Bamboo Health

Data Submission Guide for Opioid Medication Management

Michigan Opioid Medication Management System

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Version 1.0

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1 Document Overview

This document serves as a training guide and support manual for Michigan-licensed manufacturers and wholesalers who are required to report to the board every sale, delivery, or other distribution within or into Michigan of an Opioid 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. This document is also intended for Michigan-licensed pharmacies with at least one location in the State, that receives intracompany deliveries or distributions into Michigan of any Opioid to the extent those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy.

The Data Submission Guide includes such topics as:

- Reporting requirements for the Opioid Medication Management System
- Creating a System account
- Uploading your report
- Viewing your report status
- Changing your password
- Error resolution

2 Reporting Requirements

2.1 Who Must Report?

Each MI-licensed manufacturer and each MI-licensed wholesaler must report to the board every sale, delivery, or other distribution within or into Michigan of any Opioid 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, as required by Public Law 2020 Chapter 536 (LD 793) Eff. June 16, 2020.

Each owner of a MI-licensed pharmacy with at least one location within Michigan must report to the board any intracompany delivery or distribution into MI of any Opioid to the extent that those deliveries and distributions are not reported to the board by a licensed wholesaler owned by, under contract to, or otherwise operating on behalf of the owner of the pharmacy.

2.2 What Data Must Be Reported?

All sales, delivery, intracompany transfers, or other distributions of Opioids must be reported.

2.3 What is the Frequency of Reporting?

2.3.1 Per section §7249-B. Opioid medication distribution monitoring information

A manufacturer of an opioid medication that is available in this State and a wholesaler that sells or distributes an opioid medication in this State shall submit to the department, by electronic means or other format specified in a waiver granted by the department, information for this State submitted to the United States Drug Enforcement Administration's Automation of Reports and Consolidated Orders System pursuant to 21 United States Code, Subchapter I and 21 Code of Federal Regulations, Section 1304.33 at the time that information is submitted to the United States Drug Enforcement Administration.

Manufactures and wholesalers must submit the same information and frequency as to what and when they send to the United States Drug Enforcement Agency.

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).

Note: *The ARCOS format is being used for reporting with the following exception: This is a monthly report* ***not*** *a quarterly or annual report. Please ensure you take into account the format changes from 2000 to the ARCOS format (Year 2000 Formatting Changes).*

Please submit the previous 2 years prior to your first ARCOS regular submission.

2.5 What ARCOS Transaction Types Should be Included in the Report?

The system can accept the following status codes:

- ARCOS Disposition Transaction Codes (Decreases to Inventory)
- S- Sale, Disposition, or Transfer

Miscellaneous transaction codes:

- 7 – No ARCOS Activity for the Current Reporting Period

2.6 What File Extensions are Permitted for Reporting?

Preferred file extensions include .dat and .txt with a maximum size of 100 MB. The suggested naming convention for report files is as follows:

- DEA number of reporting manufacturer or distributor
- Year of reporting period

Example: *AB987643_2019.txt*

2.7 How Should the Report be Submitted?

Reports should be uploaded to the 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 has no Transactions to Report for the Reporting Period is a Report Required?

Yes. If a facility has no transactions to report for the reporting period (the previous calendar year) AND has a DEA number, a zero report must be submitted. The zero report contains a header 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. A sample zero report can be found in Appendix A.

If the facility does not have a DEA number and has no transactions to report, an exemption from reporting form can be submitted to the Board. The exemption form is located on the Board's website: https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy Opioid Medication Management and Fee Collection Program.

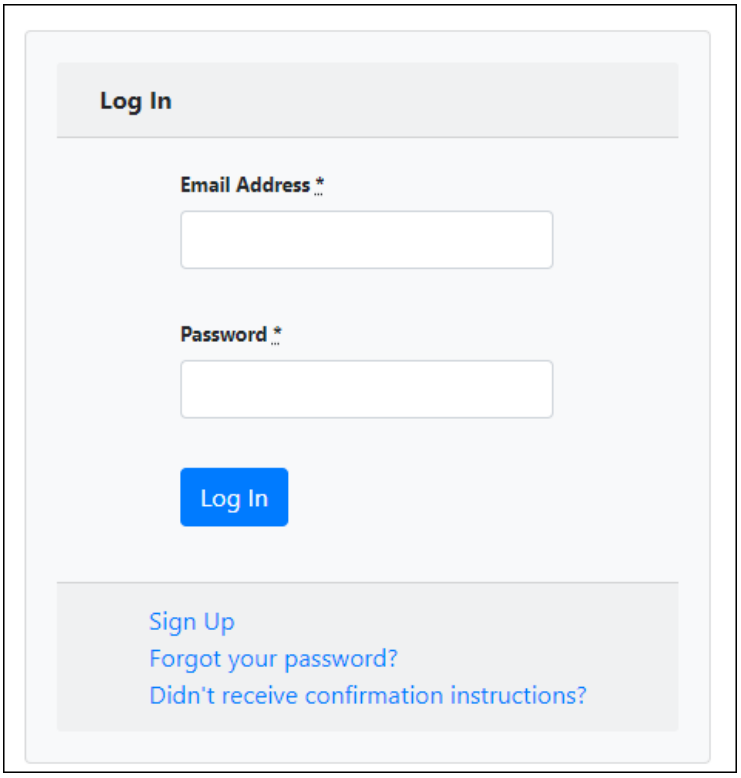
3 Accessing Clearinghouse

This chapter describes how to create your account and how to log in to the web portal to upload your Opioid product or zero report files.

3.1 Creating Your Account

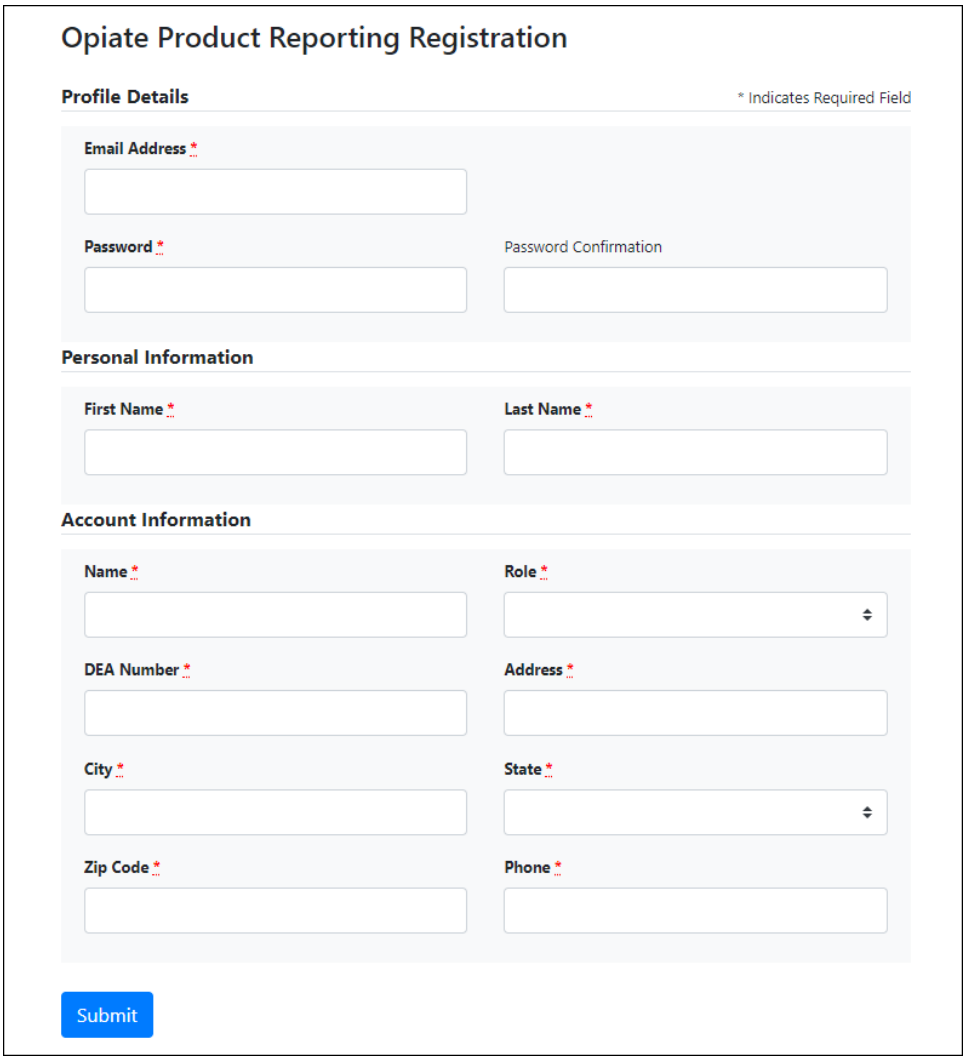
Prior to submitting your report, you must create an account by performing the following steps:

1. Open an internet browser window and navigate to the Opioid Reporting log in page located at https://pmpclearinghouse.net/Opioidreporting.

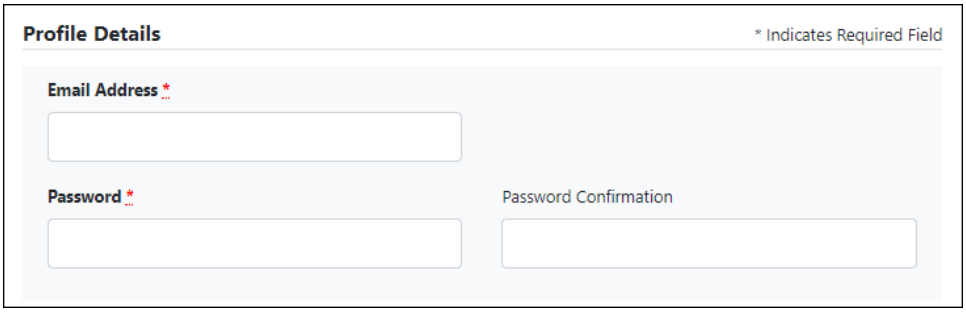


2. Click **Sign Up.**

   The **Opioid Medication Management Registration** page is displayed as shown on the following page.



3. Complete your Profile Details.



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

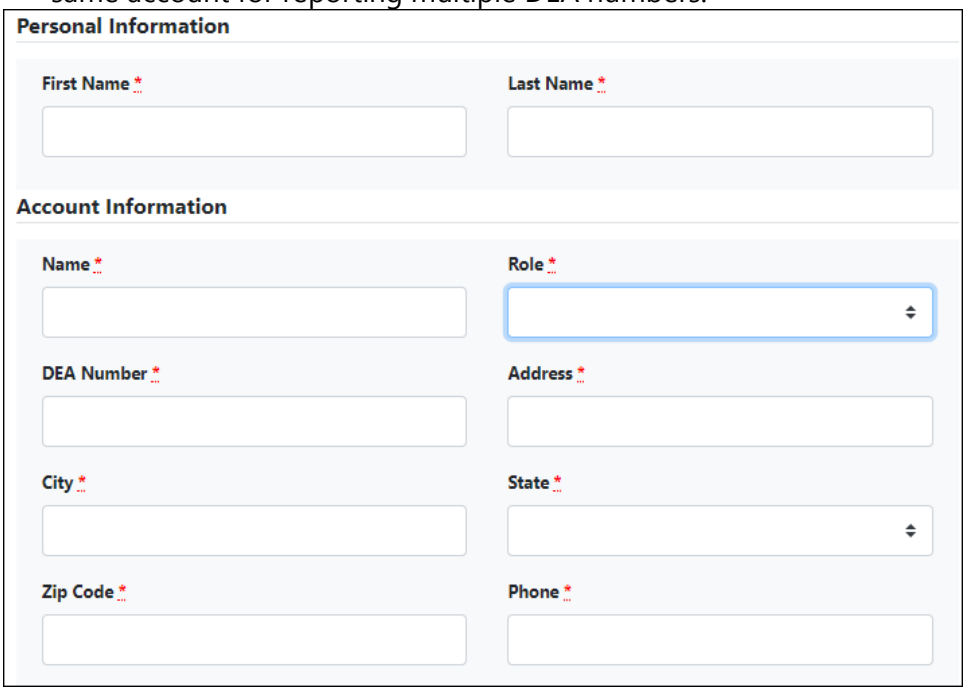
      Note: *The email address you provide here will act as your username when logging into the MEOMM system.*

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

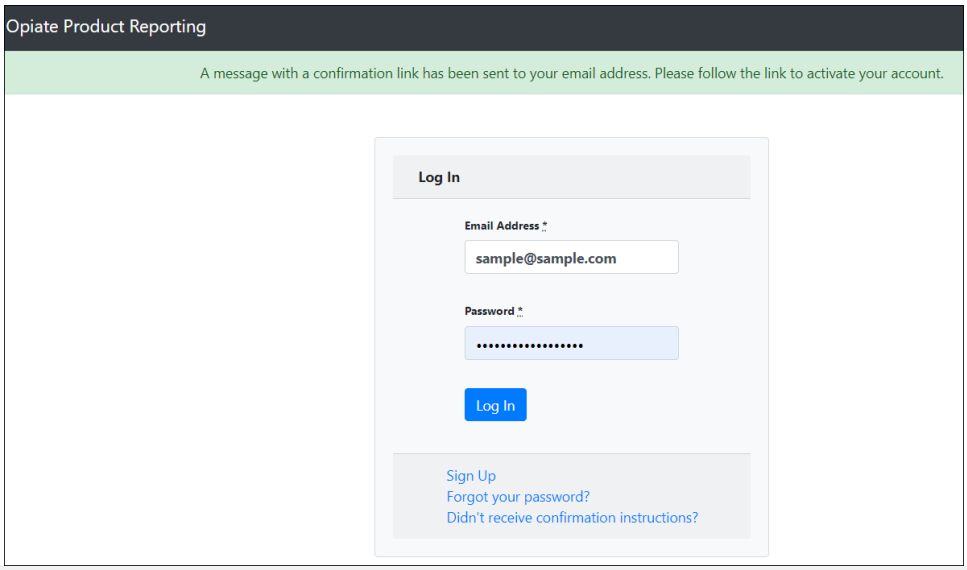
Password must contain:

- *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 Personal and Account information, noting the following:
   - Required fields are marked with a red asterisk (*).
   - Reporting by DEA is required. If you have multiple DEA numbers, create your account using your primary DEA number. You will be able to use the same account for reporting multiple DEA numbers.

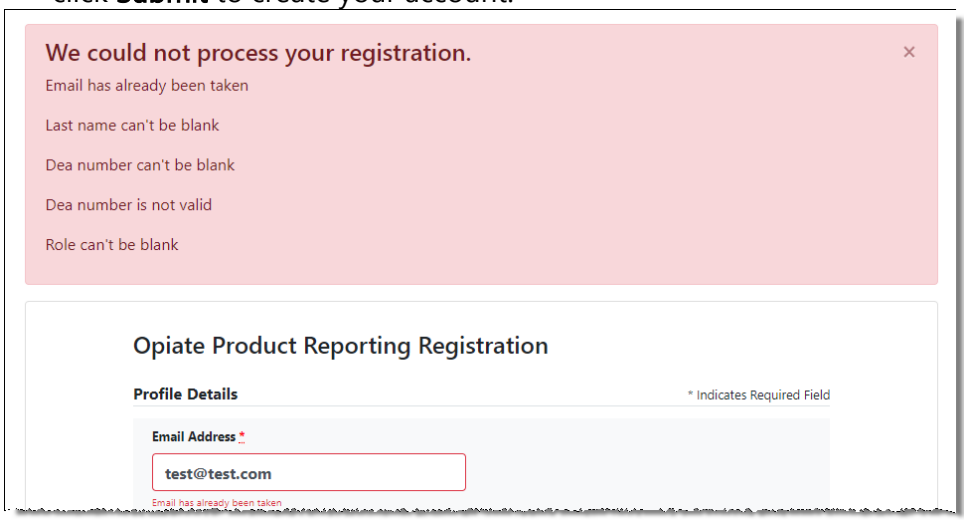


5. Click **Submit.**
   Once you click **Submit**, your DEA number will automatically be validated.
   a. If there are no errors upon submission, your account is created, and a message is displayed indicating that you need to confirm your email address to activate your account.



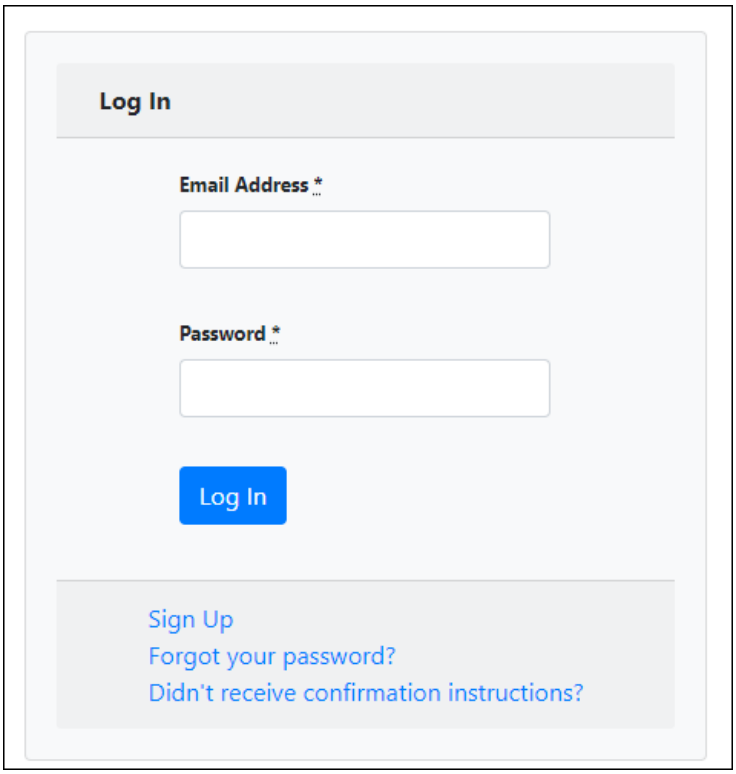
Note: *You will not be able to log in until you confirm your email address.*

b. If there are errors upon submission, the error message(s) will be displayed at the top of the page. Correct the indicated errors, then click **Submit** to create your account.



3.2 Logging in to the Opioid Reporting Site

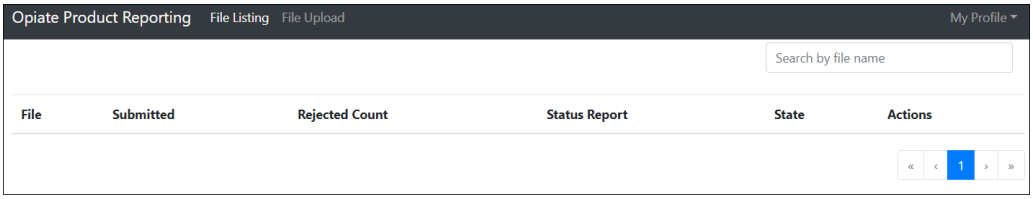
1. Open an internet browser window and navigate to the Opioid Reporting log in page located at https://pmpclearinghouse.net/Opioidreporting.



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?*** *link to have a link sent to your email address to assist with resetting your account password.*
4. Click **Login.**

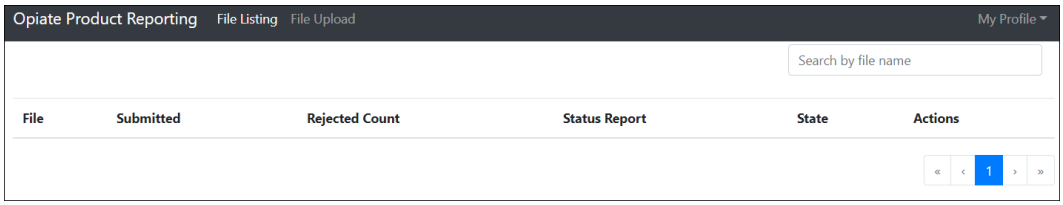
   The **Opioid Product Reporting** home page is displayed.



4 Submitting Your Report

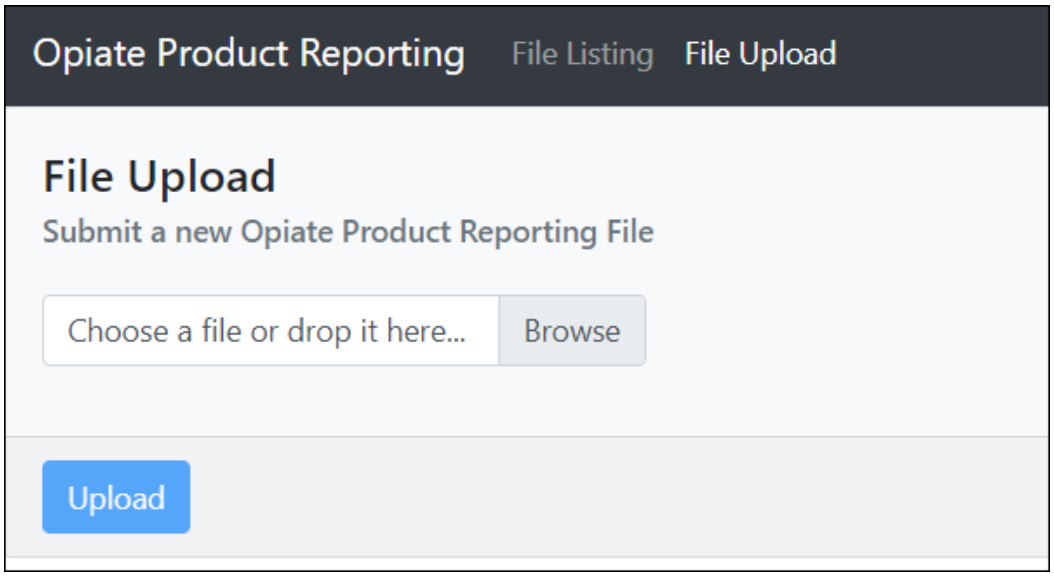
To submit your annual report:

1. If you do not have an account, perform the steps in Creating Your Account; or
2. If you have already created an account, log in. The **Opioid Product Reporting** home page is displayed.



3. Click **File Upload**.

   The **File Upload** page is displayed.



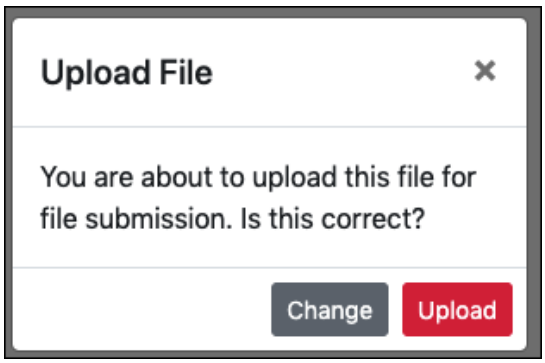
4. Click **Browse** and select the report file.

   Notes:

   - *Please refer to the Reporting Requirements section of this document for information on what data must be reported and in what format.*
   - *TXT is the required file format with a maximum size of 100 MB.*
   - *The suggested naming convention for report files is as follows: DEA number of reporting manufacturer or distributor + year of reporting period + file extension (e.g., .txt or .dat). An example file name would be "AB9876543_2020.txt".*

5. Click **Upload**.

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



6. If you need to make any changes, click **Change** to return to the File Upload page; or
7. Click **Upload** to continue with the report submission.

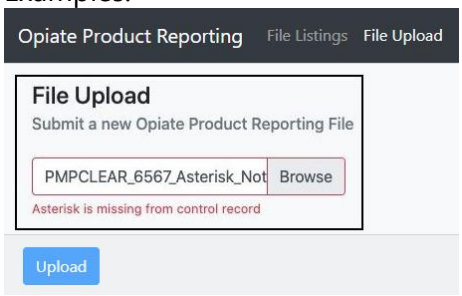
   Once you click **Upload**, your file is submitted, and a message is displayed indicating that your file was successfully submitted. You will then be redirected to the File Listing page.

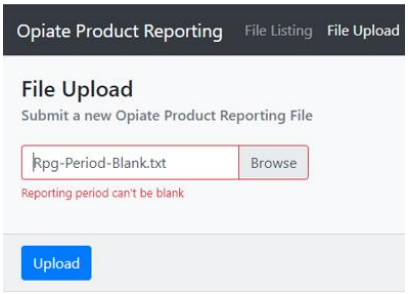
4.1 Upload Errors

When uploading a file, a validation check for the *Control Record* is done initially. Files with an incorrect *Control Record* will not upload and display an error. Common *Control Record* errors include:

- Missing/Invalid Reporting Registrant DEA
- Missing Asterisk
- Missing/Invalid Reporting Period Date
- Missing/Invalid Reporting Period

Examples:





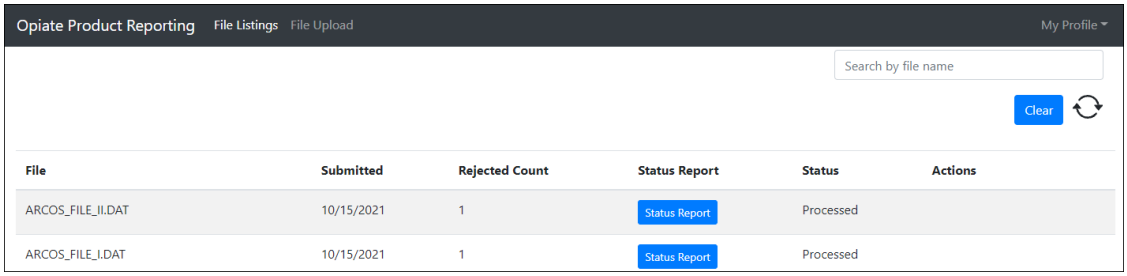
For more details regarding *Control Records* format see Appendix A.

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 Opioid product 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 Clearinghouse Website. This chapter describes the status reports, status report errors, and how to correct them.

To view a Status Report:

1. Log into Clearinghouse.
2. Click the blue *Status Report* button.



5.1 File Failed Report

In most cases, an invalid file cannot be uploaded as describe 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 **File Failed Report:**

*File Name: future_date.txt
*Date of Submission: February 16, 2021

This file could not be received into the system because the system could not recognize its content as a valid ARCOS format. Action is required to resolve the issues and a subsequent file should be submitted.

5.2 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 **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

5.3 Error Corrections

Records cannot be corrected individually. To correct errors:

1. Make corrections in the originally submitted file; or
2. Resubmit the original file with the SAME file name in its entirety.
   Note: *In order to delete a valid entry that was in error,* ***enter zero for the quantity*** *and resubmit the file using the* ***same as the original.*** *The* ***Action Indicator*** *will not be used when deleting a valid entry.*

5.4 Status Report Emails

A *Status Report* is also emailed to submitters. Like the status reports viewable within Clearinghouse, 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 Clearinghouse.

Status Report with errors
Your file submission contains 1 errors. Please click on the link above for details.

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_II.DAT
*Date of Submission: October 15, 2021

6 Changing Your Password

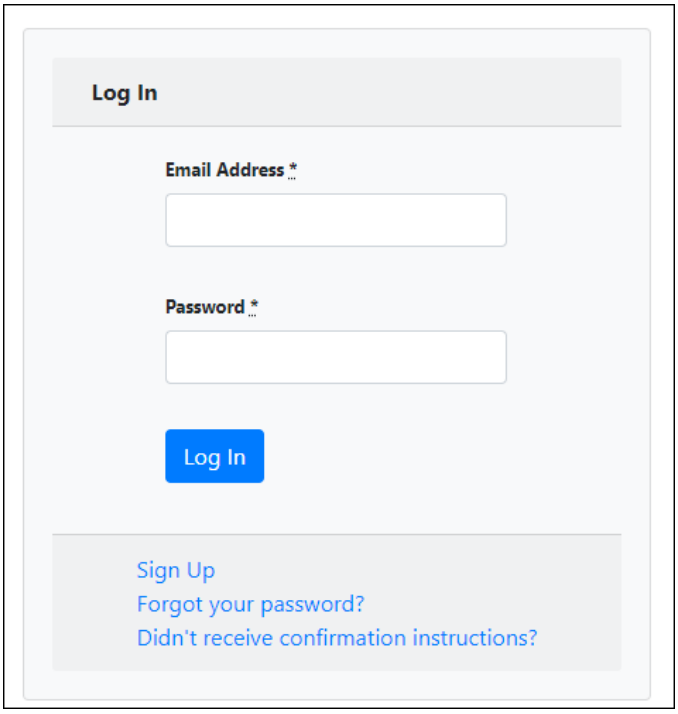
There are two ways you can manage your password:

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.

6.1 Forgotten Password

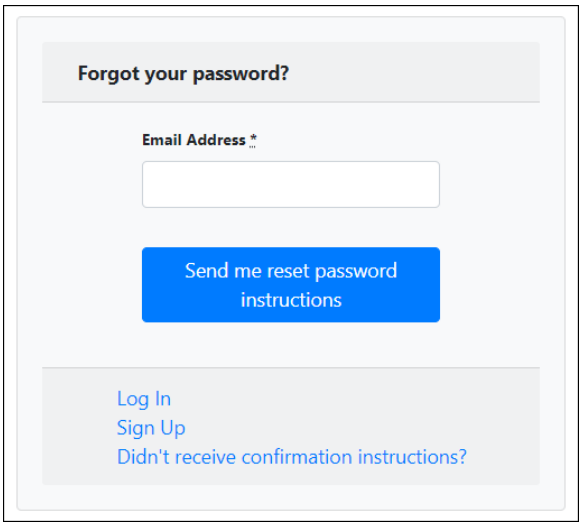
1. Open an internet browser window and navigate to the **Opioid Reporting** log in page located at https://pmpclearinghouse.net/Opioidreporting.

   The **Log In** page is displayed.



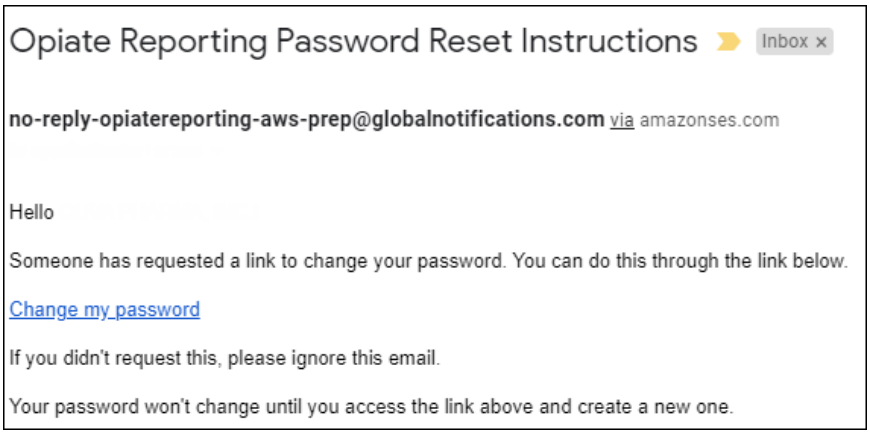
2. Click the **Click your password?** link.

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



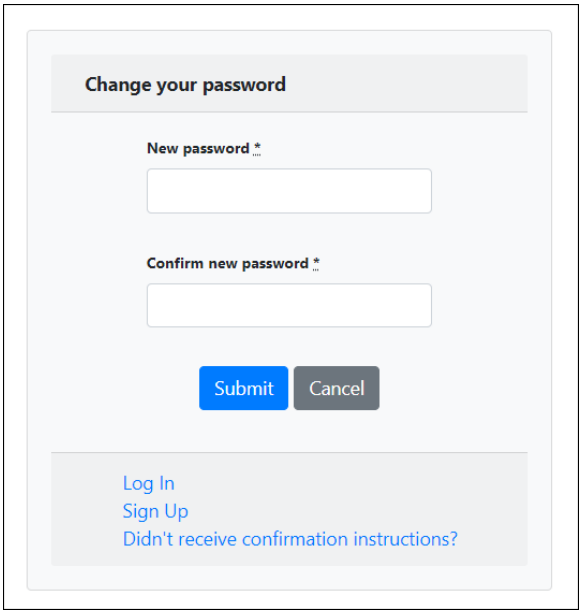
3. Enter the email address for your account in the **Email Address** field, then click **Send me reset password instructions**.

   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.



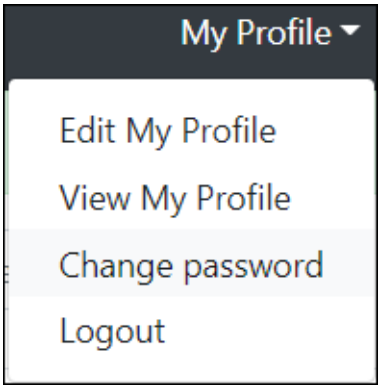
5. Enter a new password in the **New Password** field, then re-enter it in the **Confirm new password** field.
6. Click **Submit**.
   Your password is updated, and you will use the new password the next time you login to the system.

6.2 In Application Password Change

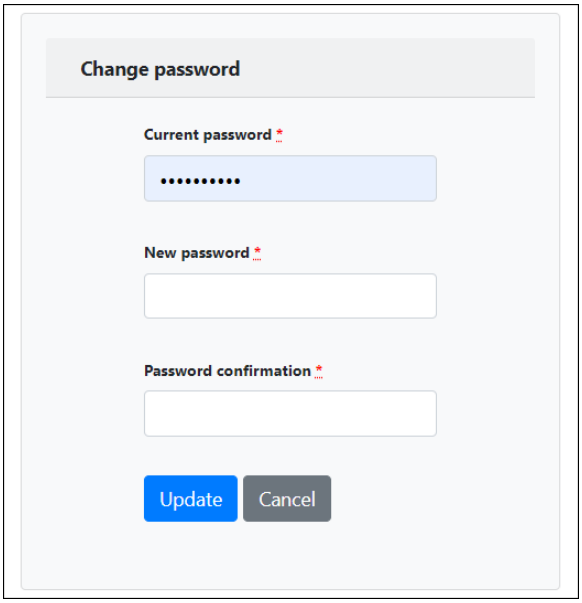
If your password has not expired, but you would like to proactively reset it, you can do so within the application at any time.

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, the 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.

7 Assistance and Support

7.1 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;

Technical assistance is available Monday through Friday from 8:00 a.m. – 5:00 p.m. CT.

7.2 Administrative Assistance

If you have non-technical questions regarding the Opioid Medication Management and Fee Program (MEOMMSFP), please contact:

Board of Pharmacy
[INSERT ADDRESS]
Phone:
Website:

Prescription Monitoring Program
Phone:
Email:

To find additional information, please refer to Michigan's Guidance Document:
[INSERT WEBSITE]

Board of Pharmacy Opioid Manufacturing Website: [INSERT WEBSITE]

8 Document Information

8.1 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.

8.2 Change Log

Version	Date	Chapter/Section	Change Made
1.0	04/01/2023	N/A	N/A; initial publication

Appendix A: ARCOS Report Requirements

ARCOS using 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 MMDDYYYYY	8	R	Should always be last day of previous year; e.g. 12312021
Reporting Frequency	1	R	"Y" for yearly should always be used
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

AB9876543*12312021YAA9999999

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**000000022BC99999990009999991231202099999999100000000001

Appendix B: Zero Report Requirements

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

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 previous year; e.g. 12312021
Reporting Frequency	1	R	"Y" for yearly should always be used
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.