


## National Tuberculosis Controllers Association

Community of Practice  
Webinar  
February 17, 2022  
Rifampin Shortage



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## TB Emergency Drug Stockpile

**Background**

- Established in 2016 to help mitigate interruption of therapy in the event of a national shortage of critical anti-TB drugs
- Interagency agreement (IAA) between DTBE and the HHS Program Support Center (PSC). A new 5-year IAA is being finalized.
- Supported by funds from the CDC Antibiotic Resistance (AR) Solutions Initiative and DTBE. Approximately \$6.5M over 6 years.
- Inventory has included isoniazid, rifampin, rifapentine, cycloserine, amikacin, capreomycin
- Stockpile drugs can be released to TB programs upon request:
  - in the case of a national shortage (as determined by FDA), or
  - when six months away from expiration
- Processed as Direct Assistance (DA) to TB Cooperative Agreements 20-2001 and 18-1801



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## TB Emergency Drug Stockpile (2)

**Reporting Shortages:**


- Programs report challenges obtaining anti-TB drugs to NTCA. CDC/NTCA reports to FDA. FDA investigates and determines whether disruption is the result of a manufacturing shortage.
- FDA reports status on their drug shortage website.

Reported by: [redacted]  
Date Reported: 12/22/21  
Manufacturer: [redacted]

Formulation	Availability and Estimated Storage Location	Market Information	Shortage Period (per 10/2021)
150 mg (NDC 42089 811-30)	available		Other
150 mg (NDC 42089 811-60)	available		Other
300 mg (NDC 42089 700-30)	available		Other
300 mg (NDC 42089 700-60)	available		Other
300 mg (NDC 42089 700-01)	available		Other
300 mg (NDC 42089 700-02)	available		Other

Legend (Revised 01/27/2021)

[FDA Drug Shortages](https://www.accessdata.fda.gov/scripts/drugshortages/) - <https://www.accessdata.fda.gov/scripts/drugshortages/>



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### TB Emergency Drug Stockpile Inventory

LOT #	DRUG	MOU	DESCRIPTION	EXPIRATION DATE	REMAINING INVENTORY* (Bottles)
3187559	Rifampin	CAP	300mg, 60s	4/30/2022	2418
3187560	Rifampin	CAP	300mg, 60s	4/30/2022	29

\* As of 2/16/2022

Between 12/22/21 and 2/16/22:

- DTBE distributed 10,639 bottles of Rifampin
- Total direct assistance (DA) is \$1,018,790.64
- 36 recipients of Tuberculosis Elimination and Laboratory Cooperative Agreement



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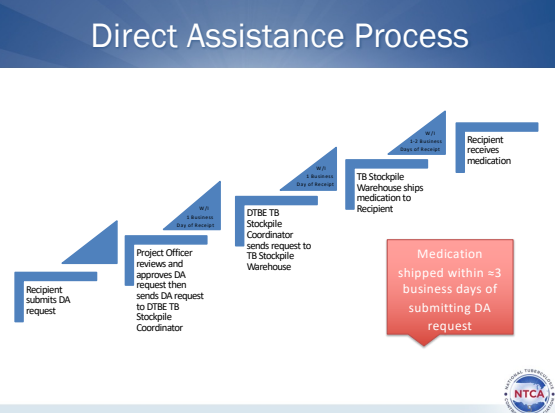

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### Direct Assistance Process

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### Direct Assistance Amendment

Direct Assistance Request Letter should include:

- Organizational letterhead
- Addressed to Grants Management Specialist
- TB Disease Burden
  - Number of TB cases reported through the National TB Surveillance System
  - Justification providing assurance that drugs will be used in treating TB patients and the drugs to be used by their expiration date
- POC and Shipping Information
  - Point of contact information (Name, Telephone number, Email)
  - Shipping address
- Quantity requested
  - Request amounts in unit of issue stated above (i.e., bottles)
- Program Performance
  - Completion of treatment [COT] percentage as reported through the National TB Surveillance System.
- Signed by Project Director/Principal Investigator AND Authorizing Official



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### Direct Assistance Amendment

- Direct Assistance request letter must be uploaded into GrantSolutions as an amendment
- Amendment type is "Direct Assistance"

**Select Amendment Type**

Grant Number	61010209 to 12191024
Project Period	6/10/2022 to 12/31/2022
Budget Period	6/10/2022 to 12/31/2022
Amendment Type	<input type="radio"/> Supplement (Type 6) <input type="radio"/> Administrative Action (Type 6) <input type="radio"/> Budget Revision (Type 6) <input type="radio"/> Cancellation of Funds (Type 6) <input type="radio"/> Change Quarter Address (Type 6) <input type="radio"/> Change PI/PO (Type 6) <input type="radio"/> Change in Key Personnel (Type 6) <input type="radio"/> Close-out reconciliation (Type 6) <input type="radio"/> Component/Project Ending (Type 6) <input checked="" type="radio"/> <b>Direct Assistance (Type 6)</b> <input type="radio"/> Grant Extension (Type 6) <input type="radio"/> NIDA Revision (Type 6) <input type="radio"/> No Cost Extension (Type 6) <input type="radio"/> Notification of a Contractor or Consultant (Type 6) <input type="radio"/> Organization Name Change (Type 6) <input type="radio"/> Release of Restrictions on NIDA (Type 6) <input type="radio"/> Successor of Interest (Type 6)



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