**Purpose:** This tool provides a comprehensive template for entities self-reporting 340B noncompliance to the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA) and/or pharmaceutical manufacturers.

**Background/Instructions:** Covered entities are responsible for correcting any instance of noncompliance with 340B Program requirements. Once an issue is identified, the entity should follow their material breach policy requiring self-disclosure to HRSA (see 340B PVP Education Tool: [Establishing Material Breach Threshold](https://www.340bpvp.com/Documents/Public/340B%20Tools/establishing-material-breach-threshold.docxd.docx)), however it’s likely that the manufacturer will need to be contacted regardless of materiality for diversion and duplicate discount compliance issues.

1. Non-material breach: work with manufacturer(s) directly to resolve issue
2. Material breach: self-disclose to HRSA and work with manufacturer(s) to resolve

This tool includes the following resources to support resolving noncompliance:

1. Recommendations for disclosing noncompliance to manufacturers
2. Sample letter for disclosure to HRSA/OPA

*NOTE: Transparency with all parties is critical and best practice for covered entities (CEs) is to disclose the full extent and duration of their breach of compliance. The covered entity is expected to work in good faith with any affected manufacturer to mutually agree on a plan to address all breaches of compliance and how restitutions should be made.*

**Sample Letter to HRSA-OPA**

**[Place letter on CE letterhead]**

Date: [Date]

Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

Re: [Entity Name; 340B ID Number]

Dear [Director, HRSA OPA]:

The purpose of this letter is to disclose a 340B compliance issue regarding [duplicate discount, patient definition, GPO Prohibition, etc.] and describe a plan for corrective action.

[Entity] ([340B ID Numbers]) discloses the compliance issues presented in this letter occurred and is dedicated to achieving complete compliance with 340B requirements and prohibitions. [Entity] offers this letter to provide a summary of the circumstance and a transparent plan for corrective action.

1. **Entity and Partner** **Background**

[Entity] is a [340B Entity type] located in [City, State] and has participated in the 340B Program since [date]. [Include the following text if relevant [Entity] contracts with [Vendor] to provide [describe services] at [Location(s) at issue].]

1. **Summary of Noncompliance**

[Brief description] occurred during [date range] and was caused by [description]. The issue was first identified on [date, method]. [Insert detailed description of the issue and scope] *(Examples of the types of details to provide include:* *If* *the issue deals with eligibility, then when did the CE believe it became ineligible? How does this date compare to the date in 340B OPAIS? Or, if the issue relates to diversion or patient definition, what time period was involved?* *If the issue affected only some CE sites, which sites? If the issue involved a particular vendor or vendors, which ones and why?**)*

1. **External Affected Parties**

[Entity] has identified the following external parties that may have been affected: *(e.g., manufacturers, contract pharmacies, wholesalers. List should reflect level of detail known at time of disclosure/update; CE may be unable to identify* *all categories of external parties at the time of initial disclosure)*.

1. **Corrective Action Plan**
2. **Internal Corrective Action Plan (within entity/partners)**

[Entity] has taken corrective actions including [description, including dates, such as evaluation/change of software/vendor, changes to policy and procedure manual, contact/action with partners such as vendors/Medicaid, changes to 340B OPAIS/Medicaid Exclusion File information]

[Entity] plans to take the following corrective actions: [description, including dates/timeline, specific goals such as evaluation/change of software/vendor, changes to policy and procedure manual, contact/action with partners such as vendors/Medicaid, changes to 340B OPAIS/Medicaid Exclusion File information, etc.]

1. **External Corrective Action Plan (beyond entity/partners, including Medicaid, manufacturers, wholesalers, etc.)**

[Entity] has taken corrective actions including [description, including dates, such as contact with external parties such as manufacturers/wholesalers/Medicaid, etc.]

[Entity] plans to take the following corrective actions: [IMPORTANT NOTE: Best practice is that entities disclose the full extent of noncompliance on all NDCs and quantities as it relates to each manufacturer’s products. The entity should work with each manufacturer prior to taking any corrective action to remedy noncompliance]. [Description, including dates/timeline, specific goals such as contact/action/letters with external parties such as manufacturers/wholesalers/Medicaid, refunds issued or planned to be issued to manufacturers, changes on 340B OPAIS, etc.]

1. **Request for** **OPA** **Action**

[Entity] respectfully presents this self-reported compliance issue and a plan for corrective action. We request that OPA please contact [name, information] within 30 days of the date of this letter to discuss or amend this plan for corrective action. [Entity] will otherwise proceed with the corrective action plan as described in this letter on [date, 30 days from date of letter]. Thank you for your attention to this matter.

Sincerely,

[Signed, Entity Authorizing Official]
[Contact information for authorizing official: Name, title, mailing address, phone number, and email address]

Name of person submitting form
Organization

***This page intentionally left blank.***

*HRSA respectfully requests manufacturer communications described in the following pages not be sent to HRSA.*

**Common recommendations from Manufacturers regarding self-disclosing**

1. **Transparency among all parties is critical.** Best practice includes fully disclosing all NDCs and quantities involved, and working with the manufacturer to mutually agree on a corrective action plan including how any repayments should be made.
2. Manufacturers often require transaction-level data to validate against their internal data.
	1. If self-disclosing for diversion, the manufacturer may need the account number, invoice number, purchase date, quantity incorrectly purchased, price paid, and suggested restitution amount.
	2. If self-disclosing for duplicate discount violations the manufacturer may need a list of dispenses, purchase date, dispense date, NPI/Medicaid provider numbers, states impacted, quantities impacted, and suggested restitution amount.
3. The entity should **not** send a check, or attempt to offset ineligible 340B purchases with WAC purchases without first discussing with the manufacturer.
4. Entities can search 340B OPAIS for the appropriate manufacturer contact information here: <https://340bopais.hrsa.gov/manufacturersearch>.
	1. Manufacturers, are expected to keep contact information up to date.
	2. It is suggested to send the notice to multiple contacts at the manufacturer including Attention: Government Pricing Programs & Price Reporting
5. Sending a self-reporting letter, or receipt of such a letter by the manufacturer, does not waive any rights of the manufacturer, including audit rights.

Entities can use the sample letter to HRSA template (p2-3) and modify it to be a letter to a manufacturer. Section V should most likely be replaced with the following:

1. **Request for Manufacturer Action**

[Entity] respectfully presents this self-reported compliance issue and plan for corrective action. We request [manufacturer’s name] please contact [name, information] within 30 days of the date of this letter to discuss or amend this plan for corrective action. Thank you for your attention to this matter

Include entity contact information on each page (Name, title, address, phone number, and email)

Please check all that apply to this compliance issue:

\_\_\_\_\_ Program eligibility \_\_\_\_\_ Duplicate discount

\_\_\_\_\_ Diversion \_\_\_\_\_ GPO prohibition

\_\_\_\_\_ Other (please describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Table 1: Entity Data, Contract Pharmacy Data

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 340B ID | HIN (if known) | Wholesaler or Distributor Name and Account Number | Entity Name, Subdivision Name | Address 1 | Address 2 | City | State | Zip | HRSA Start Date | HRSA Term. Date |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ship To or Contract Pharmacy Name | HIN (if known) | Wholesaler or Distributor Name  | Wholesaler Account Number | Address 1 | Address 2 | City | State | Zip | Contract Start Date | Contract Term. Date |
|  |  |  |  |  |  |  |  |  |  |  |

Table 2: [Manufacturer] Repayment/Credit Summary

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **11 digit NDC**  | **Pkg Units** | **Product Shipped to:****(Name, address)** | **Number of units (please report at the NDC level)**  | **[Entity] 340B Acquisition Costs per unit Represented by NDC** | **WAC or Contract Price per unit Represented by NDC** | **Contract Used to Purchase (Include Contract Number)** | **Invoice Date** | **Invoice Number** | **Chargeback Memo Number** | **Wholesaler** | **Total Refund/Credit (as agreed upon between the CE and manufacturer)**  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| TOTAL |  |  |  |  |  |  |  |  |  |  |  |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.*

*© 2022 Apexus.  Permission is granted to use, copy, and distribute this work solely for 340B covered entities and Medicaid agencies.*