DESCRIPTION/OVERVIEW
This document contains descriptions of the procedures used at UNM Hospital to maintain compliance with the 340B Drug Pricing Program.

REFERENCES

AREAS OF RESPONSIBILITY
This guideline applies to UNM Hospital (parent) and all its entities (children) that use the same CMS billing number.

GUIDELINE PROCEDURES
1. Background
Section 340B of the Public Health Service Act (1992) requires drug manufacturers Participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration/Department of Health and Human Services. Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific statutory requirements and prohibitions.

2. 340B Guideline Statements
As a participant in the 340B Drug Pricing Program, UNM Hospital guidelines are:
2.1 UNM Hospital will use any savings generated from 340B in accordance with 340B Program intent: "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992).
2.2 UNM Hospital will meet all 340B Program eligibility requirements. The specific eligibility requirements as well as a listing of the UNM Hospital covered entity locations can be found at: http://opanet.hrsa.gov/opa. The entity type for UNM Hospital is Disproportionate Share Hospital (DSH) and the 340B ID is DSH320001.
2.3 UNM Hospital is owned or operated by a state or local government. UNM Hospital will ensure the OPA Database covered entity listing is complete, accurate and correct.

2.3.1 UNM Hospital is eligible to participate in the 340B Drug Pricing Program as a DSH as defined in Section 1886(d)(1)(B) of the Social Security Act and meets the requirements of 42 USC 256b(a)(4)(L).

2.3.2 UNM Hospital does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except in accordance with GPO Policy Release on 2/7/2013.

2.3.3 UNM Hospital clinics that are non-reimbursable, or have a separate NPI, or are not located within the four walls of the parent may use a separate GPO Account (i.e., not the main parent inpatient pharmacy GPO account) to purchase clinic administered drugs as allowed by HRSA/Apexus guidance.

2.3.4 UNM Hospital will comply with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity.

2.3.5 UNM Hospital will maintain auditable records demonstrating compliance with the 340B requirement.

2.3.6 UNM Hospital will ensure that the prescriber is on the hospital’s eligible prescriber list as employed by the entity, under contract or under 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.

2.3.7 UNM Hospital will maintain records of the individual’s health care.

2.3.8 Patient is outpatient status at the time medication is administered/dispensed.

2.3.9 UNM Hospital will ensure 340B discharge prescriptions, from an inpatient location, are to be used on an outpatient basis. In those instances where discharge medications are filled prior to discharge, UNM will keep auditable records to ensure compliance with applicable policy and legal requirements with clear documentation of the purpose for early dispense, including, but not limited to:

- Patient medication counseling
- Device demonstration
- Prior authorization requirements

2.4 Duplicate Discounts: UNM Hospital has reflected its information on the OPA website/Medicaid Exclusion File, which is “carve in.”

2.4.1 UNM Hospital will inform OPA immediately of any changes to its information listed on the OPA website/Medicaid Exclusion File.
2.4.2 UNM Hospital Medicaid billing number used to bill Medicaid for 340B drugs and NPI will appear on the OPA website.

2.4.3 UNM Hospital will verify that the Medicaid billing number used to bill Medicaid for 340B drugs is listed on OPA’s Medicaid Exclusion File database at http://opanet.hrsa.gov/opa/.

2.4.4 UNM Hospital (“parent”) will provide OPA a list of all the (“children”) entities that use the same Medicaid billing number, which will be all “carved in.”

2.4.5 UNM Hospital charges patients in accordance with §2202.4 of the CMS Provider Reimbursement Manual, “Charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients’ charges used in the development of apportionment ratios should be recorded at the gross value; i.e., charges before the application of allowances and discount deductions.” As such, UNM Hospital will uniformly charge all payers including Medicaid, in accordance with §2202.4.

2.4.6 UNM Hospital will list the pharmacies serving its offsite provider-based clinics and other offsite provider-based departments as the “ship to” site with OPA, unless ship to address is already listed as a current “child site” address.

2.4.7 Contract Pharmacies will exclude Medicaid fee-for-service and Medicaid Managed Care Organization patients from 340B processing. Prescriptions filled for Medicaid fee-for-service and Medicaid Managed Care Organization patients at a contract pharmacy are to be filled using non-340B drugs.

2.4.8 Medicaid 340B requirements will be verified at least annually with the state Medicaid office to ensure no additional requirements or changes to current requirements exist, and to inquire about potential changes in the future.

2.4.9 In accordance with the State of New Mexico Medicaid Assistance Program Manual Supplement Number 10-03, UNM Hospital attaches the UD modifier to the J Code on the claim to identify that a 340B drug was administered.

2.5 UNM Hospital will establish systems/mechanisms and internal controls to reasonably ensure ongoing compliance with all 340B requirements. UNM Hospital has an internal audit plan adopted by the Executive Director of Compliance. Self-audits are performed monthly by 340B Program Auditor Internal I and provided to the Executive Director of Pharmacy, the Chief Financial Officer, Executive Director of Compliance and Directors’ of Pharmacy.

3. Diversion

3.1 340B drugs will not be resold or otherwise transferred to anyone other than UNM Hospital’s patients.

3.2 UNM Hospital describes a patient as:
3.2.1 UNM Hospital has a relationship with the individual such that records of the individual’s care are maintained.

3.2.2 The individual receives healthcare services from a healthcare professional employed by the UNM Hospital or its entities or provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the UNM Hospital.

3.2.3 The healthcare professional must be credentialed to practice at the UNM Hospital or its entities.

3.3 The UNM Hospital healthcare record will reflect the services that give rise to the prescription and the cost of maintenance of the records will be reflected on the UNM Hospital cost report.

3.4 A prescription written for a self-administered drug by a UNM Hospital credentialed healthcare professional in connection with treatment rendered outside the UNM Hospital’s facility, will be filled with 340B drugs if:

3.4.1 The patient is an UNM Hospital patient referred to the non-UNM Hospital facility for medical services and these services are part of the patient’s continuum of care. A continuum of care exists if a provider at UNM Hospital refers the patient to a non-UNM Hospital facility (under a referral agreement) or if there is a referral agreement between UNM Hospital and the non-UNM Hospital facility to work together to serve a common patient population.

3.4.2 UNM Hospital will maintain records reflecting such services and the record maintenance costs are reflected in the cost report.

3.4.3 A non-UNM Hospital prescription is proximate in type and time to UNM Hospital based services if the prescription or refill is presented within one year of the hospital encounter and the prescriber’s services are part of the same continuum of care as the prior hospital encounter.

3.5 UNM Hospital will not resell or transfer 340B drugs to a party other than a patient, unless the party is bona fide agent of the either the UNM Hospital or patient:

3.5.1 A bona fide agent of UNM Hospital includes contract pharmacies, if the contract pharmacy arrangement is established and operated in accordance with HRSA’s contract pharmacy guidelines.

3.5.2 An agent of the patient, e.g., a family member who picks up a prescription on behalf of the patient will be deemed a bona fide agent of the patient.

3.6 UNM Hospital will maintain its 340B drug inventory physically separate from its non-340B drugs, except as described in this section:

3.6.1 Only 340B drugs will be stocked at the following UNM Hospital locations:

- University Hospital Outpatient Pharmacy, 1209 University
- UNM Hospital SE Heights Clinic Pharmacy, 8200 Central, Suite 106
- SW Mesa Center for Family & Community Health Pharmacy, 301 Unser Blvd, Suite 106
3.6.2 In all inpatient areas and pharmacies, only non-340B drugs will be stocked.

3.6.3 UNM Hospital Cancer Center outpatient pharmacy inventory will be 340B, with non-340B stock, physically separate, for filling orders for UNM Cancer Center, UNMMG and other programs that are not 340B eligible. UNM Cancer Center outpatient pharmacy, an open door pharmacy, will carry a non-GPO/WAC inventory that will replace a WAC drug with a 340B drug for qualified prescriptions only.

3.6.4 Inpatient Pharmacy will utilize a virtual inventory method for Replenishing non-340B drugs used in mixed-use areas like the Emergency Department, Diagnostics, etc.

3.6.4.1 Drugs used in mixed-use areas are captured using 340B drug-split software (Talyst/Verity).

3.6.4.2 When an orderable amount is reached, an order for the drug’s replenishment with a 340B drug is placed.

3.6.4.3 The replenishment should happen as soon as an orderable amount is reached. To accommodate slow moving agents and agents in short supply due to a national drug shortage, all replenishment will occur within one year or will not be replenished.

3.6.5 All replenishment under this guideline will only be in one direction involving replenishing non-340B drugs with 340B drugs.

3.6.5.1 340B drugs will not be replenished with non-340B drugs, except in emergency situations where inpatient pharmacy borrows a 340B drug from outpatient pharmacies. These borrowed drugs may be replenished with non-340B drugs procured under inpatient pharmacy non-340B contract.

3.6.5.2 These borrowings will be tracked using the Pharmacy Department’s Lend-Borrow system.

3.6.6 Our reverse distributor company will inventory outdated 340B and non-340B drugs separately, price them for return to manufacturer for credit or destruction based on their cost at time of purchase.

3.6.7 Free drugs obtained under the pharmaceutical companies indigent drug programs and penny-buy drugs will be identified as such for inventory and returns as described above.

3.7 The contract pharmacies will maintain a tracking system to prevent drug diversion and UNM Hospital will review the tracking system to assure no 340B drug diversion:
3.7.1 The tracking system will compare patient prescriptions to dispensing records on a monthly basis.
3.7.2 The tracking system will compare 340B drug purchasing and dispensing records on a monthly basis.
3.7.3 These tracking systems may be extended to quarterly reviews if no discrepancies are found over a six month period.

3.8 UNM Hospital will perform audits of all 340B programs, including contract Pharmacies to ensure compliance with 340B rules and regulations.
3.9 Monthly, the 340B Program Auditor Internal I will review the records of patients that received 340B drugs for compliance with this guideline and all OPA 340B rules and regulations.

4. GPO Exclusion
4.1 UNM Hospital will not participate in a Group Purchasing Organization (GPO) or other group purchasing arrangements for obtaining covered outpatient drugs.
4.2 UNM Hospital will utilize the prime vendor program (Apexus) for procurement of covered outpatient drugs.
4.3 When drugs subject to the GPO exclusion do not have a 340B price, UNMH:
   4.3.1 Will purchase the drugs at a price negotiated by the prime vendor Program (Apexus) for non-340B drugs.
   4.3.2 May negotiate a non-GPO price with the manufacturer for the drug.
4.4 UNM Hospital will maintain three separate contracts, WAC, 340B and non-340B contracts with our prime distributor (Cardinal).
   4.4.1 The outpatient pharmacy areas will order covered drugs exclusively under the 340B contract.

5. Contract Pharmacies
5.1 UNM Hospital uses contract pharmacy services. The contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to, the hospital obtaining sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, utilization of appropriate methodology to ensure compliance.
   5.1.2 UNM Hospital acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the hospital of any of the foregoing policies.
   5.1.3 UNM Hospital acknowledges that if there is a breach of the 340B requirements, UNM Hospital may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation.
   5.1.4 Contract Pharmacy arrangements will prohibit dispensing 340B purchased drugs to Medicaid fee-for-service and Medicaid Managed Care Organization’s patients.
   5.1.5 UNM Hospital will inform the patient of the patients’ freedom to choose a pharmacy provider of their choice.
6. **Responsible Staff, Competency**

The following UNM Hospital staff are engaged with 340B program compliance. Comprehensive training is provided on the 340B Program. Competency is verified annually by the 340B Program Auditor Internal I through Learning Central.

6.1 **Chief Financial Officer**

6.1.1 Responsible as the principal officer in charge for the compliance and administration of the program.

6.1.2 Responsible for annually attesting to the compliance of the program in form of recertification.

6.2 **Executive Director of Pharmacy**

6.2.1 Accountable agent for 340B compliance.

6.2.2 Maintain knowledge of the policy changes that impact the 340B program which includes, but not limited to, HRSA/OPA rules and Medicaid changes.

6.2.3 Responsible for annual and/or semi-annual physical inventory of pharmacy items.

6.3 **340B Program Auditor Internal I**

6.3.1 Accountable agent for 340B compliance.

6.3.2 Day to day management of the 340B Program.

6.3.3 Responsible for documentation of policy and procedures.

6.3.4 Assure appropriate safeguards and system integrity.

6.3.5 Review and refine 340B cost savings report detailing purchasing, replacement practices and dispensing patterns.

6.4 **Executive Director Compliance and Audits**

6.4.1 Design and maintain an internal audit plan for compliance of the 340B Program.

6.4.2 Design the annual plan to cover all changes in the program from the past year.

6.5 **Director of Hospital Reimbursement**

6.5.1 Responsible for communication of all changes to the Medicare Cost Report regarding clinics or revenue centers of the cost report.

6.6 **Executive Director of Finance and Accounting/Controller**

6.6.1 Responsible for establishment of “inventory average” process (FIFO).

6.7 **Pharmacy Informatics**

6.7.1 Provide access to data from various electronic sources to help Manage the 340B Program.

6.7.2 Maintain and monitor any dedicated 340B software (splitting, etc.).

6.8 **Clinical Pharmacy Director**

6.8.1 Be aware of products covered by 340B and Prime Vendor Program Pricing.

6.8.2 Work with the Medical Staff to use effective therapeutic classes that optimize savings with optimal clinical outcomes.

6.9 **Pharmacy Purchasing Technicians**

6.9.1 Work with pharmacy administrator to establish three distribution accounts and maintain those accounts; non-GPO/WAC, 340B and GPO

6.9.2 Work with pharmacy administrator to establish and maintain direct
accounts for GPO (“own use”) class of trade as well as direct 340B accounts.

6.9.3 Responsible for ordering all drugs from the specific accounts as specified by the process employed

6.9.4 Perform bi-annual inventory.

7. **340B Enrollment, Recertification and Change Requests**

7.1 Recertification Procedure:
OPA requires entities to recertify their information as listed on the OPA database annually. UNM Hospital’s CFO annually recertifies UNM Hospital’s information by following the directions in the recertification email sent from the OPA to UNM Hospital’s Authorizing Official by the requested deadline.

7.2 Enrollment Procedure: New Clinic Sites
UNM Hospital’s 340B Program Auditor Internal I evaluates a new service area or facility to determine if the location is eligible for participation in the 340B Program. The criteria used includes: Service area must be fully integrated into DSH, appear as a reimbursable clinic on the most recently filed cost report, have outpatient drug use, and have patients that meet the 340B patient definition. After determining a clinic meets these criteria, the UNM Hospital’s Authorizing Official will complete the online registration process during the registration window (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 Oct 1; Oct 1 – Oct 15 for an effective start date of Jan 1). This includes submitting cost report information, as required by OPA. 


7.3 Enrollment Procedure: New Contract Pharmacy(ies)

7.3.1 The Executive Director of Pharmacy will ensure a signed contract services agreement, containing the 12 essential compliance elements in the Contract Pharmacy Guidance, is in place between the entity and contract pharmacy prior to submission to OPA. The Director of Purchasing will ensure UNM Hospital legal counsel has reviewed the contract and verified that all Federal, State and local requirements have been met.

7.3.2 UNM Hospital Authorizing official completes the online process at [http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true](http://opanet.hrsa.gov/opa/CERegister.aspx?isnew=true) during the registration window (Jan 1 – Jan 15 for an effective start date of April 1; April 1 – April 15 for an effective start date of July 1 – July 15 for an effective start date of Oct 1; and Oct 1 – Oct 15 for an effective start date of Jan 1).

7.3.2.1 UNM Hospital’s CFO will ensure the contract pharmacy registration request is certified online within fifteen days from the date the online registration was completed.

7.4 The Executive Director of Pharmacy will begin the contract pharmacy arrangement only on or after the effective date shown on the OPA website.

7.4.1 Changes to UNM Hospital’s Information on OPA database procedure: It is UNM Hospital’s ongoing responsibility to immediately inform OPA of any changes to its information or eligibility. As soon as UNM Hospital is aware that it loses eligibility, OPA will immediately be
notified and purchases will cease (or UNM will be required to repay manufacturers).

7.4.2 An online change request will be submitted to OPA by UNM Hospital’s Authorizing Official for any changes to UNM Hospital’s information outside of the annual recertification timeframe. A change form will be submitted to OPA as soon as UNM Hospital is aware of the need to make a change to its database entry. It is expected that changes will be reflected within 2 weeks of submission of the change request.

7.4.3 Some changes require a manual paper change form (e.g., Authorizing Official change). When a manual paper change is required, it will be completed by the authorizing official or designee and submitted to OPA.

8. 340B Procurement

340B Inventory is procured in the following settings:

8.1 Outpatient pharmacies: UNM Hospital Outpatient Pharmacy (1209), UNM Hospital SE Heights Clinic Pharmacy, SW Mesa Center for Family & Community Health Pharmacy, UNM Hospital OSIS, North Valley Center for Family & Community Health Pharmacy, UNM Hospital Outpatient & Discharge Pharmacy (4ACC), ASAP B1 Clinic, UNM Hospital Adult Infusion Center at CRTCII and reimbursable ambulatory clinics.

8.2 Contract Pharmacies

9. Mixed-use Setting Standard Processes

9.1 Purchase mixed-use inventory (according to eligible accumulations).
9.2 Administer/dispense drugs to patients.
9.3 Accumulator accumulates drug on an 11-digit NDC match until unit of use is met, prepares order, uses patient/clinic/prescriber information to determine the appropriate contract for ordering.
### GPO

**GPO/Inpatient class of trade:** Inpatient status determined by hospital at the date/time of administration

**GPO/Outpatient class of trade:** Offsite/unregistered outpatient clinics.

### Non-GPO/WAC

Products that do not have an 11-digit NDC match on the 340B contract but are otherwise eligible for 340B purchase.

Non-340B eligible outpatient, i.e.: Wasted product or lost charges

### 340B

Patients met 340B patient definition and received services on an outpatient basis in a 340B registered/participating hospital clinic

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**10. Pharmacy Replenishment Standard Processes:**

10.1 UNM Hospital Pharmacy Purchasing Technician places 340B orders based upon orders created from the split-billing system, from the wholesaler.

10.2 Pharmacy Purchasing Technician checks in 340B inventory by examining the wholesaler invoice against the order and reports inaccuracies to the wholesaler.

10.3 Pharmacy Purchasing Technician reports significant discrepancies (excessive quantities based upon utilization or product shortages) to the Director of Pharmacy Operations within 24 hours.

10.4 Pharmacy Purchasing Technician maintains records of 340B related transactions in accordance with UNM Hospital Records Management, Retention and Disposal Policy.

10.5 Inventory is stored in the inpatient pharmacy, automated dispensing cabinet, etc.
and protected by a security system. Please refer to the following guidelines and procedures found at https://hospitals.health.unm.edu/intranet7/apps/docmanagement/index.cfm?project

10.5.1 Security and Proper Storage of Drugs guidelines.
10.5.2 Automated Medication Management System procedure.
10.5.3 Ambulatory Services: Medication Procurement, Deliver, Receipt, Records, Storage, Sanitation and Security & Disposition Procedure.

11. Procurement Compliance: Purchasing Drugs on 340B Accounts

11.1 Pharmacy Wholesaler Purchases:

11.1.1 Separate Pharmacy Wholesaler accounts are maintained for the purchase of 340B drugs.
11.1.2 Each account is populated with the 340B contract load and is designated as a 340B account in the account name.
11.1.3 The contract load is performed each quarter with new purchase prices provided by HRSA/OPA through the Prime Vendor.
11.1.4 340B covered outpatient drug purchases from the pharmacy wholesaler are purchased on a 340B specific account.
11.1.5 Initial purchases are made via a non-GPO/WAC account and split into the 340B account or GPO account as accumulated (see procedure steps section #4 below)
11.1.6 The non-GPO/WAC account does not have GPO or GPO-like contracts Loaded. Allowed loads include those pricing files provided by Apexus as authorized for non-GPO/WAC accounts.
11.1.7 These purchases are made on 11-digit NDC to NDC basis.
11.1.8 If changes in purchasing are dictated by availability, changes are noted in the accumulator. 9-digit NDC match is attempted, if 11-digit match is not possible.

11.2 Direct Purchases:

11.2.1 Covered outpatient drugs not available from the pharmacy wholesaler are purchased from the manufacturer using a direct account.
11.2.2 Separate 340B accounts are maintained with each manufacturer to purchase 340B drugs.
11.2.3 The 340B designated and contract price is maintained in the Direct Purchase Database, Lawson.
11.2.4 For mixed use areas, a WAC account or WAC price will also be added to the account in the event it cannot be determined up front if the drug will be utilized in an outpatient or inpatient setting.
11.2.5 These purchases are made on an 11-digit NDC to NDC basis.

11.3 Crediting and Rebilling:

11.3.1 Credits or purchased drugs and subsequent rebills are processed in the event a 340B account is utilized for a drug purchase that should have been purchased on a non-340B purchasing account.
11.3.2 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. UNM 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 UNM Hospital’s request.
12. Physical Inventory Standard Processes

The Pharmacy Purchasing Technician and the contracted inventory company will conduct a physical inventory two times per year.

13. Transfer Standard Process

13.1 From non-340B to 340B

13.2 Transfers between non-340B and 340B inventory are only in rare circumstances and according to the following procedure:

13.2.1 The assigned employee at each site records the transaction on a borrow/loan transaction form. The 11 digit NDC number must be written on the form.

13.2.2 The assigned employee reconciles the process by transfer back to the separated non-340B inventory area through a purchase on the borrowing area’s 340B account of the same NDC and quantity that was borrowed. Reconciliation is completed within 30 days of the original loan date.

13.3 From 340B to non-340B

13.3.1 Only in the case of an emergency medical situation will drugs be transferred from a 340B inventory to a non-340B inventory. In this case, the following procedures will be used: The assigned employee at each site records the transaction on a borrow/loan transaction form. The 11-digit NDC number must be written on the form.

13.3.2 The assigned employee at each site reconciles the process by transfer back to the separated 340B inventory area through a purchase on the borrowing area’s non-340B account (non-GPO/WAC account) of the same NDC and quantity that was borrowed. Reconciliation is completed within 30 days of the original loan date.


14.1 340B eligible prescriptions may be presented (e.g., e-prescribing, hard-copy, fax, phone). Contract pharmacy verifies patient, prescriber, location, PBM eligibility file, and active prescriber list. Updates are made to this mechanism by UNM Hospital on a monthly basis.

14.2 Contract Pharmacy staff dispenses prescriptions to 340B eligible patients using contract pharmacy non-340B drug.

14.3 Contract pharmacy staff places 340B orders on behalf of UNM Hospital, based on 340B eligible use as determined by the Contract Pharmacy 340B Accumulator, from the wholesaler. Orders are triggered by package size used, placed by contract pharmacy staff using online system and communicated to UNM Hospital’s 340B Program Auditor Internal I via email

14.4 UNM Hospital pays invoice to Cardinal for all 340B drugs.

14.5 Contract Pharmacy will provide access to the portal. Portal provides an extensive suite of reports that cover claims, profitability, inventory control and audit tools.

14.6 If contract pharmacy does not receive the 11 digit NDC replenishment order within sixty (60) calendar days of original order fulfillment request, a report will be provided by the contract pharmacy for UNM Hospital to review. UNM Hospital will reimburse the contract pharmacy at a pre-negotiated rate.
DEFINITIONS

**340B Drug Pricing Program**: The 340B Drug Pricing Program 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. The 340B Drug Pricing Program is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified hospitals. Participation in the program can result in significant savings on the cost of pharmaceuticals for covered entities. The purpose of the 340B Program is to enable these covered entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services.

**340B Eligible Patient**: A patient of a covered entity that meets HRSA’s definition of a patient. A 340B eligible patient may receive 340B purchased covered outpatient drugs while admitted as an outpatient of a covered entity and/or after receiving treatment and being discharged from the covered entity.

**340B Price**: The maximum price for a covered outpatient drug that manufacturers can charge covered entities participating in the 340B drug pricing program.

**340B Pricing Program**: There are several possible 340B drug pricing programs under which an entity might enroll, if qualified, as a 340B covered entity. Possible programs include but are not limited to: Disproportionate Share Hospitals (DSH), Children’s Hospitals (PED), Critical Access Hospitals (CAH), Sole Community Hospitals (SCH) and Comprehensive Hemophilia Treatment Centers.

**340B Purchased Drugs**: Covered outpatient drugs purchased by a covered entity under the 340B Drug Pricing Program.

**Child Site**: An outpatient clinic that is eligible to participate in the 340B Program because it is an integral part of a hospital that participates in the 340B Program, as evidenced by the fact that it is reimbursable of the hospital’s Medicare Cost Report. Child Site must be separately registered with OPA.

**Contract Pharmacy**: A pharmacy other than the covered entity’s inpatient pharmacy with which the covered entity has contracted to provide comprehensive pharmacy services to 340B eligible patients utilizing covered outpatient drugs purchased under the 340B Drug Pricing Program.

**Contract Pharmacy Arrangement**: An agreement with a pharmacy other than the covered entity’s inpatient pharmacy with which the covered entity has contracted to provide comprehensive pharmacy services to 340B eligible patients utilizing 340B purchased covered outpatient drugs.

**Covered Entity**: A hospital or other facility enrolled in the 340B Drug Pricing Program and eligible to purchase covered outpatient drugs for 340B eligible patients through the program at 340B prices.
Covered Outpatient Drug: A drug defined in Section 1927(k) of the Social Security Act (42 USC § 1395r-8(k) that may be purchased, with certain possible exceptions, by covered entities under the 340B Drug Pricing Program.

Disproportionate Share Hospitals (DSH): Facilities that service a significantly disproportionate number of low-income patients.

Diversion Prohibition: The prohibition against the resale or transfer of covered outpatient drugs purchased under the 340B Pricing Program to anyone other than a 340B eligible patient of a Covered Entity.

Duplicate Discount Prohibition: The prohibition against subjecting a manufacturer to providing both a drug at a discounted price under the 340B Pricing Program and also to providing a rebate for the drug under Title XIX of the Social Security Act (Medicaid).

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.

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 healthcare services for people who are uninsured, isolated or medically vulnerable.

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.

Mixed Use Area: A location that serves both outpatients and inpatients as designated by UNM Hospital. These areas include but are not limited to: Emergency Room, Surgery Suites and Endoscopy.

Office of Pharmacy Affairs (OPA): The component within HRSA that administers the 340B Drug pricing Program. The Office of Pharmacy Affairs is located within HRSA’s Special Programs Bureau.

Public Health Services (PHS): A division of the United Stated 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), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA) and Health Resources and Services Administration (HRSA).
**Primer 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.

**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.

**Splitting Software (as it relates to 340B triple-split software for managing hospital administered medications):** Software employed, on an ongoing basis, to manage the splitting of eligible outpatient charges from inpatient charges in order to purchase eligible administered covered outpatient drugs on the 340B contract and inpatient administered drugs on the GPO contracts.

**SUMMARY OF CHANGES**
Replaces 340B – Guidelines last revised 10/23/14

**RESOURCES/TRAINING**
Learning Central Competency

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<th>Resource/Dept</th>
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**DOCUMENT APPROVAL & TRACKING**

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**ATTACHMENTS**
None.

Title: 340B Drug Pricing Program
Owner: Finance
Effective Date: 10/23/14
Doc. # 3200