

**Alabama Department of
Public Health
Drug Purchasing Programs:
340B and MMCAP**

**Satellite Conference and Live Webcast
Thursday, August 23, 2012
2:00 – 4:00 p.m. Central Time**

Produced by the Alabama Department of Public Health
Video Communications and Distance Learning Division

Faculty

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Alabama Department of Public Health

Drug Purchasing Contracts

- State bid
- Order direct or approved drug wholesaler
- 340B

Drug Purchasing Contracts

- MMCAP
 - Drugs
 - Supplies
 - Other

Background on 340B Program

- Created by Congress in 1992 to reduce safety net provider drug costs
- Administered by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA)

Background on 340B Program

- Requires drug manufacturers participating in Medicaid and/or Medicare Part B to sell “covered outpatient drugs” to “covered entities” at discounted prices determined by statutory formulas

Background on 340B Program

- Covered entity types include, among others
 - Hospitals, federally qualified community health centers, and hemophilia treatment centers and Ryan White clinics

– www.snhpa.org

Background

- Discounts based on Medicaid rebate formulas
 - Greater discounts for brand name drugs
 - Lesser discounts for generics
 - Prices are best in nation outside of “Big Four”

Background

- 25-50% off group purchasing organization (GPO) contracts
- Applies to both pharmacy-dispensed and clinic-administered drugs
- Do not need to own and operate an outpatient pharmacy to participate

Background

- OPA maintains databases of participating covered entity sites, manufacturers, and contract pharmacies
- Registered as of September 2010:
 - 14,457 active covered entities
 - 849 manufacturers
 - 2,559 contract pharmacies

Background

- Over 900 hospitals currently enrolled
 - 120+ rural hospitals have enrolled since August
 - Sole community hospitals and rural referral centers with DSH adjustment percentages 11.75%+ have been eligible since 1992

Background

- Two HRSA contractors:
 - Prime Vendor Program (PVP)
 - Pharmacy Support Services Center (PSSC)

Background

- **PVP contractor: Apexus**
 - Negotiates sub-ceiling pricing on behalf of PVP participants
 - Provides other value-added services

Background

- **PSSC contractor: American Pharmacists Association**
 - Provides technical assistance to covered entities and other stakeholders
 - Staffs 340B call center

– www.snhpa.org

Eligible Entities

- **(A) Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act)**
 - This category includes:
 - FQHC “look-alikes”
 - Consolidated Health Centers (Sec.330(e) Public Health Service Act)

Eligible Entities

- **Migrant Health Centers (Sec.330 (g) Public Health Service Act)**
- **Health Care for the Homeless (Sec.330(h) Public Health Service Act)**
- **Healthy Schools / Healthy Communities**

Eligible Entities

- **Health Centers for Residents of Public Housing (Sec. 330(i) Public Health Service Act)**
- **Office of Tribal Programs or urban Indian organizations (P.L. 93-638 and 25 USCS 1651)**

Eligible Entities

- **(B) A family planning project receiving a grant or contract under Sec. 1001 PHSA (42 USCS 3001)**

Eligible Entities

- (C) An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA) (relating to categorical grants for outpatient early intervention services for HIV disease) - Early HIV Intervention Services Categorical Grants (Title III of the RWCA)

Eligible Entities

- (D) A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA
- (E) A black lung clinic receiving funds under Section 427(a) of the Black Lung Benefits Act (30 USCS 901)

Eligible Entities

- (F) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the SSA
- (G) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988 (42 USCS 11701)

Eligible Entities

- (H) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act (25 USCS 1601)

Eligible Entities

- (I) Any entity receiving assistance under title XXVI of the Social Security Act (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary

Eligible Entities

- (J) An entity receiving funds under section 318 (42 USCS 247c) (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (42 USCS 247b(j)(2)) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary

Eligible Entities

- (K) A disproportionate share hospital (as defined in section 1886(d)(1)(B)) of the SSA:

Eligible Entities

- (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government . . .

Eligible Entities

- . . . 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 the State plan under this title

Eligible Entities

- (ii) for the most recent cost reporting period that ended before the calendar quarter involved had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75% or was described in section 1886(d)(5)(F)(i)(II) of such Act

Eligible Entities

- (iii) does NOT obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement

Eligibility: Additional Criteria

- Must be either:
 - Publicly owned or
 - Private, non-profit under contract with state or local government to provide indigent care

Eligibility: Additional Criteria

- If sole community or rural referral hospital, must also have Medicare DSH adjustment of 11.75%+
 - Medicare add-on payment for hospitals treating disproportionate share of low income patients
 - Driven by Medicaid and SSI inpatient days

Eligibility: Additional Criteria

- List of hospitals with qualifying DSH adjustments available on OPA website

Audits – HRSA Conducted

- Audits – HRSA conducted
- In general, audits are designed to assess if a covered entity:
 - Is eligible to participate in the 340B Program
 - Has sold or provided 340B covered drugs to persons who are not eligible patients

Audits – HRSA Conducted

- Has the proper controls in place to prevent and detect instances of diversion and duplicate discounts

A-133

- The A-133 audit process is a requirement for all non-Federal entities that expend \$500,000 or more of Federal awards in a year
- In addition to on-site audits, OPA is also working closely with DFI to include 340B in the A-133 audits for all federal grantees that participate in 340B

Prepare for Audit: Process, Records, and Policies and Procedures

- Look at and determine the integrity of your program
- Review OPA's database listing and update if needed
- Review policies and procedures pertaining the 340B program

Prepare for Audit: Process, Records, and Policies and Procedures

- Find necessary tracking records pertaining to purchasing, dispensing, and administration of 340B medications and have readily available

Prepare for Audit: Process, Records, and Policies and Procedures

- Identify potential problem areas in your facility today and address them before an auditor is at your door step
- Train your employees about the 340B program

Patient Definition

- Only if:
 - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care

Patient Definition

- The individual receives health care services from a health care professional who is either employed by the covered entity, or other arrangements
 - e.g. referral for services consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity

Patient Definition

- Review patients, so that non-qualified patients will be removed
- Have our qualified personnel audit the purchases and verify that eligible patients can be identified for the products ordered
- Disproportionate share hospitals are exempt from this requirement

Requirements and Prohibitions of Focus

- Focus on Patient Definition
 - Perform a few audits of specific prescription transactions so that you are comfortable describing the data sources and the stepwise process you use

Diversion

- **Diversion**
 - Are there any discrepancies that may indicate non 340B eligible patients receiving 340B drugs?
 - Do we have clear and auditable ways to identify eligible patients?

Diversion

- Do we have a sound way to manage referrals for care provided outside our facility?
- Assess your inventory management for eligible and non- eligible patients

Focus on Diversion

- **Examine the process for identifying patients that qualify for the 340B program**
- **Review accuracy of the quantity units that are dispensed for match with ordering quantities**

Inventory System or Process

- **Randomly select a product**
- **Reconcile**
 - Total Quantity Dispensed to All Patients
 - With Total Quantity Purchased By Clinic

Inventory System or Process

- Track drug specifically purchased for TB, STD, or FHS from purchase to exiting the CHD
- Ensure that it remains in supply only for specific grant

“Pearls” of Wisdom

- **Make an offensive plan to establish and maintain the integrity of the 340B program within your facility**
- **Empower someone from your facility to become an expert and utilize them as an internal audit administrator**
- **Educate, Educate, Educate**
- **Plan ahead!**

“Pearls” of Wisdom

- **Auditing yourself now may allow for an easier audit in the future**
 - If you know what is missing for your own audits you will not miss it when you do get audited
- **Start strong to finish strong**

“Pearls” of Wisdom

- **If an entity could explain the scope of services offered and thus the nature of 340B transactions, the auditors might be less likely to try to search for transactions that don't occur in your environment**
- **Have a private space available for auditors, with WIFI**

“Pearls” of Wisdom

- **The auditors should have a good idea of what records will be needed if they understand your practice**
 - However, be flexible
- **Expect some extemporaneous requests for information at the audit**

ADPH Pharmacy Contacts

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**Minnesota Multistate
Contracting Alliance
for Pharmacy**

Purchasing Drugs In ADPH

- **Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP)**

Minnesota Multistate Contracting Alliance for Pharmacy

- MMCAP's mission is to provide members with the best value in pharmaceuticals and healthcare products and services through volume contracting and diligent contract management

Minnesota Multistate Contracting Alliance for Pharmacy

- Voluntary group purchasing organization (GPO) for government facilities that provide healthcare services
- A pure cooperative

Minnesota Multistate Contracting Alliance for Pharmacy

- Operated by State of Minnesota 1985
 - Cooperative purchasing venture between Minnesota and Wisconsin
- MMCAP does not receive funding from the State of Minnesota or from any government source
- 20 employees

What Is a Group Purchasing Organization (GPO)?

- An entity helping healthcare providers – like hospitals, nursing homes, and home health agencies – realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors

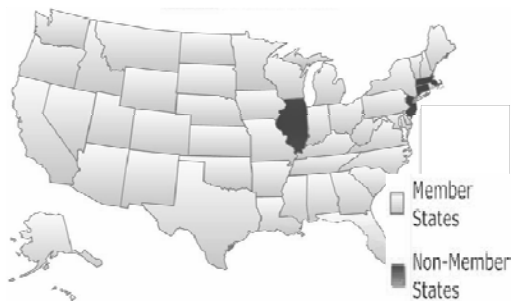
Members

- Composition
- 46 member states plus the cities of Chicago and Los Angeles
- Typical facility types
 - Public Health Corrections
 - Student Health Centers
 - Mental Health Centers

Members

- DD/MR Facilities Substance Abuse Treatment Facilities
- Nursing Facilities Hospitals/Clinics
- Membership is open to entities such as state agencies, counties, cities, school districts, and public higher education facilities

MMCAP 46 Member States Plus Chicago and Los Angeles



MMCAP and Alabama

- Alabama was the 40th state to join MMCAP
 - The original Joint Powers Agreement was signed on 8/1/02
 - The Pharmaceutical Prime Vendor selected by your state is AmeriSource-Bergen

MMCAP and Alabama

- State contacts include:
 - Charles Thomas
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State of Alabama Department of Public Health, Montgomery

MMCAP and Alabama

- Allen Rowe
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State of Alabama Department of Public Health, Montgomery
- Current Year-to-Date MMCAP Sales Volume: \$13,589,529.56

MMCAP State Contacts

- Two representatives from each state acts as liaison between MMCAP and its members
- Gives your state a voice in MMCAP operations
- Reviews membership applications and eligibility

MMCAP State Contacts

- Assists with RFP responses
 - Pharmaceuticals, Prime Vendor, etc.
- Manages state participation requirements
 - RFP notifications, contract awards, etc.
- Awards products at National Member Conference

MMCAP Benefits for ADPH

- **Reduced costs for products and services**
- **Membership is free!**
- **Wholesaler shareback credit**
- **Professional staff**
- **Local representation**
- **Member-controlled formulary**

MMCAP Benefits for ADPH

- **Advisory board**
- **Industry contacts**

Current Program Offerings

- **Pharmaceuticals**
 - Rx, OTC, Vaccine
- **Vials and Containers**
- **Pharmaceutical Wholesaler (Distribution) Services**
- **Returned Goods Processing**
- **Pharmaceutical Invoice Auditing**

Current Program Offerings

- **Clinical Pharmacy**
 - Influenza Vaccine
 - Emergency Preparedness
 - Specialty Distribution
 - Failure to Supply (Recoup \$)
 - Drug Testing Kits
 - Dental Supplies

Current Program Offerings

- **Medical Supplies**
- **Laboratory Supplies**

Wholesalers

- **States choose from several pharmaceutical wholesalers**
 - Amerisource Bergen (National)**
 - **Cardinal (National)**
 - **Morris and Dickson (Regional)**
 - **H.D. Smith (Regional)**

Wholesalers

- One-stop shopping for pharmaceuticals, vaccines, OTCs, etc.
- Sell products at the price MMCAP negotiates with its contracted manufacturers

Recent Examples Of MMCAP's Superior Pricing

- Price comparisons in 2009 and 2010
 - Results of all other studies fell within the 2.8% to 4.4% range of MMCAP price advantage
 - Separate comparisons done in six states, MMCAP vs. six national GPOs

Contract Adherence

- Maximize savings
- Example of savings purchasing from correct entity:
 - From Amerisource
 - All legend drugs
 - Prescription vials and bottles
 - Monistat

Contract Adherence

- Lidocaine
- All injections

Contract Adherence

- From PSS
 - Suture kits
 - Condoms
 - Gloves
 - Drapes
 - Laceration trays

Ways to Purchase

- Three Main Vendors For Alabama (340B and MMCAP)
 - Amerisource-Bergen
 - PSS (Soon to be World Medical Government Solutions)
 - Direct Companies

Ways to Purchase

- **Other**
 - **Direct companies**
 - **State bids**
 - **Other contracts**

Accounts

- **County Health Departments**
 - **General County Account – ABC**
 - **340B Accounts (TB, STD, Title X) – ABC or Direct**
 - **Direct Accounts**
 - **Supplies – World Medical Government Solutions (PSS)**

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