



# ARCOS Reporting

Supply Chain Conference  
Houston, Texas  
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# Citations



**21 U.S.C. § 827(b) – Availability of Records**

**21 U.S.C. § 827(d) – Periodic Reports**

**21 U.S.C. § 827(j) – Electronic Reporting**

**[<https://uscode.house.gov/>]**



**21 C.F.R. § 1304.04 – Maintenance of Records**

**21 C.F.R. § 1304.33 – Reports to ARCOS**

**[<https://www.ecfr.gov/>]**



# Who Reports To ARCOS?



- ❖ **Manufacturers, Distributors, & Reverse Distributors**
  - ❖ **Note: Per 21 U.S.C. § 802(15), this includes re-packagers & re-labelers**
- ❖ **Increases & decreases to inventory are reported from the perspective of these registrations**



- ❖ **If a company has any other types of registrations, transactions would not be reported under those registrations**



# What Is Reported To ARCOS?





- ❖ **In general, any increases and decreases to inventory of ARCOS reportable drugs, along with end-of-year inventory and certain manufacturing activities**



- ❖ **Increases to inventory include ...**
  - ✓ **Purchases/Receipt of supply**
  - ✓ **Returns from customers**
  - ✓ **Returns from Gov't or law enforcement**
  - ✓ **Received for the purpose of destruction**



- ❖ **Decreases to inventory include ...**
  - ✓ **Sales/transfer of supply**
  - ✓ **Thefts, losses, spillage**
  - ✓ **Destruction**
  - ✓ **Seizure/receipt by Gov't**



- ❖ **Manufacturing activities (examples) ...**
  - ✓ **Material manufactured**
  - ✓ **Use of material to create a preparation in another schedule**
  - ✓ **Waste recovered from manufacturing**
  - ✓ **Stability or quality testing**



- ❖ **End of year reportable inventory ...**
  - ✓ **ARCOS reportable substances and products only**
  - ✓ **Snapshot of what was on-hand at close of business December 31<sup>st</sup>**



- ❖ **Inventory resulting from a schedule change ...**
  - ✓ **Limited situations; drug not previously reportable to ARCOS becomes reportable**



- ❖ **ARCOS reportable drugs are ...**
  - ✓ **All Schedule 1 controlled substances**
  - ✓ **All Schedule 2 controlled substances**
  - ✓ **Schedule 3 narcotics and GHB preps**
  - ✓ **Selected Schedule 3 and 4 psychotropics, for which manufacturing must be reported (21 C.F.R. § 1304.33(d))**



# How To Report To ARCOS





- ❖ **Electronic reporting is mandatory, per the SUPPORT Act (2018)**
- ❖ **Account request form can be found on the ARCOS portion of the Diversion Control website**
- ❖ **Email to [ARCOS\\_Unit@dea.gov](mailto:ARCOS_Unit@dea.gov)**



- ❖ **ARCOS Online Reporting System**
- ❖ **Electronic Data Interchange (EDI)**



- ❖ **ARCOS Online Reporting System**
  - ✓ **Web interface – user friendly**
  - ✓ **Transactions validated up front**
  - ✓ **Account management; additional users**
  - ✓ **Error corrections**
  - ✓ **No formatting worries; “buttons”**



## ❖ **Electronic Data Interchange (EDI)**

- ✓ **Better for larger volume**
- ✓ **Automated uploads (allowed, not supported)**
- ✓ **Limited users – one login**
- ✓ **Error notifications after processing**
- ✓ **Importance of proper formatting**



# Common Issues



## ❖ **Uncorrected Error Transactions**

- ✓ **Transaction data is not reflected in ARCOS**
- ✓ **Can be accessed and addressed at any time in the ARCOS Online system**
- ✓ **Ability to delete if uncorrectable**
- ✓ **Should not occur if using ARCOS Online to file reports, with few exceptions**



## ❖ National Drug Codes (NDCs)

- ✓ **NDCs ending in -00 to -99 represent finished package sizes; Quantity should represent number of packages**
- ✓ **NDCs ending in -\*\* represent bulk dosage form, bulk material, or bulk liquid; Quantity represents number of units, with Unit and Strength for bulk material and liquid**



## ❖ Strength Field

- ✓ **Required for bulk raw materials and bulk liquid products; reflects purity**
- ✓ **For finished package NDCs, can be used with Quantity of 1 package to report a partial or combined package**
- ✓ **Implied decimal after 3<sup>rd</sup> digit (“1000” is 100%, “0100” is 10%, “0010” is 1%, and “0001” is 0.1%)**





## ❖ **Destructions**

- ✓ **Reported by registration under which destruction occurs**
- ✓ **Transfers to Reverse Distributors are reported as sales (Code “S”)**
- ✓ **Registration number of local DEA office is still required in Associate Registrant field**



## ❖ Inventory

- ✓ **Unless a substance becomes ARCOS reportable during the year and an “initial inventory” of that drug is required, the only inventory reported to ARCOS is end-of-year**
- ✓ **End-of-year inventory is separate from YERS (Quota) and should be included in the 4th quarter or December ARCOS submission**



## ❖ **No Activity/No Inventory**

- ✓ **Trans Code “7” is required when there is no ARCOS reportable activity during any reporting period**
- ✓ **Trans Code “8” is required when there is no ARCOS reportable inventory on hand at close of business December 31st**



## ❖ **Non-controlled or Non-reportable**

- ✓ **Non-controlled substances should never be reported to ARCOS; errors will result**
- ✓ **It is best not to include non-reportable substances, such as C-III non-narcotics, C-IV, and C-V controlled substances; errors will result if the product is not in our dictionary**



## ❖ **Proof of Processing**

- ✓ **EDI upload confirmation is not confirmation that the report was successfully processed; formatting issues not considered**
- ✓ **Email received from our Unit and confirmation in ARCOS Online are proof that the report has been processed**



# Contact Information



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