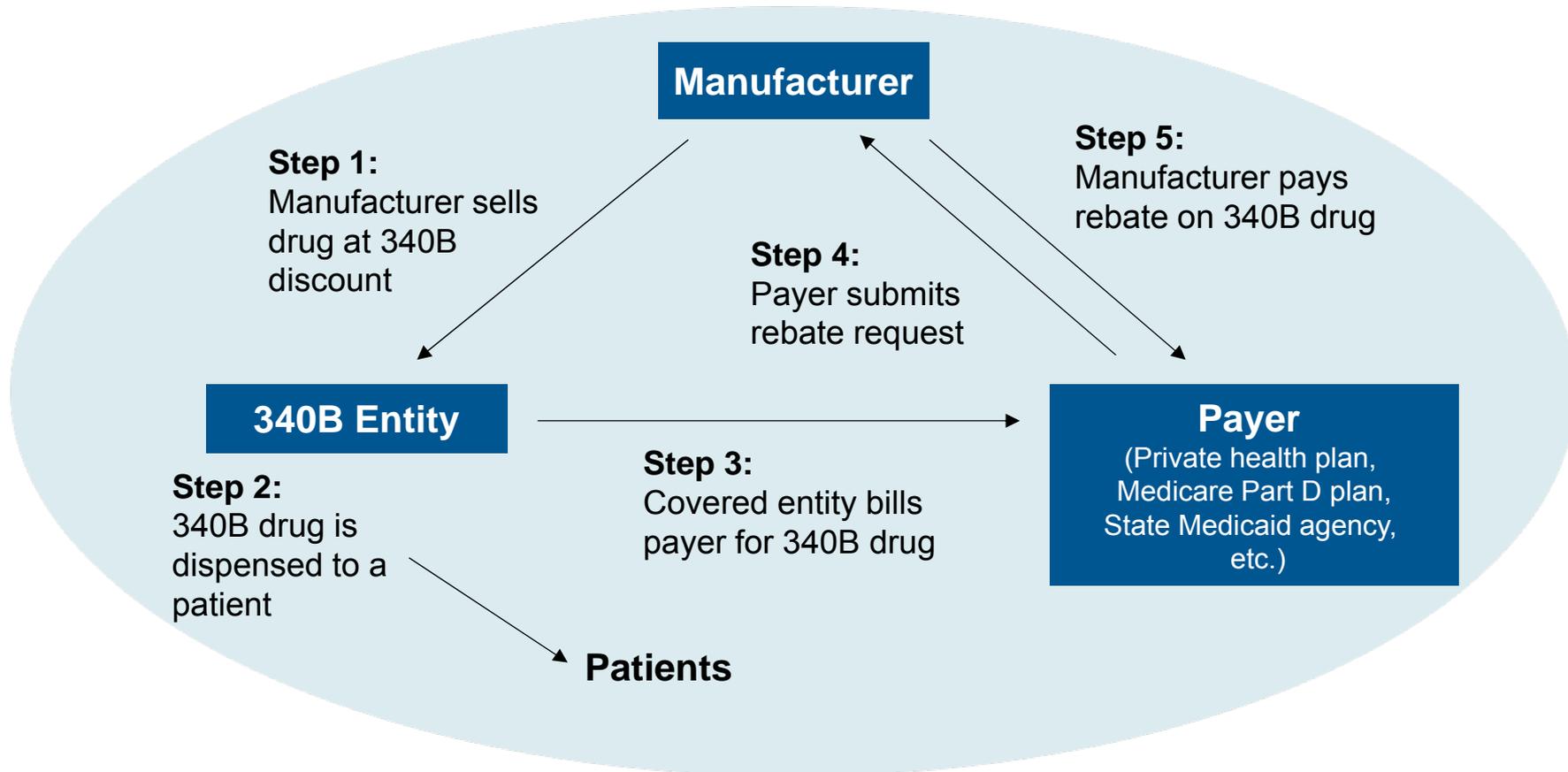
* For products with a pediatric indications and for certain blood clotting factors the rebate is set at 17.1 percent of AMP

** Presentation by Chris Hatwig, Vice President, of Apexus at the 340B Coalition Conference, July 11-13, 2011, Washington, DC

Manufacturers Are Not Subject to 340B Discounts and Medicaid Rebates

- Every 340B entity that serves a Medicaid population selects if it is going to use 340B-purchased drugs to fill prescriptions for Medicaid patients (carve-in) or purchase drugs for this population outside of the 340B program (carve-out)
 - » About half of 340B sites use 340B-purchased outpatient drugs for their Medicaid patients
 - » Entities that choose to carve-out provide HRSA with their pharmacy Medicaid provider number, which is placed in the Medicaid Exclusion File available to State Medicaid agencies
- If a 340B entity chooses to dispense 340B-purchased drugs to Medicaid patients, it is reimbursed at the actual drug acquisition cost plus a dispensing fee, effectively passing their 340B discounts to the State
- If a 340B entity chooses to carve-out Medicaid patients, it is reimbursed at the rates established by the State Medicaid agency for retail pharmacies (AWP minus a discount plus a dispensing fee)

Manufacturers May Still Offer Discounts to Medicare and Commercial Payers for Drugs Provided by 340B Entities



HRSA has requirements to prevent double discounts with Medicaid but not with other payers

Current Definition of 340B “Patient” is Based on 1996 Guidance

- An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
 - » The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare; and
 - » The individual receives healthcare services from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains within the covered entity; and
 - » The individual receives a healthcare service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC Look-Alike status has been provided to the entity
 - DSH facilities are exempt from this requirement
- An individual will not be considered a "patient" of the entity for purposes of 340B if the only healthcare service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting

Only Patients of a 340B Entity Can Receive Discounted Drugs; Patient Definition is Unclear

- Issues have been raised around certain “grey” areas, including:
 - » Employees of 340B entities, prisoners, and other state populations (e.g. mental health population) - Who can be considered a patient and when?
 - » Records maintenance requirement (e.g. addressing electronic health records and 340B entities that are not a primary place of care)
 - » Contractual or other arrangement requirement for the provider of services (e.g. what does it mean to be an “integral part” of the hospital? Can patients of the 340B entity referred somewhere else for care still be able to access discounted drugs?)
 - » Responsibility of care requirement (e.g. addressing integrated care organizations)
- New patient definition is expected to be proposed by HRSA at any time
 - » The OMB review of the HRSA’s notice was completed in April 2011*

* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”

340B Entities Can Use Multiple External Pharmacies to Dispense Drugs Purchased Under the 340B Program

- Effective April 5, 2010, 340B covered entities are permitted an unlimited number of contract pharmacies to expand their reach to patients in the community
 - » Prior guidance, published in 1996, limited covered entities to a single contract pharmacy if they lacked their own onsite pharmacy
- Use of one or more contract pharmacies does not alter the basic 340B requirements for covered entities – they continue to purchase drugs, take title of these drugs, and assume all responsibility for 340B compliance
- Covered entities are required to register all contract pharmacies with HRSA, however HRSA does not review contracts between covered entities and their contract pharmacies
- HRSA and manufacturers have the right to audit 340B pharmacies
- Since April 2010, there was a rapid growth in contract arrangements between 340B entities and outside pharmacies
 - » As of last year, about half of the 340B outpatient sites had arrangements with outside pharmacies

Agreements Between Covered Entities and Contract Pharmacies Vary

- 340B entities may use contract pharmacies services under a “ship to/ bill to” arrangement wherein the 340B entity purchases drugs under 340B and has the drugs shipped to a contract pharmacy that provides dispensing services to patients of the covered entity
 - » Covered entities purchase and take title of all 340B drugs, including those shipped to contract pharmacies for dispensing
 - » Contract pharmacy receives dispensing fee from the covered entity
 - » The covered entity ultimately receives reimbursement for the drugs dispensed
- HRSA does not offer a single a model for financial and drug distribution arrangements between covered entities and contract pharmacies, however:
 - » The agreement between a 340B entity and a contract pharmacy must specify the services that will be provided by the pharmacy
 - » Contracts must also contain provisions that ensure the following:
 - Drugs are not diverted (e.g., dispensed to anyone other than a patient of the covered entity)
 - No duplicate discounts are given (e.g., 340B drugs are dispensed to Medicaid patients)
 - Auditable records are maintained

Recent 340B Policy Releases Demonstrate HRSA Efforts to Clarify Pertinent Issues for Program Stakeholders

On May 23, 2012, HRSA has posted new policy releases to their website:

- The Accountable Care Organizations (ACO) policy clarifies 340B eligibility within ACOs by stating that inclusion of a covered entity within an ACO
 - » Does not make the entire ACO and individual entities that are a part of an ACO eligible for receiving discounted drugs under the 340B program
 - Each entity that is a part of an ACO must individually satisfy the 340B eligibility requirements to be able to access discounted drugs
 - A covered entity that is a part of an ACO is prohibited from transferring drugs to non-340B entities and their patients, including those which are part of an ACO
 - » Does not make all of the individuals receiving services from an ACO patients of the covered entity for 340B purposes
- Clarification of Non-Discrimination policy restates HRSA views on manufacturer alternate allocation procedures when the supply of a covered outpatient drug is not adequate to meet market demands. Manufacturers must:
 - » Demonstrate that 340B providers are treated the same as non-340B providers
 - » Provide a written notification to HRSA at least 4 weeks before the implementation of restricted distribution

Several Outstanding Policy Issues Need to Be Addressed Regarding the 340B Program Integrity

Definition of Patient

- Multiple stakeholders have raised concerns regarding the current patient definition that has many “grey areas” allowing for different interpretations that may lead to diversion
- HRSA issued a proposed regulation to tighten the definition of patient in 2007 but never finalized the rule
- New patient definition regulation is expected; OMB completed the review of the HRSA’s new notice in April 2011

Orphan Drugs Exclusion

- Majority of 340B entities can buy orphan drugs at 340B prices
- Only new categories of eligible entities per ACA are excluded; however, the proposed rule would allow them to buy orphan drugs at 340B prices for non-orphan indications

Contracts with Multiple Pharmacies to Dispense 340B Drugs

- Since April 2010, 340B entities are allowed to contract with multiple outside pharmacies
 - » This creates better drug access for patients but also greater risk of non-compliance and potential diversion
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Medicaid Managed Care Implications

- The ACA exempted drugs purchased under the 340B program from the new Medicaid managed care reporting requirement
 - » This provision essentially allows 340B entities to purchase and use 340B drugs for Medicaid MCO patients
 - » The provision is silent on Medicaid MCOs ability to obtain discounts for these same drugs
 - » Some Medicaid MCOs work with 340B entities to capture some of the lower pricing
- MCOs need to be able to differentiate between prescription claims for 340B drugs and those for non-340B drugs in order to correctly report data to the State
 - » Most 340B dispensing pharmacies do not know whether a patient is eligible for a 340B drug when the prescription is filled
 - » States are working with Medicaid MCOs to determine the best method for identifying 340B-eligible claims to prevent the mandatory Medicaid rebate
- For new Medicaid MCO pharmacy contracts, it is unclear if States are adjusting the proposed capitation rates to account for 340B provisions
 - » If 340B entities were not carving-out their 340B patients and the State was paying them at the 340B price, capitation rates may reflect discounts unavailable to the Medicaid MCO



Continuing Education Questions



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Continuing Education Questions

Question 1: For-profit hospitals are permitted to participate in the 340B program.

- a) True
- b) False

Question 2: 340B-enrolled acute-care hospitals receive what statutorily-minimum discount when purchasing drugs for use in the inpatient setting?

- a) 15.1%
- b) 23.1%
- c) 33%
- d) No discount for drugs used in the inpatient setting

Question 3: Drug manufactures are required to participate in the 340B program if they also participate in the Medicaid program.

- a) True
- b) False

Question 4: A 340B-enrolled entity may provide drugs purchased under the 340B program to which types of patients?

- a) Commercially-insured individuals
- b) Medicare-insured individuals
- c) Uninsured individuals
- d) Any individual seen in the outpatient setting that meets the definition of a covered patient

Question 5: A 340B-enrolled hospital may only have one contracted pharmacy.

- a) True
 - b) False
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