



NCSDDC
National Coalition
of STD Directors

Promoting Sexual Health
Through STD Prevention

NCSDDC.ORG

1029 Vermont Ave NW
Ste 500
Washington, DC 20005

202.842.4660
202.842.4542 (Fax)

Notifying HRSA of a One-Time Transfer of 340B Medication

STD programs across the country are struggling to access treatment for syphilis - an infection of considerable public health importance with serious health effects if left untreated. Penicillin G benzathine is the first-line recommended treatment for syphilis and the only known effective medication for treating fetal infection and preventing congenital syphilis (CDC). Unfortunately, the FDA has listed Penicillin G benzathine injectable suspension in current shortage with the shortage expected to last well into 2024. Pfizer is the sole manufacturer of Benzathine penicillin G with FDA approval in the United States, which is distributed under the trademarked name Bicillin® L-A.

Because of this shortage, state and local STD programs utilizing the 340B Drug Pricing Program are going to great lengths to ensure their communities have access to timely and appropriate treatment. Public health and STD programs may find themselves in a situation where stock of Penicillin G benzathine may need to be transferred from one 340B covered entity to another 340B covered entity to provide timely and appropriate treatment for individuals diagnosed with syphilis and for the prevention of congenital syphilis. If a state or local STD program determines a one-time transfer of 340B medication is necessary, the STD program should draft a memo to send to HRSA that includes the following key components:

1. List all STD 340B IDs that will be transferring 340B medications and all 340B IDs which will be receiving the transferred 340B medications.
2. Explain the relationship (i.e., ownership status if any) between the organization transferring the 340B medications and the organization receiving the 340B medications.
3. Briefly explain the types of medications, quantity of medications, and monetary value of medications to be transferred. If any manufacturer communication has taken place regarding the medications in questions, please explain.
4. Describe the policies and procedures and the system of auditable records in place to ensure the transferred 340B medications will only be used for eligible 340B patients and how the entity will prevent duplicate discounts on these medications.

The memo should be written on the STD program's letterhead and include attestations from both the transferring and receiving 340B covered entities. The attestations should address the agreement to ensure compliance with 340B Program requirements, compliance with any applicable federal, state, or local laws, and agreement to notify the Office of Pharmacy Affairs of any changes related to the transfer of 340B medications.

STD programs should provide notification to HRSA five business days prior to the transfer by emailing Mr. Wayne Hartzell at ahartzell@hrsa.gov. STD programs should retain the original memo in their files as well as the confirmation of submission and any email correspondence.

Please contact Mr. Hartzell if you have further questions regarding the process outlined for a one-time transfer of 340B medications. The NCSDD Policy team is also available to assist you in understanding or implementing the 340B drug pricing program. Please contact us at policyteam@ncsddc.org.



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