



**PRISONS**  
**Health and Wellness Services**  
**Policies and Procedures**

<b>Title</b>	<b>340B Drug Pricing Program</b>			
<b>Section</b>	TX II-26	<b>Issue Date</b> December 18, 2020	<b>Supersedes Date</b> New	<b>Next Review Date</b> December 2021

**References**

**Apexus, 340B Prime Vendor Program**  
<https://www.340bpvp.com/>  
**Health Resources and Services Administration, HRSA,**  
<https://www.hrsa.gov/>  
**N.C.G.S. 143B – 707.8**

**I. Purpose**

The North Carolina Department of Health and Human Services (DHHS) is a Section 318 Sexually Transmitted Disease (STD) grantee and confers eligibility for 340B to the Department of Public Safety through the provision of in-kind services. The purpose of this policy is to provide guidelines to the North Carolina Department of Public Safety (DPS) Division of Adult Correction/Prisons employees for maintaining a compliant 340B Drug Pricing Program.

**II. Policy**

It is the policy of the Department to comply with all necessary regulatory requirements to preserve the Department’s access to 340B pricing through partnership with DHHS, and to administer the Program consistently and effectively.

- (a) Employees who work in a Department of Public Safety (NCDPS) Division of Adult Correction (DAC)/Prisons facility shall comply with all standards set forth by this policy and abide by specific requirements mandated by the federal Health Resources and Services Administration (HRSA).
- (b) Facility staff shall utilize the provided Facility Standard Operating Procedures (SOPs) for routine daily operations.
- (c) This policy shall be reviewed by the 340B Oversight Committee on an annual basis.

**III. Definitions**

- (a) Health Resources and 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, and



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medically vulnerable. HRSA provides leadership and financial support to health care providers in every state and US territory.

- (b) Office of Pharmacy Affairs Information System (OPAIS) – An information system that provides access to covered entity and manufacturer records, user accounts, change requests, recertification, and registrations. This system increases the integrity and effectiveness of 340B stakeholder information and focuses on three key priorities: security, user accessibility, and accuracy.
- (c) Covered Entity (CE) – An organization that is eligible for the 340B Program per the 340B statute, which states an entity must not resell or otherwise transfer 340B drugs to ineligible patients.
- (d) Primary Contact (PC) – initial point of contact for a covered entity
- (e) Authorizing Official (AO) – The individual who attests that all information on the OPAIS website is correct, annually certifies the eligibility of the covered entities, attests to the compliance with all program requirements, and receives all communications from HRSA regarding the 340B Program. This individual is authorized to legally bind the agency to a contract.
- (f) 340B Patient – An offender who is being treated by an eligible provider of a covered entity within the scope of the STD grant while maintaining a patient/provider relationship.
- (g) Electronic Health Record (EHR) – Location of all documentation regarding medical history and relationship of patient/provider.
- (h) 340B Staff – Personnel who work directly with the 340B Program and require knowledge of the program to ensure accurate prescribing, dispensing, and administering of medications with appropriate documentation.
- (i) Diversion – The reselling or otherwise transferring of discounted drugs purchased under 340B account to anyone but the covered entity or an inpatient.
- (j) Material Breach – Exceeded point of noncompliance with program as stated by a threshold indicator determined by the 340B Oversight Committee which requires self-disclosure if non-correctable.



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**IV. Procedures**

- (a) Program Enrollment and Eligibility – It is essential for continuing Program eligibility that each site is actively registered to participate in the 340B Program and that the accuracy of the 340B OPAIS website is maintained. Enrollment is defined by HRSA and guidelines can be found at: [www.hrsa.gov/opa/registration/index.html](http://www.hrsa.gov/opa/registration/index.html)
- (1) All Covered Entities (CE) shall review 340B OPAIS website for accuracy on an annual basis prior to recertification.
  - (2) The 340B Consultant Pharmacist or their designee shall ensure that 340B OPAIS website is complete, accurate, and correct for the following data:
    - (A) All locations registered on the 340B OPAIS website.
    - (B) Main addresses, billing and shipping addresses, Authorizing Official (AO), and Primary Contacts (PC).
  - (3) Any change to a registered covered entity or the request for an additional covered entity must be approved by the 340B Oversight Committee.
  - (4) Dates for registrations are as follows:
    - January 1 – January 15 for an effective start date of April 1
    - April 1 – April 15 for an effective start date of July 1
    - July 1 – July 15 for an effective start date of October 1
    - October 1 – October 15 for an effective start date of January 1
  - (5) Recertification – Ensure recertification occurs each year based on guidelines/requirements set forth by HRSA for a STD Grantee. This duty shall be performed by the AO of each CE.
  - (6) Procedures for changes of 340B OPAIS – HRSA shall be notified immediately via OPAIS updates, under the direction of the 340B Oversight Committee, of any changes to the CE regarding:
    - (A) Authorizing Official.
    - (B) Primary Contact.





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- (2) Medication Distribution – Medications for the patients of covered entities shall be ordered, received, dispensed, and distributed through a HRSA approved combined purchasing and distribution model from a centralized location.
  - (3) Eligible Provider – The prescription is written by a provider employed by a covered entity where the patient receives initial treatment.
  - (4) Entity-Prescriber Relationship – The relationship of provider and patient is established at the covered entity and documented in the EHR.
  - (5) Scope of Grant – An eligible provider with a covered entity performs a service consistent with the scope of the STD prevention services grant.
- (d) 340B Oversight Committee – The committee is comprised of multiple department leads within DPS and shall have a vital role in the 340B Program. This committee shall provide guidance for program compliance, meet on a regular basis, review 340B rules/regulations/guidelines, identify audits necessary to conduct reviews of 340B compliance, approve corrective action plans, and oversee the program from an integrity view. The following department leads shall be seated on the committee:
- (1) Director of Health and Wellness Services.
  - (2) Director of DPS Pharmacy Services.
  - (3) Assistant Director of DPS Pharmacy Services.
  - (4) 340B Consultant Pharmacist.
  - (5) Chief Medical Officer.
  - (6) Chief Nursing Officer.
  - (7) Clinical Informatics Director.
  - (8) Director of Administrative Services.



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- (9) Director of Quality Assurance.
  - (10) Deputy General Counsel.
  - (11) Controller.
  - (12) Contract Specialist/Purchasing and Logistics Office – Authorizing Official.
  - (13) Primary Contacts for each covered entity.
- (e) Education and Competency – Ongoing education for staff and 340B Oversight Committee members shall be held annually. Education shall be completed, records kept according to organization policy, and records available for review upon request.
- (1) The following education shall be completed by new hires into the Central Pharmacy:
    - (A) Employees shall watch <https://www.340bpvp.com/340b-education> “340B Drug Pricing Program”, read the TX II-26 Policy and 340B SOPs, and acknowledge completion of all education.
    - (B) In addition, 340B Pharmacy staff shall complete specific modules within the 340B University OnDemand and acknowledge completion.
    - (C) The 340B Consultant Pharmacist shall attend additional training as deemed necessary.
  - (2) DPS/DAC Prisons employees shall read the TX II-26 Policy and 340B SOPs and acknowledge completion of all education.
  - (3) The 340B Oversight Committee shall complete individual education set forth by the Apex Central Pharmacy and acknowledge completion.
- (f) Inventory Management – Central Pharmacy 340B staff shall track all 340B drugs to prevent diversion. Medications purchased under a 340B registration shall be dispensed to



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patients that qualify as 340B eligible based on meeting the patient definition. The North Carolina Department of Public Safety Central Pharmacy will be the centralized distribution center for all DPS covered entities and will ensure the proper procurement and inventory of all 340B medications from wholesaler. Medications shall be dispensed to eligible patients by 340B trained staff. The inventory shall be managed by:

- (1) Physical 340B clean inventory ordered only on 340B account.
  - (2) Monthly inventory blind counts on each 340B medication.
  - (3) Dispensed via prescription only.
  - (4) Tracking of NDC number for 340B medications during ordering/dispensing/returns.
  - (5) Waste and return medications shall be documented according to facility procedure.
- (g) **Material Breach** –Diversions identified through internal self-audits and independent external audits that exceed the relevant threshold and remain non-correctable within the 340B Oversight Committee defined timeframe of review, shall be immediately reported to HRSA and applicable manufacturers Upon report of a potentially material breach, it is the responsibility of the General Counsel’s Office, in conjunction with the 340B Oversight Committee, to review and determine if a material breach occurred based on any of the audit findings related to any of the following threshold indicators: 340B purchases or impact to any one manufacturer, 340B inventory, audit samples, or prescription volume/prescription sample. If a potential breach is determined to be a material breach, the AO of the covered entity has the responsibility to notify HRSA as soon as reasonably possible. This notification will also contain any noncompliance of any part of the 340B Program for North Carolina Department of Public Safety. The AO of the covered entity shall self-disclose to HRSA and any applicable manufacturer based on the recommendation of the committee.
- (h) **Monitoring/Auditing for Compliance** – Routine auditing shall be overseen by the 340B



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Consultant Pharmacist and records shall be available for review upon notification. Audits shall account for accuracy of program and prevention of diversion within the program. The following audits shall be completed and reported to the Assistant Director of DPS Pharmacy Services and Director of DPS Pharmacy Services on a monthly basis. The audited information shall also be made available to the 340B Oversight Committee on a quarterly basis and when deemed necessary.

- (1) Apex Central Pharmacy Audits
  - (A) 340B OPAIS website for the accuracy and completeness of covered entity registrations.
  - (B) Reconciliation of 340B purchasing and dispensing to eligible patients.
  - (C) Reconciliation of 340B dispensed medication with eligible patient’s EHR noting appropriate prescribing and documentation.
  - (D) Covered entity provider list for eligibility of writing authority.
  - (E) Inventory management.
  - (F) Audits as it relates to improvement and compliance of program.
- (2) Covered Entity Audits – Ten percent (10%) of random prescriptions for the month shall be pulled on a monthly basis and shall be forwarded to a contact person at the covered entities. This person shall provide information back to Central Pharmacy as it relates to the following:
  - (A) Date of medication order.
  - (B) Date of medication receipt.
  - (C) Offender #/Name.
  - (D) Quantity received.





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(E) Healthcare staff name and date of issuance to offender if a Keep on Person (KOP) medication.

- (i) Reinvestment of Cost Savings – Apex Central Pharmacy shall track and report the cost Savings of the 340B Drug Pricing Program to the 340B Oversight Committee for reinvestment into the health care services for the NC DPS offenders.
- (j) Declared State of Emergency – When a state of emergency is declared for North Carolina, all responsibilities/duties shall continue as set forth by policy. The writing of prescriptions, dispensing of prescriptions, and the validation process shall continue dependent on patient/provider relationship. Providers shall document encounters under a covered entity when patients are relocated to other facilities due to pending emergency and for the duration of the emergency.
- (k) Partnership between DPS and DHHS
  - (1) In accordance with North Carolina General Statute 143B – 707.8, “Federal 340B Program – Department of Public Safety/Department of Health and Human Services partnership, the Department of Public Safety (DPS) shall establish and implement a partnership with the Department of Health and Human Services (DHHS) in order for DPS to be eligible to operate as a 340B covered entity”.
  - (2) In order to implement the requirements of N.C.G.S. 143B – 707.8, DPS shall:
    - (A) Register facilities in the federal 340B Drug Pricing Program under Section 318 of the Public Health Service Act to be able to access 340B Program pricing for medications used to treat the human immune deficiency virus (HIV), the hepatitis C virus (HCV), and eligible sexually transmitted diseases (STD).
    - (B) Provide DHHS all data and necessary documentation as frequently as such information is needed by DHHS.
    - (C) Ensure that the DPS Apex Central Pharmacy, and any other DPS



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Pharmacies necessary, are compliant dispensing pharmacies under the 340B Program.

- (D) Coordinate with one or more vendors to purchase STD 340B Program medications that result in the greatest overall cost savings available to the State, whether such savings are achieved by the 340B Program pricing, non-340B Program volume discounts, or a combination of both.
- (E) Develop a separate inventory to track 340B Program medications.

Todd E. Ishee  
 Commissioner of Prisons

12/18/20  
 Date