APPENDIX F 340B DRUG PRICING PROGRAM

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

This section contains the DHCFP policies and procedures for FFS 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 hospital setting.**

I. Definitions:

Duplicate discount – When a manufacturer provides a drug to a covered entity with the 340B discount, in addition to the manufacturer paying a rebate to the DHCFP on the same drug (42 USC 256b(a)(5)(A)(i) (2010)).

Contract pharmacy – 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.

Covered entity – An entity that is enrolled with the federal 340B 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)).

II. Covered Entities & The DHCFP

Covered entities choose whether to dispense 340B purchased drugs to Nevada Medicaid recipients and this decision affects how providers bill the DHCFP.

- The DHCFP requires covered entities to determine whether they will dispense only 340B drugs to Nevada Medicaid recipients (carve-in) or whether they will dispense no 340B drugs to Nevada Medicaid recipients (carve-out). **Covered entities cannot bill both 340B purchased drugs and non-340B drugs to the DHCFP.**
- Covered entities which choose to carve-in must bill the DHCFP for 340B drugs at their Actual Acquisition Cost (AAC).
- 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 the DHCFP receiving a rebate from the drug manufacturer.

III. Covered Entities & 340B

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

- Covered entities which carve-in must list all National Provider Identifier (NPI) number used to submit claims on the Health Resources & Services Administration (HRSA) Medicaid Exclusion File (MEF).
- 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.
- Covered entities are responsible to repay to the manufacturer if a duplicate discount occurs because of billing error.
- Non-compliance of the DHCFP 340B policy could result in the repayment of discounts to the manufacturer for the duplicate discount, the repayment of discounts with interest and/or the covered entity could be removed from the 340B Drug Pricing Program entirely.

IV. The DHCFP & 340B

The DHCFP has the responsibility of accurately reimbursing covered entities and appropriately collecting rebates from drug manufactures.

- The DHCFP 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 Nevada Medicaid receiving rebates from the drug manufacturers.

V. 340B Policy Statements

1. The DHCFP 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 the DHCPF must register with the HRSA.
    b. The covered entity must list all NPI numbers used to submit claims on the MEF.
2. Duplicate discounts are prohibited in the 340B Drug Pricing Program.
    a. It is the covered entities responsibility to ensure duplicate discounts do not occur.
    b. To prevent duplicate discounts from taking place:
        i. The covered entity is required to follow HRSA's rules and provide HRSA with their NPI at the time of enrollment.
        ii. The covered entity is required to ensure HRSA has their NPI on the MEF, 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 AAC.
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. Contract pharmacies are **not** permitted to bill 340B drugs to the DHCFP.
    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.
6. Covered entities are responsible for repayment to manufacturers of duplicate discounts due to covered entity failing to follow the DHCFP's billing policy.

VI. The DHCFP Fee-for-Service (FFS) NCPDP D.0 Billing Changes for 340B Outpatient Drug Claims

1. Effective July 1, 2022, FFS 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" in field 423-DN, Basis of Cost Determination.

    The above guidance supersedes all previous billing guidance for FFS 340B claims submitted via the NCPDP D.0 format.
2. Effective July 1, 2022, 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 MEF.
    - The pharmacy NPI number is listed on the HRSA 340B MEF but the Submission Clarification and Basis of Cost Determination fields did not include the correct values.

VII. The DHCFP Billing Instructions for 340B Physician Administered Drugs (PAD)

The DHCFP uses HRSA's 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 PAD claims.

1. Effective July 1, 2022, all claims and encounters for PAD purchased through the 340B program **must include**:
    - One of the following:
        - "UD," "JG," or "TB" in procedure code modifier field on the 837P and 837I.
            - UD: Medicaid level of care 13, as defined by each state (Short Description – Medicaid care level 13 state).
            - JG: Drug or biological acquired with 340B drug pricing program discount (Short Description – 340B acquired drug).
            - TB: Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes (Short Description – Tracking 340B acquired drug).

- A valid NDC number on all PAD claims and encounters. Additional billing information and guides can be found under the DHCFP Provider Portal at: https://www.medicaid.nv.gov/providers/rx/billinginfo.aspx.

A procedure code modifier is not required for any PAD that is **not** purchased through the 340B program.

2. Effective July 1, 2022, claims will deny if:

- The procedure code modifier field on the 837P and 837I claims indicates that the drug was purchased through the 340B Drug Pricing Program, but the Physician's NPI number is not listed on the HRSA 340B MEF.
- The provider NPI number is listed on the HRSA 340B MEF, but the procedure code fields did not include the correct values.

VIII. Ceiling Price Calculation for Outpatient Drugs

Effective July 1, 2022, if the submitted ingredient cost for a 340B-purchased drug exceeds the 340B ceiling price, claims will trigger a notification. The ceiling prices are determined from the Average Manufacturer Prices (AMP) and the Unit Rebate Amounts (URA). Covered entities must submit their 340B AAC to the DHCFP.

AAC for covered outpatient drug is the unit cost that the facility pays for a drug, after subtracting all discounts. A facility may establish written protocols for establishing or calculating the facility's AAC based on a monthly, quarterly, or other average of the facility's AAC. A written protocol may not include an inflation mark-up, spread, or margin to be added to the facility's actual purchase price after subtracting all discounts.

For more information, please visit HRSA's website: 340B Ceiling Price Calculation.

IX. Additional Guidance

For additional information including FAQ on the 340B program, as well as information on how to ask additional questions, please visit the HRSA website at: https://www.hrsa.gov/.

Policy and billing questions for the DHCFP can be directed to: rxinfo@dhcfp.nv.gov.