



# Ryan White Part A/B Programs The Right of Way Policy For Dual 340B Patients

## SCOPE OF COVERAGE

Applicable to all Nevada Medication Assistance Program (NMAP) In-Network pharmacies dispensing medication(s) to insured/uninsured NMAP clients.

## BACKGROUND

As a federally funded program, AIDS Drug Assistance Programs (ADAPs) are required to acquire drugs “in the most economical manner feasible” ([42 CFR Part 50, Subpart E](#)). To that end, as federally designated entities, ADAPs have access to discounted medications through the 340B Drug Pricing Program (340B Program), a Federal drug pricing program administered by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA). The 340B program guidelines permit ADAPs to use a rebate model ([63 Fed. Reg. 35239, June 29, 1998](#)) to provide medication assistance to clients.

Under the rebate model option, ADAPs can submit claims to drug manufacturers for rebates on medications purchased through a retail pharmacy network at a price higher than the 340B price. ADAPs using the rebate option on full pay medications, medication copayments, coinsurance, or deductibles achieve cost savings comparable to those received by ADAPs that directly purchase medications (direct purchase model) at the 340B price. ADAPs are unique because they are the only covered entities that may receive a 340B rebate from a drug manufacturer ([IV.3.C Cha 3. ADAP Manual, 2016](#)).

Although not a Ryan White HIV/AIDS Program (RWHAP) requirement, rebates can be used to fund community programs that align with ADAP programming and expectations, which is typically done through the process outlined in “Policy Clarification Notice [16-02](#) Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds.”

A 340B covered entity is prohibited from obtaining 340B pricing (either through a rebate or through a direct purchase model) on a drug purchased by another covered entity at or below the 340B ceiling price [[HRSA Duplicate Discount Prohibition: 42 USC 256b\(a\)\(5\)\(A\)\(i\)](#)]. All 340B covered entities, including ADAPs, must ensure that drugs that have been purchased at or below the ceiling price for a patient of a covered entity are not also subject to any additional 340B discounts.

Individuals receiving 340B medications from 340B entities must be a patient of the 340B covered entity as defined by HRSA. As defined by HRSA an individual is a “patient” of a 340B covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and
2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care remains with the covered entity; and
3. the individual receives a health care service or range of services from the covered entity which is consistent with the services or range of services for which grant funding or federally qualified health center look-a-like status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.



# Ryan White Part A/B Programs The Right of Way Policy For Dual 340B Patients

An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service (PHS) Act will be considered a “patient” of the covered entity for purposes of this definition if so registered. [{Federal Register Vol. 61, No. 207}](#)

## PURPOSE OF POLICY

The Office of HIV [Ryan White Part B Recipient/Nevada Medication Assistance Program (NMAP)] and Clark County Social Service (Ryan White Part A Recipient), have established **Nevada’s Ryan White Right-Of-Way for Dual 340B Patients Policy**. The purpose of this policy is two-fold:

- I. Establish the NMAP program as a 340B Rebate Model program. This allows both insured and uninsured clients the option of utilizing any pharmacy that participates in the NMAP pharmacy network; and
- II. This policy puts NMAP in compliance with the Duplicate Discount Prohibition (42 USC 256b(a)(5)(A)(i)) as enacted by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs and allow 340B entities to utilize their 340B medication(s) when an insured NMAP client has met their out-of-pocket maximum.

## INSTRUCTION

It is not a requirement of the Ryan White Program that you participate in the Federal 340B program. If an entity participates in the Federal 340B program it is the entity’s sole responsibility to ensure that their 340B medication is not being dispensed to NMAP patient for any reason(s). The Office of HIV, or Clark County Social Service/Ryan White Part A, **shall not** be responsible for any penalties that may be incurred as a result of a Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) or Pharmaceutical Manufacture’s audit. If an entity participates in the Federal 340B Program, the 340B covered entity(ies) are individually responsible for compliance with federal law.

For a pharmacy to participate in the NMAP pharmacy network, the pharmacy must be credentialed by NMAP’s Pharmacy Benefits Manager (PBM). As part of the credentialing process, pharmacies/340B entities must attest and comply with not dispensing 340B medication to any NMAP patient(s) for which NMAP is paying, but not limited to, any part of the client’s health insurance medication(s) cost-share (i.e., copay, co-insurance or deductible) or the full cost of medication. NMAP **shall not** be responsible for any penalties that may be incurred as a result of a Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) or Pharmaceutical Manufacture’s audit. If an entity participates in the Federal 340B Program, they are individually responsible for compliance with federal law.

Starting **January 18, 2021**, NMAP **will no longer** accept any claims for reimbursement in which a 340B medication was dispensed. All 340B covered entities will have the choice of not participating in the NMAP pharmacy network. If that entity chooses not to participate in NMAP’s pharmacy network and the entity is providing 340B pharmacy service(s) to NMAP patients, then the entity will be responsible for all patients cost\* associated with their HIV care [i.e., health insurance premiums payments, associated cost-share (medical and pharmacy), core medical and supportive services].



## **Ryan White Part A/B Programs The Right of Way Policy For Dual 340B Patients**

*\*Per HRSA Policy Clarification Notice [15-03](#), program income generated by the subrecipient must be reported to the recipient monthly. Program income must be accounted for and utilized in the year in which it is received by the subrecipient. Program income received at the end of the grant year (90-day window) will be allowed to carry forward into the following grant year. This program income must be used prior to expenditure of new funding in the subsequent period. The subrecipient is required to provide a plan (budget) as to how those funds will be utilized at the beginning of each grant year. Program income can only be used for core medical and support services, clinical quality management, and administrative expenses (including planning and evaluation) as part of a comprehensive system of care for low-income individuals living with HIV/AIDS.*

*\*\*Note: All program income, in which Ryan White funds directly or indirectly help generate, must be reported to the recipient (Ryan White Part A/B Grantee) monthly. This includes, but is not limited to, program income generated through a 340b program, medical cost-share, and tax reconciliation payment.*

For questions, please contact one of the following staff members:

- Ryan White Part A - Heather Shoop, MSW  
Ryan White Part A Grant Administrator  
[Heather.shoop@clarkcountynv.gov](mailto:Heather.shoop@clarkcountynv.gov)
- Ryan White Part B - M. Thomas Blissett  
Health Program Specialist I  
[michaelblissett@health.nv.gov](mailto:michaelblissett@health.nv.gov)