ORGANIZATION POLICY

POLICY TITLE: 340B Drug Purchasing and Compliance

POLICY NUMBER: 1232

Purpose:

A. To define a systematic approach ensuring adherence to the rules and regulations of the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (340B Program).

B. To provide guidelines and procedures for managing 340B drug purchasing and compliance at Onslow Memorial Hospital.

I. Policy:

C. Onslow Memorial Hospital participates in the 340B Program as a Sole Community Hospital and complies with guidelines and regulations to ensure that 340B drug products are purchased only for eligible facilities and patients.

D. Staff follow the processes identified within this policy which address the four key compliance elements for administration of the 340B Program:

1. Covered entity / patient eligibility compliance.

2. Anti-diversion inventory controls / compliance.

3. Medicaid pricing compliance.

4. State Medicaid cost rebate verification (compliance with "double-dipping" prohibition).

II. Definitions:

A. **340B Drug Pricing Program (340B Program) –** A drug pricing program that resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to "covered entities" including disproportionate share hospitals and sole community hospitals.

B. **Accumulators –** Computerized fields used by the Splitting Software to store quantities of qualifying outpatient drugs as part of the virtual inventory. These quantities represent the 340B drugs that are eligible for ordering as a result of having been used for a 340B eligible patient.

C. **Authorizing Official** – The Onslow Memorial Hospital officer or director that is designated as the "Authorizing Official" in the database of the Office of Pharmacy Affairs under the 340B program. The Authorizing Official must have the authority to legally bind the organization and attest to its compliance with the 340B Program requirements. The current designee is the Chief Financial Officer.

D. **Covered Entities –** Facilities and programs eligible to purchase discounted drugs through the 340B Program.

E. **Child Sites –** an off-site outpatient facility that is listed as a reimbursable facility on Onslow Memorial Hospital's most recently filed Medicare cost report (see also Hospital Based Clinic). Child Site's exclusively treat outpatients. All Child Sites will be registered and listed in the OPA 340B database. As of this document's current revision, Onslow Memorial Hospital has the following Child Sites: Onslow Diagnostics, Onslow Imaging Center for Women, SurgiCare, Onslow Rehabilitation, and Wound Care.

F. **Disproportionate Share Hospitals (DSH) –** Facilities that serve a significantly disproportionate number of low-income patients.

G. **Diversion –** Covered entities are required to prevent the resale or transfer of drugs purchased at 340B prices to non-eligible patients/facilities. Failure to ensure appropriate use is considered diversion.

H. **Group Purchasing Organization (GPO) –** An organization that represents and organizes a group of hospitals to evaluate and select pharmaceutical products. Using the purchasing power of the entire group, the GPO negotiates contracts that are more favorable than a single organization could achieve.

I. **Health Resources Services Administration (HRSA) –** An agency of the U.S. Department of Health and Human Services that is the primary Federal agency for improving access to health care services for people who are uninsured, isolated, or medically vulnerable. The primary mission of HRSA is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.

J. **Hospital Based Clinic –** A clinic that appears on a reimbursable line of the Onslow Memorial Hospital most recently filed Medicare Cost report and is thus eligible for 340B priced drugs.

K. **Medicaid Exclusion File –** Covered entities are required to designate in the application process whether 340B drugs will be utilized for Medicaid patients. HRSA maintains this information in the Medicaid Exclusion File which is available to state Medicaid programs. The purpose of this file is to exclude 340B drugs from Medicaid rebate requests. This prevents drug manufacturers from providing duplicate discounts – upfront as the 340B drug price and the later as the Medicaid rebate.

L. **Meditech** – The patient registration/management/accounting system and electronic medical record system used by Onslow Memorial Hospital.

M. **Mixed Use Area –** A location that serves both outpatients and inpatients as designated by the Onslow Memorial Hospital patient registration system. These areas include but are not limited to: Emergency Department, Surgery Suites, Post Anesthesia Care Units, Cath Lab, Endoscopy, Labor and Delivery, and Interventional Radiology.

N. **Office of Pharmacy Affairs (OPA) –** A component of the Health Resources and Services Administration Healthcare Systems Bureau which provides administration of the 340B Program, through which certain federally funded grantees and other safety net health care providers may purchase prescription medication at significantly reduced prices.

O. **Outpatient Area** – A location that exclusively or primarily serves outpatients as designated by the Onslow Memorial Hospital patient registration system. These areas include but are not limited to: All registered Child Sites, Infusion/Transfusion Center, and Ambulatory Surgical Unit.

P. **Outpatient Status –** Onslow Memorial Hospital determines that patients have an Outpatient Status according to the patient registration system at the time of medication dispensing. If the medication is a Covered Outpatient Drug, Outpatient Status qualifies a drug for 340B pricing.

Q. **Orphan Drugs** – A special status given to a drug under the Orphan Drug Act to treat a rare disease or condition upon request of a sponsor. The use of the drug to treat the rare disease or condition must meet certain criteria contained in the Orphan Drug Act in order to be classified as an Orphan Drug.

R. **Pharmacy Buyer** – The designated staff member of Onslow Memorial Hospital who performs or reviews all purchasing functions for the Department of Pharmacy.

S. **Public Health Service (PHS)** – A division of the U.S. Department of Health and Human Services with the purpose of delivering public health promotion and disease prevention programs and advancing public health science. Agencies within the PHS include the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the Health Resources and Services Administration (HRSA).

T. **Prime Vendor –** The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program. Apexus is responsible for securing sub-ceiling discounts

on outpatient drug purchases and discounts on other pharmacy related products and services for participating entities.

U. **Rebates (as it relates to the 340B Program) –** The Federal Deficit Reduction Act of 2005 (DRA) requires states to collect rebates for covered outpatient drugs administered by "physicians." In order to comply, states gather utilization data including National Drug Code (NDC), quantity, and unit of measure from claims submitted for physician administered drugs. Medicaid Agencies are not required to collect a rebate on 340B drugs.

V. **Splitting Software –** Software employed, on an ongoing basis, to manage the splitting of eligible, outpatient charges from ineligible, inpatient charges in order to purchase eligible medications on the 340B contract.

W. **Sole CommunityHospital (SCH) –** A hospital type designated by CMS due to its distance/travel time from other "like hospitals." SCHs must also maintain a Disproportionate Share Adjustment of $\geq$ 8% to qualify for 340B pricing. Unlike standard DSH hospitals, SCH hospitals may utilize GPO pricing if it is more favorable, but SCHs are subject to the Orphan Drug Exclusion.

III. Competencies Required:

A. Pharmacist staff will be provided basic training and familiarity with the 340B Pricing Program by the Pharmacy Buyer or Director of Pharmacy. The training focuses on recognizing 340B eligible drugs, patients, and prescribers for those instances where 340B transactions cannot be automatically recognized for inclusion in the computerized transaction list. Such information will be passed to the Pharmacy Buyer for appropriate 340B dispensation.

B. Pharmacy Buyer with procurement responsibilities is provided comprehensive training on the 340B Program and the compliance requirements of this program. Upon hire, this training is provided by the Director of Pharmacy and by completion of the 340B University On Demand offered by the Prime Vendor Program (Apexus). Competencies are evaluated annually. The Pharmacy Buyer will complete basic training on the 340B and Prime Vendor Programs and either attend 340B University or complete 340B University On Demand online course every 2 years. Additional education may be recommended at the discretion of the Director of Pharmacy. The Pharmacy Buyer will also be responsible for audits and maintenance of the 340B Audit Report.

IV. Covered Entity and Sub-division Eligibility Compliance:

A. Onslow Memorial Hospital is eligible to participate in the 340B Program by meeting the following criteria for inclusion:

1. Onslow Memorial Hospital is designated as a Sole Community Hospital by CMS that is owned and operated by a unit of state or local government and

2. Qualifies as a DSH with a Disproportionate Share Adjustment of $\geq 8\%$ as required by federal law to participate in the 340B Program as a Sole Community Hospital.

B. Onslow Memorial Hospital's outpatient sites bill as Hospital Based Clinics (provider-based) and appear on the most recently filed Medicare cost report, as a reimbursable clinic, to be eligible for 340B purchasing program. These sites must be registered with OPA as Child Sites of Onslow Memorial Hospital.

C. Onslow Memorial Hospital complies with the process to include a new 340B Site/Facility in the 340B Drug Purchasing Program:

1. Onslow Memorial Hospital, assisted by the Department of Finance Third Party Reimbursement Manager, evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program and documents its findings in written correspondence to the Director of Pharmacy. The Onslow Memorial Hospital Department of Finance and the Director of Pharmacy validates that the site/facility appears on the most recently filed Medicare Cost Report as reimbursable before utilizing 340B purchased drugs at the site.

2. Facility/area eligibility is validated annually with collaboration of Legal, Finance, and Pharmacy. This is accomplished at the time the Medicare Cost Report is finalized and filed. If any new eligible sites have been added, the patient medication utilization data are added to the 340B eligible drug purchases. If any previous eligible sites are removed from the Medicare cost report, the patient medication utilization data is removed from 340B eligible purchases.

3. The registration of the Onslow Memorial Hospital and its Child Sites on the HRSA/OPA site is reviewed annually in conjunction with the facility/area eligibility review. All data in the registration file is reviewed for accuracy and compliance with guidelines for registration.

D. Process to enroll a new entity sub-division name for locations not included by existing Covered Entities:

1. The Director of Pharmacy in collaboration with the Department of Finance Third Party Reimbursement Manager is responsible for completing the 340B Participant Change Form (found on the OPA web site) to submit a new entity sub-division.

2. The pharmacy then forwards the completed 340B Participant Change Form to the Chief Financial Officer for submission to OPA.

3. All information on the 340B Participant Change Form should match identically to the DEA and State Board registrations.

E. Procurement Compliance: Establishing a Prime Vendor 340B Purchasing Account:

1. Once an entity sub-division is established and the 340B eligibility of its patients is determined, a pharmacy purchasing account is established through the Prime Vendor.

2. If 340B-eligible patients are to be treated, the account is designated as a Public Health Service (PHS) account and appropriate PHS contract pricing from the Prime Vendor is loaded.

3. Eligibility of the account is verified by the Prime Vendor through OPA (see references for a listing of the Onslow Memorial Hospital prime vendor accounts).

F. Procurement Compliance: Establishing a Direct Purchase 340B Purchasing Account:

1. If it is determined a 340B-eligible medication must be purchased that is not available through the Prime Vendor, the pharmacy purchasing agent establishes a PHS account with the direct vendor. While some direct vendors use a single account for both non-PHS and PHS purchases, Onslow Memorial Hospital requests a separate PHS account when possible for easier audit and management capabilities. Eligibility in the 340B Program is verified by the direct vendor prior to the account being established.

2. The direct purchase accounts established for 340B can be found in the Department of Pharmacy Direct Purchasing database.

G. Procurement Compliance: Purchasing Drugs on 340B Accounts:

1. Prime Vendor purchases:

a. Separate Prime Vendor accounts are maintained for the purchase of 340B medications.

b. Each account is populated with the 340B contract load and is designated as a 340B account in the account name.

c. The contract load is performed each quarter with new purchase prices provided by HRSA/OPA through the Prime Vendor.

d. 340B purchases from the Prime Vender are purchased on a 340B specific account.

e. These purchases are made on an 11 digit NDC to NDC basis. The applicable NDC number submitted to the accumulator will be the one scanned at the time of administration. In the event of an unavailable scan, the NDC number will be the current preferred NDC listed in the Meditech Drug Dictionary.

f. If changes in purchasing are dictated by availability, changes are noted in the accumulator. If 11 digit NDC match is not possible, 9 digit match is attempted.

2. Direct Purchases:

a. Drugs not available from the prime vendor are purchased from the manufacturer using a direct account.

b. Separate 340B accounts are maintained with each manufacturer to purchase 340B drugs.

c. The 340B designation and contract price is maintained in the Direct Purchase database.

d. These purchases are made on an 11 digit NDC to NDC basis.

e. If changes in purchasing are dictated by availability, changes are noted in the accumulator. If 11 digit NDC match is not possible, 10 digit match is attempted.

H. Crediting and Rebilling:

1. Credits of purchased medications and subsequent rebills are processed in the event a 340B account is utilized for a medication purchase that should have been purchased on a non-340B purchasing account.

2. Credits of purchased goods and subsequent rebills are processed in the event a non-340B purchasing account is utilized to purchase drugs that are eligible for 340B purchase. Onslow Memorial Hospital petitions the manufacturer, via the distributor, to credit the non-340B purchasing account and rebill the 340B account. The manufacturer may or may not accept Onslow Memorial Hospital's request.

V. Patient/Prescriber Eligibility Compliance:

Eligible medication orders or prescriptions are filled with 340B-purchased inventory for qualified patients.

A. An individual is considered an eligible patient under the 340B program if:

1. Onslow Memorial Hospital has established a relationship with the individual, which includes maintaining records of the individual's health care; and

2. The individual receives health care services from a health care provider who is either employed by Onslow Memorial Hospital or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the individual's care remains with Onslow Memorial Hospital.

B. An individual is not considered a patient for 340B purposes if the sole healthcare service rendered is the dispensing of a drug.

C. An Onslow Memorial Hospital patient is considered qualified for 340B medications in the following cases:

1. The patient is treated in a hospital-based clinic that appears as reimbursable on the most recently filed Medicare cost report, and has an eligible medication order for physician administered drugs or an eligible prescription for pharmacy dispensed drugs (including prescriptions on discharge), written by a prescriber employed by, having clinical privileges at, under contract with, or in a referral relationship with Onslow Memorial Hospital.

2. The patient is treated in a hospital-based mixed use area or outpatient area and is classified as an outpatient by the Onslow Memorial Hospital Patient Registration System at the time of dispensing of the medication, and who

has an eligible medication order or prescription written by a prescriber employed by, having clinical privileges at, under contract with, or in a referral relationship with Onslow Memorial Hospital.

D. Medications dispensed to an inpatient are not eligible for 340B discounted drugs.

VI. Anti-Diversion Inventory Controls / Compliance:

A. 340B drugs are not resold or transferred to any party other than a patient as previously defined (unless the party is a bona fide agent of either the hospital or patient).

B. Virtual Inventory:

1. Virtual inventories are utilized to simplify the ordering, dispensing and inventory process which facilitates compliance with 340B Program regulations. The virtual inventory is maintained with splitting software that captures 340B eligible drug utilization in accumulators. The accumulators maintain the quantities of drug that can be ordered on the 340B contract.

2. Inventory in the Pharmacy is managed utilizing 340B splitting software.

3. 340B purchases are processed by procurement staff with specialized training.

4. Dispensing staff are not required to make any determinations regarding the stock to be utilized when dispensing.

5. Eligible dispenses are accumulated in virtual 340B accumulators.

6. When a shipping unit of the drug is achieved in the accumulator, the splitting software generates a 340B order for the drug.

7. The accumulator is automatically adjusted when the order is generated.

VII. Medicaid Pricing (State of North Carolina):

A. Outpatient prescriptions or prescriber's orders filled at Onslow Memorial Hospital pharmacies are **not** billed to Medicaid at the 340B cost.

B. Onslow Memorial Hospital's Medicaid Program serves its members through a managed care model. Onslow Memorial Hospital contracts with the Managed Care companies who are at risk for physician-administered drugs, and bills per the contract terms.

VIII. Compliance with Duplicate Discount Prohibition

A. State Medicaid agencies are required to exclude claims for 340B purchased drugs from Medicaid rebate requests to prevent subjecting drug manufacturers to duplicate discounts (i.e., selling 340B purchased drugs to covered entities at the discounted ceiling prices and providing Medicaid rebates on the same drugs).

B. As part of the registration process, the decision to utilize 340B purchased drugs for Medicaid patients is made by answering on the HRSA-OPA website the question: "Will you bill Medicaid for drugs purchased at 340B price?" Onslow Memorial Hospital has answered this question "No," which is described commonly as "carve out" status. Outpatient medications used for Medicaid patients at Onslow Memorial Hospital are excluded from consideration for 340B purchasing.

IX. 340B Program Oversight:

A. Oversight of the 340B Program is the responsibility of the Authorizing Official for Onslow Memorial Hospital as designated by the 340B Program. Additional oversight, as designated by the Authorizing Official, and performance of the responsibilities stated in this policy for the 340B Program are the responsibility of the 340B Leadership Group comprised of the following individuals:

1. Director of Pharmacy
2. Pharmacy Buyer
3. Department of Finance – Chief Financial Officer or designee
4. Legal Office – Senior Associate General Counsel
5. Hospital Administration – Senior VP of Clinical Services or designee

B. The 340B Leadership Group has the following responsibilities:

1. Setting the general direction and policy for 340B drug purchasing and compliance.
2. Establishing an audit plan for audits conducted by the Department of Pharmacy in collaboration with the Department of Finance as well as by an external consulting group. The external audit plan is conducted annually as defined by OPA guidelines. The current audit plan is attached as an Appendix to this policy.
3. Reviewing reports, trends, and audit results.

4. Maintaining information on current best practices by sending key Onslow Memorial Hospital personnel to related conferences and/or training programs.

5. Providing compliance and oversight direction.

6. Providing appropriate resources.

7. Determining needed modifications or expansion.

8. Correcting and/or reporting deficiencies within expected timeframes.

9. Communication to hospital leadership of potential changes/trends to the 340B program that will impact the institution.

C. Discrepancies are immediately corrected and reported to the 340B Leadership Group. Any significant discrepancies are documented, corrected, and discussed with the 340B Leadership Group within two weeks (10 business days).

D. 340B Program related records and transactions are maintained for a period of seven (7) years in a readily retrievable and auditable format.

EFFECTIVE DATE: January 2014

REVIEW DATE: _____

REVISION DATE: January 2017

AUTHORIZED BY:

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Appendix – Audit Plan

Audit Tool – Frequency	Method
OPA Website Enrollment Review – **Annual**	Confirm presence of all covered entities and accuracy of information; verify contact information including phone and e-mail information, Medicaid exclusion information and ship to/bill to information. This must include signoff by finance and legal.
Purchasing Volume Analysis – **Monthly**	Purchasing volume for each account is reviewed at a high level to ensure purchases have been transacted on the correct account. Significant changes in purchase volume are also reviewed for appropriateness. Any variances are corrected, using credit and rebill if necessary, and documented on the 340B Audit Report.
Transaction Review – **Monthly**	Each month, 20 transactions (approximately 5 per week) in the computer-generated transaction report sent to the splitting software will be reviewed for the following attributes: • Patient Status: Confirm Outpatient Status at the time of dispensing/administration. • Insurance Coverage: Confirm Patient was not covered by Medicaid. • NDC Match: Confirm 11 digit match with drug listed in report and accumulator incremented. • Quantity: Confirm that the quantity dispensed matches the amount the accumulator was incremented. • Orphan Drug Status: Confirm that drug was not categorized as an Orphan Drug on the HRSA/OPA website for the time period of treatment. • Prescriber Verification: Confirm that the prescriber meets the definition under Section VIII of this policy. Any variances are corrected and documented on the 340B Audit Report.
Audit by Third-Party Vendor – **Quarterly**	The current splitting software vendor, Verity Solutions, offers a quarterly audit to provide oversight of in-house audit accuracy and suggestions to improve HRSA audit readiness. Generally, 3 transactions are reviewed with regard to similar criteria as the Transaction Review above.