Data Submission Guide for Controlled Substance Reporting

Texas Wholesale Distributor Database

June 2024
Version 1.0

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1   Document Overview

This document serves as a training guide and support manual for Texas-licensed manufacturers and wholesalers who are required to report to the Board of Pharmacy every sale, delivery, or other distribution within or into Texas of a Schedule II-V controlled substance that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted to possess reportable drugs for administration or dispensing to patients. Per Section 431.401 of the Texas Health and Safety Code, intracompany sales (of pharmacies under common ownership) are not considered wholesaler distribution.

The Data Submission Guide includes such topics as:

- Reporting requirements for the Texas Wholesale Distributor Database (TWDD)
- Creating an TWDD Clearinghouse Account
- Uploading your report
- Viewing your report status
- Changing your password
- Error resolution

2 Reporting Requirements

2.1 Who Must Report?

Each Texas-licensed wholesaler (e.g., distributor, manufacturer, repackager, third-party logistics provider, etc.) must report to the Board every sale, delivery, or other distribution within or into Texas of any Schedule II-V controlled substance that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person in this state, with the exception of an educational or research program of a school district or public or private institution of higher education.

If the Texas-licensed wholesaler had no reportable deliveries or distributions, a "zero report" may be submitted instead (see section 2.8 for additional information).

Texas-licensed wholesalers utilizing 3PLs to distribute schedule II-V controlled substances Pursuant to Section 481.0766 of the Texas Health and Safety Code, must ensure these deliveries or distributions are correctly reported to the Board once and only once. Please coordinate with your 3PL to prevent duplicative transaction reporting.

Note: All qualifying transactions MUST be reported, regardless of whether a 3PL was utilized.

2.2 What Data Must Be Reported?

Pursuant to Section 481.0766 of the Texas Health and Safety Code, all wholesale distributions of Schedule II-V controlled substances as defined in the Texas Schedules of Controlled Substances must be reported. If no such distributions occurred, a "zero report" may be submitted (see section 2.8 for additional information).

Automation of Reports and Consolidated Orders System (ARCOS) defines the format for the data reported. Data collected shall include the following:

- Reporting Registrant DEA
- Last Day of Reporting Period MMDDYYYY
- Reporting Frequency
- Central Reporter's DEA
- Transaction Code
- Action Indicator
- NDC Number
- Quantity
- Unit
- Associate Registrant DEA

- Order Form Number
- Transaction Date (MMDDYYYY)
- Correction Number
- Strength
- Transaction Identifier

Please refer to [Appendix A](#) for specific information on character length and order

2.3 What is the Frequency of Reporting?

Pursuant to Section 481.0766 of the Texas Health and Safety Code, distributions must be reported in the same format and with the same frequency as the information reported to the Federal Drug Enforcement Administration.

2.4 In What Format Must the Data be Reported?

Data must be reported in the format defined in the **Automation of Reports and Consolidated Orders System (ARCOS)**.

Please ensure you take into account the format changes from 2000 to the ARCOS format ([Year 2000 Formatting Changes](#)).

2.5 Which ARCOS Transaction Codes Should be Included in the Report?

The TWDD Clearinghouse system may accept the following status codes:

ARCOS Transaction Codes:

- S – Sale, Disposition, or Transfer

- 7 – No ARCOS Activity for the Current Reporting Period (used only for submitting zero reports).

2.6 What File Extensions are Permitted for Reporting and Are There Any File Naming Conventions?

Preferred file extensions include .dat and .txt with a maximum size of 100 MB.

Required Naming Conventions

- The first two characters of the file name should match the state abbreviation of the state to which you are submitting, followed by an underscore, DEA number, followed by a period, and the last date of the date that is being reported in MMDDYYYY format.

  Example:

If submitting data to Texas, your file name should begin with "TX_". You will receive an error if your file name does not adhere to this.

- When submitting multiple files, it is necessary for each file to have a unique file name. When a file name is reused, each subsequent submission replaces the previous one.

  <u>Example:</u>

  A data submitter has two unique files to submit, each containing unique distributions. An acceptable way to name the files is as follows:

  - Submission one: TX_AB1234567.MMDDYYYY_1
  - Submission two: TX_AB1234567.MMDDYYYY_2

2.7 How Should the Report be Submitted?

Reports should be uploaded to the Clearinghouse Portal.

Note: From this point forward, the Clearinghouse Portal may be referred to as the TWDD website.

- For instructions on creating an account, please refer to the [Creating Your Account](#) section of this document.

- For instructions on submitting your report, please refer to the [Submitting Your Report](#) section of this document.

2.8 If a Facility Does Not Have Any Transactions to Report for the Reporting Period, is a Report Required?

If a facility does not have any transactions to report for the reporting period (the previous calendar year) AND has a DEA number, a zero report may be submitted.

A transaction is a sale, delivery, or other distribution within or into Texas of a Scheduled II-V controlled substance that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted to possess reportable drugs for administration or dispensing to patients.

Users may enter a zero report using either of the following methods:

- **Submitting a Zero Report on the Texas Wholesale Distributor Database Reporting Website**:

  [See Section 6.1 for detailed instructions.](#)

  Note: A Texas License number is required. Facilities may enter multiple licenses using one DEA.

  <u>OR</u>

- **Uploading an ARCOS-Formatted Zero Report File:**

  A zero report transaction file contains a control record identifying the reporting facility and a single transaction record with a transaction code of "7" (per DEA ARCOS coding), which indicates that there were no transactions to report during the previous reporting period. See Section 6.2 for more detailed instructions.

  Note: Use this method if your DEA number is not in the format of two letters followed by a 7-digit number.

  For instruction on submitting a zero report, please refer to the Submitting a Zero Report section within this document.
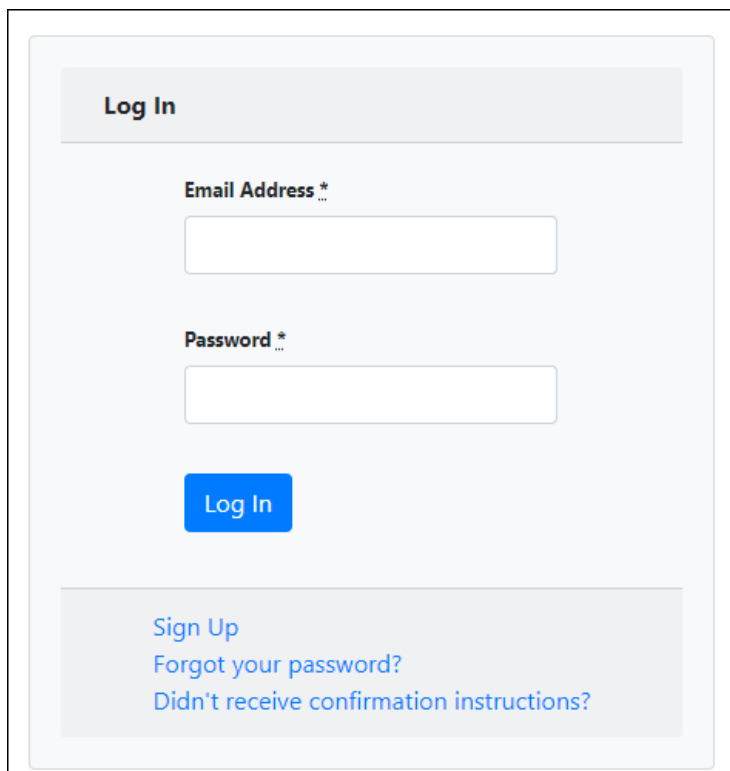
3 Accessing Controlled Substance Product Reporting

This chapter describes how to create your TWDD account and how to log in to the TWDD web portal to upload your controlled substance transaction files.

3.1 Creating Your Account

Prior to submitting your report, you must create an account with TWDD by performing the following steps:

1. Open an internet browser window and navigate to the **Product Reporting** login page located at https://pmpclearinghouse.net/opiatereporting.

2. Click *Sign Up.*

   The **Reporting Registration** page is displayed.

Opiate Product Reporting Registration

Profile Details   * Indicates Required Field

Email Address *

Password *   Password Confirmation *

Contact Information

First Name *   Last Name *

Company Information

DEA Number

Name *   Role *
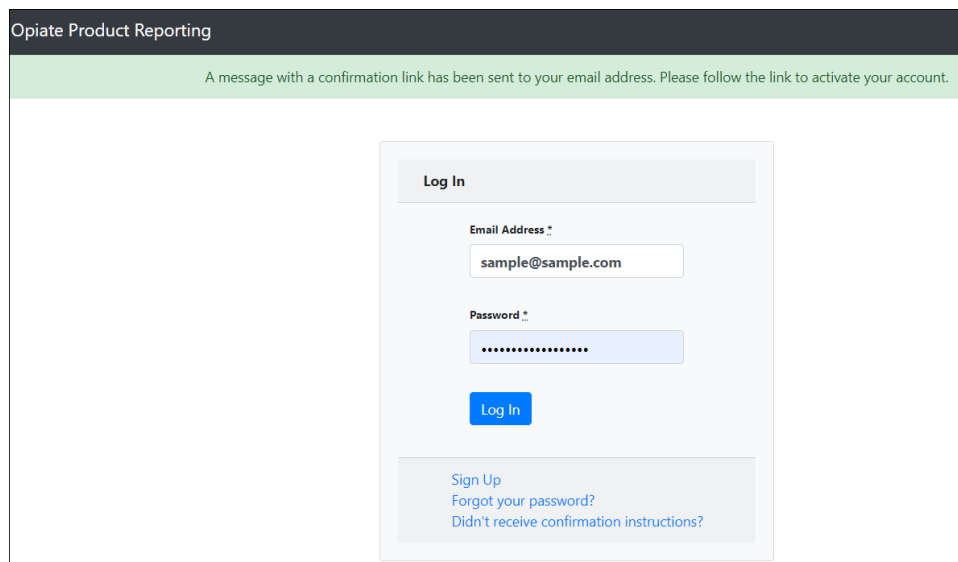
Address *   City *
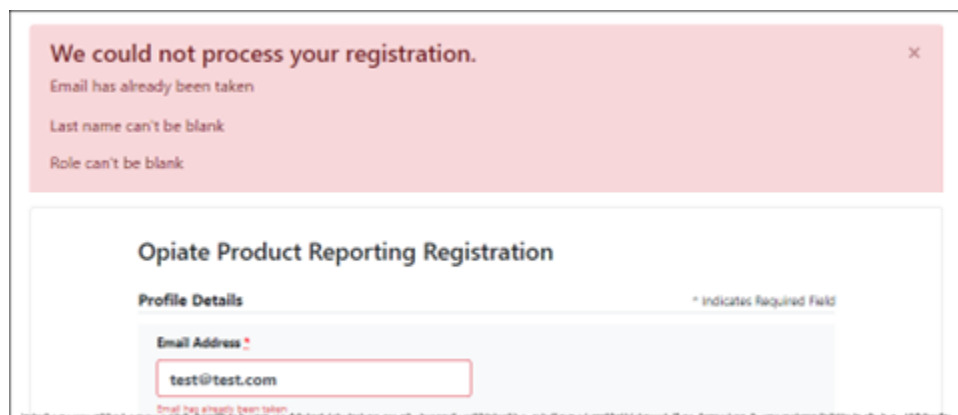
State *   Zip code *

Phone *

[Submit]

Log In
Didn't receive confirmation instructions?

3. Complete your **Profile Details**.

Profile Details   * Indicates Required Field

Email Address *

Password *   Password Confirmation *

a. Enter your current, valid email address in the **Email Address** field.

Note: *The email address you provide here will act as your username when logging into the TWDD website.*

b. Enter a password for your account in the **Password** field, then reenter it in the **Password Confirmation** field. The password requirements are provided below.

Password must contain:

- *At least fourteen (14) characters*
- *One (1) uppercase letter*
- *One (1) lowercase letter*
- *One (1) number*
- *One (1) special character, such as !, @, #, $, etc.*

4. Complete your **Contact Information** and **Company Information**, noting the following:

- Required fields are marked with a red asterisk (*).

- **Reporting** account registration does not require a DEA. You will be able to use the same account for reporting multiple DEA numbers.

5. Click *Submit.*

    a. If there are not any errors upon submission, your account is created. A message will display indicating that you need to confirm your email address to activate your account.

Note: *You will not be able to login until you confirm your email address.*
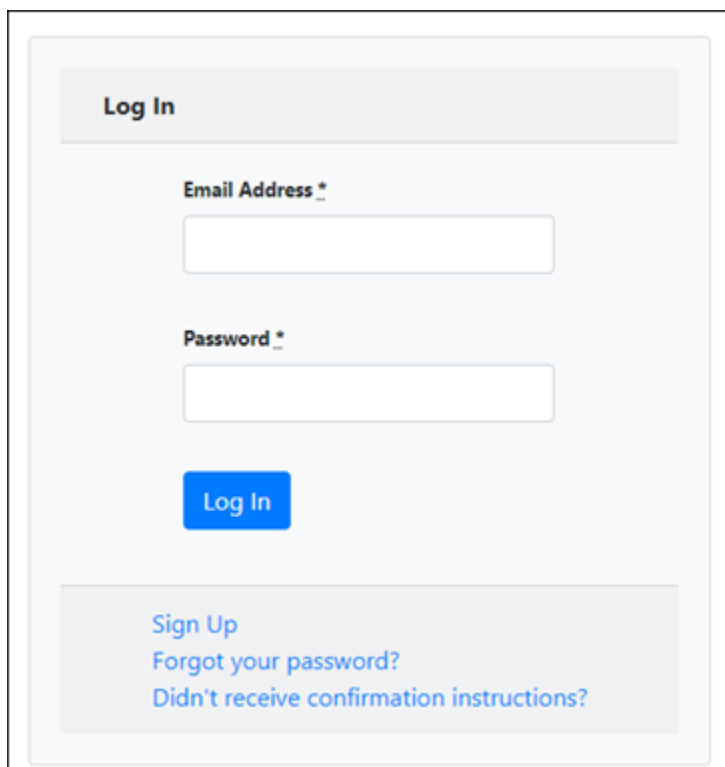
    b. If there are errors upon submission, the error message(s) will display at the top of the page.

        Correct the indicated errors, then click *Submit* to create your account.

3.2 Logging into the Reporting Site

1. Open an internet browser window and navigate to the **Reporting** page located at https://pmpclearinghouse.net/opiatereporting.

2. Enter the email address you used to create your account in the **Email Address** field.

3. Enter your password in the **Password** field.

   *Note: If you have forgotten your password, use the **Forgot your password?** option to have a link sent to your registered email address to assist with resetting your account's password.*

4. Click *Login*.

   The **Reporting** home page is displayed.
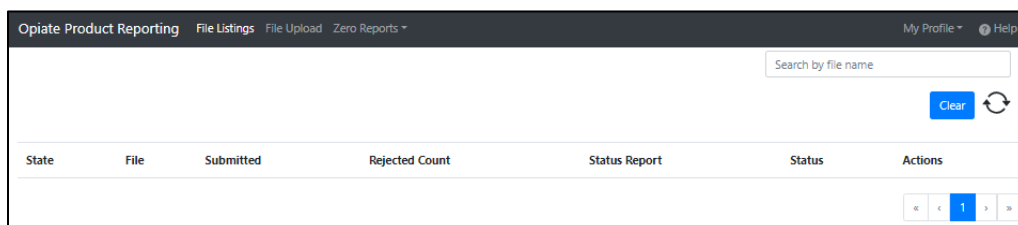
4 Submitting Your Report

4.1 Submission Overview

- If you do not have a TWDD account, perform the steps as outlined in the [Create Your Account](#) section of this document
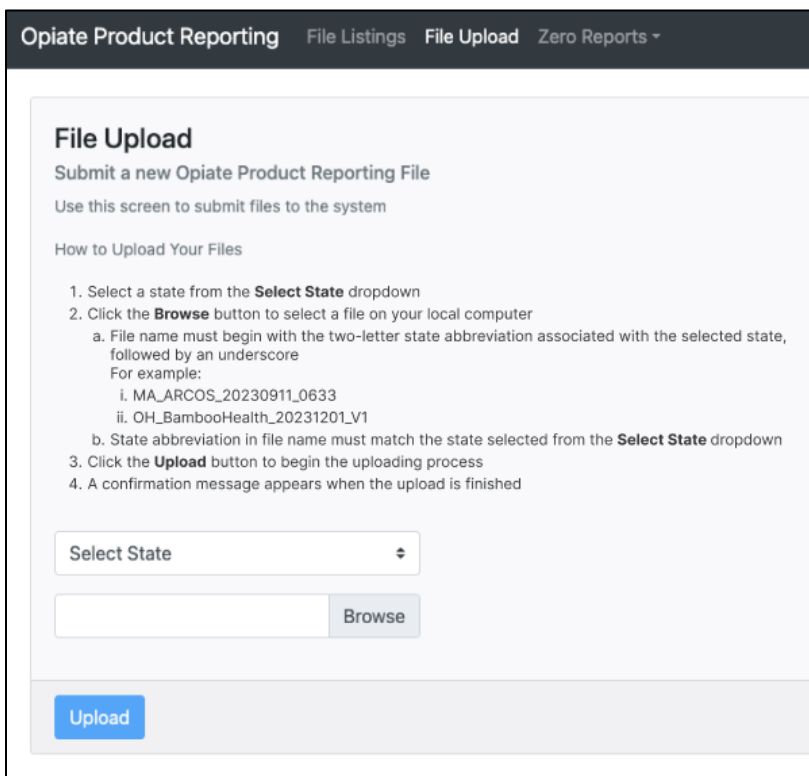
OR

- If you have already created an account, login to the TWDD Portal. This will bring you to the **Reporting** homepage.

1. Navigate to the **File Upload** page from the menu at the top of the screen.

2. Select *Texas* from the **Select State** dropdown menu.

3. Click *Browse* and select the report file.

   Notes:

   - *Please refer to the Reporting Requirements section of this document for information on who and what data must be reported and in what format.*

   - *TXT or DAT is the required file format with a maximum size of 100 MB.*

   - *File name must begin with the two-letter state abbreviation, followed by an underscore, then a unique file name consisting of reporter's DEA number, followed by a period, followed by the reporting date, and any suffixes needed to differentiate multiple reports as described in Section 2.6*
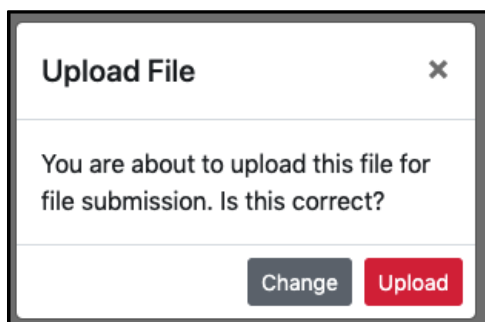
   Example:

   TX_AB1234567.MMDDYYYY.txt

   TX_AB1234567.MMDDYYYY.dat

4. Click *Upload.*

   A message will display prompting you to confirm the file submission.

5. If you need to make any changes, click *Change* to return to the **File Upload** page

   OR

6. Click *Upload* to continue with the submission of your report.

   Once you click *Upload*, your file is submitted and a message will display indicating that your file was successfully submitted. At this point, you will be redirected to the **File Listing** page. If the status displays as *Processed,* then your filed was accepted.

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> **Note:** *Users are able to refresh this page.*

A file status of *Deleted* indicates that there were errors with your submission. If this happens, you should review the errors on the **Status Report** for further details.

4.2 Upload Errors

The state abbreviation provided in the file name (TX_) will be validated against the state selected from the submission page drop-down menu (Texas).

If the state selected from the drop-down **does not** match the file name the following error message will be displayed:

An example for an appropriate control record can be found below:

Files with an incorrect **Control Record** will not upload and will display an error.

A control record looks like this: **AB9999999*01312021QAA9999999**

Field Name	Data Field Number	Column Position	Characters	Possible Values	Example
*REPORTING REGISTRANT	1	1-9	9		AB9999999
*ASTERISK	2	10	1		*
*LAST DAY OF REPORTING PERIOD	3	11-18	8		01312021
REPORTING FREQUENCY	4	19	1	M, Q, Y	Q
CENTRAL REPORTER'S NUMBER	5	20-28	9		AA9999999

*- Required field

Common **Control Record** errors include:

- Missing/Invalid Reporting Registrant DEA
- Missing Asterisk (*)
- Missing/Invalid Reporting Period Date
- Missing/Invalid Reporting Period

Examples of Control Record Display Errors:

For more information regarding the **Control Records** format, please refer to
[Appendix A](#).

5 Status Reports

Status Reports are used to confirm receipt of files and identify errors in files that have been submitted. After submission of their Texas Wholesale Distributor Database **Report**, a user will receive a **Filed Failed Report** or a **File Status Report** via email notification. This is also viewable from the **File Listing** screen within the TWDD website.

This chapter describes the status reports, status report errors, and how to correct them.

5.1 File Status Report

The *File Status Report* serves as notification that a data file was received by the system. This report will either confirm there were no errors in the file or in the event of errors, identify the specific errors.

Below is an example of a *File Status Report:*

```
+----------------+----------------------+---------------------------+------------+--------------------+
| Associate DEA  | Transaction Identifier | Column                  | Value      | Error Message      |
+----------------+----------------------+---------------------------+------------+--------------------+
| A 3642116      |                      | Ndc                       | 0092116037 | invalid NDC number |
| A 3642116      |                      | Quantity                  | 000000 4   | is not a number    |
| A 3642116      |                      | Transaction date          |            | invalid date format|
| A 3642116      |                      | Associate registrant dea  | A 3642116  | invalid DEA number |
| A 3642116      |                      | Reporting registrant dea  | R 0490499  | invalid DEA number |
+----------------+----------------------+---------------------------+------------+--------------------+

Records cannot be corrected individually. To correct the errors:
  • Make corrections in the originally submitted file.
  • Resubmit the original file with the same file name in its entirety.

*File Name: ARCOS_FILE_I.DAT
*Date of Submission: October 15, 2021
```

The *File Status Report* notifies you of the following scenarios:
- Invalid/Missing Transaction Date
- Invalid/Missing Transaction Identifier
- Invalid/Missing NDC
- Invalid/Missing Quantity
- Invalid/Missing Reporting Registrant DEA
- Invalid/Missing Associate DEA

5.2 Viewing a Status Report

To view a **Status Report**:

1. Log into TWDD website.

2. Click the blue *Status Report* button.

A simplified version of the **Status Report** is also emailed to submitters. Like the status reports viewable within the OPR website, they indicate if a file submission has errors or not. To see the error details, the user must click the *Status Report with errors* link and login to the TWDD website.

5.3 File Failed Status Report

In most cases, an invalid file cannot be uploaded as described in Section 4.1. In the instances where a file is uploaded but cannot be parsed, a *File Failed Report* is generated. In the event of a failed file, a new file must be submitted with the necessary corrections.

Below is an example of a *Failed File Report:*

5.4 Error Corrections

If a transaction record was misreported to the Board, you must follow these instructions to correct the record. Corrections must be made within the originally submitted file. You must then resubmit the file with the same file name as when it was originally uploaded.

To correct a misreported transaction record:

1. Make all necessary corrections in the originally submitted file, leaving the accurate transaction records unmodified.

2. Submit the corrected file with the exact SAME file name as the file you are correcting.
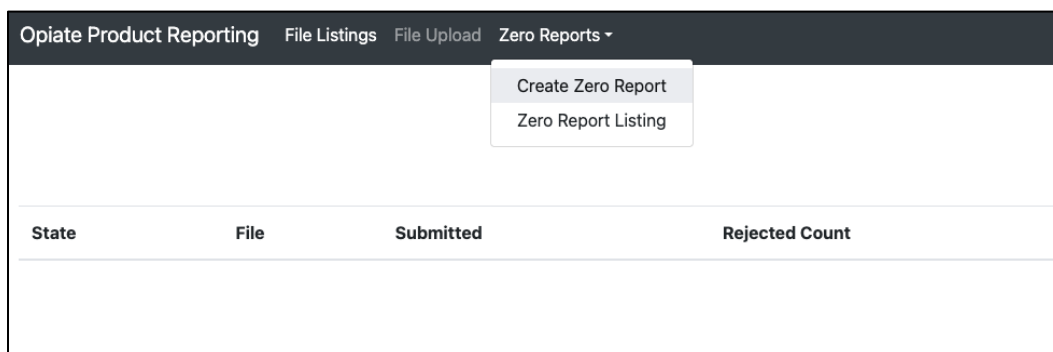
6   Submitting a Zero Report

If a facility does not have any transactions to report for the reporting period AND has a DEA number, a zero report may be submitted.

You may enter a zero report using the TWDD website or by uploading an ARCOS transaction file.
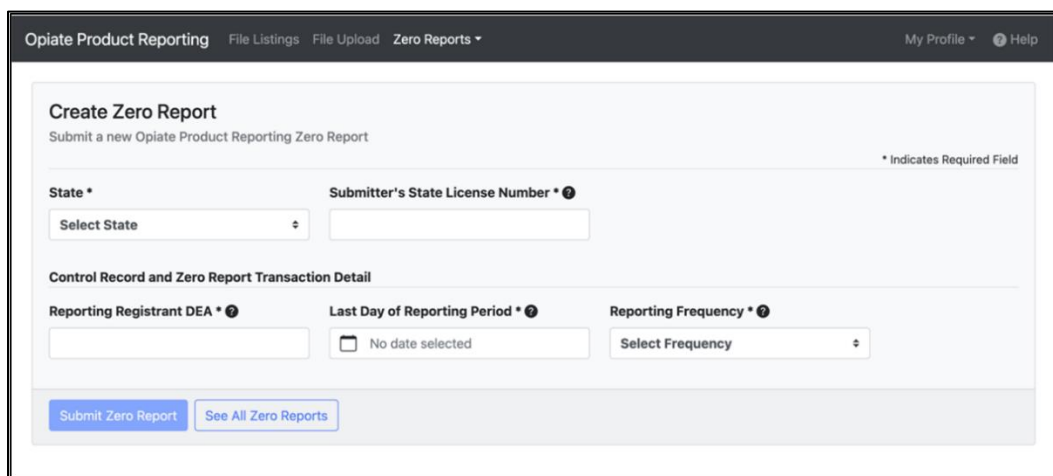
Note: A transaction is considered a sale, delivery, or other distribution within or into Texas of a Schedule II-V controlled substance that is made to any practitioner, pharmacy, hospital, veterinary hospital, or other person who is permitted to possess reportable drugs for administration or dispensing to patients.

6.1   Creating a Zero Report via TWDD Website

1. Open an internet browser window and navigate to the **Reporting Portal** page located at https://pmpclearinghouse.net/opiatereporting.

2. Navigate to the **Create Zero Report** page by clicking *Zero Reports*.

3. Choose **Create Zero Report** from the dropdown menu.

4. Populate all required fields noted with an asterisk (*) as outlined below:

a) ***State** – Select the state to which you are submitting the **Zero Report** (Texas).
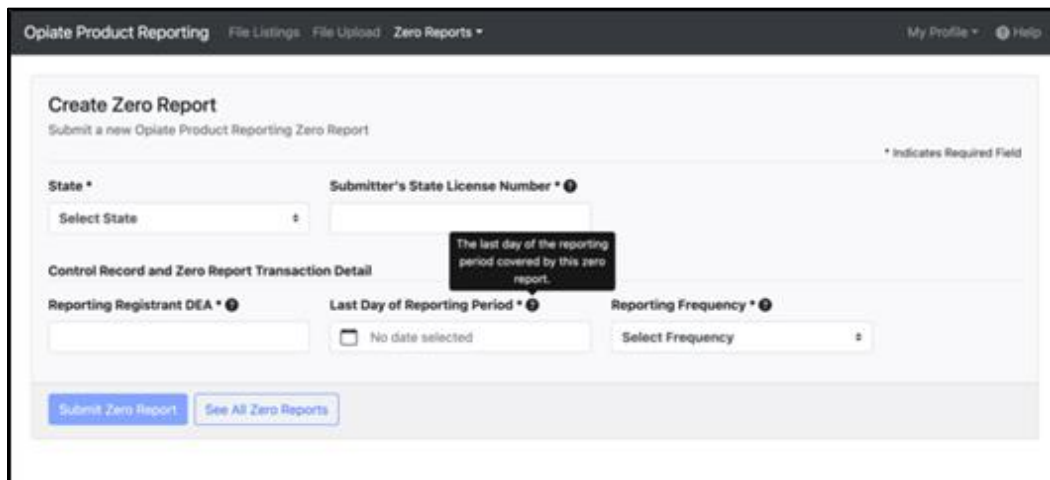
b) ***Submitter's State License Number** – Enter your Texas Department of State Health Services (DSHS) issued license number(s). The license number should be the submitter's (aka central reporter) state license number. If your entity possesses multiple license numbers from this state, please enter all license numbers associated with the DEA number entered, separating each license number with a semicolon and space ("; "). Example: 123456; 987654

c) ***Reporting Registrant DEA** – The Reporting Registrant DEA is the DEA registration number for the facility you are indicating had no reportable activity.

d) ***Last Day of Reporting Period** – The last day of the reporting period covered by a zero report. For example, when trying to report December 2023 transactions, the last day of reporting period would be 12/31/2023.

e) ***Reporting Frequency** – The Reporting Registrant DEA's reporting frequency to the State selected (e.g., quarterly or monthly).

Descriptions of each field are also available by hovering over the ❓ icons on the **Create Zero Report** page.

Below is an example for **Last Day of Reporting Period:**

5. Once all fields are populated, click *Submit Zero Report.*

   Confirm you are submitting the correct information and click *Submit.*

6. Zero reports submitted through the **Create Zero Report** page can be viewed in the **Zero Reports** page. To view the **Zero Reports** page, click on the menu bar and navigate to **Zero Reports > Zero Report Listing**.

6.2   Uploading a Zero Report via an ARCOS File

1. Your file should contain a control record identifying the reporting facility and a single transaction record with a transaction code of "7" (per DEA ARCOS coding), which indicates that there were no transactions to report during the previous calendar year.

    Please refer to [Appendix B](#) for additional information on formatting.

2. Open an internet browser and navigate to the **Reporting** page located at https://pmpclearinghouse.net/opiatereporting.

3. Click *File Upload*.

    The **File Upload** page is displayed.

4. Select *Texas* from the **Select State** dropdown menu.

5. Click *Browse* and select the report file.

> **Notes:**
>
> - *Please refer to Appendix B within this document for information on zero report requirements for TWDD.*
>
> - *File name **must begin with the two-letter state abbreviation, followed by an underscore, DEA number, followed by a period and Date Format MMDDYYYY (e.g., TX_AB123456.MMDDYYYY).***

6. Click *Upload.*

A message is displayed prompting you to confirm the file submission.

Upload File ✕

You are about to upload this file for
file submission. Is this correct?
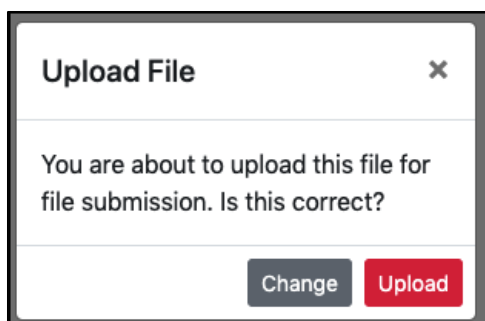
[Change] [Upload]

7. If you need to many any changes, click *Change* to return to the **File Upload** page.

OR

8. Click *Upload* to continue with the report submission.

Once you click *Upload*, your file is submitted. A message will display indicating that your file was successfully submitted. You will then be redirected to the **File Listing** page.

7   Changing Your Password
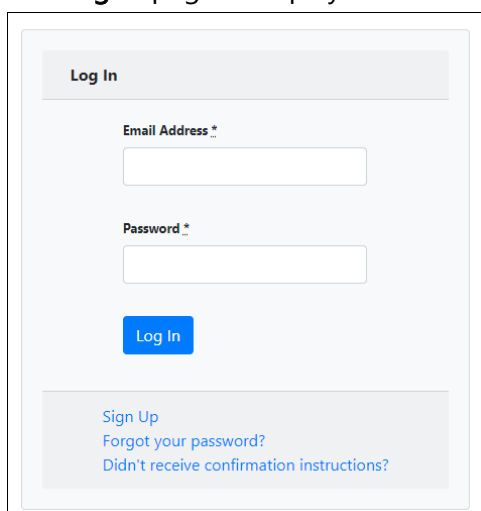
There are two ways you can manage your password:

1. If you have forgotten your password, you can reset your password.

    OR

2. You can proactively change your password within the application before it expires by updating your current password.

7.1   Forgotten Password
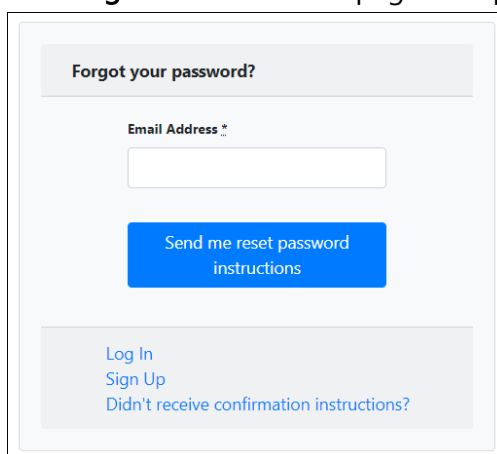
1. Open an internet browser and navigate to the **Reporting** login page located at https://pmpclearinghouse.net/opiatereporting.

    The **Log In** page is displayed.

2. Click the **Forgot your password?** Link.

    The **Forgot Your Password** page is displayed as shown on the following page.

3. Enter the email address for your account in the **Email Address** field, then click *Send me reset password instructions*.

A reset password link will be sent to your email address.
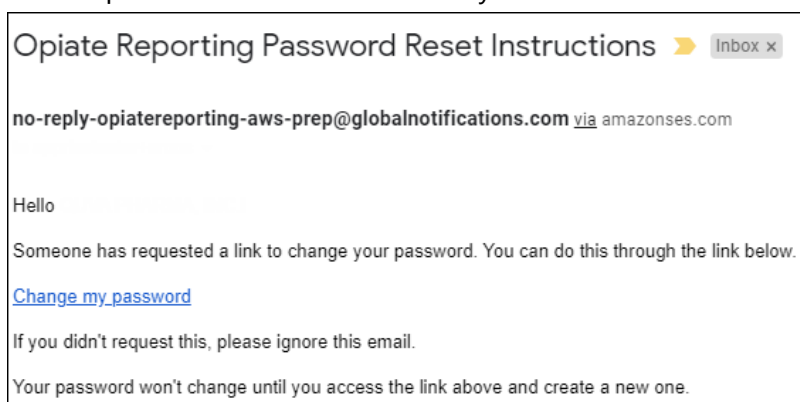
4. Once you have received the email, click the *Change my password* link.

   The **Change Your Password** page is displayed as shown on the following page.

5. Enter a new password in the **New Password** field, then re-enter it in the **Confirm new password** field.
6. Click *Submit*.
   Your password is updated, and you will use the new password the next time you login to the system.

7.2 Password Change

If your password has not expired, but you would like to proactively reset it, you can do so within the application at any time.

Note: This functionality requires that you know your current password and are logged in to the application.

1. Click **My Profile > Change Password**
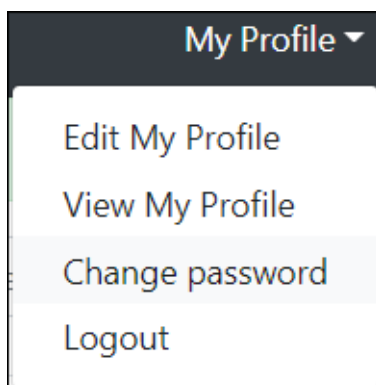
The **Change Password** page is displayed.

2. Enter your current password in the **Current Password** field.

3. Enter a new password in the **New Password** field, then re-enter it in the **New Password Confirmation** field.

4. Click *Update*.

   Your password is updated, and you will use the new password the next time you login to the system.

8 Assistance and Support

8.1 Technical Assistance

If you need additional help with any of the procedures outlined in this guide, you can:

- Contact Bamboo Health at 1-844-966-4767

OR

- Create a support request at the following URL:
  https://opiateproductreporting.zendesk.com/hc/en-us/

OR

- Help icons are on the top right-hand corner of each Texas Wholesale Distributor Database Clearinghouse page to link directly to Bamboo Health online support.
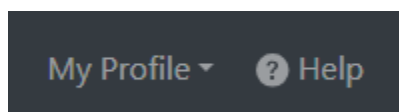
Technical assistance is available Monday through Friday from 8:00 a.m. – 5:00 p.m. CT.

8.2 Administrative Assistance

If you have non-technical questions regarding the **Texas Wholesale Distributor Database (TWDD),** please contact:

ADDRESS: Texas State Board of Pharmacy

1801 Congress Ave., Suite 13.100

Austin, TX 78701

Email: texaspmp@pharmacy.texas.gov

Phone: 1-512-305-8050

Website: www.pharmacy.texas.gov/PMP

9 Document Information

9.1 Disclaimer

Bamboo Health has made every effort to ensure the accuracy of the information in this document at the time of printing. However, information is subject to change.

9.2 Change Log

Version	Date	Chapter/Section	Change Made
1.0		N/A	N/A; initial publication

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Appendix A: ARCOS Report Requirements for Texas Wholesale Distributor Database

ARCOS uses a fixed width file format. Below are the expected columns and their width. (R=Required, O=Optional/Situational)

Control Record (first line of file)			
Field Name	**Length**	**Required**	**Notes**
Reporting Registrant DEA	9	R	
Asterisk (*)	1	R	
Last Day of Reporting Period MMDDYYYY	8	R	Should always be last day of reporting period, e.g., 12312021
Reporting Frequency	1	R	
Central Reporter's DEA	9	O	

Below is an example of a transaction record. The start of each field is underlined and has the start position number above it.

1   10 11   19 20

<u>AB9876543</u>*<u>12312021</u><u>YA</u>A9999999

Transaction Record (second and each subsequent line of file)				
Field Name	**Required**	**Length**	**Position**	**Notes**
Registrant DEA	R	9	1-9	
Transaction Code	R	1	10	"S" should always be used to represent Sale, Disposition, Transfer
Action Indicator	O	1	11	
NDC Number	R	11	12-22	
Quantity	R	8	23-30	

Unit	O	1	31	
Associate Registrant DEA	R	9	32-40	
Order Form Number	O	9	41-49	
Transaction Date (MMDDYYYY)	R	8	50-57	
Correction Number	O	8	58-65	
Strength	O	4	66-69	
Transaction Identifier	R	10	70-79	
Blank Space	R	1	80	

Below is an example of a transaction record. The start of each field is underlined and has the start position number above it.

1   101112   23   31 32   41   50   58   66   70   80

AB9876543SI000999999**000000022BC9999999000999999123120209999999910000000000001

Appendix B: Zero Report Requirements for TWDD

The following table contains the required definitions for submitting zero reports via ARCOS format to TWDD.

Control Record (first line of file)			
Field Name	**Length**	**Required**	**Notes**
Reporting Registrant DEA	9	R	
Asterisk (*)	1	R	
Last Day of Reporting Period MMDDYYYYY	8	R	Should always be last day of reporting period, e.g. 12312021
Reporting Frequency	1	R	
Central Reporter's DEA	9	O	

Transaction Record (second line and each subsequent line of file)				
Field Name	**Required**	**Length**	**Position**	**Notes**
Registrant DEA	R	9	1-9	
Transaction Code	R	1	10	"7" should always be used to represent No ARCOS Activity for the reporting period
Action Indicator		1	11	
NDC Number		11	12-22	
Quantity		8	23-30	
Unit		1	31	
Associate Registrant DEA		9	32-40	
Order Form Number		9	41-49	

Transaction Date (MMDDYYYY)	R	8	50-57	
Correction Number		8	58-65	
Strength		4	66-69	
Transaction Identifier	R	10	70-79	
Blank Space		1	80	

Sample Zero Report

A sample zero report is illustrated below. The Control Record (first line) is required along with a transaction record. The transaction record only needs Registrant DEA, Transaction Code, Transaction Date, and Transaction Identifier.

```
AA1234567*12312020Y
BB12345677                              12312020          0000000001
```