**Purpose:** This sample document is intended to provide a comprehensive template that may be used by entities to self-report 340B non-compliance to OPA and Manufacturers.

**Instructions:** Entity leaders should customize these documents with details specific to their   
circumstances.

**Contents:** Included is a sample Letter to OPA/Manufacturers, a suggested data format (Appendix I), and recommendations from manufacturers.

**Sample Letter to OPA/Manufacturers**

Date

FROM:   
[Entity’s Authorizing Official]

TO:  
Director, Office of Pharmacy Affairs  
Health Resources and Services Administration  
5600 Fishers Lane, 10C-03  
Rockville, MD 20857

MFR INFORMATION

Dear [Director, OPA] and [Manufacturer]:

This purpose of this letter is to disclose a 340B compliance issue regarding [duplicate discount, patient definition, GPO Prohibition, Orphan Drug Exclusion] and describe a plan for corrective action. The letter is divided into 5 sections:

1. **Background**
2. **Summary of Non-compliance**
3. **Corrective Action Plan**
4. **Request for Manufacturer Action**
5. **Appendix I (data)**

Based upon our calculations, [Manufacturer] is entitled to a refund of [$amount] from [Entity]. [Entity] discloses that the compliance issues presented in this letter occurred and [Entity] 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. **Background**
2. **Entity and Partner Information**

Table 1: 340B Entity Information

|  |  |  |  |
| --- | --- | --- | --- |
| **Entity Name  (list all parent and child sites)** | **340B ID** | **Type of Pharmacy Services  (in-house, physician dispensing, contract pharmacy(ies), mail order, mixed-use inpatient/outpatient setting, etc.)** | **Involved in Non-compliance (Y/N)** |
|  |  |  |  |
|  |  |  |  |

Table 2: Partner Information

|  |  |  |  |
| --- | --- | --- | --- |
| **340B Partner Name** | **340B Partner Type  (contract pharmacy, PBM, vendor, wholesaler, etc.)** | **Description of Partner’s Business Role** | **Involved in Non-compliance (Y/N)** |
|  |  |  |  |
|  |  |  |  |

1. **Entity 340B Scope of Services**The scope of the services listed in Table 1 includes providing pharmacy services to approximately [number] patients annually, which includes approximately [number] prescriptions annually. A brief overview of our pharmacy operations includes [brief description, diagram, chart, etc.]. Additional operational or policy background about our entity that is relevant to this compliance issue includes [brief description].
2. **Summary of Non-compliance**The compliance issue involved the entity sites and partners identified in Tables 1 and 2 as “involved in non-compliance.” The specific issue [brief description] occurred from [date range] and was caused by [description]. The issue was first identified by [staff] on [date, method] and reported to [staff position]**.** Specific products involved include [NDC, #packages, total quantity]. (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 on the OPA website? Or, if the issue relates to diversion or patient definition, what time period was involved?)

A**. External Impacted Parties**[Entity] has identified the following external parties (parties that are not part of the covered entity or its partners listed in Table 2) that may have been impacted:

Table 3: External Parties Impacted

|  |  |  |
| --- | --- | --- |
| **Impacted Party** | **Estimated Impact Description** | **Estimated Impact Amount** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **Corrective Action Plan**
2. **Internal Corrective Action Plan (within entity/partners)**[Entity] has already 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 database/Medicaid Exclusion File information, etc.]  
     
   [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 Database/Medicaid Exclusion File information, etc.]
3. **External Corrective Action Plan (beyond entity/partners, including Medicaid, manufacturers, wholesalers, etc.)**

[Entity] has already 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: [description, including dates/timeline, specific goals such as contact/action/letters with external parties such as manufacturers/wholesalers/Medicaid, refunds issued to manufacturers via check, credit-rebill, or other means, curtailment of future 340B purchases to offset inappropriate purchases, change to Orphan Drug opt-in/opt-out decision on the 340B Database, etc.] Additional supporting data and a detailed description of refund determination may be found in Appendix I. The plan is to process refunds on [date—within x days of receiving responses from manufacturers].

Table 4: Manufacturer Repayment Summary[[1]](#footnote-1)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Manufacturer Name** | **NDC** | **Total Packages** | **Total [Entity] 340B Acquisition Costs** | **Total Refund** |
|  |  |  |  |  |
|  |  |  |  |  |
| TOTAL |  |  |  |  |

1. **Request for Manufacturer Action**

[Entity] intends to activate this plan involving [description of plan: issue check, credit-rebill, forego future 340B purchases to offset improper purchases] for [time frame of plan] on [plan start date]. [Entity] will proceed with this plan within 30 days of [Manufacturer’s] written acceptance of this plan.

If the manufacturer has questions, or would like to discuss this plan further, please contact: [Entity Contact Information] by [date].

If [Entity] has not received any response from [Manufacturer] by [date—suggested date approximately 90 days from date letter sent], [Entity] will assume [Manufacturer] does not wish to be a party to the corrective action plan.  
  
[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]

**V. Appendix I: Data to Support Plan**

Contact Information for CE Official (include on each page of Appendix)  
Name, title, mailing address, phone number, and email address

Please check all that apply to this compliance issue:

⃝ Program eligibility/GPO ⃝ Diversion ⃝ Duplicate discount ⃝ Orphan Drug

Time Period involved: (MM-DD-YYYY until MM-DD-YYYY)

Table 5: Entity Data

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 340B ID | HIN | Entity Name, Sub-Division Name | Address 1 | Address 2 | City | State | Zip | HRSA Start Date | HRSA Term. Date |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ship To or Contract Pharmacy Name | HIN | Address 1 | Address 2 | City | State | Zip | Contract Start Date | Contract Term. Date |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Table 5: [Manufacturer] Repayment/Credit Summary

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NDC**  **(11 digit)** | **Product Shipped to: (Name of entity, shipping address, or contract Rx)** | **Contract Used to Purchase (Include Contract Number)** | **Invoice Date** | **Invoice Number** | **Charge-back Memo Number** | **Wholesaler** | **Package Units Purchased at 340B Price for Refund/ Credit (A)** | **WAC Price (or Contract Price) (B)[[2]](#footnote-2)** | **340B Price (C)** | **Difference between WAC (or Contract Price) and 340B Price (D, which equals B-C)** | **Total Refund/Credit (A\*D)** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| TOTAL |  |  |  |  |  |  |  |  |  |  |  |

Definitions: (entity to define)

Total packages-

[Entity] 340B Acquisition Cost-

**Recommendations from Manufacturers Regarding Covered Entity (CE) Self-Reporting**

1. Wholesaler involvement is critical to resolving any issue. Entities should report the wholesaler(s) involved to the manufacturer, and the wholesaler needs to work with both the CE and the manufacturer. The manufacturer will most likely need chargeback transaction level data to resolve issues, so the CE should get the supporting data directly from the wholesaler when they are preparing the communication to the manufacturer.
2. The manufacturer needs transaction level data (actual price paid and dates) to validate against their internal data. Estimated price or wholesale price information cannot be used by manufacturers to resolve the issue.
3. No action should be taken by the CE until they have a chance to work with the manufacturer to determine a mutually agreed upon plan to address how the adjustments should be made.
4. The CE should not send a check, or reverse chargebacks without first discussing with the manufacturer.
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.

*This tool, written to align with OPA policy, is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by the Office of Pharmacy Affairs 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 each stakeholder to include legal counsel as part of their program integrity efforts.*

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1. Description/definition of pricing source(s)/date(s) used in calculation should be included in the letter. Additional detail (such as manufacturer-specific data by NDC) may be placed in an Appendix. [↑](#footnote-ref-1)
2. Specify the non-340B Price at which the package units for refund/credit should have been purchased by the 340B Covered Entity, whether WAC Price or Contract Price. [↑](#footnote-ref-2)