COHESIVE HEALTHCARE MANAGEMENT & CONSULTING
Mangum Regional Medical Center

TITLE		POLICY
340B Drug Discount Purchasing Program		**DR-057**
MANUAL	EFFECTIVE DATE	REVIEW DATE
Drug Room	**06/2022**	**09/2022**
DEPARTMENT	REFERENCE	
Pharmacy; Drug Room	See Below	

SCOPE

This policy applies to the 340B drug discount purchasing program at **Mangum Regional Medical Center** ("Hospital").

PURPOSE

To define the processes that allows the Hospital to purchase pharmaceuticals at discounted prices for its qualified outpatients that is consistent with the Human Resources Services Administration (HRSA) 340B Drug Discount Purchasing Program as defined by the enactment Section 340B of the Public Health Service Act.

DEFINITIONS

340B Eligible "Covered Entity": Refers to the statutory name for facilities and programs eligible to purchase discounted drugs through the Public Health Service's 340B Drug Pricing Program.

340B Eligible Patient: Refers to individuals who have received medical treatment at the Covered Entity and have registered as a patient within the Covered Entity's electronic medical record thereby demonstrating a patient-provider relationship.

Critical Access Hospital (CAH): Refers to a specially designated, small rural hospital that qualifies for cost-based payments for Medicare services.

Medicare Cost Report: Required by CMS, an annual financial report that details all fixed and variable costs expensed to the care of Medicare patients.

Contracted Pharmacy: Refers to an arrangement through which a covered entity may contract with an outside pharmacy to provide comprehensive pharmacy services utilizing medications purchased under 340B.

HRSA: Refers to the Health Resources and Services Administration of the Department of Health and Human Services.

Orphan Drugs: Refers to drugs designated by the Food and Drug Administration (FDA) as "orphan drugs," drugs used for rare diseases or conditions. The official Orphan Drug list is posted on the Office of Pharmacy Affairs (OPA) website.

Parent/Child Sites: Refers to the primary covered entity and is often referred to as the "parent" site. All outpatient services of the covered entity that are not located within the four walls of the parent location (same physical address) must be registered on the HRSA/OPA database as a "child" of the covered entity (Parent).

Medicaid Carve-out: Refers to the process by which 340B entities may elect to purchase drugs for Medicaid patients on a non-340B contract. This activity is termed as a "Medicaid carve-out." Entities may choose to do this in order to receive fair Medicaid reimbursement. Entities must inform OPA whether they are carving in or out.

POLICY

It is the policy of the Hospital to operate the 340B Drug Pricing Program in compliance with guidelines set forth by the OPA of the HRSA; and any accompanying regulations or guidelines including, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient.

PROCEDURE

A. **Overview of 340B Drug Discount Purchasing Program Requirements:**

1. Covered Entity/Facility Eligibility – Hospitals that receive discounted outpatient drug pricing under the 340B Drug Pricing Program include certain hospitals that are public or private non-profit hospitals serving higher percentages of Medicare, Medicaid, or other indigent populations. To be eligible the Hospital must meet the following requirements:
    a. The Hospital is a Critical Access Hospital (CAH).
    b. The Hospital must meet <u>one</u> (1) of the following criteria:
        i. Be owned or operated by a unit of State or local government.
        ii. Be a public or private non-profit corporate which is formally granted governmental powers by a unit of State lor local government; or
        iii. Be 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 the State plan of this title.
2. Site of Care – Off-site outpatient facilities of the Covered Entity (Hospital) may purchase and/or provide 340B drugs to its patients, only if the site of care is listed on the HRSA/OPA 340B database. Off-site facilities eligibility is verified by

HRSA/OPA as listed as part of the Covered Entity's most recently filed Medicare Cost Report. The facility must be listed as an integral part of the Hospital and included as a reimbursable section of the Medicare Cost Report. An eligible clinic/office is considered a "child" of the Covered Entity ("parent") even if the location is within the same building of a "parent"; they must be registered separately. Outpatient services within the four (4) continuous walls of the Covered Entity (hospital/parent) do not need to be registered as a child.

3. Patient Eligibility – A patient is considered a 340B eligible patient of the covered entity, only if the following conditions are met:
   a. The patient is an *outpatient* of the Covered Entity.
   b. The Covered Entity has established a relationship with the individual, which includes maintaining records of the individual's health care at the Covered Entity (parent) or a HRSA/OPA registered site of care (child).
   c. 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 (e.g., referral for consultation) such that responsibility for the individual's care remains with the covered entity.
      Note: Employees of the Hospital (Covered Entity) are not automatically 340B eligible patients solely by virtue of their employment status. A medical relationship must extend beyond the dispensing of medications for subsequent self-administration or administration in the home setting.
4. Prescriber Eligibility – Eligible prescribers of 340B drugs are employed by the Hospital/Covered Entity or are under contractual or other arrangement with the Hospital/Covered Entity.
5. Duplicate Discount-Medicaid Carve-in Medicaid Carve-out – A covered entity may choose to carve-in 340B drugs for their Medicaid patients or Carve-out in providing 340B drugs to its Medicaid patients.
   a. The Covered Entities' selected designation would be indicated on the HRSA/OPA database.
   b. If the option to Carve-in is selected the Medicaid provider number would be provided to the Office of Pharmacy Affairs (OPA) which is then placed in the HRSA Medicaid Exclusion file provided to the State agencies. This prevents the State from taking a duplicate discount with the manufacturer's rebates.
6. Orphan Drug Rule – Orphan Drugs as designated by the Food and Drug Administration (FDA) may not be purchased by CAHs, Sole Community Hospitals, Rural Referral Centers (RRC) or Free-Standing Cancer Hospitals (CAN) under the 340B Program.

B. The Hospital is listed correctly as an eligible covered entity with the OPA on the website https://340bopais.hrsa.gov/.

C. The Hospital's eligible off-site outpatient facilities/clinics and outpatient services outside of the four (4) walls of the Hospital are listed correctly as OPA registered child site(s) of

the Covered Entity with the OPA on the website https://340bopais.hrsa.gov/. The cost of operating these sites appears on the reimbursable section of the Medicare Cost Report.

D. Contract Pharmacy(ies) of the Hospital as stipulated in the contract Pharmacy Services Agreement(s) between the Hospital "Covered Entity" and the contract pharmacy as correctly registered with the OPA.

E. 340B medications are purchased for 340B eligible outpatient use only (i.e., a patient is in an outpatient service location at the time the medication is administered/dispensed).

F. The Hospital maintains lists of eligible prescribers, eligible outpatient treatment areas and off-site clinics, and registered contract pharmacies.

G. The Hospital "Covered Entity" maintains auditable records demonstrating compliance with the 340B requirement.

H. **Responsible Parties:**

1. Authorizing Official – Attests to compliance of the program during the annual OPA recertification process.
2. Primary Contact – Designated as the Covered Entity's primary contact as listed on the OPA website.

I. **340B Enrollment, Recertification and Change Requests:**

1. The Hospital's Authorizing Official annually recertifies information listed on the OPA website.
2. New service areas or clinics/facilities are evaluated to determine if the location is eligible for participation in the 340B Program. If deemed eligible the Authorizing Official completes the online registration process during the next registration window and submits cost report information as required by OPA. New service areas are not eligible to purchase 340B drugs until they are listed on the OPA website.
3. It is the ongoing responsibility of the Covered Entity to inform OPA of any changes to its information or eligibility. An online change request is submitted as soon as the Covered Entity is aware of the need to make a change to the database entry. If the Covered Entity loses eligibility, it will notify OPA immediately and stop purchasing 340B discounted drugs.

J. 340B Drug Utilization:

1. Medications purchased under the 340B Drug Pricing Program are ONLY utilized for 340B *eligible outpatients*, as defined above, receiving medical care at:
    a. Hospital.
    b. OPA registered child site(s) (clinics/offices) of Hospital.
        i. Registered clinics/offices where medications purchased through the 340B account may be used are listed in Attachment A – List of OPA Registered Child Site(s).

c. OPA registered 340B Contract Pharmacy(ies) of Hospital as stipulated in the Contract Pharmacy Services Agreement(s) between the Hospital and the contract pharmacy.

2. Referral Prescription Capture Process:
   a. The patient's primary health care provider can recommend that the patient see another health care provider, often a Specialist.
   b. For the prescription to be 340B eligible, the visit summary documentation must be available in the patient's health record or via an electronically shared system.
   c. A referral request to the Specialist provider or clinical will be documented in the patient EHR of the Covered Entity.
   d. Prescriptions issued by the Specialist provider are eligible for the 340B discount *only if* there is a current referral visit summary or consultation note dated no less than 18 months old documented within the Covered Entity patient medical record.
   e. If there is a change in the patient diagnosis from that noted on the initial referral, a new referral request should be issued.

K. **Purchasing:**

1. As a CAH, purchase of medications through the group purchasing organization (GPO) or group purchasing arrangement for use in eligible outpatients is **permitted**.
2. Covered Entity shall maintain a "Bill to/Ship to" arrangement with the Contract Pharmacy with regard to 340B purchasing.
3. Invoices indicating 340B ordered drugs by National Drug Code (NDC), pricing, and quantities shall remain available in readily retrievable and auditable format for a period of four (4) calendar years.

L. **Drug Wholesaler Accounts:**

1, Separate accounts are maintained with the Hospital's medication wholesaler. Purchase orders are entered in the wholesaler system under the appropriate account.
   a. 340B Account – The 340B account is used for purchasing:
      i. 340B medications for eligible outpatient service locations use as defined in this policy.
   b. Group Purchasing Organization (GPO) Account or Other Discount Purchasing Agreements – The GPO account may be used for purchasing:
      i. Inpatient medications.
      ii. Outpatient medications, including 340B medications.
      iii. Orphan drugs for indications designated by the FDA.
      iv. Drugs that are "bundled", drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drugs, are not 340B eligible drugs and may be purchased on the GPO account. See section below on Billing/Utilization and Bundling.

M. **Orphan Drugs:**

1. As a CAH, Orphan Drugs, are **not** purchased under the 340B Program when used for the FDA designated Orphan Drug indication as listed on the OPA website.

N. **Inventory Management:**

1. Virtual 340B Inventory Management at contract pharmacy(ies):
    a. A third-party administrator (TPA) will assist with managing a virtual inventory of 340B eligible medications.
    b. For each 340B medication dispensed to patient(s) that reaches depletion of a full package size, the TPA will assist with virtual replenishment at 340B pricing from the pharmacy wholesaler (on behalf of Covered Entity) to replace 340B medications with the same National Drug Code-11 (NDC-11).
2. Virtual 340B Inventory Management (e.g., Manual Spreadsheet) at the Contract Entity Hospital:
    a. Each month the Contract Pharmacy generates/receives outpatient and inpatient utilization reports that reflect drug identifiers, drug description and quantity dispensed to outpatients and inpatients. This report includes data *from each treatment area in the Hospital* where 340B or GPO drugs are utilized. Patient, treatment area and provider information are used to determine the appropriate account for ordering.
        i. The outpatient utilization report is used to determine the quantity of product for purchase on the 340B (outpatient) wholesaler account.
        ii. The inpatient utilization report is used to determine the quantity of product for purchase on the GPO wholesaler account.
        iii. A virtual inventory is maintained showing:
            1. drug identifier,
            2. drug description,
            3. 11 digit-NDC number,
            4. quantity accumulated,
            5. package unit of measure, and
            6. packages eligible for ordering on each account.
        iv. Outpatient utilization is matched to the same 11-digit NDC number for the appropriate 340B product.
        v. Drug procurement quantities are accumulated based on the utilization reports and converted into wholesaler orderable quantities for each account.
        vi. A copy of each month's original outpatient and inpatient charge (utilization) files (including patient ID and date of service) are retained in the pharmacy for auditing purposes.
        vii. Each month, a report of 340B and GPO purchases from the wholesaler accounts are generated. Items that have been purchased

on each account are deducted from the total packages on the virtual inventory.

O. **Changes to Wholesaler Drug Ordering Procedures:**

1. For the purpose of 340B compliance, changes in wholesaler drug ordering procedures are managed using the following guidelines:
    a. Long Term Shortages – For situations in which there will be an extensive shortage of a medication (e.g., manufacturer backorder), the following steps occur:
        i. The pharmacy information system is updated with the new NDC number.
        ii. It is assumed that drugs in stock in the pharmacy as of this date will be used on qualified outpatients for the next 30 days.
        iii. The 340B database is updated 30 days later to allow existing inventory to be used.
    b. GPO Contract Rolls – For GPO contract rolls, the following steps occur:
        i. Identify the start date of the new contract(s).
        ii. The pharmacy information system is updated with the new NDC number.
        iii. It is assumed that drugs in stock in the pharmacy as of this date will be used on qualified outpatients for the next 30 days.
        iv. The 340B database is updated 30 days later to allow existing inventory to be used.
    c. Package Size Change – Changes in the manufacturer's package sizes result in changes in the number of doses required for reorder. In these instances, a new Change Description Master (CDM) is assigned to the line item to maintain the integrity of the inventory database.

P. **Billing/Utilization:**

1. Bundling – Based on the current Ambulatory Payment Classification (APC) group payments for a particular service, appropriate billing practices for bundled drugs is determined. The application of bundling charges is consistent throughout the organization. Based on these practices, the Hospital determines which drugs may be separately "billable" and therefore, "unbundled" in order to utilize 340B pricing.
    a. Drugs that are part of/incident to another service, and payment is not made as direct reimbursement of the drugs, are "bundled" drugs.
    b. Drugs that are "bundled" are not 340B eligible drugs and may be purchased on a GPO account.
2. Third Party Payers – Prescriptions for outpatient medications are priced according to specific price agreements with payers (i.e., insurance companies).
3. Medicaid – Prescriptions for Medicaid patients are **carved out** (i.e., the covered entity does not use 340B drugs for Medicaid patients.
4. Cash Payers – eligible patients with outpatient prescription(s) generated by eligible providers of the Covered Entity may receive 340B cash discount pricing as outlined in the contract Pharmacy Service Agreement.

Q. **Monitoring and Auditing:**

1. The following **Internal Self-Audit Guidelines** are used for the purpose of monitoring the Covered Entity's 340B Program and demonstrating its commitment to compliance:
    a. Routine – Contract Pharmacy Oversight Audit:
        i. Designate a single contract pharmacy if required by pharmaceutical manufacturer(s).
        ii. Audit sample of 10 340B claims per month will be reviewed to confirm that Medicaid claims are appropriately carved out.
        iii. Confirm that provider eligibility requirements for 340B inclusion are maintained.
        iv. Review a random sampling of 10 claims monthly against patient medical records to confirm that a patient-provider relationship had been documented to establish 340B patient eligibility.
        v. Conduct periodic On-Site tour of Contract Pharmacy to review Standard Operating Procedures (SOP).
    b. Quarterly – Database Crosswalk and reconciliation for out-patient areas (if applicable):
        i. Randomly select any drugs from the Pharmacy Information System.
        ii. Record the NDC number assigned to each drug product.
        iii. Determine if each NDC number matches the NDC number of the product on the shelf.
        iv. Review accuracy of units of measure for each product.
        v. Validate that the product is currently mapped accurately in the database crosswalk.
        vi. Log onto the OPA website to validate participation in the program at https://340bopais.hrsa.gov/.
    c. Yearly –
        i. Validation of Eligibility:
            1. Log onto the OPA website to validate participation in the program at https://340bopais.hrsa.gov/.
            2. Review the Hospital's Medicare Cost Report to identify:
                a. Any changes in classifications of departments and outpatient treatment areas.
        ii. Outpatient Treatment Areas:
            1. Review the treatment area cost centers and center numbers. This list identifies treatment areas as 'Clean' (outpatients only treated), 'Mixed' (inpatient and outpatient treated) or 'Not Eligible' for 340B pricing.
                a. Classify any new clinics and cost centers.
        iii. Wholesaler Pricing:
            1. The availability of the prices is verified by random checks of pricing in the wholesaler database.

2. Conduct reconciliation of dispensing, purchasing, and billing records.

2. The following **Independent Audit Guidelines** are used for the purpose of impartially evaluating 340B compliance:
   a. Yearly audits will be conducted by an independent auditor to assess the following risk areas:
      i. Validation of Eligibility,
      ii. Prevention of Diversion, and
      iii. Prevention of Duplicate Discounts.
   b. Audit Findings discovered as a result of an Independent Audit shall be handled consistent with the process for discovery, reporting, and resolution of Non-Compliance contained in this policy.
3. 340B Non-Compliance/**Material Breach**:
   a. Self-Disclosure – The Covered Entity agrees to conduct its 340B Program in accord with all applicable guidelines and defines a Material Breach as any error or errors that occur during a monthly audit period where the 340B purchase price of the total of medications in question exceeds five percent (5%) of the last calendar year 340B spend.
      i. If the Covered Entity was not participating in the 340B program during the entire last calendar year, the most recent calendar quarter's purchases will be annualized and any error(s) exceeding five percent (5%) of this calculation will be used to determine Material Breach.
   b. Monthly audits results are reported to the 340B Committee and the test for Material Breach is applied to each month's results.
   c. If a self-report to HRSA is required, the Covered Entity would use the appropriate reporting form on the Apexus website.
   d. Reporting – the Covered Entity agrees to notify HRSA and applicable manufacturers immediately upon determination of a Material Breach and maintain records of breach violations, including manufacturer resolution correspondence.
   e. Resolution – The Covered Entity shall make reasonable good faith efforts to resolve any discovery of non-compliance by providing communication with affected parties.
   f. It is acknowledged that as a result of documented non-compliance, the Covered Entity may be:
      i. liable for repayment to Manufacturers or subject to Civil Monetary Penalties (CMP).
      ii. terminated from 340B participation.
4. Audit Reports shall be maintained in a readily retrievable and auditable format for a minimum period of four (4) calendar years.

R. **340B Program Training and Competency:**
1. Parties occupying key 340B stakeholder roles shall complete initial basic training upon hire.

2. Educational updates and training may be provided as needed as determined necessary to keep up to date with HRSA policy guideline changes.

S. **Special Circumstances:**

1. If a new clinic meets 340B eligibility criteria, the Covered Entity's Authorizing Official will complete the online registration process during the registration window to designate the clinic as an Eligible Location. The Covered Entity will submit any updated Medicare Cost Report information, as required by HRSA.
   a. If the Covered Entity is unable to register new services/outpatient clinics because they have not yet appeared as reimbursable on the most recently filed Medicare Cost Report, then the patients of these new services/outpatient clinics may still be considered 340B eligible to the extent that they are patients of the Covered Entity.
   b. The Hospital may consider these new services/outpatient clinics that will be on the next Medicare Cost Report eligible for participation in the 340B Program immediately after dropping charges as an entity-owned location or service. The Hospital will ensure such services/outpatient clinics are registered with HRSA/OPAIS (Office of Pharmacy Affairs Information System) during the next registration period that occurs after they appear on the next filed Medicare Cost Report.
   c. If the Hospital identifies services or locations that have revenue and expenses under the Covered Entity's tax identification (ID) number and appear on the current Medicare Cost Report but are not yet registered on HRSA/OPAIS, then the patients of these services/outpatient clinics may still be considered 340B eligible to the extent that they are patients of the Covered Entity. The Hospital will ensure such services/outpatient clinics are registered with HRSA/OPAIS during the next registration period that occurs.
2. Under certain special circumstances, such as force majeure, the Hospital may consider certain services and locations 340B eligible to the extent that they are patients of the Covered Entity, and these services or locations have revenue and expenses under the Covered Entity's tax ID number even if they do not appear on the most recently filed Medicare Cost Report.

REFERENCES

Health Resources and Services Administration (2023). 340B Drug Pricing Program. Retrieved on 07/05/23 from http://www.hrsa.gov/opa/

Health Resources and Services Administration (2023). Program Requirements. Retrieved on 07/05/23 from http://www.hrsa.gov/opa/program-requirements

Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services 75 FR 10272 (2010). Retrieved on 07/05/23 from https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

Part 10 – 340B Drug Pricing Program. Section 340B of the Public Health Services Act 42 U.S.C. §256b (2023). Retrieved on 07/05/23 from https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-10

ATTACHMENTS

Attachment A – List of OPA Registered Child Site(s) of the covered entity for inclusion in the 340B program.

Mangum Regional Medical Center

Attachment A – List of OPA Registered Child Site(s) of the covered entity for inclusion in the 340B program:

1. Mangum Family Clinic
   118 S. Louis Tittle
   Mangum OK 73554
   (580)782-2000