LSU HEALTH CARE SERVICES DIVISION,
BATON ROUGE, LOUISIANA

POLICY NUMBER:	8509-15
CATEGORY:	Compliance
CONTENT:	340 B Compliance
Effective Date:	February 23, 2007
Review Date:	October 20, 2009
Review Date:	May 27, 2011
Revised Date:	November 28, 2012 August 1, 2014
Reviewed/Revised Date:	February 25, 2015
Inquiries to:	John Couk, Chief Medical Officer LSU HCSD, Medical Post Office Box 91308 Baton Rouge, Louisiana 70821-1308 Telephone: 504-568-2259 Facsimile: 504-568-2090 Telephone: 225- 354-7005 Facsimile: 225 354-7011

Deputy Chief Executive Officer
LSU Health Care Services Division

2/24/15
Date

Chief Medical Officer
LSU Health Care Services Division

2/25/15
Date

LOUISIANA STATE UNIVERSITY
Health Care Services Division
340 B Compliance

I. PURPOSE

To provide a systematic approach in protecting the integrity of and adherence to the rules and regulations set forth by the Health Resources and Services Administration's (HRSA) - Office of Pharmacy Affairs Section 340B of the Veterans Health Care Act of 1992 of the participating Louisiana State University - Health Care Services Division (LSU-HCSD) facilities.

II. SCOPE

This policy shall apply to each HCSD Disproportionate Share Hospital (DSH) and Critical Access Hospital that participates in the 340B program. This includes all employees, contract employees, or agents of HCSD providing services under the 340B program.

III. POLICY STATEMENT

It is the policy of LSUHCSD to participate in the 340B program and to comply with all Components of Section 340B of the Public Health Service (PHS) Act and to implement safe guards to protect the participants from any and all types of diversion.

Savings and revenue generated through the participation in the 340B program will be used to support a pharmacy benefit for the indigent population as well as promote disease management initiatives in our hospitals and clinics.

IV. RESPONSIBILITIES

1. Hospital Administrator, Chief Financial Officer, or Chief Operating Officer will act as the "Authorizing Official" whom shall attest to the Compliance of the programs in the form of recertification and ensure:

    a. That this HCSD policy is disseminated to and acknowledged by all appropriate department managers and their appropriate staff.

    b. That hospital specific procedures are implemented to further ensure compliance with all components of Section 340B of the Public Health Service (PHS) Act.

c. That any updates/changes of 340B regulations are implemented hospital wide.

2. The HCSD Pharmacy Directors will establish mechanisms to protect the integrity of the 340B program by:

   a. Reporting any and all types of suspected diversion to the facility compliance officer and/or administration;

   b. Denying the filling of prescriptions for patients that do not meet the covered entity "patient definition";

   c. Only filling prescriptions from a prescriber 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 care provided remains with the covered entity;

   d. Ensuring a mechanism for separating stock or stock replenishment (split-billing software); or

   e. Opposing in good faith any act or practice made unlawful by federal, state, or local law, regulation, or policy, provided that the manner of the opposition is reasonable and does not itself violate law.

   f. Monitors updates on 340-B program requirements and communicates them to the hospital compliance officer and hospital staff affected by those updates. Ensures pharmacy is in compliance with such updates.

   g. Developing a process to ensure that drugs that have an orphan status are purchased outside of the 340B program if used for the orphaned indication.

3. Hospital Compliance Liaison Officers (CLO)

   a. The Hospital CLO will provide oversight through the receipt of internal monitoring reports from pharmacy and reporting issues to the Deputy Chief Executive Officer.

   b. The Hospital CLO serves as a resource to the pharmacy director to ensure hospital wide compliance with 340B requirements, including any updates/changes in such regulations.

V. DEFINITIONS

A. **Covered Entities**: The statutory name for facilities and programs eligible to purchase discounted drugs through the Public Health Service's 340B drug

pricing program. Covered entities include federally qualified health center lookalike programs; certain disproportionate share hospitals and critical access hospitals owned by, or under contract with, State or local governments; and several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients, and family planning clinics.

B. **Diversion**: Covered entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount (340B) to an individual who is not a patient of the entity. Any such practice qualifies as diversion. There are several common situations in which this might occur. First, if individuals other than patients of the covered entity obtain covered outpatient drugs from its pharmaceutical dispensing facility, the entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount (e.g., separate purchasing accounts and dispensing records). Second, a larger institution which contains an eligible entity within its structure is required to establish separate purchasing accounts and maintain separate dispensing records for the eligible entity. Third, the covered entity itself may not use the covered outpatient drug in excluded services (e.g., inpatient services). If an entity offers services excluded from the drug discount program, the entity must develop a separate method for purchasing and dispensing drugs for excluded services.

C. **Patient**: An individual is considered a patient of a covered entity (with the exception of State operated or funded AIDS drug assistance programs) only if: (1) the covered entity has established a relationship with the individual, which includes maintaining records of the individual's health care; (2) the individual receives health care services ***via a face to face or telemedicine encounter pursuant to R.S. 40:1300.381, et seq., and R.S. 37:1271*** 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 the responsibility for the individual's care remains with the covered entity.

D. **Contract Pharmacy**- A pharmacy that is not own or operated by the LSU HCSD facility but has a contract to provide pharmacy services on behalf of the LSU facility utilizing medications purchased under the 340B program.

E. **Split Billing Software** – Split Billing Software provides a mechanism to replenish drug stock based on eligible transactions. The software utilizes billing information from the pharmacy system to accumulate medication utilization data specific to outpatients in order to generate an order to purchase 340b medications. The initial medication purchase utilizes non-contract drugs.

VI. PARTICIPATION

The LSU HCSD facility qualifies to dispense these discounted drugs by the following criteria:

Critical Access Hospital

- meet the definition per the relevant section of the SSA.
- the hospital must provide the CMS assigned Medicare Provider Number.
- is owned or operated by a unit of State or local government
- Hospital that wishes to use 340B drugs for their outpatient clinics must certify they are an integral part of the hospital and be reimbursable on the Medicare cost report.

VII. 340B ENROLLMENT, RECERTIFICATION, CHANGE REQUESTS

Recertification Procedure
OPA requires entities to recertify their information as listed in the OPA database annually. It is the responsibility of each facilities Administrator or designee (as described above) to annually recertify their facility's information by following the directions in the recertification email sent from the OPA to [Entity's Authorizing Official] by the requested deadline. Specific recertification questions should be sent to: 340b.recertification@hrsa.gov

VIII. 340B PROCUREMENT, INVENTORY MANAGEMENT, DISPENSING

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

- Outpatient pharmacy – The purchased inventory is purely 340b.
- Hospital, Outpatient and Mixed-use areas – inventories are maintained through a combination of separate inventories and stock replenishment maintained by split billing software.
- Contract pharmacy – if applicable

IX. DIVERSION

The LSU HCSD facility shall develop safe guards to prevent diverting 340B discounted drugs to non patient, entities within an organization that are not eligible to

receive the 340B discount and to services within the organization that do not qualify to participate.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting or other institutional setting.

LSU HCSD shall develop safe guards to prevent using 340B discounted drugs in service areas that provide both inpatient and outpatient services. Examples include observation patients on inpatient units, operating suites, EDs, etc.

X. MEDICAID BILLING REQUIREMENTS

LSU HCSD facilities will bill Medicaid per Medicaid reimbursement requirements as reflected on OPA website/Medicaid Exclusion File. Medicaid reimburses for 340B drugs per State policy and does not collect rebates on claims from any claims submitted from an LSU HCSD facility.

In order to protect pharmaceutical manufacturers from providing a "duplicate discount", DHH will accept the requested reimbursement from each 340B participating facility and not request rebates for these prescriptions as identified in the memorandum of understanding. A duplicate discount is an instance where a manufacturer gives both an up-front 340B discount to a covered entity at the time of purchase and a post-purchase discount to a state Medicaid agency after Medicaid pays the covered entity for the drug and submits a rebate request to the manufacturer under the Medicaid rebate program.

XI. AUDIT CRITERIA (See Addendum A – audit tool)

- LSU HCSD facilities maintain auditable records demonstrating compliance with the 340B requirement described in the preceding bullets.
  - Prescriber is on the hospital's eligible prescriber list as employed by the entity, or 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. [Source: Medical Staff provider list, include description of relationship between entity and prescribers and any supporting documentation]
  - 340B drugs are used in outpatient areas that appear as reimbursable on the most recently filed CMS cost report. [Source: Cost Report – Clinic areas listed on reimbursable line.]
  - Hospital maintains records of the individual's health care. [Source: ADT policy to include assignment of medical record number]

- Patient is an outpatient at the time medication is administered/dispensed. [Source: ADT/hospital billing reports demonstrating patient type.]
- Bills Medicaid per Medicaid reimbursement requirements, and has reflected its information on the OPA website/Medicaid Exclusion File
  - Informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File

- Medicaid reimburses for 340B drugs per state policy and does not collect rebates on claims from facility. [Source: State policy(ies) for 340B reimbursement/billing/duplicate discount prevention (State Medicaid Manual, etc.);
- Facility has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements. [Source: Policy on filling electronically generated outpatient prescriptions to ensure compliance with provider rule. Use of split billing software to ensure GPO drugs are not used on outpatients in mixed patient population areas.
- Facility has an internal audit plan adapted by the internal compliance officer and conducted annually. [Appendix:, also reference Section IX]
- Contract pharmacy services (if applicable), the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to, that the hospital obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the hospital has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism)

  Signed Contract Pharmacy Services Agreement(s) complies with 12 contract pharmacy essential compliance elements (http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf). [Appendix I: provide copy of agreement, compliance elements, reference where contract is maintained
- Audit Team: Each facility should have an audit team comprised of:
  - Compliance Officer
  - Director of Pharmacy (Inpatient/Outpatient)
  - Pharmacy Buyer
  - ADT Manager
  - IT Director

XI. CONSEQUENCES

It is critical that all employees of the HCSD understand that any violation of this policy could result in the hospital or all of HCSD to be dropped from the 340-B Discount Drug Program. Any violation of this policy will subject the employee to appropriate disciplinary actions, up to and including termination of employment.

(Addendum A)

Self Assessment Audit Tool

Data: Gather the following... (*Suggested Sample)	Assessment Criteria

Purpose: The purpose of this tool is to provide a sample internal audit process to assist participating covered LSU HCSD Facility leaders in conducting a 340B data and transaction compliance self-assessment, to promote program integrity.

Instructions:

1. Identify which team members within the hospital will be involved in the self-assessment and meet to discuss the project and assign responsibilities and timelines. Additional non-pharmacy staff include, but are not limited to: revenue management, billing, compliance, information technology, medical records, etc.
2. Gather the data and sample listed in the left column "Data and Suggested Sample."
3. Perform the assessment described in the right column "Assessment."
4. Check the box when the assessment criterion has been met.
5. Correct any area not meeting the assessment criteria. If you need help, contact Apexus Answers (ApexusAnswers@340bpvp.com) and they will provide assistance, or connect you with a resource that can provide help.
6. Incorporate this practice into organizational/departmental policy and procedures.
7. Repeat at regular intervals and maintain records of all self-assessment activity.

Entity Eligibility		
Operating Policy: 340B Entity Eligibility	☐	Policy addresses all criteria in this section
Other Documents: A pharmacy-generated list of all clinics/areas that actually use 340B drugs Most recently filed, completed Medicare Cost Report (Worksheet A)	☐	Pharmacy generated list of areas using 340B contains only reimbursable clinics on the most recently filed Medicare Cost Report, Worksheet A
Copy of OPA database entry for entity/contract pharmacy	☐	All OPA database information is accurate/complete, including addresses of clinics and pharmacies, and a plan is in place to updated OPA as soon as possible with changes
Contract with the state/local government or proof of governmental ownership/operation	☐	Contract is signed by an official authorized to bind the government, the original date of the agreement pre-dates (or effective at date of registration) the 340B registration date on the OPA database, the contract is for the care of indigent patients and is still in force
Most recently filed, completed Medicare Cost Report (Worksheet E-Part A--line 4.03)	☐	Medicare Cost Report Worksheet E-Part A--line 4.03 shows a number ≥8% (for RRC, SCH only; this does not apply to CAH)
Contract from contract pharmacy, if applicable	☐	Contract terms (for 340B pharmacy services) address and demonstrate compliance with published guideline compliance elements
Patient, Prescriber Eligibility: Mixed Use, Outpatient Pharmacy, Contract Pharmacy		
Operating Policy: 340B Patient/Prescriber Eligibility	☐	Policy addresses all patient/prescriber eligibility criteria for 340B use in mixed use and outpatient pharmacy
Other Documents: Eligible provider list for entity (including credentialed and per diem: name, NPI, date of eligibility/termination, assigned clinics and any contracts)	☐	Provider NPI matches the eligible provider list for mixed-use/outpatient sample at the time of prescribing

Data: Gather the following... (*Suggested Sample)	Assessment Criteria
Proof of provider-entity relationship (contract/employment records, referral documentation, other)	Provider-entity relationship is substantiated by contract/employment/other records per clinic site
Description of hospital definition of outpatient and access to system (such as Admission Discharge Transfer/ADT) which enables verification of outpatient status at the time of 340B administration Report from combination of accumulator system/outpatient pharmacy/contract pharmacy for a specified time frame: Patient ID, Rx# evidence of medical record as outpatient, date/time of medical service and/or date written, date/time of 340B administration/dispensing, prescriber name and NPI, NDC, QTY, cost, patient status at the time of administration, bill code/payer, clinic identification/service type *Target highest, moderate, and low (penny priced) spend/drugs dispensed (outpatient pharmacy) or that generated 340B replenishments for a specified time interval and patient type (mixed-use setting/contract Rx) and randomly select a sample of patients receiving these drugs	The policy for determining outpatient status is actually used; this may involve verifying fields for the time/date stamp from the ADT or bed management system when evaluating mixed-use settings At time of administration/dispensing, patient had: 1. health record maintained by entity, status of outpatient 2. service resulting in 340B prescription provided by entity (or via contract/referral/other arrangements) and entity was responsible for the care 3. prescription from provider listed on the eligible provider list NOTE: If 340B drugs are used for referral prescriptions, a policy documenting the criteria for use is followed
Procurement, Orphan Drug Prohibition[1]	

[1] Information about orphan drugs is based upon the published Notice of Proposed Rulemaking found here: http://www.gpo.gov/fdsys/pkg/FR-2011-05-20/pdf/2011-12423.pdf Final regulation has not been published.

Operating Policy: 340B Procurement		Policy addresses all procurement criteria for 340B use in mixed use, orphan drugs, and outpatient pharmacy
Other Documents: Hospital wholesaler account(s) list, description of accounts (340B, GPO, etc.)		HOSPITAL has separate purchasing usage/records for 340B and orphan drugs for orphan indications.
Wholesaler invoices for the specified sample of outpatient pharmacy and or mixed-use setting samples		340B was not used to purchased orphan drugs for orphan indications. Expired or unused 340B drugs are returned to the wholesaler or destroyed (not donated/diverted)
Dispensing/administration records for specified time of sample: Patient ID, Rx#, NDC, quantity, cost, date/time of medical service and/or date written, date/time Rx dispensed/administered, bill code-payer, amount billed, amount paid, prescriber name and NPI, clinic identification (or service type) * Target highest, moderate, and low (penny priced) drugs by NDC, for outpatient pharmacy/mixed use/contract Rx samples		Wholesaler invoice price for a specific NDC on a specific date matches reported billing cost from dispensing/administration records (esp. for Medicaid retroactive claims) The entity pays for, owns and receives reimbursement for 340B drugs (esp. in contract pharmacy situation) • May need to convert from units to quantity dispensed • May need to look at prior quarter's pricing due to delays in quarterly price fluctuations • Costs may not match if hospital doesn't bill payer at cost, and this should be explained

Medicaid/Duplicate Discount Prevention		
Operating Policy: Medicaid Billing, Duplicate Discount Prevention		Policy addresses all Medicaid/Duplicate Discount Prevention criteria
Other Documents: Medicaid Exclusion information for all sites from OPA database		Medicaid billing information (OPA database) for all entity sites is accurate and complete, based upon state policy, and reflects current practices

		by the entity
State Medicaid Policy for prevention of duplicate discounts on 340B drugs		State Medicaid Pharmacy Director(s) verify (in writing/via email, maintain record): 1. Claims from sample were paid per state 340B reimbursement guidelines, per entity's record of billing, and consistent with entity's listing in the Medicaid Exclusion File 2. State Medicaid's method of determination for whether or not to collect rebates on entity's claims 3. If entity has had satisfactory discussion/engagement with Medicaid to ensure prevention of duplicate discounts If State Medicaid does not have a 340B policy to exclude 340B claims from rebate requests, entity does not use 340B for Medicaid prescriptions
Medicaid claims (with invoice/payment records) from a specified timeframe for outpatient pharmacy and physician-administered drug setting samples; it may be helpful to have Medicaid claim transaction numbers, the entity's Medicaid Provider Number/NPI and NCPDP number when verifying with Medicaid *Target highest, moderate, and low (penny priced) spend/drug		