**340B Contract Pharmacy Carve-In for Medicaid Registration**

**Purpose:** In this tool, you will find the contract pharmacy carve-in for Medicaid request checklists and form with instructions on how to complete the form for HRSA’s review. This tool includes two checklists and a form to complete to ensure covered entity compliance with contract pharmacy guidelines. Each section of the form is linked to the instructions so that you can navigate back and forth between the instruction section and form.

**Background:** Covered entities that use contract pharmacy arrangements are expected to comply with all requirements in the Final Notice regarding Contract Pharmacy Services published in 75 Fed. Reg. 10272 (Mar. 5, 2010). Under those guidelines, contract pharmacies serving Medicaid fee-for-service (FFS) patients are prohibited from using 340B drugs to dispense Medicaid FFS prescriptions and must carve-out unless:

1. the covered entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts;
2. the covered entity has reported any such arrangement to HRSA; and
3. HRSA has approved such arrangement.

Entities are responsible for ensuring that all applicable elements listed in this document are addressed. Please read each section carefully and provide complete answers. HRSA reserves the right to request additional information or ask questions regarding the request.

Contract pharmacy carve-in requests are reviewed by HRSA, and once approved, the arrangement is listed with a carve-in effective date in the 340B Office of Pharmacy Affairs Information System (340B OPAIS). The carve-in effective date will be the first day of the following quarter after the request is approved. The start date will be reflected in the covered entity’s 340B OPAIS record, as well as in the Contract Pharmacy Carve-Ins Report. A covered entity may not dispense 340B drugs to Medicaid FFS patients at the contract pharmacy until a carve-in effective date is listed in the 340B OPAIS.

Currently, HRSA’s policy for duplicate discount is specific to Medicaid FFS. However, states may place certain requirements on covered entities regarding the prevention of duplicate discounts for covered outpatient drugs reimbursed by Medicaid managed care organizations (MCOs). HRSA encourages 340B covered entities to work with their state to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs. For more information see the 340B Drug Pricing Program December 12, 2014 policy release, “[Clarification on Use of the Medicaid Exclusion File](https://www.hrsa.gov/sites/default/files/hrsa/opa/clarification-medicaid-exclusion.pdf).”

**Prior to Completing Contract Pharmacy Carve-In Request Checklist**

The following checklist will help the covered entity determine that the state Medicaid FFS program that they intend to carve-in will allow carving-in at contract pharmacies. It is recommended to complete these steps before submitting the Contract Pharmacy Medicaid Carve-In Form to ensure that carving-in Medicaid FFS at contract pharmacies is permitted.

|  |  |  |
| --- | --- | --- |
|  | **Action** | **Description** |
|[ ]  Determine if the state allows covered entities to carve-in Medicaid FFS at contract pharmacies | Before starting a contract pharmacy carve-in request, review your state’s Medicaid and [Children’s Health Insurance Program (CHIP) plan and amendments](https://www.medicaid.gov/state-resource-center/medicaid-state-plan-amendments/index.html). The plan—specifically, the state plan amendments (SPAs)—may include valuable information about your state’s regulations regarding carving-in 340B at contract pharmacies. Covered entities should ensure that the state Medicaid FFS program allows contract pharmacy carve-in arrangements. If your SPA does not allow contract pharmacy carve-in please work with your state Medicaid office and the Centers for Medicare & Medicaid Services (CMS) to revise the SPA. If you’d like 340B contact information for individual state Medicaid programs, go to <https://www.340bpvp.com/resource-center/medicaid>. A Medicaid and CHIP state plan is an agreement between a state and the federal government describing how that state administers its Medicaid and CHIP programs. The state plan sets out groups of individuals to be covered, services to be provided, methodologies for providers to be reimbursed, and the administrative activities that are underway in the state. |
|[ ]  Review the state’s SPA to determine requirements for carving-in Medicaid at contract pharmacies | When a state is planning to make a change to its program policies or operational approach, it will send SPAs to CMS for review and approval. States also submit SPAs to request permissible program changes, make corrections, or update their Medicaid or CHIP state plan with new information. |
|[ ]  Review the covered entity’s contract pharmacy contracts and registrations in OPAIS  | Contract pharmacy contracts should list each contract pharmacy location participating in the contract pharmacy arrangement by name and address. In addition, the contract should identify all covered entity sites, either individually by name and address or by an inclusive statement of all covered entity sites, participating in the contract pharmacy arrangement.In the 340B OPAIS, each carve-in contract pharmacy location must be registered to each covered entity site (parent and child/grantee site 340B IDs) that will participate in the contract pharmacy carve-in arrangement. If each contract pharmacy location is not registered to each covered entity site participating in the carve-in arrangement, entities may register contract pharmacies during the next open registration period. Please note: contract pharmacies should not be listed under the covered entities shipping address section, and should be registered only as a contract pharmacies. |

**340B Contract Pharmacy Medicaid Carve-In Form**

In each table, if more information needs to be added to a table, please add additional rows. [(click](#Instructions) **[here](#Instructions)** [to go directly to the instructions section)](#Instructions)

**Table 1.**

|  |
| --- |
| **Covered Entity Information** |
| 1. Parent/grantee entity’s name |  |
| 1. Parent/grantee entity’s 340B ID
 |  |
| 1. Parent/grantee entity’s physical address (including suite number, if applicable)
 |  |
| 1. Contact information for parent/grantee entity’s authorizing official
 |  |
| 1. Contact information for parent/grantee entity’s primary contact
 |  |

**Table 1a**. [(click **here** for instructions to this section)](#Instructions)

|  |
| --- |
| **List All Covered Entity Sites Carving-In Medicaid at Contract Pharmacies** |

|  |  |  |
| --- | --- | --- |
| **340B ID** | **Covered Entity Name – Subdivision Name** | **Street Address** |
| CH123456 | Community Health Center – Anytown Clinic | 1234 Clinic town Rd, Anytown, MD 12345 |
|  |  |  |
|  |  |  |

**Table 1b.** [(click **here** for instructions to this section)](#b)

|  |
| --- |
| **List All Contract Pharmacy Locations Carving- In Medicaid** |

|  |  |  |
| --- | --- | --- |
| **Contract Pharmacy Name** | **Contract Pharmacy Address** | **Contract Pharmacy NPI that will be used to bill Medicaid** |
| Pharmacy Name #36 | 1234 Pharmacy Rd, Anytown, MD 12345 | 1053373480 |
| Pharmacy Name #54 | 5678 Pharmacy Rd, Anytown, MD 45678 | 1336236272 |
|  |  |  |
|  |  |  |
|  |  |  |

**Table 1c.** [(click **here** for instructions to this section)](#c)

|  |
| --- |
| **Medicaid States That Will Be Carved-In By Each Covered Entity Site At Contract Pharmacy** **And Medicaid Billing Information** |

|  |  |  |  |
| --- | --- | --- | --- |
| **(1) Medicaid state to be carved-in***List one state per row* | **(2) Covered entity site (340B ID) that will carve- in the Medicaid state at contract pharmacy(ies)***List one covered entity site (340B ID) per row* | **(3) State assigned Medicaid number(s) that will be listed on the Medicaid bill to the state** | **(4) Contract Pharmacy NPI(s) that will be listed on the Medicaid bill to the state***May list more than one contract pharmacy per covered entity site (340B ID) and Medicaid state* |
| OR | DSH123456 | None | 1053373480, 1336236272 |
| OR | DSH123456A | None | 1053373480, 1336236272 |
| WA | DSH123456Z | 123456 | 1234567890 |
|  |  |  |  |

**Table 1d.** [(click **here** for instructions to this section)](#d)

|  |
| --- |
| **List of States Carving- In and State Medicaid Agency Contact Information** |

|  |  |  |
| --- | --- | --- |
| **Medicaid State to be Carved-In**  | **Contact Name** | **State Medicaid Agency Name, State Medicaid Agency Contact Address, Email, Phone** |
| OR | Mr. Medicaid Coordinator | OR HCA, 1234 Healthcare Rd, Anytown, OR 12345 MrMedicaid@medicaid.state.us 555-666-1212 ext 34 |
| WA | WA HCA, Mr. Medicaid Coordinator | 1234 Healthcare Rd, Anytown, WA 12345 MrMedicaid@medicaid.state.us 555-666-1212 ext 34 |

**Table 2.** [(click](#Medicaid) **[here](#Medicaid)** [for instructions to this section)](#Medicaid)

|  |
| --- |
|  **State Medicaid Policies and Plan Amendment References** |
| **Medicaid State to be Carved- In** | **Link to State Medicaid Plan Amendment** | **Location or reference to use of 340B Drugs at Contract Pharmacies**  |
| OR | Example hyperlink: <https://www.medicaid.gov/medicaid/spa/downloads/or-20-0017.pdf>  | Page 11, Section D-Benefits, number 6  |
| WA | Example hyperlink: <https://www.medicaid.gov/medicaid/spa/downloads/or-20-0017.pdf>  | Page 11, Section D-Benefits, number 6  |
|  |  |  |

**Table 3.** [(click](#T3i) **[here](#T3i)** [for instructions to this section)](#T3i)

|  |  |  |
| --- | --- | --- |
| **Medicaid State** | **Carve-in or Carve-out at Contract Pharmacy** | **Summary of Covered Entity’s Policy and Procedure****to Prevent Duplicate Discount at Contract Pharmacies** |
| OR | Carve-in | Sample: As required by the state of OR, 340B drug claims to Medicaid FFS will be flagged with an xx modifier at the point of sale. As summarized in table 1c above, the contract pharmacies will include the Medicaid billing number the covered entity site lists on the MEF. Monthly, we will review 100% of the 340B Medicaid FFS claims to ensure the xx modifier was included on the claim to the state. Quarterly, we will review the Medicaid exclusion file to ensure that each covered entity site lists the Medicaid billing number listed on 340B claims from contract pharmacies. In addition, we will review the state’s 340B billing requirements on a quarterly basis and update our policies and procedures, practice, and 340B OPAIS records accordingly. |
| WA | Carve-in | Summary of policies and procedure. |
| All states except OR and WA | Carve-out | Sample: Except for OR and WA Medicaid, all other state Medicaid FFS plans will be carved-out. On a monthly basis we will review 100% of our contract pharmacy claims to ensure that Medicaid FFS (except for WA Medicaid) was not billed for 340B drugs. |
|  |  |  |

**Table 4.** Submission Checklist [(click **here** for instructions to this section)](#Policies)

Email your completed Contract Pharmacy Medicaid Carve-in Request Form along with the required documentation listed below to OPAexclusion@hrsa.gov**.**

|  |
| --- |
| **Contract Pharmacy Medicaid Carve-In Request Submission Checklist** |

|  |
| --- |
| **General** |
|[ ]  Complete all sections of Contract Pharmacy Medicaid Carve-in Request Form |
| **Duplicate Discount Prevention** |
|[ ]  Submit electronic copy of entity’s policies and procedures on prevention of duplicate discounts at contract pharmacies |
|[ ]  Highlight the specific section and page in the covered entity’s policies and procedures on the prevention of duplicate discounts  |
| **Contract Pharmacy Oversight** |
|[ ]  Submit electronic copy of the covered entity’s policies and procedures on contract pharmacy oversight |
|[ ]  Highlight the specific section and page in the covered entity’s policies and procedures on prevention of duplicate discounts at contract pharmacies |
|[ ]  Provide a listing of all auditable record sources available from all involved parties |
| **Attestations** |
|[ ]  Statement from covered entity’s authorizing official attesting compliance with federal/state/local/other laws, regulations and guidances (sample [**here**](#Sample1)) or this may be included in a cover letter |
|[ ]  Written acknowledgment/ approval by state Medicaid representative (sample [**here**](#Sample2)) |

**Instructions for Completing Contract Pharmacy Carve-In Form**

1. **Entity and Contract Pharmacy Information**

Enter all of the covered entity information including entity name, 340B ID, address and contact information for authorizing official and primary contact. Note: only the authorizing official can sign the attestation.

* 1. List all covered entity 340B IDs, include all 340B IDs that will carve-in Medicaid FFS at one or more contract pharmacy locations [(click **here** to go to Table 1a).](#Table1a) All participating covered entity sites must be listed as carving-in to the 340B Program in OPAIS prior to submitting the carve-in request. If not currently listed as carved-in on the Medicaid Exclusion File (MEF), entities may submit a change request to [340B OPAIS](https://340bregistration.hrsa.gov/login) and begin carving-in to the 340B Program in the following quarter.
	2. List the names and addresses of all contract pharmacies requesting to carve-in. All contract pharmacies must be registered under each participating covered entity site (this includes all 340B IDs) prior to submitting the carve-in request [(click **here** to go to Table 1b).](#Table1b) If the contract pharmacies are not registered, entities may register them during the next open registration period.
1. List each Medicaid state to be carved-in at contract pharmacy. For each Medicaid state, list each covered entity site (340B ID from table 1a) and the contract pharmacy NPI (from table 1b) to identify the contract pharmacy location(s) that will serve patients of the covered entity site and carve-in the Medicaid state. List the billing number(s) that will be listed on the Medicaid bill to the state. Billing number(s) may include the billing provider’s national provider identifier (NPI) only, state-assigned Medicaid number only, or both the NPI and state-assigned Medicaid number. List the date the covered entity site would like to begin carving-in the Medicaid state at the identified contract pharmacy location(s) [(click **here** to go to Table 1c)](#Table1c).

Each covered entity site (340B ID) listed in column 2 must:

* register the contract pharmacy location(s) listed in column 3 in the 340B OPAIS before submitting the carve-in request;
* answer “yes” to the Medicaid billing question for all involved 340B IDs in the 340B OPAIS and list each Medicaid state from column 1 and the corresponding Medicaid billing number(s) from columns 4 and 5; and
* not begin carving-in at a contract pharmacy location until a contract pharmacy carve-in effective date is listed in the 340B OPAIS.
1. List each Medicaid state to be carved-in (from table 1c, column 1) and the corresponding Medicaid agency name and contact information ([click **here** to go to Table 1d)](#Table1d).

Note that a covered entity’s policies and procedures should list the Medicaid states that are carved-in and those that are carved-out at contract pharmacy(ies).

1. **State Medicaid Policies** [(click **here** to go to Table 2)](#Table2)

For each Medicaid state to be carved-in (from table 1d, column 1) provide a link to the state Medicaid plan and amendments and reference the section of the plan in which 340B drugs are addressed. If the state plan does not address 340B drugs or 340B carve-ins, provide references to any other state or local rules or guidance about use of 340B drugs at contract pharmacies.

1. **Summary of Covered Entity Policies and Procedures** [(click **here** to go to Table 3)](#Table3)

List the Medicaid states that will be carved-in and carved-out at contract pharmacies. Summarize the covered entity’s policies and procedures to prevent duplicate discounts and comply with state Medicaid requirements and HRSA’s contract pharmacy oversight guidelines.

1. **Submission Checklist** [(click](#Checklist) **[here](#Checklist)** [to go to checklist)](#Checklist)
	1. Completed tables 1, 2 and 3 of Contract Pharmacy Medicaid Carve-in Request Form
	2. Policies and procedures on duplicate discount prevention
		1. Provide an electronic copy of the entity’s policies and procedures on prevention of duplicate discounts at covered entity sites and contract pharmacies.
		2. Highlight the specific section and page in the policies and procedures on the prevention of duplicate discounts at contract pharmacies.
	3. Policies and procedures for contract pharmacy oversight
		1. Provide an electronic copy of the policies and procedures for covered entity’s oversight of 340B Program compliance at contract pharmacies (internal and external audits).
		2. Highlight the specific section and page in the policies and procedures that details the auditing procedures and frequency.
	4. Statement Confirming Compliance with Federal/State/Local/Other Laws
		1. The authorizing official must provide a written attestation that the entity complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying federal, state, and local regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: [Public Law 102-585, Section 602](https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf), [340B Guidelines](https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf), [340B Policy Releases](https://www.hrsa.gov/opa/program-requirements/policy-releases)]

([click **here** for attestation sample letter)](#Sample1)

* 1. Written Acknowledgment/Approval by State Medicaid Representative
		1. Provide a signed and dated document from an appropriate Medicaid official stating approval of the contract pharmacy fee-for-service-only carve-in arrangements with specified parties.

([click](#Sample2) **[here](#Sample2)** [for FFS carve-in arrangement sample letter)](#Sample2)

*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.*

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**Sample Attestation 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 provide a written attestation that [Entity Name] complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying federal, state, and local laws, regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity.

Sincerely,

[Signed, Entity Authorizing Official]
[Contact information for authorizing official]:

Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person submitting form:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Sample Letter of Approval from State Medicaid Agency Representative**

**[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: Acknowledgement/approval of 340B carve-in at contract pharmacy arrangement by state Medicaid Agency representative

Dear [Director, HRSA OPA]:

This document dated [insert date] acknowledges the agreement between [Entity Name, 340B ID] and [State Medicaid Office] regarding the approval to carve-in fee-for-service Medicaid claims, processed at contract pharmacies, to the 340B Program.

Details of the agreement are as such:

Points could include:

* Type of contract pharmacy setting(s): retail vs. facility administered
* Use of entity’s MPN/NPI for claims vs. use of contract pharmacy’s MPN/NPI
* Use of any claim identifiers
* Description of inventory management processes; virtual vs. physical
* Any unique/state-specific processes

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

[Signed, Covered Entity Authorizing Official]
Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

[Signed, Medicaid Agency Representative]
Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Email address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_