**Purpose:** This tool provides a sample self-audit for community health centers (CH/FQ/FQHC/FQHCLA/NH) to comply with 340B requirements regarding the prevention of duplicate discounts.

**Background:** Section 340B(a)(5)(A)(i) of the Public Health Service Act prohibits duplicate discounts—that is, a covered entity purchasing a drug at a 340B price and a manufacturer paying a Medicaid rebate on that same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

*Note: The data included in the Medicaid Exclusion File is provided by covered entities for drugs billed under Medicaid fee-for-service and does not apply to Medicaid managed care organizations. HRSA encourages 340B covered entities to work with their state to develop strategies to prevent duplicate discounts on drugs reimbursed through Medicaid Managed Care Organizations (MCOs)*

**This self-audit tool is part of a series focusing on three compliance elements:**

 **1. Eligibility**

 **2. Prevention of Diversion**

 **3. Prevention of Duplicate Discounts**

Prior to completing the Prevention of Duplicate Discounts Self-Audit Tool, covered entities are encouraged to:

* Map their 340B drug universe (this tool is available in [Word](https://docs.340bpvp.com/documents/public/resourcecenter/340b-universe-mapping-template.docx) and [Excel](https://docs.340bpvp.com/documents/public/resourcecenter/340b-universe-mapping-template.xlsx))
* Complete the [Covered Entity Self Audit: Policy and Procedure](https://docs.340bpvp.com/documents/public/resourcecenter/covered-entity-self-audit-policy-and-procedure.docx).

**Instructions:** Covered entities should complete this tool quarterly, however exact parameters should be adjusted to meet entity-specific auditing needs.

1. Identify and collect relevant data, as follows:
2. Policies and procedures related to drugs administered or dispensed as part of medical encounters and prescriptions dispensed at entity-owned outpatient/retail pharmacies
3. Billing codes identifying Medicaid payers
4. Medicaid provider numbers(s) (MPN) and National Provider Identifier (NPI) number(s) used to bill 340B and non-340B drugs
5. 340B and non-340B drug administration/dispense records for the most recent 3 month period.
6. Billing records corresponding to administration/dispense records identified in step 1d
7. HRSA Medicaid Exclusion File (MEF) listing for the same 3 month period identified in step 1d

(<https://340bopais.hrsa.gov/medicaidexclusionfiles>)

1. State Medicaid 340B billing policies and procedures for 340B drugs administered/dispensed
2. Communication with state Medicaid agency (if applicable)
3. Select audit samples. Modify audit sample size based on entity’s policies and procedures.
	1. **Carve-out audit sample**: For the main site, each associated site, and each entity-owned retail pharmacy that bills *non-340B drugs* to Medicaid, select all drug administration/dispense records for the audit period
	2. **Carve-in audit sample**: For each parent, offsite outpatient facility, and entity-owned retail pharmacy that bills *340B drugs* to Medicaid, randomly select 20 340B drug administrations/dispenses for which Medicaid was the payer (including primary, secondary, and tertiary billing codes) for the audit period

|  |
| --- |
| **CHC Duplicate Discount Self-Audit Tool** |
| 1. Main site entity name
 |  |
| 1. Main site entity and associated site(s) clinic 340B ID(s)
 |  |
| 1. Date of the LAST self-audit
 |  |
| 1. Audit sample period of LAST self-audit
 |  |
| 1. Date of THIS self-audit
 |  |
| 1. Audit sample period of THIS self- audit

*(Note: 1st day of audit sample period should be the day after the last day of the previous audit sample)* |  |
| 1. Name and title of individual completing THIS self-audit
 |  |
| 1. Signature of individual completing THIS self-audit
 |  |
| 1. Summary of results:

**Note areas for improvement identified**Review results with 340B steering committee and determine next steps to resolve issues with impacted manufacturers and whether results are indicative of a material breach leading to a self-disclosure to HRSA.* Refer to [Establishing Material Breach Threshold Tool](https://docs.340bpvp.com/documents/public/resourcecenter/establishing-material-breach-threshold.docx) as a resource
 |
| 1. Actions to be taken:

Develop a corrective action plan, if applicable.* Attach corrective action plan that addresses the compliance issues identified in this self-audit and resolution procedure with impacted manufacturers
* Attach corrective action plan resolutions, including completion date, when finished
 |

|  |
| --- |
| **Compliance Element: Prevention of Duplicate Discounts***Ensure that the covered entity’s Medicaid billing practices are consistent with its 340B OPAIS listing of carving in (entity uses 340B drugs for its Medicaid patients and bills Medicaid for drugs purchased at 340B prices) or carving out (entity does not use and bill Medicaid for drugs purchased at 340B prices).* *Duplicate discounts are prohibited by section 340B(a)(5)(A) of the PHSA; that is, a drug purchase shall not be subject to both a discount under section 340B of the Public Health Service Act and a Medicaid rebate under section 1927 of the Social Security Act.* |
| **CARVE-OUT ASSESSMENT****Table 1*** List the name of each main site, associated site, and entity-owned retail pharmacy listed on 340B OPAIS in column 1
* List the 340B ID of the main site and associated site(s) in column 2
	+ Note that entity-owned retail pharmacies do not have a 340B ID. For these pharmacies, list the 340B ID(s) for which the pharmacy is listed as a shipping address in 340B OPAIS.
* Review the Medicaid Exclusion File for the audit period to complete column 3
 |
|

|  |  |  |
| --- | --- | --- |
| **(1)****Name of main site, associated site(s), or entity-owned retail pharmacies** | **(2)****340B ID** | **(3)** **Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) are not listed on the HRSA Medicaid Exclusion File?** |
| **YES** | **NO** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 1 Assessment Questions** |  **Yes** |  **No** | **N/A** | **Unsure** |
| 1. **Are the Medicaid provider number (MPN) and National Provider Identifier (NPI) numbers used by health center sites and entity-owned retail pharmacies to bill non-340B drugs excluded from the HRSA Medicaid Exclusion File?**

Answer “Yes” to the question only if all answers are YES in column 3, “Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) are not listed on the HRSA Medicaid Exclusion File.”  |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **For the main site, associated sites, and entity-owned retail pharmacies that carve-out, is Medicaid *never* the payer for 340B drugs?**
* For the main site, associated sites, and entity-owned retail pharmacy

 listed in Table 1, identify billing codes used to bill Medicaid claims.* From the medical encounter and pharmacy dispensing

and billing records, select *all* administrations/dispenses for the audit period (including primary, secondary and tertiary billing codes)* Sort report(s) by billing codes
* Verify that a Medicaid billing code is not the payer for any 340B drug.

\*Answer “Yes” to the question only if a Medicaid billing code is not the payer for any 340B drug. |  |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

|  |
| --- |
| **CARVE-IN ASSESSMENT****Table 2*** List the name of each main site, associated site, and entity-owned retail pharmacy that bills 340B drugs to Medicaid in column 1
* List the 340B ID of the main site and associated site(s) in column 2
	+ Note that entity-owned retail pharmacies do not have a 340B ID. For these pharmacies, list the 340B ID(s) for which the pharmacy is listed as a shipping address in 340B OPAIS.
* List all state Medicaid programs the clinic/pharmacy bills in column 3A
* List the Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) used to bill 340B drugs to state Medicaid program in columns 3B and 3C
* Review the Medicaid Exclusion File for the audit period to complete column 4
* Locate Medicaid policies for billing of 340B drugs administered/dispensed as part of outpatient medical encounters and for billing of 340B drugs dispensed at retail pharmacies to complete column 5
 |
|

|  |
| --- |
| **Table 2****Carve-In MEF Verification Table****Time period tested: begin date \_\_\_\_\_to end date\_\_\_\_\_\_** |
|  **(1)** **Name of main site, associated site(s), or entity-owned retail pharmacy(ies)** | **(2)****340B ID** | **(3)****Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) used to bill Medicaid for 340B drugs** | **(4)****Are MPNs and NPIs listed accurately on the HRSA Medicaid Exclusion File?** | **(5)****State Medicaid 340B billing policy available?** |
| **(A)****State** | **(B)****MPN** | **(C)****NPI** | **YES** | **NO** | **YES** | **NO** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

 |
| **Table 2 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Are all Medicaid provider numbers (MPNs) and National Provider Identifier (NPI) numbers used to bill 340B drugs to Medicaid accurate on the HRSA Medicaid Exclusion file for all state Medicaid programs in which the entity sites/pharmacies participates?**

Answer “Yes” to the question only if all answers are “YES” in column 4, “Are MPNs and NPIs listed accurately on the HRSA Medicaid Exclusion File?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |
| 1. **For each entity site/pharmacy listed in Table 2, is the state Medicaid 340B pharmacy billing policy readily available for all state Medicaid programs in which the site participates?**

Identify state specific requirements for each state Medicaid agency (E.g. UD modifier on UB-04 claim form or NCPDP coding on pharmacy claims)PVP resource for state Medicaid contacts and requirements: <https://www.340bpvp.com/resource-center/medicaid/> Answer “Yes” to the question only if all answers are “YES” in column 5, “State Medicaid 340B billing policy available?” |  |  |  |
| *If response is “No” or “Unsure,” explain: (Identify and discuss each outlier)* |

|  |
| --- |
| **CARVE-IN BILLING VERIFICATION****Table 3*** For each of the 20 340B drug administration/dispenses selected in step 2b of the instructions (page 1) and for the date range selected, verify that the covered entity’s carve-in practice is consistent with its listing in the MEF and state Medicaid agency’s billing requirements to complete columns 1-5
* Verify that the MPNs and NPIs used to bill Medicaid are those listed in the Medicaid Exclusion File (MEF) to complete column 6
* Review mechanisms required by each state Medicaid agency to identify a drug as 340B when it is billed as part of an outpatient medical encounter (e.g. UD modifier on UB-04 claim form) and from a retail pharmacy (e.g. defined NCPDP code)
* Verify that the state Medicaid billing practice is being followed, and complete column 7
* Attach actual data to substantiate Medicaid billing for each 340B drug administration/dispense
 |
|

|  |
| --- |
| **Table 3****Carve-In Billing Verification Table****Time period tested: begin date \_\_\_\_\_to end date\_\_\_\_\_\_** |
| **(1)****Sample ID****(prescription number or dispense tracking number)** | **(2)****Date of dispense** | **(3)****Name of 340B drug dispensed or****administered** | **(4)****Name of main or associated site(s) that administered/dispensed the drug, or entity owned retail pharmacy that dispensed the drug** | **(5)****Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) used to bill Medicaid**  | **(6)****Are MPNs and NPIs used to bill Medicaid consistent with those listed on the MEF?** | **(7)****State Medicaid 340B billing requirements followed?** |
| **YES** | **NO** | **YES** | **NO** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

 |
| **Table 3 Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **For each 340B drug sample tested in Table 3, are the Medicaid provider numbers (MPNs) and National Provider Identifier (NPI) number(s) used to bill Medicaid consistent with those listed in the Medicaid Exclusion File?**

Answer “Yes” to the question only if all answers are “YES” in column 6, “Are MPNs and NPIs used to bill Medicaid consistent with those listed on the MEF?” |  |  |  |
| *If response is “No” or “Unsure,” explain:* |
| 1. **For each 340B drug sample tested in Table 3, is Medicaid billed according to state requirements?**

Answer “Yes” to the question only if all answers are “YES” in column 7, “State Medicaid 340B billing requirements followed?” |  |  |  |
| *If response is “No” or “Unsure,” explain:* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Does the covered entity have a system in place to ensure that a non-340B drug is never billed to Medicaid using a Medicaid Provider Number and National Provider Identifier (NPI) number that is listed on the MEF?**
* For each clinic and entity-owned retail pharmacy listed in Table 2, identify billing codes used to bill Medicaid claims.
* From the administration/dispense records and corresponding billing records at each clinic and entity-owned retail pharmacy listed in Table 2, and for the same 3 month period, identify all drug administrations/dispenses billed to Medicaid.
* Validate that there is no instance of a non-340B drug being billed to Medicaid using a Medicaid provider number and National Provider Identifier number listed on the MEF

Answer “Yes” to the question only if there was no instance of a non-340B drug being billed to Medicaid using a Medicaid provider number and National Provider Identifier number listed on the MEF. |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* |

*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.*

*© 2020 Apexus. Permission is granted to use, copy, and distribute this work solely for 340B covered entities and Medicaid agencies.*