PURPOSE:

A. To define a systematic approach to protect the integrity of and 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 Rancho Los Amigos National Rehabilitation Center. Note –Rancho Los Amigos National Rehabilitation Center is officially listed on the HRSA-OPA site as a "Covered Entity" under the name of Rancho Los Amigos National Rehabilitation Center.

POLICY:

A. Rancho Los Amigos National Rehabilitation Center (RLANRC) participates in the 340B Program and complies with guidelines and regulations to insure that 340B drug products are purchased only for eligible entities and patients.

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

   a. Covered entity / patient eligibility compliance / Provider eligibility compliance
   b. Anti-diversion inventory controls / compliance.
   c. Medicaid pricing compliance.
   d. State Medicaid cost rebate verification (compliance with "double-dipping" prohibition).

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.

B. Covered Entities (CE) - Facilities and programs eligible to purchase discounted drugs through the 340B Program.

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

D. 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.

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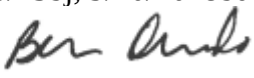
Approved By: 

E. 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.

F. 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.

G. Hospital Based Clinic - A clinic that appears on a reimbursable line of the Rancho Los Amigos National Rehabilitation Center most recently filed Medicare Cost report and is thus eligible for 340B priced drugs.

H. 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.

I. Mixed Use Area - A location that serves both outpatients and inpatients as designated by the Rancho Los Amigos National Rehabilitation Center patient registration system. These areas include but are not limited to: Surgery Suites, Special Procedures, Urology, PACU, MRI, Nuclear Med and Diagnostic Laboratory.

J. 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.

K. Public Health Service (PHS) – A division of the United States 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).

L. Prime Vendor - The 340B Prime Vendor Program (PVP) is managed by Cardinal through a contract awarded by Health Resources and Services Administration (HRSA), the federal government branch responsible for administering the 340B Drug Pricing Program.

TRAINING AND EDUCATION:

A. Pharmacy staff will complete basic training on the 340B Program initially upon hire and competency verified annually.
B. Upon initial training the staff will read policy Pharm 1.47.0 - 340b Hospital Policy and view the following online training video: https://www.brainshark.com/apexus/topfive340bBasics
C. Education updates and training, as needed.

COVERED ENTITY ELIGIBILITY COMPLIANCE:

A. Rancho Los Amigos National Rehabilitation Center is eligible to participate in the 340B Program by meeting the following three criteria for inclusion:

   a. County of Rancho Los Amigos National Rehabilitation Center government for provision of patient services.
   b. Disproportionate Share Hospital (DSH) maintaining a percentage greater than 11.75%.
   c. Does not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.

B. Rancho Los Amigos National Rehabilitation Center site appear on the most recently filed Medicare cost report (MCR), as a reimbursable, to be eligible for 340B purchasing program.

C. Rancho Los Amigos National Rehabilitation Center complies with the process to include a new 340B Site/Facility in the 340B Drug Purchasing Program:

   a. The Rancho Los Amigos National Rehabilitation Center Department of Finance 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 Department of Pharmacy Services. The Rancho Los Amigos National Rehabilitation Center Department of Finance and Pharmacy Services validates that the site/facility appears on the most recent Medicare Cost Report as reimbursable before utilizing 340B purchased drugs at the site.

   b. Facility/area eligibility is validated 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.

c. The registration of the covered entity and the sub names on the HRSA/OPA site is reviewed 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:

a. The coordinator of the 340B Drug Purchasing Program in collaboration with the Department of Finance is responsible for completing the 340B Participant Change Form (found on the OPA web site) to submit a new entity sub-division.
b. The pharmacy then forwards the completed 340B Participant Change Form to the Covered Entity Authorizing Official for submission to OPA.
c. All information on the 340B Participant Change Form should match identical to the DEA and State Board registrations.

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

a. 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.
b. If 340B-eligible patients are to be treated, the account is designated as a 'PHS' account and appropriate PHS contract pricing from the Prime Vendor is loaded.
c. Eligibility of the account is verified by the Prime Vendor through OPA (see references for a listing of the Rancho Los Amigos National Rehabilitation Center prime vendor accounts).

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

a. Prime Vendor (Cardinal) purchases:
   1. Separate Prime Vendor accounts are maintained for the purchase of 340B medications.
   2. Each account is populated with the 340B contract load and is designated as a 340B account in the account name.
   3. The contract load is performed each quarter with new purchase prices provided by HRSA/OPA through the Prime Vendor.
   4. 340B purchases from the Prime Vender are purchased on a 340B specific account.
   5. RLANRC utilizes the split billing software (340b Verity solutions) and purchases inventory according to eligible accumulations. These purchases are made on an 11 digit NDC to NDC basis. New medications or NDCs (not previously in the system), without accumulations, will be ordered using the WAC account.
   6. In special circumstances RLANRC procurement will carve out a medication, to be given only to an outpatient patient, from the split billing program. RLA

b. Direct Purchases:

1. Medications not available from the prime vendor are purchased from the manufacturer using a direct account.
2. Prior to ordering the procurement staff checks the accumulation balances in Verity before placing the order and orders the medication using the appropriate account (340b, GPO or WAC) and decrements the accumulation in Verity accordingly.
3. For medications not available from the prime vendor, and is not part of the split billing accumulation, the procurement staff will manually determine the appropriate account to order from. All manual ordering will be documented and justified.

c. Eligible 340b Medications

The definition of 340b covered drug shall be consistent with section 1927 (k) of the Social Security Act:

1. FDA approved prescriptions drugs
2. Over-the-counter (OTC) drugs written on a prescription
3. FDA-approved insulin
4. Prescription biological products (vaccines excluded)

PATIENT/PRESCRIBER ELIGIBILITY COMPLIANCE:

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

A. An individual is considered a patient of a covered entity if:
   a. The covered entity has established a relationship with the individual, which includes maintaining records of the individual's health care.
   b. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the individual's care remains with the covered entity.

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

C. A Rancho Los Amigos National Rehabilitation Center patient is considered qualified for 340B medications in the following cases:
   a. 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, under contract or referral relationship with Rancho Los Amigos National Rehabilitation Center.

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

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ANTI-DIVERSION INVENTORY CONTROLS / COMPLIANCE

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)

A. Outpatient Pharmacy Dispensing
   a. RLANRC outpatient pharmacy only dispenses outpatient and outpatient discharge medication prescriptions written by an eligible RLANRC prescriber. All outpatient pharmacy prescriptions are filled with 340b –purchased medications.
   b. The outpatient pharmacist is responsible for ensuring the patient and prescriber eligibility is validated prior to the 340b medications being dispensed.
   c. Dental Clinic patients are not eligible for 340b discounted medications. All Dental Clinic prescriptions will be filled using inventory purchased from the WAC account. Dental inventory is kept on a physically separate self in the Outpatient Pharmacy.

B. Pharmacy Inventory Management (Virtual)
   a. RLANRC maintains one inventory utilizing the 340b Verity Solutions software. The software accumulates drug, in the appropriate account (340b, WAC and GPO) based upon patient status, patient location and provider information. Medication(s) administered to the "Observation patient" will accumulate according to their encounter status at the time of administration. All accumulation occurs at the 11-digit NDC Level and a full package-size will need to be accumulated before replenishment.
   b. RLANRC procurement staff places orders in Cardinal for DHS Pharmacy Affairs review. After order review and submission, the Verity software will split the purchases according to eligible accumulations. An 11-digit to 11-digit NDC match is used to order 340b drugs. All non-accumulated 340b or GPO medications will be ordered using the WAC account.
   c. RLANRC procurement staff receives shipment, verifies quantity received with quantity ordered and resolves and documents any discrepancies.
   d. RLANRC procurement staff monitors the Split billing software and resolves any software inaccuracies. All manual manipulations will be documented with an explanation.
   e. RLANRC procurement will monitor charges dropped in the system to ensure it was appropriately accumulated in the split software.

C. Transfer of drugs to/from Outpatient (340b) inventory to/from Inpatient inventory:

   a. The pharmacy department minimizes the need for transfer of drug from one inventory to the other by carrying adequate inventory levels of Formulary medications.
   b. In the event a loan must occur (emergency use only) a borrow/loan transaction is recorded on the 340B Borrow/Loan Transaction Log.
   c. The loan is reconciled by transferring back using the same NDC and quantity that was borrowed.

D. Material Breach

RLANRC defined a "material breach" of compliance as a violation(s) that exceeds 5% of Rancho's total annual 340B purchases. Such violations require self-disclosure. Violations identified through internal self-audits, independent external audits, or otherwise that meet or exceed this threshold, and that remain non-correctable within a reasonable timeframe, will immediately be reported as soon as reasonably possible to HRSA at (340Bselfdisclosure@hrsa.gov) and applicable manufacturers using the Self-Disclosure to HRSA and Manufacturer Template.

RLANRC has a 340B Program Oversight Committee that oversees this process, reviews potential violations, performs materiality assessment, and determines if a breach has occurred. The committee identifies to whom to self-disclose the breach dependent on that materiality determination and the corrective action plan resolution.

On behalf of RLANRC, the 340B Oversight Committee reviews this policy annually, makes decisions about the material breach definition and self-disclosure and submits changes to the hospital's Executive Leadership for approval.

RLANRC maintains records (including all internal or external correspondence and corrective action plans) of violations, materiality assessment, and resolution of manufacturer self-disclosure and/or formal self-disclosure to HRSA.

E. Self-Audit (Quarterly)
    a. RLANRC will have a monitoring program to ensure compliance with the 340B program. RLANRC will:
        i. Review the HRSA 340B Database to ensure the accuracy of the information for the parent site, off-site locations and contract pharmacy;
        ii. Ensure compliance with the GPO Prohibition;
        iii. Ensure covered outpatient drugs purchased through the 340B program are dispensed or administered only to patients eligible to receive 340B drugs; and,
        iv. Reconcile dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs.
            - 10 outpatient prescription per pharmacy per quarter
            - 10 clinic orders where 340B drugs are administered per quarter
            - An oversight committee will review internal audit results and assess the findings for any material breaches in 340B program requirements and will report any such breaches as described above.
    b. RLANRC will maintain records of 340B related transactions as required in a readily retrievable and auditable format for 3 years.
F. Independent Audit
    a. Conducted by the Verity Group every quarter.

MEDICAID PRICING (MEDI-CAL):

A. Outpatient prescriptions filled at Rancho Los Amigos National Rehabilitation Center Outpatient pharmacy are billed to Medi-Cal at 340B actual acquisition cost using UD modifier.

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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 covered entity registration, Rancho Los Amigos National Rehabilitation Center documents the use of 340B purchased drugs for Medicaid patients. This is done by answering on the HRSA-OPA website the question: Will you bill Medicaid for drugs purchased at 340B price?
C. Answering YES to this question, places the 340B purchases on the Medicaid exclusion list. Answering NO to this question eliminates drugs purchased at 340B prices from the Medicaid exclusion file.
D. The Medicaid exclusion list is provided to the State via HRSA-OPA and maintained as part of the Medicaid Exclusion file on the HRSA web site (see references). Rancho Los Amigos National Rehabilitation Center documentation of the Medicaid exclusion for each covered entity can be found on this website.

CONTRACT PHARMACY SERVICES

When required, contracts will be established that will allow RLANRC to dispense 340b drugs to covered patients through contract pharmacy services

A. Establishment of Contract Pharmacy Services
    a. Service provided by contract pharmacies are 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.
    b. RLANRC ensures that a signed contract pharmacy 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. Legal Counsel has reviewed the contract and verified that all Federal, State, and local requirements have been met.
    c. The RLANRC Covered Entity Authorizing Official – RLANRC's Chief Executive Officer – will complete the online process during the HRSA open registration window DHS Pharmacy Affairs ensures that the Contract Pharmacy Registration Form is signed by a responsible representative of each organization and the original is submitted to OPA by mail or fax, within 15 days from the date the online registration was completed.
    d. RLANRC begins the contract pharmacy arrangement only on or after the effective date shown on the OPA website.
    e. RLANRC will conduct periodic audits to confirm 340B program compliance.

B. Provision of Contract Pharmacy Services
    RLANRC will ensure that a policy and process is in place for the use of 340B Contract pharmacy services that is consistent with HRSA 340B guidelines whenever 340B Contract pharmacy services are utilized.

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C. Contract Pharmacy Oversight and Monitoring
   a. Contract Pharmacy Fill Process:
      i. RLANRC screens for 340B eligibility and verifies patient, prescriber and outpatient clinic eligibility and submits claims for all prescriptions referred to and subsequently filled by the Contract pharmacy. At no time does the Contract pharmacy perform eligibility screening and/or fills prescriptions without RLANRC prior eligibility verification and approval.
      ii. Contract Pharmacy uses 11-digit NDC match accumulation and replenishment model for all for RLANRC's 340B dispensation.
      iii. RLANRC implements a "bill-to, ship-to" arrangement to replenish all 340B drugs filled by its Contract fill pharmacy; the Contract pharmacy receives the shipment, the invoices are billed to RLANRC.
      iv. RLANRC receives, reviews and reconciles the invoices for drugs dispensed by the contract pharmacy and pays for all 340B drugs.
   b. RLANRC routinely conducts internal reviews of its Contract pharmacy for compliance with 340b Program requirements.
      i. All Contract pharmacy prescriptions are written from RLANRC clinic included as a reimbursed outpatient service cost center on the most recently filed Medicare Cost Report.
      ii. The care that resulted in the 340B prescription is supported in the patient's medical record.
      iii. The prescribing provider is employed, contacted or under another arrangement with RLANRC at the time of writing the prescription so that RLANRC maintains responsibility for the care.
      iv. An 11-digit NDC match can be documented for accumulation and/or replenishment of a 340B dispensation.
      v. RLANRC ensures that no prescriptions are billed to Medicaid by the Contract pharmacy
   c. RLANRC conducts routine audits of the contract central pharmacy for compliance with 340B program requirements.
      i. Quarterly internal audit
      ii. Independent annual audit
      iii. All Contract pharmacy invoices are reviewed and reconciled for accuracy (11-digit NDC match and quantity).

340B PROGRAM OVERSIGHT:

A. Oversight of the 340B Program is the responsibility of the Director of Pharmacy. The oversight of the 340B Program is the responsibility of the 340B Leadership Group comprised of the following individuals:
   a. Director of Pharmacy
   b. Department of Finance – CFO
   c. Legal Office – County Counsel

Reviewed: 9/30/15bj, 9/20/2018bdk, 4/19/2022 TT

d. Hospital Administration – Chief Executive Officer, C.E.O.

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

a. Setting the general direction and policy for 340B drug purchasing and compliance.
b. Establishing an audit plan for audits conducted by the Department of Pharmacy Services 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.
c. Reviewing reports, trends, and audit results.
d. Maintaining information on current best practices by sending key Rancho Los Amigos National Rehabilitation Center personnel to related conferences and/or training programs.
e. Providing compliance and oversight direction.
f. Providing appropriate resources.
g. Determining needed modifications or expansion.
h. Correcting and/or reporting deficiencies within expected timeframes.
i. Communication to hospital leadership of potential changes/trends to the 340B program that will impact the institution.

REFERENCES:

Listing of Rancho Los Amigos National Rehabilitation Center, accessed on June 20, 2012 via the HRSA Office of Pharmacy Affairs (select “Search Covered Entities” and search for “Rancho Los Amigos National Rehabilitation Center”): http://opanet.hrsa.gov/opa/

Listing of Rancho Los Amigos National Rehabilitation Center Prime Vendor Accounts, Accessed on June 20, 2012 via the Cardinal website (requires assigned user ID and password):

Rancho Los Amigos National Rehabilitation Center Medicaid Exclusion File, Accessed on June 20, 2012 via the HRSA Office of Pharmacy Affairs (select “Search Medicaid Exclusion File” and search for Medicaid State “[California]”, Entity Type “[DSH]”, and Participating “All”): http://opanet.hrsa.gov/opa/

Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs website, Accessed on June 20, 2012 via http://opanet.hrsa.gov/opa/

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
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.
Eligible patient review for clinics & mixed use areas - Monthly	Review 25 patients from mixed use areas to ensure patient status was Outpatient and eligible for 340B purchase. Any variances are corrected and documented on the 340B Audit Report.
Eligible drug review - Monthly	Review 340B purchases for drugs which are primarily utilized for inpatient use. Select 25 drugs and review to ensure that these were utilized for patients in outpatient status. Any variances are corrected and documented on the 340B Audit Report.
Review of Charges vs Purchases (every six months)	For 5 selected drugs, review 340B eligible patient charges to validate the 340B purchases for the same time period.
Compare prescription drugs accumulated against drugs purchased - Monthly	For 5 selected drugs, verify that the correct quantity is purchased on the 340B accounts based on the quantity.