ARCOS Unit

Phone: 202-307-8600

Email: ARCOS_Unit@usdoj.gov

Fax: 202-307-8612
Controlled Substances Act

21 U.S.C. § 827: Manufacturers and Distributors are required to report Controlled Substance activity to the Attorney General

Attorney General delegates to DEA

DEA = ARCOS
Controlled Substances Act

ARCOS = Automation of Reports and Consolidated Orders System
ARCOS Unit

- Understanding reporting requirements
- Technical issues
- NDC dictionary
Who Reports to ARCOS?

- Manufacturers
- Repackagers*
- Relabelers*
- Distributors
- Reverse Distributors

*Per 21 U.S.C. § 802(15), these activities are considered “manufacturing”
What is Reported to ARCOS?

- Acquisition and Distribution
- End-of-year Inventory
- C-I, C-II, C-III narcotics and GHB materials
- Destruction
What is Reported to ARCOS?

- Manufacturing
  (see Section 6 of Handbook)

- Also psychotropics listed in 21 C.F.R. § 1304.33(d)
What is Reported to ARCOS?

- No activity for reporting period
- No end-of-year inventory (ARCOS)
- Theft and loss
- Returns vs. purchases
- Waste
What is Reported to ARCOS?

Repackaging and Relabeling

- Registered as Manufacturer
- Contact FDA for labeler code
- General Email: EDRLS@fda.hhs.gov
- Do not use original NDC
What is Reported to ARCOS?

End-of-Year Inventory

- Quarterly: Part of 4th quarter report
- Monthly: Part of December report
- Separate from YERS report (Quota)
- On-hand as of COB December 31st
- Transaction Code 8 – no inventory
What is Reported to ARCOS?

Manufacturing

- 4th quarter or December submission
- Cumulative for the year
- Section 6 of Handbook
Filing Reports

Due the 15th day of the month following the end of the reporting period (21 C.F.R. § 1304.33(b))

Extensions cannot be granted by the ARCOS Unit
Filing Reports

- Quarterly or monthly
- Electronic or manual
- EDI upload print-out is not confirmation that the report was successfully processed
- Cannot file prior to end of period
Filing Reports

Methods of Reporting

- ARCOS Online
- EDI (text file) upload
- DEA Form 333
- Obtain an online account
Filing Reports

Methods of Reporting

ARCOS Online

- Initial release – eliminated PC Field Edit
  - Direct entry into website; errors detected “up front”
- Error correction (any reporting method)
  - Account management
Filing Reports

Methods of Reporting

EDI Upload

- PC Field Edit – no longer supported
- Must be text file format; 80-character
- Large volume

Integration with ARCOS Online
Filing Reports

Methods of Reporting

DEA Form 333

- Must be requested
- Longer process – mailing, data entry
- Good backup option; computer problems
Filing Reports

Central Reporting

- "Single" = default reporting method, one registration
- "Central" = records for multiple registrations held at one location
- Field office authorization required

(21 C.F.R. 1304.04)
Filing Reports

Central Reporting

Proper formatting of Control Record – Central Reporter registration must be included in appropriate field (EDI and paper reporting only)
Filing Reports

Reporting Exceptions

- DEA cannot grant exceptions to requirements imposed by the Controlled Substances Act under 21 U.S.C. § 827(d)
- Reporting of controlled substance activity as required by the Attorney General
Filing Reports

Reporting Exceptions

• HOWEVER ... DEA may grant an exception from ARCOS reporting provisions of 21 C.F.R. 1304.33 to the extent that they go beyond what is required by statute (per 21 C.F.R. § 1307.03)
Filing Reports

Reporting Exceptions

Simply put ... Exception requests must be directed to the Assistant Administrator in charge of the Diversion Control Division.

Must continue reporting until or unless an exception is granted.
Updating Contact Information

- Paper request form – ARCOS website ("ARCOS Participant Information Update Form")
- Email or letter is fine
- ARCOS Online – “Manage Participant Data” button
Updating Contact Information

- Reporter’s responsibility to keep contact information current
- POC for reporting issues – delinquencies, errors, announcements
- Also reporting frequency updates
ARCOS NDC Dictionary

Submitting Labels or Documentation

- Email to ARCOS_Unit@usdoj.gov
- Fax to 202-307-8612
- Upload via ARCOS Online reporting system – must be pdf file
ARCOS NDC Dictionary

Submitting Labels or Documentation

Transactions cannot be processed unless the NDC has been added to the ARCOS dictionary
ARCOS NDC Dictionary
Non-Reportable vs. Non-Scheduled

Non-Reportable = Controlled
Substances not reportable to ARCOS

Can be added to ARCOS dictionary – help clear errors and future reporting

Examples include anabolic steroids and C-V Codeine preparations
ARCOS NDC Dictionary

Non-Reportable vs. Non-Scheduled

- Non-Scheduled = Not C-I through C-V Controlled Substance
  - Cannot be added to ARCOS dictionary
  - Will always result in an error if reported
  - “Controlled Substance Schedules” on Diversion website
Non-Reportable vs. Non-Scheduled

- Non-Scheduled = Not C-I through C-V
- Controlled Substance

- Examples include over-the-counter medications and List 1 Chemicals
ARCOS NDC Dictionary

Use of “Generic” NDCs

- “G” number or “pseudo” provided by ARCOS Unit
- Import/export documentation
- Reverse Distributors
- Manufacturing activities
ARCOS Transactions

- ARCOS Online: Fillable fields
- EDI (text file): 80-character string
- DEA Form 333: 63 boxes (characters)
ARCOS Transactions

- Control Record
- Transaction Code
- Action Indicator
- National Drug Code
- Quantity
- Unit Code
- Associate Registration
- Order Form Number
- Correction Number
- Strength
- Transaction Date
- Transaction ID
ARCOS Transactions

Control Record

- “Year 2000 Formatting Changes”
- EDI (text file) and paper report only
- Problems with Control Record = report not processed
ARCOS Transactions

Control Record

- Reporting Frequency = “M” or “Q”
- Date must be end-of-period and 8-digit
- Improper use of Central Reporter field; subsidiaries only & registered Central Reporters
ARCOS Transactions

Transaction Code

- Section 5.4.3 through Section 5.8.3 of ARCOS Registrant Handbook
- Section 6 of Handbook for manufacturing activities
- Appendices 1 & 2: What is required for each Transaction Code
ARCOS Transactions

Transaction Code

- Acquisitions and Increases
- Dispositions and Decreases
- Inventory
- Manufacturing
- Miscellaneous/Other
ARCOS Transactions

Transaction Code

- Trans Code “P” vs. Trans Code “R”
- Trans Codes “1” and “5” – contact ARCOS Unit; do not use “F”
- Trans Code “Y” – reported by registrant performing destruction
ARCOS Transactions

Transaction Code

- Inventory = Trans Codes “3,” “4,” or “8”; if not present, no credit given for ARCOS end-of-year inventory

- Trans Code “7” required if no activity for reporting period
ARCOS Transactions

Transaction Code

Manufacturing ...

If uncertain, email ARCOS Unit detailed information on activity

Remember, cumulative at end of the year; permission needed for more frequent
ARCOS Transactions

Transaction Code

- Exceptions to Manufacturing ...

- Quantity of a drug is used to produce a product containing the same drug in the same schedule

- Waste, samples, etc. must still be reported
ARCOS Transactions

Action Indicator

- EDI (text file) upload and paper form only; not ARCOS Online

- Used in 3 instances – Insert ("I"), Delete ("D"), or Adjust ("D" & "A")
ARCOS Transactions

Action Indicator

- Delete/Adjust Transaction Pairing – See Section 7.8.2 of the Handbook
- Action Indicator cannot be used on error transactions
- Action Indicator “A” cannot be used without Action Indicator “D”
ARCOS Transactions

National Drug Code (NDC)

- Remember 5 – 4 – 2 format, with zero fill in each section
- Example: 12345-123-1 would be 12345-0123-01
- Example: 1234-0123-01 would be 01234-0123-01
ARCOS Transactions

*National Drug Code (NDC)*

- Again ... NDC must be in ARCOS dictionary before transaction can be processed

- Only report materials per 21 C.F.R. § 1304.33
ARCOS Transactions

Quantity

- **Bulk, raw material**: Used with Unit and Strength to report *weight or volume*
- **Bulk, finished product**: Used to report *total number of tablets, capsules, etc.*
- **Finished product/package**: Used to report *total number of packages*
ARCOS Transactions

Quantity

- The Quantity must be greater than zero to avoid an uncorrectable error
ARCOS Transactions

Unit (or Unit Code)

If the NDC represents a bulk, raw material, the Unit must be ...

- $1 = \text{micrograms}$
- $2 = \text{milligrams}$
- $3 = \text{grams}$
- $4 = \text{kilograms}$
ARCOS Transactions

Unit (or Unit Code)

* If the NDC represents a bulk liquid, the Unit can be *blank* to report number of milliliters, *or* ...

* 5 = milliliters
* 6 = liters
If the NDC represents a finished package, the Unit must be ...

- Blank (most likely)
- D = dozens (x12)
- K = thousands (x1,000)
ARCOS Transactions

Associate Registration

- On the “other end” of the transaction, in most instances
- Can also reference local DEA office in instances such as destruction
- Not always required – see Appendices 1 & 2 in Handbook
ARCOS Transactions

*Order Form Number*

- Required for acquisition and distribution transactions involving C-I and C-II drugs; possible exception with unsolicited returns
- DEA Form 222 or CSOS
ARCOS Transactions

**Correction Number**

- Needed for EDI (text file) upload and paper reporting only

- All uncorrected errors can be queried and corrected in **ARCOS Online**, no matter reporting method
ARCOS Transactions

**Correction Number**

- Can be found on mailed print-outs following submissions; likely discontinued in the future

- Full list can be obtained by contacting the ARCOS Unit
ARCOS Transactions

Strength

- Purity – when reporting a raw material; combined with Quantity and Unit

- Partial or Combined Package (%) – when reporting a finished package; combined with Quantity of 1
ARCOS Transactions

Transaction Date

- Should represent date of physical change of possession
- EDI (text file) format – use 8-digit date
- Calendar feature – ARCOS Online
ARCOS Transactions

Transaction ID

- Always required – no matter reporting method or type of transaction

- ARCOS Online – automated; adjustable in error corrections and possible duplicates
ARCOS Transactions

Transaction ID

- Unique to each transaction line in a report, with some exceptions ...

  - Correction to transaction from previous reporting period

  - Deleting or adjusting a previously submitted transaction
Error Transactions

- Transactions that cannot be processed for various reasons; different from inaccurate transactions
- Correction procedure depends on reporting method; however ...
- All error transaction corrections can be made in ARCOS Online!
Error Transactions

- Correction Number only applies to EDI (text file) upload and paper reporting
- Requests for deletion not likely to be approved; new error deletion feature
- ARCOS Online catches errors up front; only E76 and those related to NDC additions (i.e. still keep an eye on your errors)
Error Transactions

Most Common

- By far, E76 – NDC not found in ARCOS dictionary (42% as of 2/6/2017)
- 2nd most is E16 – Transaction Date outside reporting period (13% as of 2/6/2017)
Error Transactions

Most Common

- 3rd most is E38 – Quantity/Strength issue (9% as of 2/6/2017)

- 4th most is E53 – Order Form missing from transaction (6% as of 2/6/2017)

- Contact ARCOS Unit for assistance!
Title 21 U.S. Code and Title 21 Code of Federal Regulations

*Unofficial* versions of 21 U.S.C. and 21 C.F.R. available under “Resources” tab on Diversion Control Division website

Contact Government Printing Office for *official* versions
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

§ 827(a)(3) – “Complete and accurate”

§ 827(b) – “Contain such relevant information as may be required by ... the Attorney General”; “Maintained separately from all other records”
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

§ 827(b) – “Readily retrievable”; “Kept and available, for at least two years, for inspection and copying”
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

§ 843(a)(4)(A) – Corresponding violations to 21 U.S.C. § 827 ... “Furnish false or fraudulent material information in, or omit any material information from, any application, report, record, or other document required to be made, kept, or filed”
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 U.S.C.

§ 843(a)(4)(A) – Corresponding violations to 21 U.S.C. § 827 ...

- Administrative actions
- Fines and penalties
- Loss of registration
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 C.F.R.

§ 1304.33 – ARCOS reporting requirements; who reports, what is reported, when are reports due; types of transactions and excepted or exempted transactions
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 C.F.R.

§ 1304.04(a) – “Inventory and other records required to be kept ... must be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying”
Title 21 U.S. Code and Title 21 Code of Federal Regulations

21 C.F.R.

Note regarding record retention: If State Law requires a longer retention period, it is expected that records for that period will be available

(citing 21 C.F.R. § 1307.02)
References and Resources

- “Resources” tab on Diversion Control website ...

- Controlled Substance Schedules


- Links to other agencies
References and Resources

- ARCOS section of Diversion Control website (under “Reporting” tab) ...

- ARCOS Registrant Handbook

- ARCOS Online system

- Account request forms

- Announcements
References and Resources

- ARCOS section of Diversion Control website (under “Reporting” tab) ...
- Formatting guidelines
- NDC dictionary (text file)
- Retail Summary reports
- Participant Info Update Form
- FAQs
References and Resources

ARCOS Registrant Handbook

- Section 5 – Transaction Records, including Transaction Codes
- Section 6 – Manufacturing
- Section 7 – Deleting, Adjusting, and Inserting
- Appendices 1 & 2 – Matrices for types of transactions
References and Resources

*Diversion Control Website*

- Contact information; addresses, phone numbers, email addresses
- Upcoming events and presentations from previous events
References and Resources

Food and Drug Administration

✓ Drug Registration and Listing

✓ EDRLS@fda.hhs.gov

✓ Obtain labeler code; other NDC related questions
References and Resources

DailyMed

- National Library of Medicine
- Current drug products; labels and detailed product information
- Submissions from Food and Drug Administration
References and Resources

ARCOS Unit

- Phone: 202-307-8600
- Email: ARCOS_Unit@usdoj.gov
- Fax: 202-307-8612
Questions?
Reporting By Text File

**EDI Upload**

- Manual ARCOS EDI Upload:
  - https://apps.deadiversion.usdoj.gov/arco-edi/

- Automated ARCOS EDI Upload:
  - https://apps.deadiversion.usdoj.gov/arco-edi/FileUploadManager
Reporting By Text File

EDI Upload

Windows Security

The server apps.deadiversion.usdoj.gov is asking for your user name and password. The server reports that it is from.

User name
Password
Remember my credentials

OK  Cancel
Reporting By Text File

EDI Upload

Select Files To Upload

Browse...
Browse...
Browse...
Browse...
Browse...
Browse...

The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the “Submit” button only once.

Submit

Privacy Notice
Under Construction
Reporting By Text File

EDI Upload
Reporting By Text File

EDI Upload

EDI Reporting Upload Page

Select Files To Upload
myarcosreport.txt

The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the “Submit” button only once.

Submit

Privacy Notice
Under Construction
Reporting By Text File

EDI Upload

ARCOS Online Reporting System

Announcing ARCOS Online (PDF)
Additional Enhancements to ARCOS Online (PDF)

Electronic Data Interchange (EDI) Program

Download ARCOS EDI Request Form (PDF)
ARCOS Participant Information Update Form (PDF)

Resources:

ARCOS Registrant Handbook (or Download PDF version)
National Drug Code Dictionary (TEXT)
Download Readme NDC Dictionary Instructions (TEXT)

Retail Drug Summary Reports
Questions & Answers
ARCOS Reporting Notices
Background: What is ARCOS and What Does it Do?
ARCOS Bulletins
Year 2000 Formatting Changes

Background: What is ARCOS and What Does it Do?
### THE TRANSACTION RECORD - AUTOMATED REPORTERS

(Year 2000 Format beginning January 1, 1999)

<table>
<thead>
<tr>
<th>Example Data</th>
<th>FIELD NAME</th>
<th>COLUMN</th>
<th>POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA99999999</td>
<td>REGISTRANT NUMBER</td>
<td>1-9</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>TRANSACTION CODE</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>ACTION INDICATOR</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>000543751**</td>
<td>NDC NUMBER</td>
<td>12-22</td>
<td></td>
</tr>
<tr>
<td>00000002</td>
<td>QUANTITY</td>
<td>23-30</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>UNIT</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>BB99999999</td>
<td>ASSOCIATE REGISTRANT NUMBER</td>
<td>32-40</td>
<td></td>
</tr>
<tr>
<td>000453890</td>
<td>ORDER FORM NUMBER</td>
<td>41-49</td>
<td></td>
</tr>
<tr>
<td>01311997</td>
<td>TRANSACTION DATE (mmddyyyy)</td>
<td>50-57</td>
<td></td>
</tr>
<tr>
<td>91070022</td>
<td>CORRECTION NUMBER</td>
<td>58-65</td>
<td></td>
</tr>
<tr>
<td>0900</td>
<td>STRENGTH</td>
<td>66-69</td>
<td></td>
</tr>
<tr>
<td>0000000088</td>
<td>TRANSACTION IDENTIFIER</td>
<td>70-79</td>
<td></td>
</tr>
</tbody>
</table>

(Leave Blank) 80

**Changes:**

The TRANSACTION RECORD format for automated reporting has been modified for ARCOS-2. The new format has been adopted to ensure compliance with Year 2000 requirements and includes the following changes:

1. The Transaction Date field has been expanded to a 4 digit year. Each field following the Transaction Date has been shifted to the right 2 positions/columns.
2. The Document Id field has been eliminated (Col. 78-80).
3. Column 80 must contain a Blank.
4. Effective Date: January 1, 1999.
THE CONTROL RECORD - AUTOMATED REPORTERS
(Year 2000 Format beginning January 1, 1999)

(Example Data)
AB99999999
*01311999
Q
AA99999999

FIELD NAME
REPORTING REGISTRANT
ASTERISK
LAST DAY OF REPORTING PERIOD (mmddyyyy)
REPORTING FREQUENCY (M or Q)
CENTRAL REPORTER'S NUMBER

COLUMN
1-9
10
11-18
19
20-28

Changes:
The Last Day of Reporting Period field has been modified to include the 4-digit year.
Reporting By Text File

EDI Upload

This is the Control Record, or report header

RP999999999*12312016Q
Reporting By Text File

EDl Upload

These are the Transaction Records that will appear below the Control Record

<table>
<thead>
<tr>
<th>Reporting Registar</th>
<th>Trans. Code</th>
<th>Assoc. Registration Number</th>
<th>Action Ind.</th>
<th>Unit</th>
<th>NDC Number</th>
<th>Quantity</th>
<th>Order Form Number</th>
<th>Trans. Date</th>
<th>Trans. ID</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>RP99999999</td>
<td>12345012301</td>
<td>RB888888888</td>
<td></td>
<td></td>
<td>02468024602</td>
<td>00000004</td>
<td>161234567</td>
<td>10012016</td>
<td>100000</td>
<td>100000001</td>
</tr>
<tr>
<td>RP99999999</td>
<td>12345012301</td>
<td>RS777777777</td>
<td></td>
<td></td>
<td>162468246</td>
<td>11152016</td>
<td>12312016</td>
<td>100000002</td>
<td>100000</td>
<td>100000002</td>
</tr>
<tr>
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<td>12345012301</td>
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<td>162468246</td>
<td>12312016</td>
<td>12312016</td>
<td>100000003</td>
<td>100000</td>
<td>100000003</td>
</tr>
</tbody>
</table>
Reporting By Text File

EDI Upload

Sample of what a text file report would look like – Control Record plus Transactions

This is how to check for TAB key use, extra spaces, etc. in Microsoft Word
Reporting By Text File

EDI Upload
Reporting By Text File

EDI Upload

- Saved in plain ASCII text format
- File extension must be .txt
- If Notepad, change “encoding” to ANSI and save file
- Must be uploaded to process
Reporting By ARCOS Online

Stay tuned for live demo!!