



340B Drug Pricing Program

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Agenda

- Discuss the 340B drug pricing program
 - How the program is defined
 - Who is eligible
- Enrollment
 - Dates to be aware of
 - Source Documentation requirements
- Contract Pharmacies
- Compliance
- Billing

What is the 340B Drug Pricing Program

- 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act
- Intended to allow safety net hospitals to use drug savings to continue and expand services to the patient populations they serve

What is the 340B Drug Program

- The statute requires drug manufacturers participating in the Medicaid program to provide covered outpatient drugs to certain covered entities at a reduced price
- Covered outpatient drugs include:
 - FDA approved outpatient prescription drugs
 - Over-the-counter drugs with a prescription
 - Clinic administered drugs (provider based)
 - Biologicals
 - FDA approved insulin
 - Vaccines **ARE NOT** included

Program responsibilities

- HRSA is responsible for oversight of the program through the Office of Pharmacy Affairs
 - Enrollment
 - Recertification
 - Compliance
 - Establish mechanism to prevent duplicate discount
- Covered entities are responsible for preventing diversion and duplicate discounts, permit audits
- Manufacturers are responsible for accurate pricing

Benefits of the program

- Hospitals that participate in the program can benefit through the following:
 - Significantly reduced prices for outpatient medications
 - Savings achieved between 25%-50% vs. Group Purchasing Organization (GPO) pricing
 - Increased number of drugs on formularies
 - Ability to better serve indigent and vulnerable patients
 - Increased services offered to patients
 - Contract pharmacy relationships

Eligibility



Who is eligible for 340B pricing

- Eligible covered entities include (not an exhaustive list)
 - Disproportionate Share Hospitals (DSH)
 - Qualified Children's Hospitals (PED)
 - Critical Access Hospitals (CAH)
 - Sole Community Hospitals (SCH)
 - Rural Referral Centers (RRC)
 - Free Standing Cancer Hospitals (CAN)
 - Federally-Qualified Health Centers (FQHC)
 - Family Planning Clinics (FP)
 - Ryan White Care Act Clinics (RWI)
 - Black Lung Clinics (BL)

Eligibility requirements

- Owned or operated by a state or local government
- A public or private non-profit corporation, which is formally granted governmental powers by a unit of a state or local government
- A private non-profit hospital, which has a contract with a state or local government to provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under a state plan under this title

Eligibility requirements

Qualification summary

Entity	Non-Prof Gov contract	DSH %	GPO Exclusion	Orphan Drug
Disproportionate Share Hospital (DSH)	Yes	>11.75%	Yes	No
Children's Hospital (PED)	Yes	>11.75%	Yes	No
Free-standing Cancer Hospital	Yes	>11.75%	Yes	Yes
Critical Access Hospital (CAH)	Yes	N/A	No	Yes
Rural Referral Center (RRC)	Yes	≥ 8%	No	Yes
Sole Community Hospital (SCH)	Yes	≥ 8%	No	Yes

Enrollment



Enrollment

- Effective October 2012 HRSA changed its enrollment process:
 - January 1 – January 15 for an effective date of April 1
 - April 1 – April 15 for an effective date of July 1
 - July 1 – July 15 for an effective date of October 1
 - October 1 – October 15 for an effective date of January 1
- Registration into the program is done online at:
 - <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>

Enrollment

- Supporting documentation must be submitted on same day as on-line registration
 - Must be complete at the time of registration or enrollment request will be deleted and not reviewed
- Overnight packages not accepted – documents must be submitted via email or fax
- Supporting documents include:
 - Medicare Cost Report
 - Worksheets A and C demonstrates potential eligible clinics above line 118. Must be reimbursable departments of the hospital
 - Worksheet E, Part A determines disproportionate share percentage. PEDs can submit Worksheet S-3 in lieu of E

Enrollment

- Supporting documentation (cont'd)
 - Certification of Ownership by State or Local Government
 - Certification of Contract between Private, Non-profit Hospital and State/Local Government
- At the time of enrollment, hospitals must declare how it intends to bill Medicaid (carve in or carve out)
 - If carve in, must provide Medicaid provider number/NPI.
- DSH, PED, and CAN facilities must agree not to purchase outpatient drugs from a GPO at the time of enrollment

Outpatient / Contract Pharmacies



Outpatient / Contract Pharmacies

- Hospitals can enter into an agreement with one or multiple outpatient or retail pharmacies to provide 340B drugs to qualified patients on behalf of the covered entity
- The outpatient pharmacy dispenses 340B drugs to eligible patients and provides all counseling and adjudication services, as well as inventory management
- Contract Pharmacy receives a fee for each prescription dispensed
- All revenue and co-pays collected for each prescription are passed onto the covered entity

Outpatient / Contract Pharmacies

- The contract pharmacy is required to provide reports and other documentation to support 340B compliance on behalf of the covered entity
- The covered entity should annually review and audit the contract pharmacy to ensure compliance
- Benefits
 - Covered entity is able to expand its services throughout the community and receives all co-pay and third party reimbursement adjudicated by the contract pharmacy on its behalf
 - Contract pharmacies benefit from the fees negotiated per prescription without incurring the cost of the drug

Outpatient / Contract Pharmacies

- Enrollment
 - Covered entities may enroll contract pharmacies based on the same quarterly schedule
 - Contract Rx: registration form must be complete; original, signed copy must be received by OPA
 - Contract Rx registration forms are due to OPA within 15 days from the date online registration was completed

Compliance



Compliance and the 340B pricing program

- Areas of focus
 - Duplicate discount
 - GPO exclusion rule
 - Orphan drug exclusion
 - Diversion

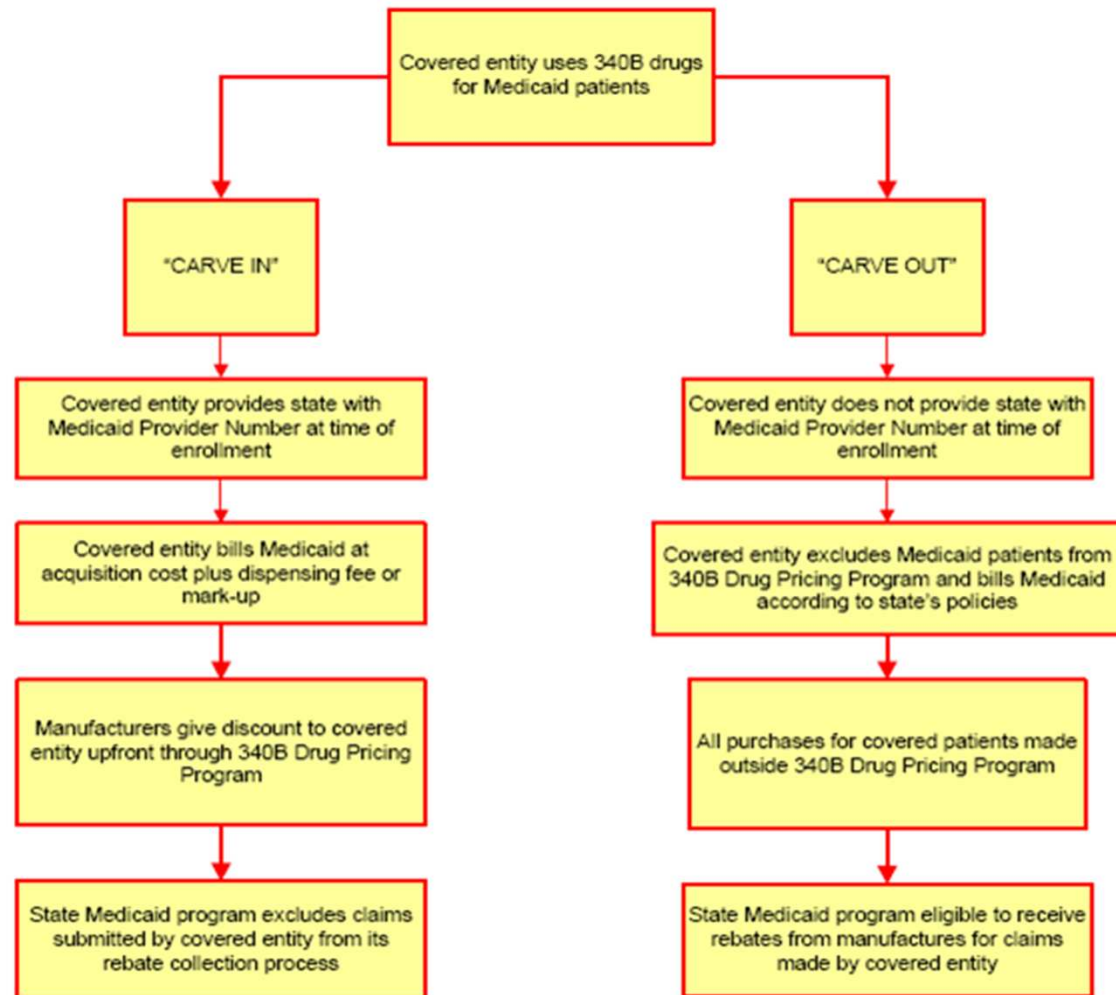
Compliance

Duplicate discounts

- Manufacturers are at risk of giving duplicate discounts to both the state when they submit rebates and to the hospital as they procure product at 340B prices
- To eliminate the potential of duplicate discounts the hospital must do the following:
 - “Carve In” Medicaid patients and bill the state at 340B acquisition cost plus any allowable dispensing fee.
 - Some states require a different methodology
 - “Carve Out” Medicaid patients from utilization and bill the state per other agreed upon arrangement.

Compliance

Duplicate discounts



Compliance

GPO exclusion rule

- Applies to DSHs, PEDs, CANs
- These covered entities are **prohibited** from purchasing any covered outpatient drug through a GPO
- A certification to abide by this prohibition must be signed by the covered entity at the time of enrollment
- To avoid purchasing covered outpatient drugs through GPO accounts, a third wholesaler account can be set up to make these purchases at current market price or wholesale acquisition cost (WAC)
- Does **not** apply to inpatient drugs

Compliance

Orphan drug exclusion

- In January 1983, Congress passed the Orphan Drug Act to encourage pharmaceutical manufacturers to develop drugs to treat rare diseases for very small patient populations
- The legislation provided tax incentives, patent and market protections and waivers of drug approval application fees and annual U.S. Food and Drug Administration (FDA) product fees
- Applies to CAHs, SCHs, RRCs and CANs

Orphan drug exclusion

- Orphan drug exclusion (cont'd)
 - The OPA recently proposed guidelines that would allow 340B pricing for orphan drugs used for disease states other than the one that gave the drug its orphan
 - Hospitals using orphan drugs will need to develop auditable systems to ensure they are **not** buying orphan designated drugs under the 340B Drug Pricing Program
 - A list of approved orphan drugs can be found at the following website:
 - <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>

Compliance Diversion

- 340B program is for **outpatient** use only
- Covered entity must **not** resell or transfer 340B drugs to a person who is **not** a patient of the covered entity
- Definition of a patient
 - Individuals receiving drugs must be patients of the covered entity
 - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care
 - The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements, such that the responsibility for the care provided remains with the covered entity

Compliance Diversion

- 340B drugs should **not** be transferred or sold to other facilities that are **not** a part of the covered entity.
 - Medicare Cost Report Test-drugs may only be sent to departments or offsite facilities that are above line 118
- Covered entity should have the following wholesaler accounts set up in the hospital's name.
 - GPO account
 - 340B account
 - WAC account

Compliance and inventory management

- Two methodologies to be used
 - Separate inventory for 340B drugs
 - Virtual inventory using split billing software
 - Split billing software programs track inpatient and outpatient utilization, in many cases at the point of administration
 - The software is able to “split” purchase orders into eligible 340B purchases and non-340B purchases (inpatient). The software also acts as a “bank,” keeping count of eligible units dispensed until a full package size or the re-order point is reached
 - Provides documented audit trail

Sanctions for non-compliance

- Failure to comply with the program's anti-diversion provision could result in a forcible return of the discounts received back to the manufacturer or disqualification from the program
- If an individual intentionally diverts 340B drugs, he or she may be criminally liable under the Prescription Drug Marketing Act
- Manufacturers have the right to audit the records of covered entities to protect against diversion

340B compliance consulting

- Help ensure compliance with regulations and that optimal processes are in place for the oversight and management of the 340B programs
 - Evaluate ‘buy and return’ process for employee pharmacy
 - Ensure financial oversight is appropriate for contract pharmacies
 - Determine whether the contract pharmacy software is functioning optimally
 - Assess how policies and procedures are used in practice

Billing

How do hospitals bill for 340B drugs?

- Dependent on two things:
 - Patient third party payer
 - Is the hospital carving in or carving out eligible Medicaid patients?
- **For non-Medicaid eligible outpatients, bill as you always have**
- **If carve in:**
 - Provider IDs should be on the federal Medicaid Exclusion file.
 - Must bill actual acquisition cost for 340B drugs.
 - Reimbursement is the lesser of the acquisition cost, the Federal Upper Limit, or federal 340B pricing.
 - Oregon also requires a UD modifier to identify 340B drugs to the state
- **If carve out:**
 - Must bill for those drugs under a separate Medicaid ID and NPI
 - For Medicaid eligible outpatients, bill as you always have



Q&A

About Cardinal Health Pharmacy Solutions

Pharmacy Solutions is a business unit of Cardinal Health

Professional services

- Management services
 - Inpatient pharmacy practice
 - Outpatient pharmacy practice
- Consulting and projects
- Support services
- Remote Order Entry Service

Business intelligence products

- Medication Order Management System
- Drug Cost Opportunity Analytics

Quick facts

- ✓ Complete **120+ accreditation surveys** and mock audits annually
- ✓ Authored publications
 - *Assuring Continuous Compliance with Joint Commission Standards, 8th ed.*
 - *Competence Assessment Tools for Health-Systems Pharmacies, 4th ed.*
- ✓ Process **over 5 million medication order lines** remotely each year
- ✓ Manage more than **\$1 billion in annual drug spend**
- ✓ We **reduce pharmaceutical expenditures** by 3% - 5% through our supply chain solutions
- ✓ We help hospitals understand **profitability by service line**, as well as cost per DRG and cost by admitting physician

Solving our customers' needs

Safety and Quality	Workflow & Efficiencies	Cost Control	Leadership & Management
✓ Accreditation and regulatory compliance	✓ Automation optimization	✓ Inventory costs	✓ Inpatient pharmacy practice
✓ Medication safety programs	✓ Operational productivity	✓ Competitive pharmaceutical pricing	✓ Outpatient pharmacy practice
✓ 24x7 pharmacy coverage	✓ Medication order turnaround time	✓ GPO contract optimization	
		✓ Drug costs and clinical programs	
		✓ Charge capture	

Thank you!

