



COLORADO

Department of Health Care
Policy & Financing

340B Policy and Procedures Manual

Outpatient Drugs and Physician Administered Drugs



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I. Purpose

This document contains the Health First Colorado policies and procedures for Managed Care Organization and Fee-for-Service providers who participate in the 340B Drug Pricing Program. This guidance applies to prescription drugs dispensed in an outpatient setting (i.e., pharmacy) and drugs administered in a physician’s office or clinic. **This guidance does not apply to prescription drugs provided in an inpatient or outpatient hospital setting.**

II. Definitions

A **duplicate discount** is when a manufacturer provides a drug to a covered entity with the 340B discount, in addition to the manufacturer paying a rebate to Health First Colorado on the same drug (42 USC 256b(a)(5)(A)(i) (2010)).

The term **contract pharmacy** is an arrangement in which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services. Contract pharmacies can be made available to covered entities which do not have access to available or appropriate “in-house” pharmacy services.

A **covered entity** is defined as an entity that is enrolled with the 340B Federal Drug Pricing Program and is required to adhere to all state, federal and 340B regulations pursuant to the 340B Public Health Service Act (42CFR1.A 10.3 and 42CFR1.A 10.10 (2018)).

III. 340B Background

The 340B Drug Pricing Program is a federal program that requires drug manufacturers to provide prescription drugs to eligible covered entities at significantly reduced prices.

Covered Entities and Health First Colorado

Covered entities choose whether to dispense 340B purchased drugs to Health First Colorado members and this decision affects how providers bill Health First Colorado.

- Health First Colorado requires covered entities to determine whether they will dispense only 340B drugs to Health First Colorado members (carve-in) or whether they will dispense no 340B drugs to Health First Colorado members (carve-out). **Covered entities cannot bill both 340B purchased drugs and non-340B drugs to Health First Colorado.**
- Covered entities which choose to carve-in must bill Health First Colorado for 340B drugs at their acquisition cost.
- Covered entities must ensure that there is a mechanism in place which does not allow for duplicate discounts; i.e. the covered entity cannot receive a drug at a 340B discounted price in addition to Health First Colorado receiving a rebate from the drug manufacturer.

Covered Entities and 340B

When an eligible entity enrolls in the 340B Drug Pricing Program it accepts the responsibility of complying with all provisions.



- Covered entities which carve-in must have their NPI number listed on the HRSA Medicaid Exclusion File.
- Covered entities must comply with the no diversion stipulation which mandates that 340B drugs may not be resold or transferred to a person who is not a patient of the entity.
- Non-compliance could result in: the repayment of discounts, the repayment of discounts with interest and/or the covered entity could be removed from the 340B Drug Pricing Program entirely.

Health First Colorado and 340B

Health First Colorado has the responsibility of accurately reimbursing covered entities and appropriately collecting rebates from drug manufactures.

- Health First Colorado identifies and excludes all 340B drug claims from the utilization data submitted to drug manufacturers to ensure that covered entities are not getting a discounted drug in addition to Health First Colorado receiving rebates from the drug manufactures.

IV. 340B Policy Statements

1. Health First Colorado allows covered entities to dispense 340B drugs at the provider level (i.e. carve-in).
 - a) Any covered entity that is billing 340B drugs to Health First Colorado must register with the Health Resources and Services Administration (HRSA).
 - b) The covered entities' NPI number must be listed on the Medicaid Exclusion File (MEF).
2. Duplicate discounts are prohibited in the 340B Drug Pricing Program.
 - a) To prevent duplicate discounts from taking place, the **covered entity** is required to follow HRSA's rules and provide HRSA with their NPI at the time of enrollment.
 - b) HRSA lists the covered entity and their NPI on the Medicaid Exclusion File, which lets states and manufacturers know that drugs billed under those NPI number(s) are **not** eligible for rebate.
3. The submitted ingredient cost on a claim must be the 340B acquisition cost.
4. Manufacturers are permitted to audit covered entities' records if they suspect product diversion or that multiple discounts are taking place.
 - a) Covered entities are responsible for creating and maintaining a system which inhibits this to ensure compliance.
5. The Dispensing Fees (DF) paid on Fee-for-Service outpatient drug claims for 340B entities shall be tiered based upon a pharmacy's Total Annual Prescription Volume. **This policy is not**



specific to 340B pharmacies; this applies to most pharmacy providers. Health First Colorado does not pay a dispensing fee on physician administered drug claims. Below are the tiers for DFs:

- a) Less than 60,000 total prescriptions filled per year=\$13.40 per prescription
 - b) Between 60,000 and 90,000 total prescriptions filled per year= \$11.49 per prescription
 - c) Between 90,000 and 110,000 total prescriptions filled per year=\$10.25 per prescription
 - d) Greater than 110,000 total prescriptions filled per year=\$9.31
6. Contract pharmacies are **not** permitted to bill 340B drugs to Health First Colorado.
- a) The **use of contract pharmacy services is voluntary** and covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all. Covered entities should conduct their own business review and patient assessment to determine what level of pharmacy services are needed, and the appropriate delivery mechanism for those services.

V. Health First Colorado Fee-for-Service NCPDP D.0 Billing Changes for 340B Outpatient Drug Claims

A. Effective June 1, 2017, Fee-for-Service 340B claims submitted via the National Council for Prescription Drug Programs (NCPDP) D.0 format must include the following:

- Value of “20” in field 420-DK, Submission Clarification Code; and
- Value of “08” or “05” in field 423-DN, Basis of Cost Determination.

The above guidance supersedes all previous billing guidance for Fee-for-Service 340B claims submitted via the NCPDP D.0 format.

B. Effective November 1, 2018, claims will deny if:

- The Submission Clarification and Basis of Cost Determination fields indicate that the drug was purchased through the 340B Drug Pricing Program but the pharmacy NPI number is not listed on the HRSA 340B Medicaid Exclusion File.
- The pharmacy NPI number is listed on the HRSA 340B Medicaid Exclusion File but the Submission Clarification and Basis of Cost Determination fields did not include the correct values.

VI. Health First Colorado Billing Instructions for 340B Physician Administered Drugs

Health First Colorado uses HRSA’s Medicaid Exclusion File (MEF) to identify all 340B drug claims. This process allows for the claim to be excluded from the rebate stream, thereby avoiding duplicate



discounts. **However, an additional identifier is required at the claim submission level for all 340B physician administered drugs.**

340B claim level identifier is as follows:

- As of March 1, 2017, all claims and encounters for physician administered drugs purchased through the 340B program should include the “UD” code modifier on the 837P, 837I and CMS 1500 claim formats.
- For any physician administered drugs not purchased through the 340B program, no code modifier is required.
- A valid national drug code (NDC) number must be included on all claims and encounters for physician administered drugs. To assist providers with billing, a HCPCS/NDC crosswalk can be found under Appendices at: <https://www.colorado.gov/HCPF/billing-manuals>.

VII. Ceiling Price Calculation For Outpatient Drugs

Effective May 1, 2019, if the submitted ingredient cost for a 340B-purchased drug exceeds the 340B ceiling price, claims will trigger a message. The ceiling prices are determined from the Average Manufacturer Prices (AMP) and the Unit Rebate Amounts (URA). Covered entities must submit their 340B acquisition cost to Health First Colorado. **Managed Care Organization’s outpatient drug encounters are exempt from the ceiling price logic.**

For more information please visit HRSA’s website: [340B Ceiling Price Calculation](#).

VIII. Additional Guidance

FAQS on the 340B program itself, as well as information on how to ask additional questions, can be found on the HRSA website.

Policy and billing questions for Health First Colorado can be directed to:
hcpf_Colorado.SMAC@state.co.us