

# SAMPLE 340B POLICIES AND PROCEDURES FOR CDC SECTION 318 GRANTEES AND SUBGRANTEES



**National Coalition  
of STD Directors**

*Disclaimer: This information is provided by NCSD for general information purposes and does not constitute legal advice. These Sample 340B Policies and Procedures are designed for 318 grantees and subgrantees, including, but not limited, to those receiving a grant or contract funded under the PCHD NOFO (19-1901) and the Ending the HIV Epidemic (EHE) NOFO (20-2010).*

# INSTRUCTIONS FOR USING THIS RESOURCE

## Why create policies and procedures addressing 340B compliance?

The Health Resources and Services Administration (HRSA), the agency that is responsible for oversight and integrity of the 340B Drug Pricing Program (340B Program), recommends that 340B covered entities develop a set of stand alone policies and procedures that address all of the components of 340B Program compliance. Policies and procedures standardize operations and practices throughout the organization and are helpful to ensure ongoing compliance during staff and other organizational transitions.

In the event of a 340B audit, HRSA auditors will request to see a covered entity's 340B policies and procedures. If the covered entity does not have policies and procedures addressing 340B operations and compliance or they are considered insufficient, the auditor may issue a finding and the covered entity will be required to develop or enhance its 340B policies and procedures as a part of its corrective action plan (CAP). Therefore, it is strongly encouraged that covered entities develop comprehensive 340B policies and procedures in advance of an audit and include a process for regularly reviewing and updating them as needed.

## What is the purpose of this resource?

This resource is designed to assist 318 grantees and subgrantees in developing their own 340B policies and procedures that ensure a high level of 340B Program oversight and integrity. The template format for each relevant policy area can be used as a starting point, but should be specifically tailored to the unique needs and operations of the organization. For each area of 340B compliance, the template includes the following items:

- **Policy Purpose:** This is a high-level statement of the objective of the policy, which usually relates to an area of 340B statutory law or HRSA regulation or guidance.
- **Policy Statements:** The Policy Statements set forth the covered entity's general guidelines and principles to be followed under a given set of circumstances.
- **Background/Sources:** This section includes a brief description of the applicable law or policy and links, where available, to NCSD, HRSA, or Apexus resources. Apexus is HRSA's contracted vendor to provide educational materials and tools to support 340B stakeholder compliance.
- **Definitions:** It is typical for policies and procedures to include definitions of unique terms to ensure the reader understands their meaning. In this resource, key definitions are included in Appendix A.

- **Procedures:** This section includes step-by-step instructions to support the covered entity in completing a task or oversight function.
- **Approvals:** Each policy and procedure must be reviewed and approved. This table includes a running log of signature approvals and dates.

### How should I use this resource?

1. Identify all individuals (both within and outside of the organization) who will have a role in drafting, editing, reviewing, and approving the 340B policies and procedures.
2. Assign initial roles and responsibilities and timeframes for completion.
3. Review the sample policies and procedures in this resource and, based on the issues covered here, customize a draft policy and procedure manual for your organization.
4. Submit the draft manual for review and approval according to your organization's requirements.
5. Ensure every staff person working on 340B compliance has reviewed and has ongoing access to the 340B policy and procedure manual.
6. Regularly review and update the 340B policy and procedure manual according to your organization's requirements.
7. Maintain all previous versions.

# TEMPLATE POLICIES & PROCEDURES

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SUBJECT: <b>GENERAL STATEMENT OF 340B PROGRAM POLICY &amp; PARTICIPATION</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To comply with all 340B Program requirements, ensure 340B program savings and revenue are used in a manner consistent with the intent of the 340B Program, and establish a process for regularly reviewing and updating as needed [Covered Entity’s] 340B policies and procedures.

**Policy Statements:**

- [Covered Entity] participates in the 340B Drug Pricing Program (340B Program) in order to expand access to affordable prescription drugs and essential health care services for its eligible patients.
- Any savings or revenue generated from [Covered Entity’s] participation in the 340B Program are used [to support expanded and enhanced services for the medically underserved patients in our service area/to further the purpose of the federal grant under which it is eligible for 340B discounted drugs.]
- [Covered Entity] complies with all 340B requirements and has policies and procedures in place to monitor and ensure compliance.
- [Covered Entity’s] 340B policies and procedures are regularly reviewed and updated.

**Background/Sources:** The 340B Drug Pricing Program is a federal program that requires pharmaceutical manufacturers to provide drugs at a discount to certain safety net providers, referred to as “covered entities.” The 340B Program was enacted in 1992 to help covered entities “stretch scarce Federal resources as far as possible reaching more eligible patients and providing more comprehensive services.” (H.R. Rep. 102-384(II)). The Office of Pharmacy Affairs (OPA), located in the Health Resources and Services Administration (HRSA), is responsible for the oversight and integrity of the 340B Program. Covered entities are responsible for complying with all 340B Program Requirements, including the maintenance of auditable records. Auditable records include, but are not limited to, the covered entity’s 340B policies and procedures outlining the steps a covered entity takes to ensure 340B compliance.

⇒ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on “Grantees”, then select “Self-Audit: Policy and Procedure”)

**Definitions:** See Appendix A.

**Procedures:**

1. [Covered Entity] ensures its continued eligibility for the 340B Program by checking the status of its 318 grants or contracts on a semi-annual basis and updating the grant or contract as needed to prevent any gap in eligibility.
2. [Covered Entity] uses savings and revenue generated from its 340B Program participation to provide affordable and comprehensive services to more eligible patients.
  - a. Specifically, [Covered Entity] uses the savings and revenue for the following activities, including, but not limited to: [insert list of activities]
  - b. [Apexus (HRSA’s contracted vendor to provide technical assistance) has a resource to assist covered entities in documenting how they use 340B savings. (select “Grantees” and then “Calculating 340B Net Financial Impact and Use of Savings”)]
3. [Covered Entity] has systems in place to regularly check and ensure its compliance with 340B requirements that are described in detail in its 340B policies and procedures.
4. [Covered Entity] reviews its 340B policies and procedures on a [quarterly/annual] basis and updates them as needed to reflect changes in 340B Program requirements or operations.

**Approvals:**

Title	Signature	Approval Date

Organization Name:	Department:	
SUBJECT: <b>340B ROLES, RESPONSIBILITIES, AND EDUCATION</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To assign individual roles and responsibilities for ensuring integrity and compliance with all 340B Program requirements and ensure responsible individuals are properly trained.

**Policy Statements:**

- [Covered Entity] complies with all 340B Program requirements and has mechanisms in place to ensure appropriate oversight and integrity of its 340B participation and operations.
- Staff or individuals under contract with [Covered Entity] that are involved in 340B compliance understand and fulfill their respective roles and responsibilities.

**Background/Sources:** As a part of its oversight responsibility, a covered entity is responsible for identifying all individuals involved in 340B compliance, including the individuals serving as the covered entity’s Authorizing Official and Primary Contact. The covered entity must also ensure that individuals responsible for 340B compliance are appropriately trained to perform their respective roles.

- ⇒ HRSA: <https://www.hrsa.gov/opa/educational-resources/index.html>
- ⇒ Apexus: [340B Compliance for the C-Suite](#)
- ⇒ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (click on “Grantees”; there are several job descriptions and a list of possible staff in the Title X “Sample Policies & Procedures”).

**Definitions:** See Appendix A.

**Procedures:**

1. The following staff are responsible for 340B Program implementation and oversight: [Insert all titles, not names, that have a role in ensuring 340B

compliance and what their primary responsibilities entail or refer to their employment contracts.]

- a.** [Insert Title] serves as [Covered Entity's] Authorizing Official (AO).  
[Note: The AO is usually the CEO, CFO, COO, or Director of Pharmacy. It must be a person who is authorized to legally bind the covered entity and execute contracts on its behalf. For some 318 grantees, the AO may be the grantee of record or the Clinic Director. The AO is the main point of contact for HRSA and receives notifications regarding recertification and other important updates. The AO must annually attest to the accuracy of the information in the Office of Pharmacy Affairs Information System (OPAIS) and [Covered Entity's] continued compliance with 340B Program requirements.]
          - b.** [Insert Title] serves as [Covered Entity's] Primary Contact (PC). [The Primary Contact is the secondary point of contact for the covered entity. While the PC may also receive information from HRSA, this person has no legal authority to bind the covered entity. The PC can help update records in OPAIS and perform other administrative functions; however, only the AO can submit changes or recertification to HRSA for approval. The PC should be someone other than the AO.]
- 2.** *[If applicable]* The following contractors support [Covered Entity's] 340B compliance: [insert titles (e.g., outside counsel, independent auditors, third party administrators) and their primary responsibilities].
- 3.** [Covered Entity] provides training and educational materials to ensure that staff or contractors involved in 340B implementation and compliance understand and comply with 340B Program requirements.
  - a.** [Covered Entity] documents 340B Program training and education in each staff person's employment records.
  - b.** [Covered Entity] ensures that any contract or agreement with a third-party vendor or contractor addresses 340B education and compliance requirements.
  - c.** [Covered Entity] provides educational updates and training as needed and verifies 340B competency for staff and contractors involved with 340B Program implementation and compliance on a regular basis [consider specifying the time period].
- 4.** *[If applicable]* [Covered Entity] has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program. Specifically, the Oversight Committee [add details of the Committee's makeup and oversight responsibilities]:
  - a.** Is comprised of [insert titles of individuals who sit on the committee].
  - b.** Meets [insert frequency of meetings].
  - c.** Performs the following functions: [insert the role of the committee].



**Approvals:**

<b>Title</b>	<b>Signature</b>	<b>Approval Date</b>



Organization Name:	Department:	
SUBJECT: <b>ELIGIBILITY AND REGISTRATION</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To ensure [Covered Entity’s] eligibility to participate in the 340B Drug Pricing Program and registration in the 340B Office of Pharmacy Affairs Information System (OPAIS).

**Policy Statements:**

- [Covered Entity] is eligible for 340B discounted drug pricing through its receipt of a federal grant or contract funded by Section 318 of the Public Health Service Act for the prevention and treatment of sexually transmitted diseases (STDs).
  - [Covered Entity] is a [direct grantee or subgrantee] of a 318 grant and receives [describe the nature of the funding; specifically, whether it is for direct funding, in-kind funding (laboratory testing kits, medications or something else), or both.]
- [Covered Entity] enrolls only those health care delivery sites that are a grantee or subgrantee of a Section 318 grant or contract in OPAIS and all information is updated and accurate at all times for each such location.

**Background/Sources:** The entities eligible for 340B pricing are set forth in statute and generally include certain hospitals and federally funded grantees. Recipients of funding under Section 318 of the Public Health Service Act are eligible for 340B pricing, including EHE (NOFO 20-2010) and PCHD (NOFO 19-1901) grantees and subgrantees. Although a 318 grantee or subgrantee may be eligible to participate in the 340B Program, it must register each health care delivery site that received the 318 funding (direct or in-kind or both) in 340B OPAIS before manufacturers will begin selling 340B drugs. HRSA has designated the first two weeks of every quarter for registering newly eligible entities with 340B discounts commencing the beginning of the following quarter.

⇒ HRSA: <https://www.hrsa.gov/opa/eligibility-and-registration/index.html>

**Definitions:** See Appendix A.

**Procedures:**

***Eligibility***

1. [Covered Entity] has and retains a copy of the grant, contract, or agreement supported by Section 318 funds of the Public Health Service Act demonstrating its eligibility for the 340B Program.
  - a. The grant or contract(s) lists each participating health care delivery site.  
A copy of the grant or contract is located [insert location].
2. [Covered Entity] regularly checks the terms of the 318 grant or contract to ensure it is effective and executes new grants or contracts as needed to prevent a gap in eligibility if possible.

***Registration***

1. [Covered Entity] understands 340B registration dates and has all of the information necessary, including the federal grant number and Notice of Funding Opportunity number, to register each eligible health care delivery site and any associated contract pharmacies in OPAIS.

<b>Registration Dates</b>	<b>Effective Dates</b>
January 1 - 15	April 1
April 1 - 15	July 1
July 1 - 15	October 1
October 1 - 15	January 1

2. [Covered Entity] registers each eligible health care delivery site and contract pharmacy in OPAIS.
3. [Covered Entity] ensures that 340B OPAIS is complete and accurate for all 340B eligible locations and contract pharmacies in accordance with Policy and Procedure on Recertification and Change Requests [Insert Policy Number, if applicable].
4. [Covered entity] terminates the applicable 340B registration if any of its participating health care sites loses its 318 grant or contract and 340B eligibility.
5. [Covered entity] does not purchase 340B inventory at any sites that are not 340B eligible and manages remaining 340B inventory at a site that has lost 340B eligibility in accordance with Policy and Procedure on Purchasing and Inventory Management [Insert Policy Number, if applicable].

**Approvals:**

<b>Title</b>	<b>Signature</b>	<b>Approval Date</b>



Organization Name:	Department:	
SUBJECT: <b>RECERTIFICATION AND CHANGE REQUESTS</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To ensure the accuracy of [Covered Entity’s] information for each participating health care delivery site and any associated contract pharmacies in OPAIS and continued compliance with 340B requirements.

**Policy Statements:**

- [Covered Entity] ensures that 340B OPAIS is complete and accurate for all 340B eligible health care delivery sites [and contract pharmacies].
- [Covered Entity] participates in the annual recertification process to ensure the accuracy of the information in OPAIS and the continued eligibility for each 340B eligible health care delivery site [and contract pharmacy].
- [Covered Entity] verifies that all of its 340B eligible health care delivery sites [and contract pharmacies] are compliant with 340B requirements.

**Background/Sources:** Each year, a 340B covered entity is required to annually recertify eligibility to participate in the 340B Program and continue purchasing drugs at discounted 340B prices. The covered entity’s AO and PC will receive an email notification from HRSA before the recertification process begins. The recertification process requires the AO to ensure that all information in OPAIS is accurate and attest to the covered entity’s compliance with 340B requirements. The covered entity can update information in OPAIS at any time during the year (not just during recertification) by submitting an online change request to HRSA for approval.

⇒ HRSA: <https://www.hrsa.gov/opa/recertification/recertification.html>

**Definitions:** See Appendix A.

**Procedures:**

1. [Covered Entity] checks each registration record in OPAIS on a [monthly, bi-monthly, semi-annual] basis to verify the accuracy of the information for each 340B eligible health care delivery site [and contract pharmacy].



2. [Covered Entity] updates the information in OPAIS on an as needed basis by submitting a change request.
  - a. [Covered Entity] immediately notifies HRSA of any changes to its grant or contract status impacting eligibility by terminating a site (or sites) that are no longer eligible.
  - b. [Covered Entity's] Authorizing Official notifies HRSA immediately of any changes to the information in OPAIS by submitting an online change request.
  - c. [Covered Entity] will assess when changes made to the Medicaid Exclusion File will be reflected and will adjust billing as needed to prevent duplicate discounts. See Policy and Procedure on Medicaid and the Prevention of Duplicate Discounts [Insert Policy Number, if applicable].
3. [Covered Entity] ensures all information is updated in OPAIS, including the names of the Authorizing Official and Primary Contact, prior to the beginning of the annual recertification process.
  - a. The Authorizing Official and Primary Contact are different individuals.
  - b. The AO must be someone who can legally bind [Covered Entity] with the Federal Government. For many organizations, the AO is the CEO, COO or CFO. For 318 grantees or subgrantees, the AO may be the grantee of record or the Clinic Director.
4. [Covered Entity]'s Authorizing Official annually recertifies information in OPAIS.
  - a. The Primary Contact or other authorized individual updates the information in OPAIS.
  - b. Only the AO attests to [Covered Entity's] compliance with 340B requirements and submits the final recertification request to HRSA.
  - c. Questions regarding the recertification process are submitted to: [340B.recertification@hrsa.gov](mailto:340B.recertification@hrsa.gov).

**Approvals:**

Title	Signature	Approval Date

Organization Name:	Department:	
SUBJECT: <b>PATIENT ELIGIBILITY AND PREVENTION OF DRUG DIVERSION</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To ensure that [Covered Entity] [and its contract pharmacies] dispense or administer 340B drugs to eligible patients as defined by HRSA guidance.

**Policy Statements:**

- [Covered Entity’s] 340B eligible health care delivery sites [and contracted pharmacies] purchase and dispense or administer 340B drugs.
  - *[Include if applicable]* [Covered Entity] also operates health care delivery sites that do not participate in the 340B Program. [Covered Entity] follows procedures to prevent 340B inventory from being dispensed or administered at those locations. See Policy and Procedure on Purchasing and Inventory Management [Insert Policy Number, if applicable].
- [Covered Entity’s] 340B eligible health care delivery sites [and contracted pharmacies] dispense or administer 340B drugs only to individuals meeting HRSA’s three-pronged patient definition.
- If drug diversion is discovered, [Covered Entity] immediately develops a corrective action plan to prevent any further instances, contacts any impacted manufacturers, and follows its policies and procedures regarding self-disclosure to HRSA. See Policy and Procedure on Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if applicable].

**Background/Sources:** The 340B statute (42 U.S.C. § 256b(a)(5)(B)) prohibits the sale or transfer of a 340B purchased drug to persons who are not “patients” of the covered entity, referred to as drug diversion. Only patients as defined by HRSA guidance can receive 340B priced drugs.

**Definitions:** See Appendix A.

**Procedures:**

1. [Covered Entity] confirms on a [specify frequency] basis that purchasing orders are only made by 340B qualified health care delivery sites.

- a. If a purchase is made by a non-340B qualified site, [Covered Entity] will immediately cease such purchasing and contact the manufacturer to identify a corrective action plan (this may involve a credit/rebill or some other solution). [Covered Entity] will assess whether the purchase(s) constitutes a material breach triggering self-disclosure to HRSA. See Policy and Procedure on Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if applicable].
- 2. [Covered Entity] verifies and documents that each patient receiving a 340B drug meets HRSA’s patient definition. To qualify for a 340B drug, [Covered Entity] must retain auditable records that demonstrate:
  - a. [Covered Entity] has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care.
    - i. [Briefly describe Covered Entity’s medical record system]
  - 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 care provided remains with the covered entity.
    - i. [Describe processes for confirming provider eligibility (e.g., employment agreements, third-party vendor contracts etc.)]
    - ii. [Refer to location(s) where a list of professionals is readily accessible]
  - c. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided to the entity.
    - i. For a sexual health definition of patient, an individual, at a minimum should receive a sexual history and review of STD risk factors at every visit and any testing and treatment that is subsequently warranted per CDC guidelines.
- 3. An individual is not a patient of [Covered Entity] if the only health care service received is the dispensing of a drug for subsequent administration (e.g., over-the-counter drugs).
- 4. [Covered Entity] may dispense 340B purchased medications for partners of 340B eligible patients being treated for an STD (referred to as expedited partner therapy).
- 5. An employee of [Covered Entity] may receive a 340B drug, provided that the individual meets the 340B definition of a patient.
- 6. Insurance status is not relevant for determining patient eligibility for 340B drugs.
- 7. Once an individual meets the 340B definition of a patient, any drug medically indicated and prescribed by the treating clinician may be purchased under the 340B Program, including HIV prevention medications.



8. A 340B eligible patient may receive refills at the 340B price provided that [Covered Entity] has documented the health care service generating the initial prescription and refills in the patient’s medical record.
9. [Covered entity] may administer physician/clinician administered drugs purchased under the 340B program to 340B eligible patients, including PrEP injectables.
10. [Covered Entity] ensures that all staff or third party vendors involved with 340B Program implementation understand and comply with 340B entity and patient eligibility requirements.
11. If instances of drug diversion are discovered (340B drugs being dispensed to ineligible patients), [Covered Entity] will immediately institute a corrective action plan to prevent further instances, contact any impacted manufacturers to identify a solution (this may involve a credit/rebill, repayment, or some other solution). [Covered Entity] will assess whether the drug diversion constitutes a material breach triggering self-disclosure to HRSA. See Policy and Procedure on Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if applicable].

**Approvals:**

Title	Signature	Approval Date

Organization Name:	Department:	
SUBJECT: <b>MEDICAID BILLING AND PREVENTION OF DUPLICATE DISCOUNT</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To ensure that [Covered Entity] is billing Medicaid (both fee-for-service and managed care, if applicable) appropriately for 340B drugs and preventing the occurrence of duplicate discounts.

**Policy Statements:**

- [Covered Entity] [dispenses or administers / does not dispense or administer] 340B drugs to eligible patients insured under the State’s Medicaid fee-for-service (FFS) program and ensures that the information in HRSA’s Medicaid Exclusion File (MEF) is accurate.
- [Covered Entity] [dispenses or administers /does not dispense or administer] 340B drugs to Medicaid managed care patients. [Covered Entity] follows applicable policy regarding billing Medicaid managed care organizations or pharmacy benefit managers for 340B drugs to prevent the unauthorized collection of rebates by the State.

**Background/Sources:** Manufacturers are protected from paying both a 340B discount upfront on a drug sold to a covered entity and a Medicaid rebate to a state on that same unit of drug. This is referred to as a duplicate discount and is prohibited by law (42 U.S.C. § 256b(a)(5)(A)(i); 42 U.S.C. § 1396r-8(j)(1)). In 1992, when enacting the 340B Program, Congress directed the Secretary to develop a mechanism to prevent duplicate discounts (at that time, the Medicaid drug rebate program only applied to Medicaid fee-for-service programs). The Secretary created the Medicaid Exclusion File (MEF) which requires covered entities to specify whether they intend to dispense or administer 340B drugs to Medicaid fee-for-service patients (an all or nothing election), and, if so, to include all Medicaid provider numbers and National Provider Identifiers (NPIs) in the MEF that the covered entity will use to bill Medicaid. States will pull claims for drugs in its manufacturer rebate requests if they are billed with Medicaid or NPI numbers included in the MEF.

With passage of the Affordable Care Act in 2010, Congress extended rebate requirements to Medicaid managed care drugs, but once again exempted 340B drugs

to protect manufacturers from paying two discounts on the same unit of drug. However, unlike in Medicaid FFS, Congress left it up to each state and its contracted managed care organizations to establish a method to identify 340B drugs and prevent duplicate discounts. Some states have navigated this successfully requiring the use of modifiers or the retrospective submission of data identifying which claims include 340B drugs, while others have relied on the MEF or prevented covered entities from being able to use 340B drugs with Medicaid managed care patients. It is essential that a covered entity work with its state and its MCOs to understand any requirements to prevent duplicate discounts, as well as to ensure it may retain the right to use or not use 340B drugs with its Medicaid patients.

⇒ HRSA: <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html>

⇒ Apexus: [Medicaid Exclusion File Checklist](#)

**Definitions:** See Appendix A.

**Procedures:**

### ***Medicaid Fee-for-Service***

1. *[If dispensing/administering 340B drugs to Medicaid FFS patients, referred to as “carving-in”]* [Covered Entity] dispenses or administers 340B drugs to 340B eligible patients insured under the State’s Medicaid FFS program and has indicated this in OPAIS.
  - a. For each 340B health care delivery site, [Covered Entity] has entered all Medicaid numbers and National Provider Identifiers (NPIs) with which it will bill Medicaid FFS for 340B drugs in the [Medicaid Exclusion File](#).
    - i. A full list of Medicaid provider numbers and NPIs used to bill Medicaid for 340B drugs can be found [in OPAIS/refer or add a link to the location where this information may be found].
  - b. [Covered Entity] updates this information on an as needed basis to ensure it is accurate at all times and understands that any changes that are made before the 15th of the month prior to the quarter take effect at the beginning of such quarter.
    - i. [Covered Entity] works with the State to ensure proper billing at all times and in circumstances where the MEF has not yet been updated to reflect the [Covered Entity’s] current billing practices.
  - c. [Covered Entity] bills Medicaid FFS programs in accordance with state billing and reimbursement policies for 340B drugs.
    - i. [If possible, insert a link to or specify the state’s billing/reimbursement policy for 340B drugs, including for self-administered and physician/clinician-administered drugs.]

- ii. [Covered Entity] maintains auditable records demonstrating how it is billing Medicaid FFS programs at all times.
- 2. [If dispensing or administering non-340B drugs to Medicaid FFS patients, referred to as “carving-out”] [Covered Entity] dispenses or administers non-340B purchased drugs to Medicaid FFS patients and has indicated this election in the OPAIS Medicaid Exclusion File.)
  - a. [If possible, insert a link to or specify the state’s billing/reimbursement policy for non-340B drugs, including for self-administered and physician/clinician-administered drugs.]
  - b. [Covered Entity] bills Medicaid FFS programs in accordance with state billing reimbursement policies for non-340B drugs.
- 3. [If Covered Entity has contract pharmacy arrangements] [Covered Entity’s] contract pharmacies [carve-in/carve-out] 340B drugs when billing Medicaid FFS.
  - a. [If carving-in] [Covered Entity] has an arrangement with the state Medicaid agency and the contract pharmacy to prevent duplicate discounts. This arrangement has been submitted to HRSA. [Insert link to or location of the arrangement]

### **Medicaid Managed Care**

- 1. [If the State has a billing or reimbursement policy that applies to 340B drugs dispensed or administered to Medicaid managed care patients] [Covered Entity] bills and is reimbursed in accordance with the State’s policy for 340B drugs dispensed or administered to patients insured under the State’s Medicaid managed care plans.
  - a. [Covered Entity] follows State requirements, if any, to identify 340B drugs for purposes of preventing the State’s unauthorized collection of rebates on 340B drugs.
  - b. [Refer to the policy language for billing Medicaid MCOs or their contracted pharmacy benefit managers (PBMs); include a link if available.]
- 2. [If there is no statewide policy that addresses billing and reimbursement for 340B drugs dispensed or administered to Medicaid managed care patients] [Covered Entity] follows contractual requirements regarding identification of and billing 340B drugs to Medicaid managed care plans and pharmacy benefit managers to prevent duplicate discounts.
  - a. [Refer to location of Medicaid MCO or PBM contracts]
- 3. [If Covered Entity has contract pharmacy arrangements] [Covered Entity] has [an agreement with a contract pharmacy/agreements with multiple contract pharmacies] to dispense [340B/non-340B] drugs to [Covered Entity’s] patients insured by Medicaid MCOs or PBMs.
  - a. [If carving-in] Contract pharmacy bills Medicaid MCOs and PBMs in accordance with the policies outlined in the agreement.

- b. [Covered Entity] has policies and procedures in place to ensure compliance with applicable requirements to identify 340B drugs for the purposes of preventing duplicate discounts. See Policy and Procedure on Contract Pharmacy Arrangements and Oversight [Insert Policy Number, if applicable].

**Duplicate Discounts**

1. If [Covered Entity] discovers incorrect Medicaid billing for 340B drugs or circumstances which may generate a duplicate discount such as inaccurate Medicaid or NPI numbers in the Medicaid Exclusion File, [Covered Entity] will institute a corrective action plan to prevent further instances of incorrect billing or duplicate discounts.
2. [Covered Entity] will notify impacted manufacturers of instances of duplicate discounts and work together with the manufacturer and State, if appropriate, to identify a solution.
3. [Covered Entity] will notify the State of instances of incorrect Medicaid billing for 340B drugs and work with the State to identify a solution.
4. [Covered Entity] will assess whether any such instances of duplicate discounts constitute a material breach and trigger the requirement to self-disclose to HRSA. See Policy and Procedure on Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if applicable].

**Approvals:**

Title	Signature	Approval Date

Organization Name:	Department:	
SUBJECT: <b>PURCHASING AND INVENTORY MANAGEMENT</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
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**Policy Purpose:** To ensure the proper purchase and inventory management of 340B drugs for the purposes of preventing drug diversion and duplicate discounts and complying with all other applicable 340B Program requirements.

**Policy Statements:**

- [Covered Entity] purchases 340B drugs only at its 340B qualified sites.
- [Covered Entity] uses the following inventory management method(s): [physical 340B only-inventory; physically separated 340B and non-340B inventory; virtual/replenishment model; mixed virtual and physical inventory model etc.]
- [Covered Entity] is able to track and account for 340B drugs at all times.
- [Covered Entity] dispenses or administers 340B drugs only to 340B eligible patients.
- [Covered Entity] follows applicable federal and state Medicaid policy to prevent duplicate discounts.
- [Covered Entity] maintains auditable records to verify compliance with 340B Program requirements. See Policy and Procedure Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if appropriate].

**Background/Sources:** Covered entities registered in OPAIS may purchase 340B drugs and dispense or administer them to eligible patients. Covered entities must have auditable purchasing and dispensing records that document compliance with all 340B requirements, including the prohibition of drug diversion and duplicate discounts. The most common ways that covered entities manage 340B inventory is to physically separate their 340B and non-340B inventory and/or to use a virtual inventory or replenishment model. Under a virtual inventory/replenishment model, drugs are dispensed from a single physical inventory to both 340B eligible and non-eligible patients. Rather than maintaining separate physical inventories, a virtual inventory is maintained electronically through the use of electronic tracking systems. A virtual inventory/replenishment model is more commonly used with contract

pharmacies, but can also be used to manage a covered entity’s in-house pharmacy or centralized location used for storing and dispensing drugs.

Each covered entity is assigned a unique 340B ID and is considered a separate entity for purposes of the 340B Program. HRSA does not allow the sharing of 340B inventory with unique 340B IDs unless approved by HRSA. Grantees may submit a written request for HRSA approval to purchase 340B inventory under one account and distribute the inventory to multiple, unique 340B IDs operating under the same federal grant number (referred to as a “Grantee Combined Purchasing and Distribution Request”). This is common in the context of the 318 Program, where a state STD division is awarded a Section 318 grant and purchases inventory under its 340B ID and then dispenses it to its 318 subgrantees. The 318 subgrantees are also able to register for their own 340B IDs and purchase 340B drugs to expand their respective formularies and medication offerings to their patients.

Manufacturers are prohibited from refusing to sell 340B priced drugs to covered entities (except in very limited circumstances such as a drug shortage) or charging covered entities more than the statutory ceiling price on a 340B drug. A covered entity can confirm that it is not being overcharged by checking the 340B ceiling price database in OPAIS. If it is being overcharged or is unable to purchase 340B drugs, the covered entity should try to work with the manufacturer first to come to a solution. If a solution cannot be agreed upon, the covered entity can submit a notice to HRSA and seek a resolution pursuant to the Administrative Dispute Resolution Process.

⇒ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on “Grantees”, then select: “340B Manual Dispense Tracking Log” or “Grantee Combined Purchasing and Distribution Request” or “Controlled Substance Ordering System (CSOS) Compliance Considerations”

⇒ Apexus: [Ceiling Price Unavailable/Incorrect Ceiling Price Notification for HRSA](#)

**Definitions:** See Appendix A.

**Procedures:**

***Purchasing***

1. [Covered Entity] purchases drugs from [Insert supplier/distributor names and account numbers, including any Group Purchasing Organization (GPO) agreements (e.g., Apexus)]
2. [Covered Entity] purchases [340B/non-340B/both 340B and non-340B] drugs.
  - a. [Describe processes for separating 340B and non-340B purchases, such as purchasing under 340B IDs, HIN numbers, different 340B and non-340B accounts etc.]

3. *[If applicable]* [Describe any bill-to/ship-to arrangements. For example, 340B drugs may be billed to a 340B ID, but shipped to a central warehouse or a contract pharmacy.]
4. [Covered Entity] checks HRSA’s 340B Ceiling Price database on an as needed basis to confirm it is not being overcharged for 340B drugs.

**Inventory Management**

1. [Covered Entity] uses the following inventory management method(s): [physical 340B only-inventory; physically separated 340B and non-340B inventory; virtual replenishment model; mixed virtual and physical inventory model]
2. [Describe in detail how the inventory management method(s) works. For example, how is 340B and non-340B inventory physically separated (e.g., in different parts of a storage room, stickers, etc.). For virtual or replenishment models, describe the software used to track and replenish 340B inventory. Describe any other processes used to track and manage inventory.]
  - a. [See Apexus’ Sample Policies and Procedures for Grantees -- Title X Family Planning Providers on Inventory Management (pages 16-20) for detailed information on inventory management processes and operations.]
3. [Covered Entity] disposes of 340B inventory in accordance with manufacturer guidance and state law.

**Compliance**

1. [Covered Entity] [and any contracted pharmacies to dispense 340B drugs] only dispense(s) to individuals meeting the 340B definition of a patient. See Policy and Procedure on Patient Eligibility and Prevention of Drug Diversion [Insert Policy Number, if applicable].
2. [Covered Entity] maintains auditable records demonstrating inventory management processes and compliance with applicable 340B Program requirements. See Policy and Procedure on Compliance, Material Breach, and Self-Disclosure [Insert Policy Number, if applicable].

**Approvals:**

Title	Signature	Approval Date



Organization Name:	Department:	
SUBJECT: <b>CONTRACT PHARMACY ARRANGEMENTS AND OVERSIGHT</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
Page __ of __	Review Schedule:	

**Policy Purpose:** To ensure that 340B contract pharmacy arrangements comply with applicable 340B Program requirements and that [Covered Entity] retains responsibility for such compliance.

**Policy Statements:**

- [Covered Entity] has a written arrangement with each contract pharmacy to dispense 340B drugs to [Covered Entity’s] 340B eligible patients.
- [Covered Entity] ensures that its contract pharmacies comply with all applicable 340B Program requirements and [Covered Entity] retains responsibility for non-compliance.
- [*If applicable*] [Covered Entity] has an agreement with a third-party administrator (TPA) to support implementation and oversight of its 340B contract pharmacy arrangement(s).

**Background/Sources:** A covered entity may contract with a pharmacy vendor or multiple pharmacy vendors to dispense medications to 340B eligible patients on the covered entity’s behalf. HRSA requires these arrangements to be in writing and for each contract pharmacy to be registered in OPAIS. Covered entities retain full responsibility for contract pharmacy compliance with all 340B requirements, including the prevention of drug diversion and duplicate discounts. Covered entities are required to independently audit its contract pharmacy arrangements on an annual basis and maintain auditable and readily available records demonstrating 340B compliance. Covered entities often engage third-party administrators to help manage their contract pharmacy arrangements.

- ⇒ NCSD: <https://www.ncsddc.org/resource/340b-and-ending-the-epidemics/> (select 340B Contract Pharmacy Toolkit)
- ⇒ HRSA: <https://www.hrsa.gov/opa/implementation/contract/index.html>
- ⇒ HRSA: [HRSA Guidance on contract pharmacy arrangements](#)



⇒ Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on “Grantees”, then select “Contract Pharmacy Medicaid Carve-in Checklist” or “Self-Audit: Contract Pharmacy”)

**Definitions:** See Appendix A.

**Procedures:**

1. [Covered Entity] has a written agreement in place with each contract pharmacy executed before OPAIS registration.
  - a. The agreement specifies all of the pharmacy locations at which 340B drugs will be dispensed.
  - b. The agreement includes all of HRSA’s required elements for a contract pharmacy arrangement. See HRSA, Notice Regarding 340B Drug Pricing Program -- Contract Pharmacy Services, 75 FR 10272, 10277 (Mar. 5, 2010).
2. [Covered Entity] registers each contract pharmacy location in OPAIS prior to the use of 340B drugs at that site.
3. [Covered Entity/Covered Entity’s TPA] purchases 340B drugs on Covered Entity’s 340B account(s) and has it shipped to each contract pharmacy.
  - a. [Specify inventory purchasing and shipping processes (e.g., bill-to/ship-to arrangements).]
  - b. [Covered Entity] uses a [physical separation/virtual replenishment model] at its contract pharmacies.
    - i. [*If a replenishment model is used*] [Discuss which software is used to track drugs; whether replenishment occurs at an 11-digit National Drug Code (NDC) level; and when orders are triggered (usually once a certain amount of inventory is dispensed).]
  - c. [Discuss any other procedures used to verify and monitor 340B inventory at the contract pharmacy]
4. [Covered Entity’s] contract pharmacies dispense 340B drugs to eligible patients.
  - a. [Insert how prescriptions are sent to the contract pharmacy (e.g., e-prescribing, hard copy, fax, phone etc.)]
  - b. [Insert how 340B eligible patients are identified (e.g., Covered Entity identifies a 340B patient at point of service and indicates eligibility on the prescription or through some other form of identification; patient is dispensed a non-340B drug and then the inventory is replenished with 340B product once [Covered Entity/TPA] confirms patient eligibility retrospectively etc.)]
5. [Discuss how billing for drugs is handled with the patient and insurer and how funds/fees are split between [Covered Entity], contract pharmacy, and TPA, if applicable.]

- a. [Covered Entity] [dispenses/does not dispense] 340B drugs to individuals insured under the State’s Medicaid fee-for-service program in accordance with Policy and Procedure on Medicaid and Prevention of Duplicate Discounts, [Insert Policy Number, if applicable].
- b. [Covered Entity] [does/does not dispense] 340B to individuals covered under the State’s Medicaid managed care program in accordance with Policy and Procedure on Medicaid and Prevention of Duplicate Discounts, [Insert Policy Number, if applicable].
- 6. [Covered Entity] ensures that patients are informed of their right to go to the pharmacy provider of their choice and are not required to receive their medications from [Covered Entity] or any of [Covered Entity’s] contract pharmacies.
  - a. [Specify how this is done? Is it discussed at each visit during which 340B drugs are prescribed? Is it noted in a patient’s medical record or on patient paperwork?]
- 7. [Covered Entity] [conducts/engages an independent auditor to conduct] annual audits of its contract pharmacies to ensure ongoing compliance with 340B Program requirements.
- 8. [Covered Entity] maintains auditable records on its contract pharmacy arrangements in accordance with Policy and Procedure on Compliance, Material Breach, and Self-Disclosure, [Insert Policy Number, if applicable].

**Approvals:**

Title	Signature	Approval Date

Organization Name:	Department:	
SUBJECT: <b>COMPLIANCE, MATERIAL BREACH, SELF-DISCLOSURE</b>	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
Page __ of __	Review Schedule:	

**Policy Purpose:** To ensure [Covered Entity’s] compliance with 340B Program requirements.

**Policy Statements:**

- [Covered Entity] retains auditable records demonstrating compliance with 340B Program requirements.
- [Covered Entity] regularly monitors 340B Program operations and compliance at all of its 340B qualified health care delivery sites [and contract pharmacies] and is able to identify instances of material breach.
- [Covered Entity] contacts the relevant parties, as appropriate, if instances of 340B noncompliance are discovered in accordance with federal, state, and local law.
- [Covered Entity] has a definition of material breach of 340B Program requirements triggering HRSA’s self-disclosure requirements.
- [Covered Entity] informs HRSA of instances of material breach, as required by 340B Program rules.

**Background/Sources:** Covered entities are required to comply with all 340B Program requirements, including the prevention of drug diversion and duplicate discounts. Since 2012, HRSA has been conducting routine audits of covered entities in its attempt to improve the oversight and integrity of the 340B Program. Each year, HRSA has increased the number of audits of covered entities. HRSA recommends that covered entities have 340B policies and procedures that address 340B compliance and that they conduct internal audits on a regular basis to verify compliance. If a covered entity discovers any material breach of 340B Program requirements, it is required to implement a corrective action plan to prevent additional instances of non-compliance and report (or self-disclose) any such finding(s) to HRSA.

⇒ NCSD: <https://www.ncsddc.org/resource/340b-and-ending-the-epidemics/> (select HRSA Audit Overview and Checklist)



- ⇒ HRSA: [340B Peer-to-Peer Program, 340B Compliance Improvement Guide](#)
  - ⇒ HRSA: Program Integrity/Audits - <https://www.hrsa.gov/opa/program-integrity/index.html>
  - ⇒ HRSA: Entity Self-Disclosure - <https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html>
  - ⇒ Apexus: [HRSA 340B Audit Overview](#)
  - ⇒ Apexus: [Sample HRSA 340B Audit Data Request](#)
- Apexus: <https://www.340bpvp.com/resource-center/340b-tools> (Click on “Grantees”, then select “Self-Disclosure to HRSA and Manufacturer Template” or “Establishing Material Breach Threshold”)

**Definitions:** See Appendix A.

**Procedures:**

1. [Covered Entity] retains auditable records demonstrating oversight of and compliance with 340B Program requirements.
  - a. [Describe how long records are retained as required per federal, state, and local law.]
  - b. [Describe the format in which records are retained and readily accessible.]
2. [Covered Entity] conducts internal audits of records and transactions involving participation in the 340B Program on a [describe frequency: monthly, quarterly, or semi-annual etc.] basis and develops a corrective plan to correct processes that result in noncompliance with 340B Program requirements.
  - a. [Describe the individuals responsible for the internal audit.]
  - b. [Describe the process of the internal audit -- what is reviewed, including the percentage of records (e.g., OPAIS records, the Medicaid Exclusion File, purchasing and dispensing records, patient medical records, inventory management records etc.)]
  - c. [Describe how variances in compliance are corrected and in what timeframe.]
  - d. [Describe how the results of internal audit are retained and readily accessible.]
3. [Covered Entity] defines a material breach as: [Insert the method for determining whether a breach rises to the Covered Entity’s definition of material breach. Some examples include: X% of total 340B purchases or impact to any one manufacturer; \$X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer; X% of total 340B inventory (units); X% of audit sample; X% of prescription volume/prescription sample]
  - a. [See [Apexus 340B Tools](#), Click on “Grantees”, and Select “Establishing Material Breach Threshold”]
4. [Covered Entity] contacts the state, Medicaid managed care organizations, and any impacted manufacturers, as appropriate, if instances of duplicate discount or drug diversion are discovered. See Policy and Procedure on Medicaid Billing

and Prevention of Duplicate Discounts [Insert Policy Number, if applicable] and Policy and Procedure on Patient Eligibility and Prevention of Drug Diversion [Insert Policy Number, if applicable].

5. [Covered Entity] reports instances of the material breach to HRSA in accordance with HRSA guidance.

**Approvals:**

Title	Signature	Approval Date



## APPENDIX A

### DEFINITIONS

**318 Grantee and Subgrantees:** An entity or program that receives a grant, in the form of direct funding or an in-kind contribution, that is authorized and funded under Section 318 of the Public Health Service Act to prevent and treat sexually transmitted diseases. Section 318 funds the PCHD (NOFO 19-1901) and EHE (NOFO 20-2010) grant programs.

**340B Ceiling Price:** The maximum amount a drug manufacturer can charge a covered entity for a 340B drug. The statutory formula is: 340B ceiling price = average manufacturer price (AMP) - Unit Rebate Amount (URA).

**340B Drug Pricing Program:** A federal program that requires pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program to provide outpatient drugs to 340B covered entities at or below the 340B ceiling price. The purpose of the 340B Program is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

**340B Identifier (340B ID):** A unique identification number provided by HRSA that identifies an entity as eligible for 340B discounted drugs.

**340B OPAIS:** The database operated by the Office of Pharmacy Affairs that includes information on eligible covered entities, contract pharmacy arrangements, and participating drug manufacturers. It also includes 340B pricing information.

**Average Manufacturer Price (AMP):** AMP is the average price paid to a manufacturer for a drug by wholesalers or retail community pharmacies for drugs distributed to retail community pharmacies.

**Contract Pharmacy:** A 340B covered entity may contract with a pharmacy or pharmacies to provide pharmacy dispensing services to the covered entity's eligible patients.

**Covered Entity:** A facility or program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program. It generally includes certain hospitals and federal grantees.

**Drug Diversion:** The sale or transfer of a 340B purchased drug to an individual who does not meet the 340B definition of a patient. This can also occur if drugs are sold or transferred to an entity that is not eligible for 340B pricing.

**Duplicate Discount:** A prohibited duplicate discount occurs when a covered entity purchases a drug at a 340B price and a Medicaid agency collects a rebate on the same unit of drug.

**Eligible Patient:** An individual is a patient of a 340B covered entity and eligible for 340B drugs if: (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; (2) the individual receives a health care service from a health care professional who is either employed or under contract or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided remains with the covered entity; and, (3) the individual receives a health care service or range of services that is consistent with the grant funding that made the entity eligible for 340B.

**Group Purchasing Organization (GPO):** An organization that leverages the collective purchasing power of its members to obtain discounts from manufacturers and other vendors.

**Health Industry Number (HIN):** HINs are randomly assigned 9-digit identifiers used by drug wholesalers and manufacturers to identify entities.

**Health Resources and Services Administration (HRSA):** An agency in the U.S. Department of Health and Human Services (HHS) primarily responsible for improving access to health care services for uninsured, underinsured, and medically vulnerable individuals. The Office of Pharmacy Affairs (OPA) is a division in HRSA and responsible for the oversight and implementation of the 340B Drug Pricing Program.

**Medicaid Carve-in or Carve-out:** When a covered entity elects to use 340B drugs with its Medicaid patients and indicates such in OPAIS, this is called "carving-in." When a covered entity does not use 340B drugs with its Medicaid patients, this is called "carving-out." It is generally an all or nothing election in Medicaid FFS programs. Covered entities should consult their state pharmacy laws and managed care contracts for guidance in dispensing 340B drugs to Medicaid managed care patients.

**Medicaid Exclusion File (MEF):** A database in OPAIS in which covered entities enter all of the Medicaid numbers and National Provider Identifiers (NPIs) that they intend to use to bill Medicaid fee-for-service programs for 340B drugs.

**National Provider Identifier (NPI):** A 10-digit identifier for health care providers used in financial and administrative transactions adopted under HIPAA.



**Office of Pharmacy Affairs (OPA):** The HRSA division responsible for oversight and implementation of the 340B Drug Pricing Program.

**Pharmaceutical Manufacturer:** A manufacturer is an entity engaged in the production, processing, packing, labeling, and distribution of prescription drugs and sells outpatient drugs to 340B covered entities.

**Recertification:** An annual process required by law whereby covered entities must verify continued eligibility for 340B drugs and compliance with 340B Program requirements.

**Replenishment:** Replenishment occurs when a non-340B drug is dispensed to a 340B-eligible patient by the contract pharmacy, and the covered entity later replaces the non-340B dispensed drug with a 340B drug.

**Unit Rebate Amount (URA):** The rebate amount owed by a manufacturer to a state Medicaid program based on a statutory formula. For brand name drugs, it is the greater of (23.1% of AMP or AMP - best price), plus price inflation penalties, if applicable. For generic drugs, 13% of AMP, plus the inflationary adjustment, if applicable.

**Wholesaler:** A drug wholesaler (also called a distributor) is an organization that provides drugs to entities, acting as the distributor between the drug manufacturer and the entity.

## APPENDIX B

### BLANK POLICY AND PROCEDURE TEMPLATE

This template can be cut and pasted as needed to include additional policies and procedures.

Organization Name:	Department:	
SUBJECT:	Approval Date:	
	Effective Date:	
Policy #:	Last Revised:	
Page __ of __	Review Schedule:	

**Policy Purpose:**

**Policy Statements:**

**Background/Sources:**

**Definitions:**

**Procedures:**

**Approvals:**

Title	Signature	Approval Date