HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Prevention of Duplicate Discounts **Effective Date: 1/1/2019**
Policy Number: 703 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

Purpose: To ensure that Hardin County General Hospital and Clinic (HCGH&C) is preventing duplicate discounts.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

HCGH&C has elected to purchase drugs for its Medicaid patients through other mechanisms and will not be purchasing 340B drug for use within the hospital setting at this time.

Contract Pharmacies

1. HCGH&C's contract pharmacies carve out.
    a. HCGH&C has an arrangement with the state Medicaid agency to prevent duplicate discounts.
    b. HCGH&C has reported this arrangement to HRSA.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: Contract Pharmacy Operations **Effective Date: 1/1/2019**
Policy Number: 707 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entity remains responsible for ensuring that its contract pharmacy operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy.

Purpose: To ensure that Hardin County General Hospital and Clinic (HCGH&C) remains responsible for all 340B drugs used by its contract pharmacy.

Reference:

Federal Register / Vol. 61, No. 165 / Friday, August 23, 1996 / Notices
https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

Background:

HCGH&C uses contract pharmacy services in accordance with HRSA requirements and guidelines.

HCGH&C has obtained sufficient information from the contract pharmacy contractor to ensure compliance with applicable policy and legal requirements.

The signed contract pharmacy services agreement complies with 12 contract pharmacy essential compliance elements.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

1. HCGH&C facilitate both the design and implementation of the 340B contract pharmacy program.

2. HCGH&C has a written contract is in place for each contract pharmacy location.
    a. Hardin County Pharmacy, LLC.
       7 Ferrell Road
       Rosiclare, IL 62982

3. HCGH&C registers each contract pharmacy location on HCGH&C HRSA 340B OPAIS prior to the use of 340B drugs at that site.

4. HCGH&C uses a replenishment model using an 11-digit to 11-digit NDC match.
    a. Non-replenishment 340B inventory is stored at HCDP, and clearly marked as belonging to the 340B entity.
5. 340B-eligible prescriptions are presented to HCDP via e-prescribing, hard copy, fax, or phone.
    a. HCP verifies patient, prescriber, and outpatient clinic eligibility.
    b. Updates are made to this mechanism by HCGH&C when appropriate.

6. HCDP dispense(s) prescriptions to 340B eligible patients using HCDP non-340B drugs.

7. HCDP&C implements a bill-to, ship-to arrangement with the contact pharmacy.
        i. HCP orders 340B drugs based on 340B eligible use as determined by need.
        ii. Orders are triggered by need of stock.
    a. Invoices are billed to HCGH&C.

8. HCDP receive shipment.
9. HCDP verifies quantity received with quantity ordered.
    a. Identifies inaccuracies.
    b. Resolves inaccuracies.
    c. Documents resolution of inaccuracies.

10. HCDP notifies HCGH&C if HCDP doesn't receive 11-digit NDC replenishment order within reasonable time of original order fulfillment request.

11. HCGH&C reimburses HCDP at a pre-negotiated rate for such drugs.

12. HCGH&C receives and reviews the invoice for drugs shipped to its contract pharmacy.

13. HCGH&C pays invoice to Mckesson for all 340B drugs.

14. HCDP provides a monthly report to the HCGH&C.

15. HCDP adjusts claims when variance or discrepancy has occurred.
    a. HCDP uses approved methods with knowledge and agreement of HCGH&C regarding reconciliation between inventory and invoices with adjustments as necessary to match changes.
    b. Claim adjustments may occur only within no more than 90 days of original billing and not without prior notice and approval of entity.

16. HCDP will not use 340B drugs for Medicaid patients (carve-out). [Insert entity-specific process here including how contract pharmacy(ies) verifies that 340B drugs are not used or accumulated for Medicaid patients and prevents duplicate discounts for outpatient prescriptions, including those that are billed to the AIDS Drug Assistance Program (ADAP)].

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: Contract Pharmacy Oversight and Monitoring **Effective Date: 1/1/2019**
Policy Number: 710 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

Purpose: To ensure that Hardin County General Hospital & Clinic (HCGH&C) maintains 340B Program integrity and compliance at its contract pharmacy.

Reference:
Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices
https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

1. HCGH&C routinely conducts internal reviews of each registered contract pharmacy for compliance with 340B Program requirements. [Insert entity specifics here] The following elements will be included when conducting self-audits of contract pharmacy(ies) to ensure program compliance:
    a. Prescription is written from a site of care that is registered on the HRSA 340B OPAIS and included as a reimbursed outpatient service cost center on the most recently filed Medicare cost report.
    b. Patient eligibility: The episode of care that resulted in the 340B prescription is supported in the patient's medical record.
    c. Provider eligibility: The prescribing provider is employed, contracted, or under another arrangement with the entity at the time of writing the prescription so that the entity maintains responsibility for the care.
    d. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation or administration (if a virtual inventory is used).
    e. HCGH&C can document that no prescriptions were billed to Medicaid unless the contract pharmacy is listed as a carve-in contract pharmacy on the HRSA 340B OPAIS.

2. HCGH&C conducts independent audits of each registered contract pharmacy for compliance with the 340B Program requirements. [Insert entity specifics here].
   Note: It is HRSA's expectation that covered entities will use annual independent audits as part of fulfilling their ongoing obligation of ensuring 340B Program compliance.
   a. Independent audits will include reviews of:
      i. 340B eligibility.
      ii. 340B registration.
      iii. Documented policies and procedures.
      iv. Inventory, ordering, and record keeping practices for all 340B accounts.
      v. Review of the listing in the Medicaid Exclusion File and its reflection in actual practices.
      vi. Testing of claims sample to determine any instance of diversion or duplicate discounts in a set period of time.

3. HCGH&C has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites, including off-site outpatient facilities. [Insert entity-specific process for all state Medicaid agencies that are billed].

4. HCGH&C follows all state practices consistent with state guidance and [Entity] Medicaid billing numbers/NPI numbers are properly reflected in the Medicaid Exclusion File.
   a. The following state Medicaid programs are billed by [Entity]: [Insert entity specifics here].

5. HCGH&C 340B Oversight Committee reviews audit results. [Insert entity-specific process here].
   a. Assess whether audit results are indicative of a material breach [Refer to HCGH&C Policy and Procedure "340B Noncompliance/Material Breach" [Insert [Entity's specific policy and procedure reference number here]].

6. HCGH&C maintains records of 340B-related transactions for a period of [time interval] in a readily retrievable and auditable format located [reference]. [Insert entity specifics here].

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Covered Entity Eligibility **Effective Date: 1/1/2019**
Policy Number: 700 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Hardin County General Hospital and Clinic (HCGH&C) must meet the requirements of 42 USC §256b(a)(4)(N) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

Purpose: To ensure Hardin County General Hospital and Clinic eligibility to participate in the 340B Program.

II. DEFINITIONS

Covered outpatient drug: HCGH&C interprets Section 1927(k) of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm) to include the following drugs when used in the situations described [list] and exclude the following drugs when used in the situations described [list].

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

1. HCGH& C basis for 340B eligibility is determined by the following:
   Is a private, nonprofit hospital that 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 under this title.
   i. Contract will be signed and dated by both parties.
   ii. See attached

2. HCGH&C has identified that at this time HCGH&C will not be dispensing 340B drugs to patients

3. HCGH&C ensures that HRSA 340B OPAIS is complete and accurate for all 340B eligible locations including the parent entity, off-site locations, and contract pharmacy. Refer to HCGH&C Policy and Procedure "340B Program Enrollment, Recertification, and Change Request" #701
   a. All off-site locations that use 340B drugs are registered on HCGH&C's HRSA 340B OPAIS.
   b. All main addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.

c. HCGH&C regularly reviews its 340B OPAIS records Refer to HCGH&C Policy and Procedure “340B Program Compliance Monitoring and Reporting” #709.
d. HCGH&C informs HRSA immediately (within 60 days) of any changes to its information by updating the HRSA 340B OPAIS/Medicaid Exclusion File
e. [Include as Appendix [#]: download from HRSA 340B OPAIS with version date.]

4. HCGH&C annually recertifies HCGH&C information on HRSA’s 340B OPAIS. Refer to HCGH&C Policy and Procedure “340B Program Enrollment, Recertification, and Change Request” #701

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Inventory Management **Effective Date: 1/1/2019**
Policy Number: 706 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entities must be able to track and account for all 340B drugs to ensure the prevention of diversion.

Purpose: Ensure the proper procurement and inventory management of 340B drugs.

Background:
340B inventory is procured and managed in the following settings:

- Contract pharmacy

Inventory methods for each of the above areas within the entity shall be described within the inventory management policy and procedure.

HCP uses one of the following inventory methods:

a. Physically separates 340B and non-340B purchased inventory.

Pharmacists and technicians dispense 340B drugs only to patients meeting all the criteria in Refer to HCGH&C Policy and Procedure "Patient Eligibility/Definition" #702
Physical inventory (340B only) is maintained at Hardin County Pharmacy, LLC.

1. HCGH&C identifies all accounts used for purchasing drugs in the contract pharmacy.

2. HCP maintains physical inventory on a day to day basis. An inventory count is conducted by HCGH&C monthly.

3. HCP performs daily inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order.

4. HCGH&C places 340B drug orders.

5. Hardin County Pharmacy receives shipment.

6. HCGH&C and HCP verifies quantity received with quantity ordered.
    a. Identifies inaccuracies.
    b. Resolves inaccuracies.
    c. Documents resolution of inaccuracies.

7. HCGH&C maintains records of 340B related transactions for a period of five years in a readily retrievable and auditable format located.
    a. These reports are reviewed by as part of its 340B oversight and compliance program.

Wasted 340B medication

1. HCP staff documents wastage on a wastage transaction log.
2. HCP staff communicates wastage to the 340B pharmacy coordinator.
3. HCDP replaces medication through appropriate purchasing account.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Inventories **Effective Date: 1/1/2019**
Policy Number: 712 **Med Staff:**
Regulation: **Admin:**

I. POLICY

To describe the procedures used for recording and processing the inventory of the 340B Pharmacy program, implemented through contracts with Hardin County Pharmacy on January 1, 2019 and Golconda Pharmacy on July 1, 2019.

II. DEFINITIONS

III. RESPONSIBILITY

Hardin County and Golconda Pharmacist, Clinic Director, Accounts Payable manager and Chief Financial officer.

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Hospital accounts for the 340B program with McKesson drug company were established As specified by contracts with Hardin County and Golconda pharmacies. The physical inventories for the 340B program are maintained separately in each pharmacy from the retail stock. The retail pharmacy provides the software to maintain and track the 340B inventory in each entity.

340B orders are placed by the retail pharmacists. The invoices generated by the orders are received by the CFO and reviewed, then forwarded to the AP manager to be posted. McKesson drug company sends statements bi-monthly which are matched to invoices and posted. Payments are automatically withdrawn by McKesson through ACH agreement on the 10^{th} and 25^{th} of each month.

At the end of each month, the Pharmacy Director prints detailed reports of monthly cost of goods sold and final remaining inventory. The Hospital Clinic nursing supervisor does a physical count of the 340B inventory and validates the monthly reports. The end of month reports are forwarded to the hospital CFO and Clinic director. The cost of goods sold are expensed by the CFO and balanced to the 340B general ledger inventory asset account. Monthly revenue checks, based on 340B contract specifications, are delivered to hospital accounts receivable to be processed.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Noncompliance Material Breach **Effective Date: 1/1/2019**
Policy Number: 708 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements.

Purpose: To define Hardin County General Hospital & Clinic (HCDP&C) material breach of 340B compliance and self-disclosure process.

II. DEFINITIONS

Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.

Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach. Examples of thresholds include:

a. X% of total 340B purchases or impact to any one manufacturer.
b. $X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer.
c. X% of total 340B inventory (units).
d. X% of audit sample X% of prescription volume/prescription sample.

Reference:
340B University: Establishing Material Breach Documentation Tool
https://docs.340bpvp.com/documents/public/resourcecenter/establishing-material-breach-threshold.docx

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

1. HCGH&C established threshold of what constitutes a material breach of 340B Program compliance is.
    a. HCGH&C ensures that identification of any threshold variations occurs among all its 340B settings, including contract pharmacies (if applicable).

2. HCGH&C assesses materiality.

a. HCGH&C maintains records of materiality assessments.

3. HCGH&C reports identified material breach immediately to HRSA and applicable manufacturers.
    a. Maintain records of material breach violations, including manufacturer resolution correspondence, as determined by organization policy.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: Patient Eligibility Definition | **Effective Date: 1/1/2019**
Policy Number: 702 | **Med Staff:**
Regulation: | **Admin:**

I. POLICY

Policy: Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities.

Purpose: HCGH&C ensures that 340B drugs are dispensed/administered/prescribed only to eligible patients.

II. DEFINITIONS

Administer: Give a medication to an individual, typically in a hospital or a clinic, based on a health care provider's order.

Dispense: Provide a medication, typically in a hospital or a clinic, based on a health care provider's order to be administered to a patient.

Inpatient status: Patient who has been admitted to the Nursing Floor under acute care orders.

Outpatient status: Any Patient who has been registered for testing or procedures. Qualifying patient classes are PC,PN,ER,TR, and OS.

Prescribe: Provide a prescription for a medication to an individual to be filled at an outpatient pharmacy.

III. RESPONSIBILITY

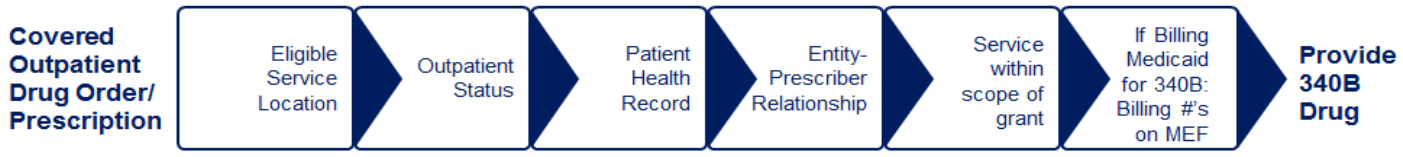
IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Procedure

HCGH&C will implement the following 340B eligibility determination filters:



1. HCGH&C validates site eligibility.
    a. Refer to HCGH&C Policy and Procedure “Covered Entity Eligibility” #700
2. HCGH&C determines patient status.
    a. Patient must be in outpatient status at the time the medication is dispensed/administered or prescribed at HCGH&C or a location listed on the HCGH&C HRSA 340B OPAIS.
    Outpatient status is determined by the service performed at HCGH&C. Qualifying patient classes will be PC,PN,ER,TR, and OS.
3. HCGH&C maintains records of individual’s health care.
4. HCGH&C determines provider eligibility.
    a. Provider is employed by the entity, under contractual or other arrangements with the entity, and the individual receives a health care service from this professional such that the responsibility for care remains with the entity.
5. HCGH&C determines patient’s Medicaid status Refer to HCGH&C Policy and Procedure “Prevention of Duplicate Discounts” #703

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: Prime Vendor Program, Enrollment and Updates **Effective Date: 1/1/2019**
Policy Number: 711 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: The purpose of the Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients.

Purpose: Assist Hardin County General Hospital and Clinic (HCGH&C) participation in the PVP to receive the best 340B product pricing, information, and value-added products.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Enrollment in PVP:

1. HCGH&C completes online 340B Program registration with HRSA.

2. HCGH&C completes online PVP registration https://www.340bpvp.com/register/apply-to-participate-for-340b/.

3. PVP staff validates information and sends confirmation email to HCGH&C.

4. HCGH&C logs in to www.340bpvp.com, selects user name/password.

Update PVP Profile:

1. HCGH&C accesses www.340bpvp.com.
2. HCGH&C clicks Login in the upper right corner.
3. HCGH&C inputs PVP log-in credentials.
    a. In the upper right corner:
        i. Click “My Profile” to access page. https://members.340bpvp.com/webMemberProfileInstructions.aspx
4. HCGH&C clicks “Continue to My Profile” to access page https://members.340bpvp.com/webMemberProfile.aspx
    a. Find a list of your facilities.
        i. Click on the 340B ID number hyperlink to view or change profile information for that facility.
    b. Update HRSA Information:
        i. Complete the 340B Change Form as detailed above.
            a) After the HRSA 340B OPAIS has been updated, the PVP database will be updated during the nightly synchronization.
            b)

5. HCGH&C updates the 340B Prime Vendor Program (PVP) Participation Information:
    a. Edit [Entity's] DEA number, distributor and/or contacts.
    b. Click submit.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: Program Compliance Monitoring and Reporting **Effective Date: 1/1/2019**
Policy Number: 709 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entities are required to maintain auditable records demonstrating compliance with the 340B Program requirements.

Purpose: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Procedure:

1. Hardin County General Hospital & Clinic (HCGH&C) develops an annual internal audit plan approved by the internal compliance officer or as determined by organizational policy.

2. HCGH&C reviews the HRSA 340B OPAIS to ensure the accuracy of the information for the contract pharmacy (if applicable).

3. HCGH&C ensures compliance with the GPO Prohibition.

4. HCGH&C reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.

5. HCGH&C reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs. HCGH&C will select records from a drug dispensing file and perform the audit monthly, and or quarterly.

6. HCGH&C reconciles dispensing records and Medicaid billing practices to demonstrate that HCGH&C practice is following the Medicaid billing question on the HRSA 340B OPAIS.

7. HCGH&C 340B Oversight Committee reviews the internal audit results

a. Assess whether audit results are indicative of a material breach Refer to HCGH&C Policy and Procedure “340B Non-Compliance/Material Breach” #708

Specifically, HCGH&C utilize the Apexus Self Audit Tools (Appendix A) provided by the Prime Vendor Program to ensure compliance with the 340B Program Requirements. These tools are completed every quarter and reviewed by the Oversight Committee.

HCGH&C maintains records of 340B-related transactions for a period of five years in a readily retrievable and auditable format.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Program Education and Competency **Effective Date: 1/1/2019**
Policy Number: 705 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose: To establish 340B education and competency requirements for Hardin County General Hospital and Clinic's (HCGH&C) 340B key stakeholders, based on their roles and responsibilities in the 340B Program.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Procedure:

1. HCGH&C determines the knowledge and educational requirements for each 340B Program role Refer to HCGH&C Policy and Procedure "340B Program Roles and Responsibilities" #704
2. 340B key stakeholders complete initial basic training upon hire.
3. 340B key stakeholders complete additional training as identified in #1 above.
4. HCGH&C provides educational updates and training, as needed.
5. HCGH&C conducts annual verification of 340B Program competency.
6. Training and education records are maintained per organizational policy and available for review.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Program Education and Competency **Effective Date: 1/1/2019**
Policy Number: 705 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose: To establish 340B education and competency requirements for Hardin County General Hospital and Clinic's (HCGH&C) 340B key stakeholders, based on their roles and responsibilities in the 340B Program.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Procedure:

1. HCGH&C determines the knowledge and educational requirements for each 340B Program role Refer to HCGH&C Policy and Procedure "340B Program Roles and Responsibilities" #704
2. 340B key stakeholders complete initial basic training upon hire.
3. 340B key stakeholders complete additional training as identified in #1 above.
4. HCGH&C provides educational updates and training, as needed.
5. HCGH&C conducts annual verification of 340B Program competency.
6. Training and education records are maintained per organizational policy and available for review.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Program Enrollment, Recertification, and Change Requests | **Effective Date: 1/1/2019**
Policy Number: 701 | **Med Staff:**
Regulation: | **Admin:**

I. POLICY

Policy: Eligible hospitals must be registered on, and maintain the accuracy of, the HRSA 340B OPAIS to participate in the 340B Program.

Purpose: To ensure Hardin County General Hospital and Clinic (HCGH&C) registration on, and accuracy of, the HRSA 340B OPAIS.

References:

340B Drug Pricing Program: Hospital Registration Instructions (http://www.hrsa.gov/opa/files/hospitalreginfo.pdf)

Registration dates:

- January 1–January 15 for an effective start date of April 1
- April 1–April 15 for an effective start date of July 1
- July 1–July 15 for an effective start date of October 1
- October 1–October 15 for an effective start date of January 1

340B Contract Pharmacy Guidelines (https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf).

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

Enrollment

1. HCGH&C is eligible to participate in the 340B Program Refer to HCGH&C Policy and Procedure “Covered Entity Eligibility” #700
2. HCGH&C identifies upcoming registration dates and deadlines.
3. HCGH&C identifies its authorizing official and primary contact.
4. HCGH&C has available the required documents:
    a. Medicare cost report:
        i. Worksheet S, S-2

ii. For outpatient facilities:
    1) Worksheet C
    2) Worksheet A
    3) Working trial balance

b. Certification of ownership status

5. HCGH&C completes registration on the HRSA 340B OPAIS (https://340bopais.hrsa.gov/).

Recertification Procedure

1. HCGH&C annually recertifies HCGH&C information on the HRSA 340B OPAIS.
    a. The authorizing official completes the annual recertification by following the directions in the recertification email sent from HRSA to the authorizing official prior to the stated deadline.
        i. HCGH&C submits specific recertification questions to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Outpatient Facilities

1. HCGH&C determines that a new outpatient service or facility is eligible to participate in the 340B Program.
    a. The criteria used include that the outpatient service must be fully integrated into the CAH, appear as a reimbursable service or clinic on the most recently filed cost report, have outpatient drug use, and have patients who meet the 340B patient definition.

2. HCGH&C authorizing official completes the online registration process during the registration window.
    a. [Submit any updated Medicare cost report information, as required by HRSA: http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/criticalaccesshospitals/index.html]

Enrollment Procedure: New Contract Pharmacy(ies)

1. HCGH&C has a signed contract pharmacy services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance, in place between the entity and contract pharmacy prior to registration on the HRSA 340B OPAIS. https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf
    a. HCGH&C has reviewed the contract and verified that all federal, state, and local requirements have been met.

2. HCGH&C has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented. Refer to HCGH&C Policy and Procedure "Contract Pharmacy Oversight Management" #710

3. HCGH&C authorizing official or designee completes the online registration during one of four registration windows.
    a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration was completed.

4. HCGH&C begins using the contract pharmacy services arrangement only on or after the effective date shown on the HRSA 340B OPAIS.

Procedure for Changes to HCGH&C Information in HRSA 340B OPAIS

1. HCGH&C will notify HRSA immediately of any changes to HCGH&C information on its HRSA 340B OPAIS. Refer to HCGH&C Policy and Procedure “Covered Entity Eligibility” #700.

2. HCGH&C authorizing official will complete the online change request as soon as a change in eligibility is identified.
    a. HCGH&C will expect changes to be reflected within a reasonable amount of time.

VI. DOCUMENTATION

HARDIN COUNTY GENERAL HOSPITAL
HOSPITAL-WIDE POLICY

Title: 340B Program Rules and Responsibilities **Effective Date: 1/1/2019**
Policy Number: 704 **Med Staff:**
Regulation: **Admin:**

I. POLICY

Policy: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

Purpose: To identify Hardin County Generals Hospital & Clinic's (HCGH&C) key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

II. DEFINITIONS

III. RESPONSIBILITY

IV. EQUIPMENT

V. PROCEDURES

INFECTION CONTROL: N/A

1. HCGH&C's key stakeholders involved with HCGH&C 340B Program are:
    a. Hardin County General Hospital and Clinic
    b. Hardin County Pharmacy LLC.
    c. City of Rosiclare

2. HCGH&C's key stakeholders' roles and responsibilities with HCGH&C 340B Program are:
    a. Hardin County General Hospital and Clinic
        i. Adhere to all Federal, State, and local laws and requirements.
        ii. Use any saving generated from 340B in accordance with 340B Program intent.
        iii. Meet all 340B Program eligibility requirements.
        iv. Comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines.
        v. Maintain auditable records demonstrating compliance with the 340B requirements.
        vi. Maintain records of individuals health care.
        vii. Bill Medicaid per Medicaid reimbursement requirements and as HCGH&C reflected its information on the OPA website/Medicaid Exclusion File.
        viii. Maintain systems/,mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
        ix. Sustain an internal audit plan adapted by the 340B compliance agent and conducted annually, and an external audit plan.

x. Uses contract pharmacy services and the arrangement is performed in accordance with OPA requirements and guidelines including but not limited to:
    1. HCGH&C obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and HCGH&C has utilized an appropriate methodology to ensure compliance.
    2. Signed Contract Pharmacy Services Agreement(s) complies with 12 contract pharmacy essential compliance elements.

xi. Acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by HCGH&C of any of the foregoing policies.

xii. Neither party will use drugs purchased under Section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA, by the covered entity.

xiii. Understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts

b. Hardin County Pharmacy LLC
    i. Adhere to all Federal, State, and local laws and requirements.
    ii. Maintain physical inventory of drugs purchased by covered entity while covered entity maintains title of the drug. A ship to bill to procedure will be followed.
    iii. Agreement specifies the responsibility of the contract pharmacy to provide comprehensive pharmacy services (ex: dispensing, record keeping, patient conseling.)
    iv. Contract Pharmacy may provide other services to the covered entity or its patients at the option of the covered entity. Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.
    v. Provide the covered entity with reports consistent with customary business practices. (ex: quarterly dispensing reports, billing statements)
    vi. The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of Section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities.
    vii. The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines. Both parties agree that they will not resell or transfer a drug purchased at Section 340B prices to an individual who is not a patient of the covered entity
    viii. Neither party will use drugs purchased under Section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to

prevent duplicate discounts. Any such arrangement shall be reported to HRSA, by the covered entity.

ix. Understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts

x. The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

xi. Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

c. City of Rosiclare
    i. Maintain Contract with HCGH to provide care to community.

3. HCGH&C has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program, or other similar oversight process, including that the committee will meet on a regular basis to review Policy and Procedures, self-audits, and general compliance issues of the 340B program.

4. HCGH&C 340B Oversight Committee:
    a. Meets on a regular basis (At least once a quarter)
    b. Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
    c. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.
        i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
        ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
    d. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
        i. 340B Oversight Committee assesses if the results are indicative of a material breach Refer to HCGH&C Policy and Procedure "340B Noncompliance/ Material Breach" # 708
    e. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

The following HCGH&C staff are potential key players in the 340B Program, including governance and compliance, and should be standing members of the 340B Steering Committee. [Entity] will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals should be the sponsors of the 340B Oversight Committee.

A. Chief Executive Officer
    - Responsible as the principal officer in charge for the compliance and administration of the program
    - Responsible for attesting to the compliance of the program in form of recertification
B. Chief Financial Officer
    - Must account for savings and use of funds to provide care for the indigent under the indigent care agreement
    - Maintain invoices, statements and receipt of Revenue from Contract Pharmacy.
C. Director of Clinic
    - Accountable agent for 340B compliance
    - Agent of the CEO or CFO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance
    - Must maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes
    - Day to day Manager of the program
    - Responsible for documentation of policy and procedures
    - Manage inventory control processes
    - Continuously monitor product min/max levels to effectively balance product availability and cost efficient inventory control
    - Assure appropriate safeguards and system integrity
    - Perform annual inventory and monthly [or other interval] cycle counts
    - Assure compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payers, and locations
    - Review and refine 340B cost savings report detailing purchasing, and replacement practices, as well as dispensing patterns
    - Monitor ordering processes, integrating most current pricing from wholesaler, analyze invoices, shipping, and inventory processes
    - Designs and maintains an internal audit plan of the compliance of the 340B program
    - Design the annual plan to cover all changes in the program from the past year
D. Clinic Nurse Manager
    - Responsible for annual or semi-annual physical inventory of pharmacy items
E. Owner of Contract Pharmacy
    - Support the Pharmacy software selection of tracking software to manage the 340B program
    - Archive the data so as to be available to auditors when audited
    - Be aware of products covered by 340B and Prime Vendor Program pricing
    - Responsible for establishing distribution accounts and maintaining those accounts; i.e., 340B account, etc.

- Responsible for ordering all drugs from the specific accounts as specified by the process employed
- Provide the Covered Entity with statements needed to quarterly and Annual Self-Audits.

VI. DOCUMENTATION