

340B DRUG PROGRAM - Nevada Medication Assistance 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. An AIDS Drug Assistance Program (ADAP) is a State/Territory-administered program authorized under Part B of the Ryan White HIV/AIDS Program that provides U.S. Food and Drug Administration (FDA)-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance, Medicaid, or Medicare.

Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. The current legislative language for ADAP is found in 42 U.S. Code § 300ff-26 - Provision of Treatments, Section 216.

This section contains **State of Nevada Ryan White Part B: Nevada Medication Assistance Program (NMAP)** policies and procedures for Ryan White providers who participate in the 340B Drug Pricing Program. This guidance applies to prescription drugs dispensed in an outpatient setting (i.e., pharmacy).

I. Definitions:

NMAP Patient – When individuals meeting an ADAP's financial and medical eligibility criteria and enrolled as active ADAP clients are deemed “patients” of the ADAP for the purposes of the 340B Program guidelines. See Patient Definition Guidelines: 61 Fed. Reg. 55156 (October 24, 1996). A client is deemed an NMAP patient as long as NMAP is paying any portion of the client’s health insurance medication(s) cost-share (i.e. copay, co-insurance, or deductible), regardless of the federal funding used to establish the subrecipient as a 340b entity. Once the client has met their out-of-pocket maximum (OOPM) and NMAP is no longer paying any of the client’s medication(s) cost-share an 340b pharmacy may dispense their 340b medication(s) to client(s).

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 NMAP on the same drug (42 USC 256b(a)(5)(A)(i) (2010)).

Prohibition on Diversion of 340B Drugs – A 340B covered entity is prohibited from obtaining 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price. See Patient Definition Guidelines: 61 Fed. Reg. 55156 (October 24, 1996).

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 & NMAP

NMAP is a covered entity and will not allow any claims to be paid in which an 340B drug was provided to an NMAP patient.

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 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 claim is submitted to NMAP and causes a duplicate discount to occur.
- Non-compliance of the NMAP 340B policy could result in the repayment of discounts to the manufacturer for the duplicate discount and the repayment of discounts with interest.

IV. National Council for Prescription Drug Programs D.0 Billing Changes for 340B Outpatient Drug Claims

1. Effective July 1, 2022, the National Council for Prescription Drug Programs (NCPDP) D.0 format **must include** the following to identify 340B claims:
 - Value of “20” in field 420-DK, Submission Clarification Code; and/or
 - Value of “08” in field 423-DN, Basis of Cost Determination.
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.
 - The pharmacy National Provider Identifier (NPI) number is listed on the Health Resources & Services Administration (HRSA)340B Medicaid Exclusion File (MEF).

V. 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/>.

Ryan White HIV/AIDS Program AIDS Drug Assistance Program (ADAP) Manual Revised 2016 at: https://hab.hrsa.gov/sites/default/files/hab/clinical-quality-management/adapmanual_0.pdf.

Nevada Medication Assistance Program (NMAP) Service Standard 15-05 at: <https://endhivnevada.org/wp-content/uploads/2021/03/15-05-SS-Nevada-Medication-Assistance-Program.pdf>

Policy and billings question for NMAP can be directed to: NVRWPB@health.nv.gov.