ANN ARBOR REGIONAL HEALTHCARE COMPLIANCE CONFERENCE: HCCA

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340B DRUG PRICING PROGRAM

- Created in 1992 to enable eligible "covered entities" -- certain categories of hospitals – to obtain discounts on covered outpatient drugs (estimated 20-50% off retail & wholesale prices)
- Administered/overseen by Health Resources and Services Administration (HRSA), which is an agency within the Department of Health and Human Services (HHS)
- HRSA states purpose of 340B Program is to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"
- Discounts are borne by pharmaceutical manufacturers
- Complex and challenging for hospitals, manufacturers and HRSA
- Highly politicized program -- tied to the drug pricing debate

340B PROGRAM: FUTURE IS UNCERTAIN

LITIGATION CONTINUES AS TO

"The 340B program is the single most, politicized matter that we deal with." -HRSA Representative

ELIGIBLE HOSPITALS IN 340B PROGRAM

- Must meet a minimum Medicare disproportionate share hospital adjustment percentage (DSH) greater than 11.75% (standard in place since 1992)
- This measure identifies hospitals that treat a disproportionate number of low-income Medicare and Medicaid inpatients.
- Must be state or local government-owned/operated OR nonprofit with government contracts to provide health care services to low-income individuals not eligible for Medicaid or Medicare
- As of 2016 there are 2,399 hospitals participating in the 340B program (GAO report, June 18, 2018)

AFFORDABLE CARE IMPACT ON 340B PROGRAM

- Expanded Participation for Rural and Other Hospitals
- Integrity Requirements for Drug Manufacturers
- Integrity Requirements for Covered Entities
- Dispute Resolution Process

KEY POINTS

AFFORDABLE CARE ACT EXPANDED 340B PROGRAM

MAJORITY QUALIFY AS:

- Disproportionate share hospitals (>11.75%)
- Children's Hospitals
- Critical Access Hospitals
- Free Standing Cancer Hospitals
- Sole Community Hospitals
- Rural Referral Centers

OTHER TYPES:

- Tribal/Urban Indian Health Centers
- Native Hawaiian Health Centers
- Rural Referral Centers
- Black Lung Clinic Programs
- Comprehensive Hemophilia Diagnostic Treatment Centers
- Federally Qualified Health Centers
- Ryan White HIV/AIDS Program Grantees
- Other Specialized Clinics

MECHANICS OF HOSPITAL AS A COVERED ENTITY

- Register as 340B hospital
- Qualify off-campus locations as provider-based (add to hospital Form 855A)
- Add off-campus locations as "child sites" with 340B Program
- Contract with retail pharmacies
- Contract with third party administrator
- Establish process to confirm "eligible patients" filling prescriptions at retail pharmacies
- Use (often complex) IT systems to manage

COVERED ENTITY REQUIREMENTS

- **Keep 340B registration information accurate and up to date** Register new outpatient facilities and contract pharmacies as they are added.
- **Recertify eligibility** every year.
- **Prevent diversion to ineligible patients** Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.
- **Duplicate Discount Prohibition** Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
- **Prepare for program audits** Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

DISCOUNTED OUTPATIENT DRUGS TO PATIENTS

The 340B law prohibits the resale or transfer of discounted outpatient drugs to anyone other than a patient of the covered entity. Specifically, the individual:

(1) must have an established relationship with the covered entity such that the entity maintains records of the individual's care;

(2) must receive care from a professional employed by the covered entity or under contract or other arrangement (e.g., referral for consultation) with the covered entity such that responsibility for the care remains with the covered entity; and

(3) with respect to grantees and sub-grantees, must receive health services from the covered entity that are consistent with the services for which grant funding has been provided to the entity. Under the guidelines, an individual is not considered a patient of the covered entity if the only health care service received by the individual from the entity is the dispensing of a drug for subsequent self-administration or administration in the home setting.

INTEGRITY REQUIREMENTS FOR COVERED ENTITIES PER ACA

- Procedures to update 340B information at least annually
- Procedures to verify accuracy of information
- More detailed guidance for billing covered outpatient drugs to Medicaid
- Establish single, universal, and standardized identification system for identifying all Covered Entities to facilitate covered drug ordering, purchasing, and delivery (including process for chargebacks)
- Impose additional sanctions for "knowing" and intentional violations
  - Consisting of payment of interest to manufacturers
- Exclude 340B participation for systematic and egregious violations
- Refer matters, as appropriate, to FDA, OIG or other agency

DISPUTE RESOLUTION PROCESS IMPACTED BY ACA

- Procedures for remedies and enforcement of orders
- Designate official or body to review and decide disputes
- Deadlines and procedures to ensure fair, efficient and expeditious resolution of claims
- Discovery procedures to allow Covered Entity to obtain information from manufacturers and 3rd parties to establish a claim of overcharging
- Require manufacturers to conduct an audit of Covered Entity ***before*** instituting dispute resolution process
- Consolidate claims by multiple manufacturers against Covered Entity, as appropriate
- Consolidate claims of multiple Covered Entities against manufacturer, as appropriate

MANUFACTURER AND HRSA AUDIT TRENDS

Authority to Audit	Focus of Audit Concerns
• HRSA • Any participating manufacturer	• Diversion • Over purchasing of 340B drugs • Lack of auditable records for operational compliance • Lack of audit trail re drug usage to an individual patient • Failure to identify eligible vs. non-eligible patients

ESTABLISHING AND MAINTAINING AUDIT-READINESS

- Review and update policies and procedures
- Education and training regarding policies and procedures
- Review 340B purchasing practices
  - Confirm appropriate use of GPOs (or nonuse)
  - Split billing software
- Validation of Covered Entity eligibility and information

ESTABLISHING AND MAINTAINING AUDIT-READINESS

- Validation of patient eligibility processes
- Review 340B covered drug distribution
- Process and procedures for logging issues and complaints
- Monitoring and auditing operational compliance
  - Including checklists for contract pharmacies
- Documentation

RESOURCES

- https://340bopais.hrsa.gov/
- https://www.hrsa.gov/opa/index.html
- https://www.gao.gov/products/GAO-18-480
- https://www.340bhealth.org/members/340b-program/overview/
- https://www.340bpvp.com/controller.html

QUESTIONS?

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