Policy No. DOC 4.5.63	Effective Date: 12/20/2024	Revised:
Signature:		Position Title: Rehab and Programs Bureau Chief

DEPARTMENT 340B OPERATION POLICY MANUAL

APPLICABILITY

All divisions, facilities, and programs of the Department of Corrections.

DEPARTMENT 340B Operational Policy Manual

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I. Introduction and Purpose

A. Introduction

This document encompasses the policies and procedures governing the Montana Department of Corrections' 340B Program. Its contents are subject to regular evaluation and can be updated by the Authorizing Official to align with the evolving nature of the State of Montana's 340B Program and any changes in programing parameters. Serving as a roadmap for success, the policy and procedure document reinforces the Department of Corrections' commitment to operating a compliant 340B Program that aligns with the State's overall mission of delivering exceptional healthcare and pharmacy services to the incarcerated population.

B. Purpose

To provide guidance and establish standard operating procedures for the 340B Program at the Montana Department of Corrections. The manual outlines the responsibilities and processes related to eligibility, program management, purchasing, inventory management, pharmacy operations, program integrity, recertification, program evaluation, documentation, training, and revisions. This manual applies to all employees and contractors involved in the 340B Program at Montana Department of Corrections. It covers all aspects of program implementation and compliance. This manual specifically addresses the requirements and considerations for a Covered Entity with the STD Clinic designation under the 340B Program as defined by Health Resources & Service Administration and the Office of Pharmacy Affairs.

II. 340B Program Overview

A. Background

Established in 1992, the 340B Program aims to maximize federal resources by granting Covered Entities access to heavily discounted medications and reducing the need for additional government subsidies. These savings are vital for enabling diverse grantees to sustain exceptional services and keep their doors open. In Montana, where pharmacy benefits and health services must be provided to the incarcerated population, the 340B Program expands the State's service capacity by significantly lowering pharmaceutical costs while maintaining high-quality care.

B. Program Goals

The State of Montana is mandated to provide healthcare and medical benefits to its incarcerated population. To achieve cost savings in pharmacy drug expenses for this population, the Montana Department of Corrections utilizes the 340B Program. The program allows the Department to allocate the generated savings towards other state-funded services. By leveraging the 340B Program, the State not only ensures exceptional care for the incarcerated population but also expands upon its commitment to achieving the overall mission and objectives set by the State.

C. Covered Entity Responsibilities

Covered Entities bear the responsibility for all aspects of compliance for the 340B Program, as mandated by the federal government. In line with this, the Montana Department of Corrections is obligated to fulfill various requirements, including preventing duplicate discounts, verifying patient and provider eligibility, managing pharmacy replenishment and inventory, and ensuring data accuracy in preparation for audits conducted by HRSA. Additionally, the State is required to maintain an accurate database and complete the recertification process annually. It is important to note the State reviews responsibilities every six months and updates when applicable. Please find below a list and description of Covered Entity responsibilities:

1. **Compliance with program requirements:** Covered Entities must adhere to the rules and regulations set forth by the Health Resources and Services Administration (HRSA) to ensure compliance with the 340B Program.
2. **Patient eligibility verification:** Covered Entities are responsible for confirming the eligibility of patients who receive 340B discounted medications, ensuring that they meet the program's criteria.
3. **Provider eligibility verification:** Covered Entities must verify the eligibility of healthcare providers to prescribe or dispense 340B drugs, ensuring they meet the program's requirements.
4. **Duplicate Discount Prevention:** Covered Entities must take measures to prevent the occurrence of duplicate discounts by ensuring that patients do not receive both 340B discounted medications and Medicaid drug rebates for the same drugs.
5. **Pharmacy inventory management:** Covered Entities need to effectively manage their pharmacy inventory to track 340B drugs, maintain proper records, and prevent diversion or misuse of medications.
6. **Data management and reporting:** Covered Entities are responsible for managing and maintaining accurate data related to 340B drug purchases, patient utilization, and compliance. They may be required to submit reports to HRSA as part of the program's auditing and oversight processes.
7. **Compliance audits:** Covered Entities may undergo audits conducted by HRSA or third-party auditors to assess compliance with the 340B Program. They must cooperate and provide necessary documentation and information during these audits.
8. **Recertification:** Covered Entities must complete an annual recertification process to verify their continued eligibility and compliance with the 340B Program. This process involves updating information and attesting to compliance with program requirements.

III. Eligibility Requirements

As a Covered Entity, the Montana Department of Corrections has the responsibility to ensure compliance with all requirements necessary to maintain eligibility in the 340B Program. This includes fulfilling the obligations and criteria set forth by the Health Resources and Services Administration (HRSA) to participate in the program successfully. By fulfilling these requirements, the Montana Department of Corrections can continue to benefit from the advantages and opportunities provided by the 340B Program. The State places significant focus on mitigating risks related to the patient, prescribing physician, medication, and site location within the 340B Program. This includes implementing measures to ensure patient safety, such as verifying patient eligibility and preventing medication errors. The State also works to maintain an eligible database and accurate medical records, which are essential for determining and maintaining program eligibility. By prioritizing these areas, the State aims to minimize risks and maintain compliance with the 340B Program's requirements.

A. Sexually Transmitted Disease (STD) Clinic Designation

The Public Health Service Act specifies which Covered Entities are eligible to participate in the 340B Program. There are currently fifteen grantee designation types under four covered entity classes qualifying for 340B. The Montana Department of Corrections qualifies for the 340B Program as a Sexually Transmitted Disease Clinic under Section 318, 42 USCS § 247c. Section 318 of the Public Health Service Act authorizes STD funding. Projects under Section 318 are awarded to the state and local health departments, academic, and public health organizations. The U.S. Department of Health and Human Services' Center for Disease Control

and Prevention (CDC) oversees and funds the prevention of sexually transmitted diseases (STD's).
The State must submit site locations to the Office of Pharmacy Affairs for eligibility approval. Sites can be submitted on a quarterly basis during an open Office of Pharmacy Affairs registration window outlined below for the following quarter:

1. January 1st - January 15th
2. April 1st - April 15th
3. July 1st - July 15th
4. October 1st - October 15th

Following the approval of an eligible site location, contract pharmacy implementation can occur. Upon the completion of contract pharmacy implementation, pharmacy claims submitted for eligible inmates from the designated site can be submitted for 340B eligibility. Site Locations (site locations are provided in the appendix) must be recertified annually during the STD recertification window.

IV. 340B Program Management

A. Montana Department of Corrections Program Primary Contacts

1. Authorizing Official: Health Service Bureau Chief
2. Primary Contact: Medical Health Services Manager
3. 340B Program Manager: Managed Care Registered Nurse
4. 340B Finance Manager: Sr. Accounting Manager
5. Outside Consultant: Pharmaceutical consultant contractor

B. Compliance Oversight Roles and Responsibilities

1. OPAIS 340B Authorizing Official (AO):
The AO is the final decision maker for all aspects of the program and is responsible for maintaining the integrity of the 340B Program. The AO is accountable for all aspects of program compliance. In addition to maintaining signatory rights all registration confirmations and program updates need to be confirmed by accepting emails sent directly to the authorizing officials email linked to the OPAIS database.

2. OPAIS Primary Contact:
The primary contact plays a crucial role in supporting the authorizing official in ensuring overall compliance with the 340B Program. Depending on the specific task, the primary contact has the authority to make certain updates in the OPAIS database. However, it is important to note that any changes made by the primary contact still require approval from the AO, which is confirmed through email confirmation.

3. 340B Program Manager:
The 340B Program manager holds the responsibility for the day-to-day operations of the 340B Program. This includes overseeing the management of Third-Party Administrators (TPAs) and contract pharmacy operations. Additionally, the program manager plays a vital role in maintaining compliance by conducting spot checks on the recommended number of claims by HRSA monthly. They collaborate with TPAs and contract pharmacies to resolve issues related to ineligible claims or inventory reconciliation. The program manager also updates policies and procedures as necessary, ensuring they align with program requirements. They are responsible for organizing and managing data reporting, as well as other components

required for an HRSA audit preparation. Furthermore, during the implementation phase, the 340B Program manager assumes full responsibility for all aspects of TPA implementation.

4. **340B Finance Manager:**
   The finance manager assumes responsibility for inventory reconciliation by processing payments for selected wholesaler invoices to replenish the pharmacy's 340B inventory. During the implementation phase, this individual is tasked with establishing a dedicated 340B wholesaler account. Moreover, the finance manager is also responsible for receiving checks from the pharmacy as part of pharmacy collections, which are then utilized for 340B replenishment. The difference between the collected amount and the replenishment cost is recorded as savings for the state, and the finance manager reports the financial aspects to the authorizing official.

5. **Outside Consultant:**
   The outside consultant will partner with the State on all aspects of the 340B Program helping maintain compliance and mitigate risk. Consultant will work closely with all stakeholders and their respective 340B deliverables well as anything else the State needs to operate a successful 340B Program. Consultant will also assist with the TPA and contract pharmacy. **Please see Mock Audit Sample Universe & Audit Requirements**

C. Claim Auditing and Monitoring

Monthly Claim Monitoring:
The State is required by HRSA to validate twenty (20) claims each quarter to ensure program integrity is maintained. The State will validate twenty (20) claims **monthly**, documenting findings and correcting errors if applicable. The State will check that the following eligibility criteria are met; Patient, Provider, Covered Entity Location, Medication, & Date of Service.

1. Monthly the Covered Entity will run a captured claims report for the previous months' activity.
2. The State will randomly select twenty (20) claims to validate.
3. The State will confirm data components within internal EMR/EHR or required state records:
   a. **Patient:** Patient Name & DOB are consistent with the transaction record
   b. **Provider:** The provider responsible for writing the script is credentialed, employed, or has a working relationship with the Montana Department of Corrections.
      1) In the event a provider terminates with the state refills are eligible for up to one year following the provider's departure.
      2) New prescriptions following the providers departure are not eligible.
   c. **Covered Entity Location:** The script record is sent from an eligible state Department of Corrections 340B location as represented as active on the OPAIS database or a referral clinic.
   d. **NDC:** Medication dispensed to the patient is clearly documented in the patients' medical record.
   e. **DOS:** The Date of Service for the transaction is closely aligned with what is referenced in the medical record.
4. Monthly results from spot checks will be documented and utilized to display checks and balances during an HRSA audit.
5. If corrective action is needed like reversals, etc., it will be submitted to the 340B TPA Account management team. At the States discretion confirmation of fix may be kept along with monthly audit results.

D. Third Party Administrator

The Third-Party Administrator (TPA) will identify claims that are eligible for 340B, create invoicing, and facilitate replenishment back to the contract pharmacy.

1. See Appendix: 340B (TPA) Operational Description and Responsibilities

E. Third Party Consultant - Compliance

On a biannual basis, the consultant will conduct mock audits on the behalf of the State. The mock audit will be consistent with the actual HRSA audit. At the State's discretion, consultant can also support the Montana Department of Corrections with ongoing monthly claim spot checking and program maintenance. The consultant is committed to operating as an additional resource of the Montana Department of Corrections helping the state maintain a sustainable compliant 340B Program.
Please see 7.2 for a description of biannual mock auditing services.

V. Purchasing and Inventory Management

A. Drug Procurement

Upon the identification of an eligible 340B transaction, and after meeting or exceeding the minimum threshold for package quantity, replenishment will be triggered by 340B TPA back to Contract Pharmacy (CP). The State will be invoiced 340B pricing through the 340B Wholesaler. Please find below an example from 340B TPA virtual accumulation platform displaying purchase orders with 855 and 810 confirmation tracking.

B. Inventory Management

The program will operate on a virtual accumulation model managed by 340B TPA. The pharmacy will begin with their existing inventory. Replenishment for identified eligible 340B prescriptions will therefore restock the pharmacy at no cost eliminating the need to stock separate inventory for 340B and retail. Please find below a description of each major date component pertaining to the State's virtual accumulation model.

1. Inventory Due Accumulation Tracking:
   a. The 340B price file will contain the package quantity per National Drug Code.
   b. When an eligible claim is identified units dispensed will apply towards accumulations for the corresponding NDC. Following the minimum package quantity threshold being met or exceeded the TPA will trigger replenishment.
      1) An 855 file will be sent to the wholesaler accounting for the request to order.
      2) An 810 file will be sent back to the TPA upon fulfillment of delivery at the pharmacy. Following confirmation, the accumulations will be adjusted by NDC reflecting the delivery and recipe of medications.
      3) The virtual accumulation model eliminates potential diversion of inappropriately utilized medication by only replenishing medication after 1. Claims have been identified as eligible and 2. NDC's have met or exceeded the designated minimum package threshold required for replenishment included on the price file loaded by the TPA.

2. Overstock Data Tracking:
   a. Following a reversal of a claim identified as ineligible when replenishment has already occurred the units affiliated with the reversal will be listed in the accumulative total for each NDC.
   b. Units associated with dispensations to eligible patients of an NDC listed in Overstock will trend lower rather than be replenished resulting from the overstock adjustment.
      1) Example: NDC: 88888888888 Overstock QTY: 30
      2) 30 units of NDC 88888888888 dispensed to eligible Montana Department of Corrections patient
      3) 0 units due to pharmacy as the medication was replenished previously when determined eligible and reapplied to a new eligible patient following the reversal.

3. Orders for eligible 340B medications will be triggered by the 340B TPA and replenished through a wholesaler account owned and operated by the Covered Entity. Purchase Order Tracking will be made available to the state by the TPA in the event of an audit. The consultant will support the Montana Department of Corrections at the states discretion to help the process run smoothly.
   a. Please reference the picture in 5.1 displaying the TPA Order Platform
   b. Please find below Wholesaler Account Numbers by grantee site
      1) STD59620; Helena (Administration)
      2) STD596201; MWP
      3) STD59632; RSNU
      4) STD593014; Pine Hills
      5) STD59722; MSP

C. Diversion and Duplicate Discount Prevention

Below please find the measures in place to prevent drug diversion and ensure that 340B drugs are used solely for eligible patients.

1. Diversion of Medication to Non-340B Patients:
   a. Montana Department of Corrections will operate a virtual inventory model. The contract pharmacy partner will begin the program with the pharmacies' existing inventory purchased through the standard retail account owned operated by the pharmacy. The pharmacy will use medications purchased at the pharmacies pricing (non-340B) when dispensing to Montana Department of Corrections patients.
   b. The state will replenish medications based on an NDC match back to the pharmacy at 340B pricing **only after** claims have been identified as eligible for the 340B Program and medications have met or exceeded package quantity.
   c. Upon the replenishment of NDC's tied to eligible transactions, the State's 340B responsibility is complete per eligible transaction.
      1) The pharmacy can restock inventory on the shelf and dispense as normal.

2. Medicaid Fee for Service & 340B Duplicate Discount:
   a. The State of Montana has elected to **CARVE OUT** Medicaid from 340B.
   b. Patients will only be sent to the contract pharmacy utilizing eligible non-Medicaid fee for service BIN and PCN payor groups.
   c. Medicaid BIN and PCN's blocked globally and applied to Montana Department of Correction's 340B Program.
      1) Please find below the current list of BIN and PCN Medicaid Blocks applied in the business logic of the states 340B Program:
   d. Patient Medicaid Change - Montana Department of Corrections

VI. Patient Eligibility Verification and Confidentiality

A. Patient Eligibility Verification

Offenders within the custody of the Department of Corrections, and housed within the covered entity, have suspended Medicaid coverage. Suspended coverage automatically assures patient eligibility for the 340B Program.

B. Patient Confidentiality

The Department of Corrections protects the rights of employees, enforces high standards of professional conduct, and provides guidelines of performance and conduct for Department employees. See DOC Policy 1.3.2, Performance and Conduct, as well as the Montana Department of Corrections HIPAA Confidentiality Agreement.

VII. Program Integrity and Compliance

A. Compliance with 340B Program Requirements

Operating a compliant 340B Program in line with the program's intent as defined by the Health Resources and Services Administration (HRSA), is of significant benefit to the Montana Department of Corrections including yet not limited to the following elements:

1. **Access to Affordable Medications:**
   The 340B Program was created to help eligible healthcare organizations, known as Covered Entities, stretch their scarce resources to serve vulnerable or underserved populations. Compliance with HRSA guidelines ensures that the state can access discounted drugs, helping the Montana Department of Corrections provide essential medications to patients at significantly reduced costs.

2. **Financial Sustainability:**
   By adhering to 340B Program requirements, the State can maximize savings on pharmaceuticals the Montana Department of Corrections is entitled to and help prevent duplicate discounts. This enables the state to allocate more of their limited resources to other critical healthcare services, infrastructure improvements, or expanding services to reach more patients in need.

3. **Improved Patient Outcomes:**
   Access to affordable medications can lead to better patient compliance with prescribed drug regimens, ultimately resulting in improved health outcomes. By adhering to HRSA guidelines, the State can enhance the quality of care they provide to their patients.

4. **Community Health Impact:**
   The 340B Program aims to improve the health of underserved populations. By operating a compliant program, the State can positively impact Montana’s incarcerated population by ensuring discounted drugs are available to those who need them and prevent diversion from ineligible patients, enabling the State to stretch resources as far as possible.

5. **Enhanced Program Integrity:**
   Adhering to HRSA’s strict guidelines and reporting requirements and maintaining program integrity will ensure the State avoids legal and financial repercussions, such as fines or exclusion from the program, that could result from non-compliance. Non-compliance with program requirements can lead to HRSA audits, which may result in recoupment of savings and other penalties. Operating a compliant program minimizes the risk of audits and associated financial consequences.

6. **Transparency and Accountability:**
   Operating a compliant 340B Program by ensuring OPAIS records are accurate and up to date, promotes transparency, accountability, as well as the long-term viability of the State’s 340B Program. At the State’s discretion and upon request by the United States Department of Health and Human Services, or the subordinate agencies, such as the HRSA, which administer the national 304B Program, the State will demonstrate how savings benefit patients and the overall mission of the Department of Corrections.

7. **Audits and Self-Audits:**
   The State will conduct a mock audit biannually in line with the exact methodology defined by HRSA. Please see below a description of the State’s audit procedures and data universe elements.

Covered Entity Data Request
1. Provide policies and procedures on the following topics:
A. Description of covered entity's registration and recertification process
B. Process for ensuring that the 340B OPAIS record is up to date and accurate for the parent, applicable off-site outpatient facilities/grant-associated sites, and contract pharmacies (including regular review and timely update of 340B OPAIS records)
C. Process for determining which sites are eligible; address whether each service area in which 340B drugs are purchased, ordered, or provided is included on the grant or reimbursable on the covered entity's most recently filed Medicare cost report (MCR)
D. Description of procurement process (including contract pharmacy, if applicable)
E. Prevention of GPO Prohibition violations (applies only to DSH, PED, and CAN)
F. Definition for any exclusions to the definition of covered outpatient drugs (e.g., bundled drugs, orphan drugs, or inpatient drugs)
G. Covered entity's process for conducting oversight of its contract pharmacy(ies): • Internal audits • Independent audits
H. How the covered entity accounts for 340B inventory or accumulation, if applicable (physical inventory vs. virtual inventory replenishment)
I. Prevention of diversion at **covered entity**—process for confirming the following: • Site eligibility location • Referral/responsibility of care remained with covered entity • Medical/patient health record • Patient eligibility (including status change) • Provider eligibility (relationship) • Service in the scope of grant (if applicable/non-hospital)
J. Documenting and accounting for wastage of a drug not administered Prevention of diversion at **contract pharmacy**—process for confirming the following: • Site eligibility location • Referral/responsibility of care remained with covered entity • Medical/patient health record • Patient eligibility • Provider eligibility (relationship) • Service in the scope of grant (if applicable / non-hospital)

1. Provide policies and procedures on the following topics: (cont.)

K. Mechanism to prevent duplicate discounts at **covered entity** and off-site facilities/grant associated sites for:

- Physician administration
- Outpatient prescriptions
- Billing multiple state Medicaid agencies, if applicable

L. Mechanism to prevent duplicate discounts at **contract pharmacies** for outpatient prescriptions

M. When and how covered entity would self-disclose and covered entity's definition of noncompliance material breach

N. Definition of eligible site when the location is not on the MCR yet or for a special circumstance (e.g., COVID-19, flooding)

2. Provide Covered Entity Eligibility Documentation

Hospitals

A. A listing of locations where health care services are provided to persons for whom the hospital deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including physical addresses

B. The applicable MCR(s), including the encrypted signature stamp on worksheet S:

- The MCR that was used at the time of the last recertification in OPAIS
- The MCR filed closest to the start of the sample period

C. The MCR(s) filed since the start of the sample period through the date of the on-site/remote audit For each off-site outpatient facility that utilizes 340B drugs (at the facility or through contract pharmacy), provide the trial balance that was **submitted to CMS** with the MCR(s). For each MCR and corresponding trial balance, include a trial balance crosswalk.

For each off-site facility, the trial balance crosswalk should include:

- 340B ID
- Name of each off-site outpatient facility as identified on 340B OPAIS
- Address of the off-site outpatient facility
- MCR line number and cost center description, as listed on MCR worksheets A and C
- Trial balance name and department code/account
- The location code or shorthand used to identify the site in the electronic health record (EHR)
- Whether 340B drugs are utilized during encounters at each site

2. Provide Covered Entity Eligibility Documentation (cont.)

Grantees

A. A listing of locations where health care services are provided to persons for whom the grantee deems itself responsible for the health care services provided for purposes of meeting 340B eligibility, including:

- Name
- Physical address
- Location code or shorthand used to identify the site in the covered entity's electronic health record (EHR).

B. Notice of Grant Award (NGA) and/or sub-grantee documentation, or FQHC-LA designation or FQHC638 compact agreement.

- Include forms 5A (scope of services) and 5B (service locations) if grantee is listed in HRSA's Electronic Handbook (EHB)
- Sub-grantee documentation may include:
  a. Notice of Funding Award between the primary grantee and sub-grantee

C. NGA project narrative that clearly indicates the sub-grantee's receipt of funding In-kind support (e.g., contracts, agreements, or memoranda of understanding)

3. Provide a 340B Universe for the Sample Period

A. Include a narrative describing the methodology, system/software by which the data were gathered, and any limitations or exclusions (e.g., whether reversed transactions or any other elements were excluded, other 340B orders or dispenses, direct purchases included, or other purchasing mechanisms). Define each area of service on the spreadsheet(s) with column headings name and indicate which area the spreadsheet represents.

B. Provide a list of all 340B drugs that were administered or dispensed to patients from the parent site, off-site facilities/grant-associated sites, and pharmacies (entity-owned and contracted) during the 6-month sample period (preferably in Excel format or another electronic format).

Include the following data elements in the listing:

- The drug/product name
- NDC
- The acquisition cost
- The type of account the drug was purchased through, purchase account, and the associated 340B ID number
- The quantity issued
- The patient ID number (this is typically the medical record number or prescription number, but can be any number you assigned that will allow tracking through the covered entity's system to retrieve all information associated with the order)
- The payer (all payers including Medicaid, primary, secondary and tertiary payers)
- The date the order (mixed-use pharmacy) or prescription (entity-owned or contract pharmacy) was written
- The ordering provider

3. Provide a 340B Universe for the Sample Period (cont.)

C. The location/site at which the 340B drug was administered/ordered (mixed-use pharmacy) or prescribed (in-house or contract pharmacy)

- The date the drug was administered or dispensed

A sample of administrations/dispenses will be selected for testing during the on-site/remote audit. For the selected items, individual records will need to be available in either electronic or paper format. If EHRs are used, provide an individual with system knowledge to navigate the EHR (including billing information) and the split-billing software/third party. Scans of hard copies of selected documents may be requested to be uploaded to the NIH secure site.

*The **covered entity** must ensure that no protected health information (PHI) and personally identifiable information (PII), such as a patient's name, date of birth, and address, is submitted in the data request list uploads*

4. Provide a Provider List

Provide a list of the covered entity's eligible providers, including:

- First name
- Last name
- NPI
- Whether employed/contracted, including start and termination dates of employment/contract (preferably in Excel format)

Note: Be prepared to show the auditor proof of employment, contract, or credentialing for providers during the on-site/remote audit.

5. Provide Purchasing Documentation

A. Provide a list of all accounts (wholesaler, direct, and consignment) used to purchase drugs for the parent, off-site facilities/grant-associated sites, and all pharmacies (entity-owned and contracted),

- Wholesaler name
- Account number
- Account name
- Location that receives the drugs (e.g., unique identifier for covered entity site or pharmacy
- Locations that dispense the drugs (e.g., unique identifier for covered entity site or pharmacy)
- For 340B accounts, include the 340B ID associated with account (the 340B ID used to open/establish the account)

B. Provide a copy of one invoice, during the sample period, for each account identified in the listing of accounts requested above. If an invoice is not available within the sample period, provide the most recent invoice available.

C. Provide a list of covered entity (parent, off-site facilities/grant-associated sites, and all pharmacies (entity-owned and contract pharmacies) 340B drug purchase orders made during the 6-month sample period (preferably in Excel format).

5. Provide Purchasing Documentation (cont.)

Include the following data elements in the listing:

- Ordering location (parent, off-site facilities/grant-associated sites, or contract pharmacy)
- Wholesaler name
- Account number
- Invoice number
- Invoice date
- Drug description
- Drug NDC
- Quantity ordered
- Price paid

6. Provide Contract Pharmacy Documentation

A. Provide a list of all covered entity's contract pharmacies since the beginning of the audit period through the date of the on-site/remote audit.

For each contract pharmacy location, indicate whether the pharmacy is used by the covered entity.

B. For each of the contract pharmacies, provide the original agreement and any amendments/addenda. Highlight the following areas in each contract pharmacy agreement/amendment/addendum:

- Signatures, including dates, of both parties executing the contract
- Name and address for each contract pharmacy location participating in the contract pharmacy agreement
- Each covered entity location by name and address **or** a general statement that inclusively identifies the parent and all covered entity location(s) participating in the contract pharmacy agreement

C. Provide a cover page or a statement on letterhead from the organization that conducted the last independent audit of the covered entity's contract pharmacies.

The document should include:

- Audit date
- Period audited
- Who performed the audit
- Scope of the audit

D. Provide supporting documentation of any internal contract pharmacy audits conducted by the covered entity from the start of the sample period through the date of the on-site/remote audit.

B. Reporting Requirements

The state of Montana will require electronic, standard and customizable reports for all areas required for implementation, operation, and compliance to federal and state requirements related to a 340B discount pharmaceutical program.

C. Material Breach and Corrective Action

The Authorizing Official solely has the discretion to determine if a breach of compliance is deemed material as outlined by HRSA. The State of Montana and consulting partner will proactively mitigate risk reducing the chance to near zero of a material breach.
On a case-by-case basis in the unlikely event of a breach determined to be material the state will determine the best plan needed for self-reporting or financial reconciliation.

VIII. Recertification Process

Annually during the designated window for STD grantees upon notification from HRSA the primary contact or authorizing official will facilitate the recertification process on the OPAIS database. An email will be sent to both parties with a unique link to login and recertify each site location:

a. STD59620; Helena (Administration)
b. STD596201; MWP
c. STD59632; RSNU
d. STD593014; Pine Hills
e. STD59722; MSP

IX. Program Evaluation, Performance Reviews, and Quality Improvement

A. Annual Program Evaluation

The outside consultant will formally conduct a 340B Program annually review. Program opportunities and threats will be identified if applicable. The outside consultant will deliver an action plan to the state's primary contact and support the states action plan for quality improvement upon request.

B. Biannual Performance Reviews

The consultant will conduct a strategic performance review on a biannual basis. In addition to mitigating risk the performance review will outline savings, program performance, inventory reconciliation reviews as well as TPA technical solution reviews.
Following the delivery of the performance review and collaboration between the consultant and Montana Department of Corrections will orchestrate program enhancements, if necessary, with the appropriate 340B Program stakeholders such as the TPA, contract pharmacy, wholesaler etc.

X. Documentation and Record Keeping

A. Documentation Requirements

OPAIS Database:
Eligibility documentation will be maintained and current on the OPAIS database. The Authorizing Official will review quarterly and make appropriate changes as needed.

Captured Claims:
Captured claims will be housed at the 340B TPA for a minimum of seven (7) years and available to the state upon request at any time. The state will have access to the cloud-based platform offered by 340B TPA to physically pull claims in real time if needed.

Purchase Order History:
Purchase orders will be housed both at the TPA level within the platform as well as in the wholesalers. In the event of an audit purchase order history will be able to be presented to HRSA. The TPA will house purchase order history for seven years.

Policy and Procedures:
The policy and procedure document is an evolving product that should be validated as current at a minimum every year; however, every six months is recommended. When program changes or stakeholder changes occur, the policy and procedure document should be updated immediately. This document is required to be presented to HRSA when the onsite audit occurs.

340B Pharmacy Service Agreements:
The state is required to maintain the Pharmacy Service Agreement (PSA) with Diamond Pharmacy. If changes occur, an amendment is sufficient to be included with the existing contract. The PSA will be required to present to HRSA in the event of an audit.

XI. Record Retention

The Department of Corrections understand that health care information is protected by a right of privacy and will maintain health record confidentiality as well as retain and store offender health records in accordance with Montana statute, 41-3-201, MCA; Title 50, Chapter 16, MCA, and DOC Policy 1.5.5, Offender Records Management, Access and Release. DOC Policies 1.5.6, Offender Records Access and Release, and 4.5.38, Offender Health Record Access, Release, and Retention. Offender's protected health information (PHI) shall not be made accessible to Legislative Auditor Division without a HIPAA-compliant release and if applicable 42 CFR Part-2 compliant releases signed by the offender.

XII. Programing Training and Education

The Consultant Group will support the Montana Department of Corrections in providing staff training to new program managers, primary contacts, authorizing officials, or other state employees.

XIII. Policy and Procedure Updates

The policy and procedures template will be reviewed yearly and made current. Each section will need to be validated as well as the Operational components found in the Appendix.

XIV. Glossary and Appendix

A. Glossary

1. **340B Program:** A federal program that provides eligible healthcare organizations access to discounted pharmaceuticals.
2. **340B TPA:** Third Party Administrator responsible for adjudicating claims and determining claim eligibility for 340B. Maintains virtual accumulation inventory tracking and auditable records to be used during an audit.
3. **45 CFR parts 160,162, and 164:** The Security Rule requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information.
4. **American Society for Industrial Security (ASIS):** Largest membership organization for security management.
5. **Authorizing Official:** Per HRSA, an authorizing official is someone who represents and confirms that he/she is fully authorized to legally bind a 340B covered entity into a relationship with the federal government and has knowledge of the practices and eligible programs at that site.
6. **Bank Identification Number (BIN):** 1st part of payer identification used to process a prescription.
7. **Blocks:** Application of program parameters preventing undesired (NDC's or payer groups primarily) claims from processing through the 340B Program.
8. **Buy-outs:** Synonymous with True-Up as defined in 10. Different offerors will refer to this process either as a "True-Up or "Buy-out."
9. **Covered Entity:** An eligible healthcare organization that participates in the 340B Program.
10. **Health Insurance Portability and Accountability Act (HIPAA):** Law in 1996, as amended, that restricts access to private medical information.
11. **Health Resources & Services Administration** (**HRSA):** Department within the U.S. Department of Health and Human Services. Combined with the Office of Pharmacy Affairs 340B

was established and maintained by these governmental organizations part of U.S. Department of Health and Human Services.

12. **HITECH:** Act of 2009 legislation that was created to drive the adoption of Electronic Health Records.
13. **Information Systems Security Association International (ISSA):** membership organization for security management.
14. **InfraGard:** National non-profit organization serving as a public-private partnership between U.S. businesses and the FBI.
15. **Intrusion Detection System (IDS):** application that monitors network traffic.
16. **Intrusion Prevention System (IPS):** Intrusion Prevention System used for data security measures preventing breaches.
17. **National Drug Code (NDCs):** NDC -9, NDC-11
    a. 9-Digit replenishment occurs when first 9 numbers are matched together
    b. 11 Digit replenishment occurs when all 11 digits match
18. **Offeror's Contract Liaison** – Contracting stakeholder at 340B TPA.
19. **Product Code Number (PCN):** Product Code Number – 2nd part of payer identification used to process a prescription.
20. **Security Information and Event Management (SIEM):** enables centralized compliance auditing and reporting across an entire business infrastructure.
21. **Sexually Transmitted Disease (STD) Clinic:** Eligible grantee designation that the state of Montana Department of Corrections qualifies for the 340B Program as.
22. **SOC II:** One of the most reputable and standardized auditing requirements for respected Pharmacy Benefit Management companies.
23. **State's Contract Liaison:** Contracting stakeholder at Montana Department of Corrections.
24. **True-ups:** Process of reconciling captured NDC's in the 340B Program after 90 or 120-day window after being dispensed and not able to be replenished back to the pharmacy. Reasons for unfulfillment include manufacturer discontinuation, ongoing out of stock or below the minimum replenishment threshold.
25. **Type III third party audit:** reports that test the operation of measures periodically using robust standards or frameworks such as ISAE 3402/SSAE16 and SOC reports.

B. Appendix

Documentation of Eligibility:

STD59620 Montana DPHHS (Active)

Main Details

Name	Montana DPHHS
Subdivision Name	Montana Department of Corrections
Type	Sexually Transmitted Diseases
340B ID	STD59620
Grant Number	NH25PS005168-05-00
Nature of Support	Direct Funding (dollars received from CDC or an intermediate organization) Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Please Describe the "in-kind" Support	
Time period section 318 funding or in-kind support was received	7/13/2022

Contacts

Authorizing Official	**Primary Contact**
Montana Department of Corrections Cindy McGillis-Hiner, Health Services Bureau Chief (406) 444-5439	Montana Department of Corrections Margaret BROCKHAUS, PROJECT MANAGER (406) 410-1401

STD593014 Montana Department of Public Health and Human Services/Pine Hills (Active)

Main Details

Name	Montana Department of Public Health and Human Services/Pine Hills
Subdivision Name	
Type	Sexually Transmitted Diseases
340B ID	STD593014
Grant Number	NH25PS005168-05-00
Nature of Support	Direct Funding (dollars received from CDC or an intermediate organization) Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Please Describe the "in-kind" Support	
Time period section 318 funding or in-kind support was received	8/11/2022

STD596201 Montana Department of Public Health and Human Services/MWP (Active)

Main Details

Name	Montana Department of Public Health and Human Services/MWP
Subdivision Name	
Type	Sexually Transmitted Diseases
340B ID	STD596201
Grant Number	NH25PS005168-05-00
Nature of Support	Direct Funding (dollars received from CDC or an intermediate organization) Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Please Describe the "in-kind" Support	
Time period section 318 funding or in-kind support was received	8/11/2022

STD59632 Montana Department of Public Health and Human Services/RSNU (Active)

Main Details

Name	Montana Department of Public Health and Human Services/RSNU
Subdivision Name	
Type	Sexually Transmitted Diseases
340B ID	STD59632
Grant Number	NH25PS005168-05-00
Nature of Support	Direct Funding (dollars received from CDC or an intermediate organization) Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Please Describe the "in-kind" Support	
Time period section 318 funding or in-kind support was received	8/11/2022

STD59722 Montana Department of Public Health and Human Services/MSP (Active)

Main Details

Name	Montana Department of Public Health and Human Services/MSP
Subdivision Name	
Type	Sexually Transmitted Diseases
340B ID	STD59722
Grant Number	NH25PS005168-05-00
Nature of Support	Direct Funding (dollars received from CDC or an intermediate organization) Note: In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.
Please Describe the "in-kind" Support	
Time period section 318 funding or in-kind support was received	8/11/2022

Contacts

Authorizing Official

Montana Department of Corrections
Cindy McGillis-Hiner, Health Services Bureau Chief
(406) 444-5439

Primary Contact

Montana Department of Corrections
Todd Boese, Managed Care RN
(406) 444-4761