

Instructions for Reporting Wholesaler/Distributor Transactions

All wholesale/distributions of all controlled substances and tramadol to a Tennessee licensee are required to be reported to the Tennessee Board of Pharmacy pursuant to TCA 53-10-312. A wholesale or distribution transaction involves the transfer of possession to a licensee (distributor, wholesaler, dispenser or a prescriber) whether or not money is involved. In other words, if the drug moves from the DEA number of a manufacturer, wholesaler, or distributor to the DEA number of an in-state licensee then it must be reported. This reporting is separate from a pharmacy or other dispenser's reporting prescriptions that are dispensed to patients. If you have a Manufacturer/Wholesaler/Distributor (MWD) license from the Board of Pharmacy, you must submit a report at least once every month, no later than 45 days after the earliest transactions being reported. If there is no transaction to report, the licensee should file a "Zero Report". Failure to report is not the same as a Zero Report.

Reporting Process for MWD transactions:

Email File Submission

Initially, transactions will be reported via secure email to tn.arcos@tn.gov. All files should be in.txt format. The filename should include ###.mmddyyyy, where ### is the wholesaler's/seller's DEA number and mmddyyyy is the last date of the reporting period. Please follow format requirements noted below.

Data Submission for MWD Transactions

Format

Submit the data in ARCOS format, see the table below.

File Format – ARCOS

Control Record		
Field Description	*Required or Optional	Length
Reporting Registrant DEA Number ¹	Required	9
Asterisk (*)	Required	1
Last Day of Reporting Period (mmddyyyy)	Required	8
Reporting Frequency (M)	Required	1
Central Reporter's DEA Number ¹	Optional	9

***Required – This information is required. If the data is not present, the file will be rejected.**

***Optional – Data for this field is not required; however, you must leave the specified number of spaces if no data is input into these fields.**

¹ DEA – If either party does not have a DEA#, use 'TN' + last 7 digits of the TN Board of Pharmacy License Number preceded by zeros (e.g. TN0001234). This may occur with transfers of tramadol-containing products.

Transaction Record			
Field Description	*Required or Optional	Length	Position Location
Registrant DEA Number¹	Required	9	1-9
Transaction Code²	Required	1	10
Action Indicator	Optional	1	11
NDC Number	Required	11	12-22
Quantity	Required	8	23-30
Unit	Optional	1	31
Assoc Registrant DEA Number¹	Required	9	32-40
Order Form Number	Optional	9	41-49
Transaction Date (mmddyyyy)	Required	8	50-57
Correction Number ³	Optional	8	58-65
Strength	Optional	4	66-69
Transaction Identifier	Required	10	70-79
Blank Space	Required	1	80

***Required – This information is required. If the data is not present, the file will be rejected.**

*Optional – Data for this field is not required; however, you must leave the specified number of spaces if no data is input into these fields.

¹ DEA – If either party does not have a DEA#, use 'TN' + last 7 digits of the entity's Board License Number preceded by zeros (e.g. TN0001234). This may occur with transfers of tramadol-containing products.

² Transaction Code – For explanation, see Appendix A – Transaction Code for transaction types.

³ Correction Numbers are only required if the transaction is a correction of a previous submission. Board of Pharmacy staff will provide a correction number if an error is detected.

If you have any questions, please email tn.arcos@tn.gov and we will respond as soon as possible.

Appendix A: Transaction Code

ACQUISITION TRANSACTION CODES

A Tennessee registrant can acquire controlled substances by buying them or by having previously sold controlled substances returned. Acquisitions of controlled substances, irrespective of the manner in which they are acquired, increase the registrant's inventory.

Code P: Purchase or Other Receipt

Transaction code P, purchase or other receipt, is used to report controlled substance acquisitions under three different scenarios:

- a. The acquisition of a controlled substance by one registrant from another.
- b. The transfer of a controlled substance from one physical location to another.
- c. Establishing the initial stock on hand of a controlled substance for a new registrant.

Code R: Return

Transaction code R is used to report the receipt of returned controlled substances when the manufacturer or distributor requests their return. Returns reported under transaction code R do not necessarily involve a monetary transaction. Reportable controlled substances received by a supplier may include substances being returned for credit, salvage, re-work, or non-GMP (good manufacturing process) quality, as well as outdated or unused controlled substances.

Code V: Unsolicited Return

Transaction code V is used to report the receipt of an unsolicited return of a reportable controlled substance. An "unsolicited return" is a return that has not been requested by the manufacturer or distributor. The situations needing transaction code V are described below:

Unknown Shipper

- a. Use transaction code V when a Schedule III narcotic shipment is received without any identifying markings indicating the name of the firm that shipped the drugs. In the associate registrant number field (Field 7), enter "UNKNOWN" in all capital letters and left justified.
- b. Use transaction code V when a Schedule I or II product is received without the prior issuance of a DEA Form 222, and without any identifying markings indicating the name of the firm that shipped the product. In the associate registrant number field (Field 7), enter "UNKNOWN" in all capital letters and left justified.

Known Shipper

c. Use transaction code V when a Schedule III narcotic shipment is received without prior notification and the shipper is known. The shipper's DEA Registration Number is entered into the associate registrant number field (Field 7).

d. Use transaction code V when a Schedule I or II shipment is received without the prior issuance of an order form, DEA Form 222, and the shipper is known. The shipper's DEA registration number is entered into the associate registrant number field (Field 7) and the order form number is entered in the DEA order form number field (Field 8).

DISPOSITION TRANSACTION CODES

Controlled substances can be sold, destroyed, taken by the government, or stolen (theft). Under the manufacturing process there are a number of additional ways to dispose of controlled substances: (1) non-recoverable waste, (2) used in manufacturing, (3) distribution of samples, and (4) used in preparations. Dispositions of controlled substances, irrespective of the manner in which they are disposed, decrease the registrant's inventory.

Code S: Sale, Disposition, or Transfer

Transaction code S is used when a controlled substance is physically transferred to another DEA registrant. This is not necessarily a monetary transaction. Samples to customers are included in this category. However, a sample that does not leave the registrant's premises is reported as a transaction code Q. The sale of reportable controlled substances reduces the manufacturer's or distributor's inventory. In cases where a controlled substance is shipped directly from a supplier to a registrant's customer and is never physically on the registrant's premises (e.g., the registrant only does the billing), the registrant must not report the transaction. The supplier does the reporting.

Code Y: Destroyed

Transaction code Y is used for reporting authorized destructions of controlled substances. Enter the registration number of the local DEA area office in the associate registrant number field (Field 7).

Code T: Theft

Transaction code T is used to report controlled substances stolen from your premises. This does not eliminate the requirement to prepare an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106. Contact your local DEA office for further details.

Code Z: Receipt by Government or Seizures

Transaction code Z is used to report the transfer (e.g., samples or seizure) of reportable controlled substances from a manufacturer or distributor to a government official. When a controlled substance is received by an agent of DEA or FDA, the DEA registration number of their Area Office must be entered in the associate registrant number field (Field 7). "OFFICER" is the entry in Field 7 for any other non-

registered government official such as a customs officer; an agent of the Bureau of Alcohol, Tobacco, and Firearms; or state and local police officers. This entry must be in all capital letters and left justified within Field 7.

MISCELLANEOUS TRANSACTION CODES

Code 7: No ARCOS Activity for the Current Reporting Period

Transaction code 7 is used to report the lack of controlled substance activity for the current reporting period. This lack of activity must be reported to the state. Transaction code 7 is used when there has been no business activity for any and all controlled substances during the reporting period. It is not necessary to report no (i.e., zero) activity for each NDC product; a single transaction code 7 will suffice. Submitting a transaction code 7 will prevent the Board of Pharmacy from placing the registrant in a delinquent reporting status. Transaction code 7 requires the following fields:

- reporting registration number
- transaction code 7
- transaction date (last day of the reporting period)
- transaction identifier

Code X: Lost-in-Transit

Transaction code X is used by the seller to report the loss or theft of an in-transit shipment of a reportable controlled substance. It is reported in addition to the normal sales transaction (transaction code S). Transaction code X is an explanatory transaction code which does not affect a registrant's inventory. Enter the DEA registration number of the intended purchaser in the associate registrant number field (Field 7). If the product lost in transit was a Schedule I or II controlled substance the selling registrant must file an official theft report, U.S. Department of Justice, Drug Enforcement Administration, Report of Theft or Loss of Controlled Substances, DEA Form 106, with the local DEA office.