

Data Submission Guide for Opiate Reporting

Minnesota Opiate Product Registration System

February 2023 Version 1.4



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1 Document Overview

This document serves as a training guide and support manual for Minnesota-licensed manufacturers and wholesalers who are required to report to the board every sale, delivery, or other distribution within or into Minnesota of an opiate 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 Minnesota-licensed pharmacies with at least one location in the State, that receives intracompany deliveries or distributions into Minnesota of any opiate 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 MN Opiate Product Registration System (MNOPR)
- Creating an MNOPR System account
- Uploading your report
- Viewing your report status
- Changing your password
- Error resolution

2 Reporting Requirements

2.1 Who Must Report?

Each MN-licensed manufacturer and each MN-licensed wholesaler must report to the board every sale, delivery, or other distribution within or into Minnesota of any opiate 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.

Each owner of a MN-licensed pharmacy with at least one location within Minnesota must report to the board any intracompany delivery or distribution into MN of any opiate 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 opiates as defined in Minnesota Statute section 152.02, Subd. 3-5 must be reported.

2.3 What is the Frequency of Reporting?

An annual report must be submitted by March 1 for the previous calendar year.

If a manufacturer or wholesaler fails to provide the information required on a timely basis, the board may assess an administrative penalty of \$500/day as defined in Minnesota Statute section 151.066, Subd.2.

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 an annual report **not** a monthly or quarterly report. Please ensure you take into account the format changes from 2000 to the ARCOS format (<u>Year 2000 Formatting Changes</u>).

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

The MNOPR 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 MNOPR website.

- For instructions on creating an account, please refer to the <u>Creating Your</u> Account section of this document.
- For instructions on submitting your report, please refer to the <u>Submitting</u>
 <u>Your Report</u> 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. For instruction on submitting a Zero Report, please refer to the Submitting a Zero Report section within this document.

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://mn.gov/boards/pharmacy/opiateproductregistrationfee/ > Opiate Product Registration and Fee Collection Program.

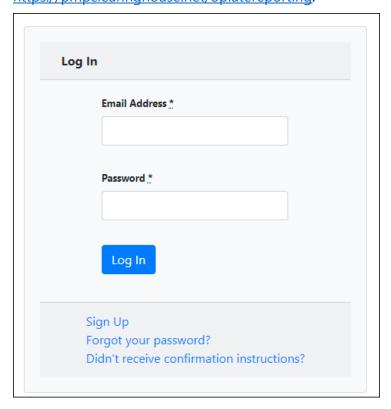
3 Accessing Clearinghouse

This chapter describes how to create your MN OPR account and how to log in to the MNOPR web portal to upload your opiate product transaction or zero report files.

3.1 Creating Your Account

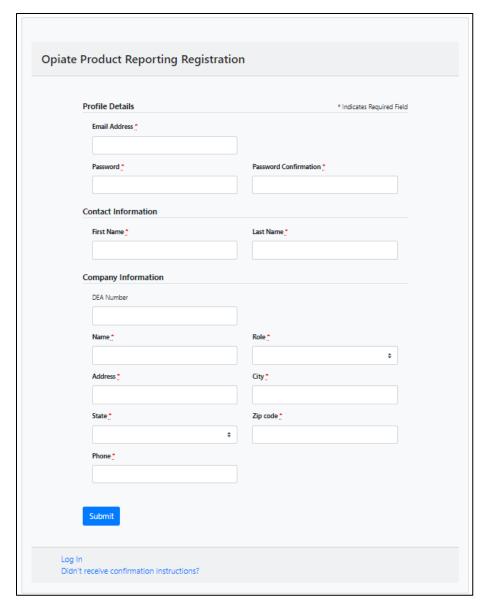
Prior to submitting your report, you must create an account by performing the following steps:

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

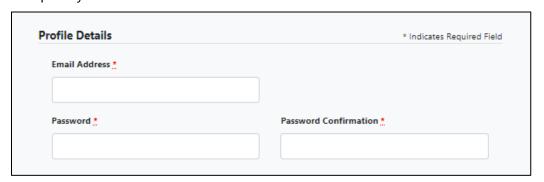


2. Click Sign Up.

The **Opiate Product Reporting Registration** page is displayed as shown on the following page.



3. Complete your Profile Details.



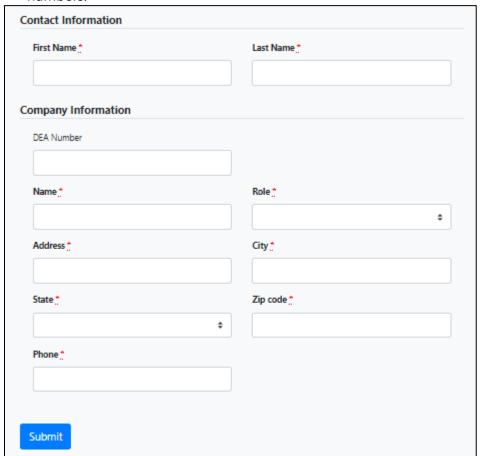
a. Enter your current, valid email address in the Email Address field.

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

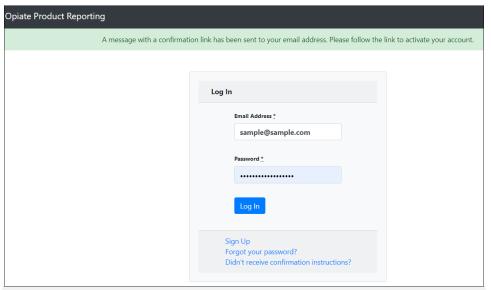
b. Enter a password for your account in the **Password** field, then re-enter it in the **Password Confirmation** field. The password requirements are provided below.

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 **Contact Information** and **Company Information**, noting the following:
 - Required fields are marked with a red asterisk (*).
 - Opiate Product 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 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.



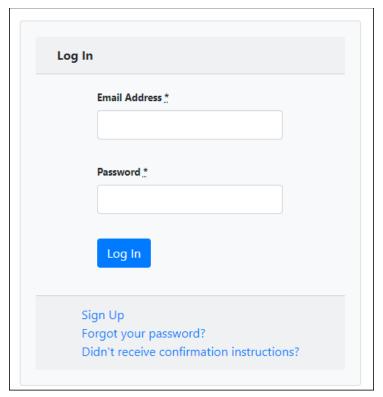
Note: You will not be able to log in until you confirm your email address.

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 Opiate Product Reporting Site

 Open an internet browser window and navigate to the Opiate Product Reporting log in page located at

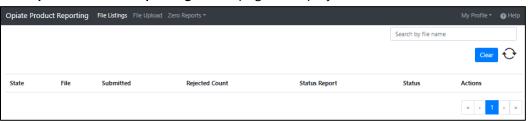


- 2. Enter the email address you used to create your account in the **Email Address** field.
- 3. Enter your password in the **Password** field.

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.

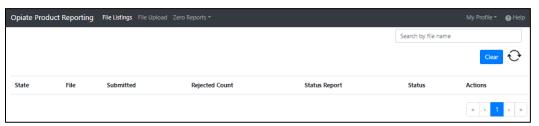
The Opiate Product Reporting home page is displayed.



4 Submitting Your Report

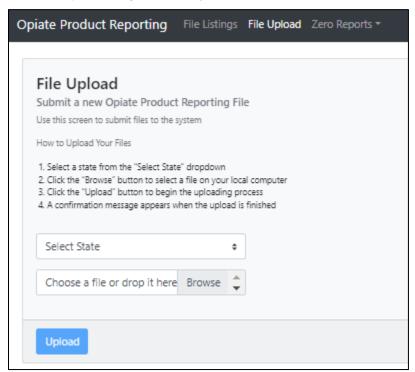
To submit your annual report:

- 1. If you do not have an MN OPR account, perform the steps in <u>Creating Your Account</u>; or
- 2. If you have already created an account, log in to the MN OPR. The **Opiate Product Reporting** home page is displayed.

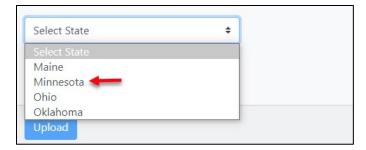


3. Click File Upload.

The File Upload page is displayed.



4. Select Minnesota from the **Select State** dropdown.



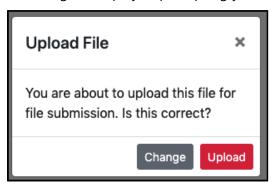
5. Click **Browse** and select the report file.

Notes:

- Please refer to the <u>Reporting Requirements</u> 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".

6. Click **Upload**.

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



- 7. If you need to make 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, and a message is displayed indicating that your file was successfully submitted. You will then be redirected to the File Listing page.

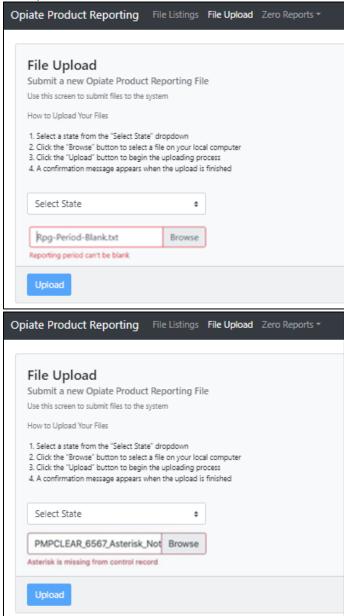
4.1 Upload Errors

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:



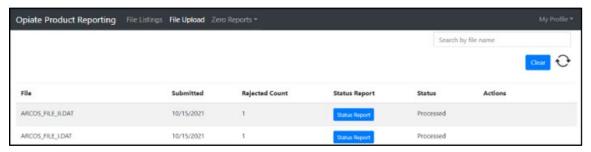
For more details regarding Control Records format see Appendix A.

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 opiate 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 <u>Section 4.1</u>. 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:

*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			
ecords 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.							
• Make correct			ty.				

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

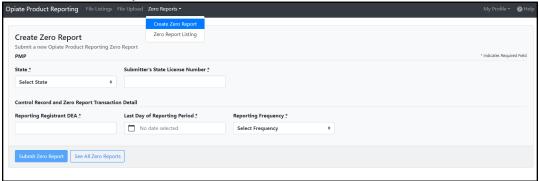
6 Submitting a Zero Report

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 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. Zero Reports can be submitted through a quick entry form within the application or via an ARCOS formatted file.

6.1 Quick Entry Zero Report

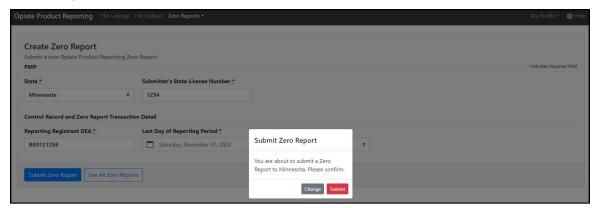
 Open an internet browser window and navigate to the Opiate Product Reporting log in page located at https://pmpclearinghouse.net/opiatereporting.



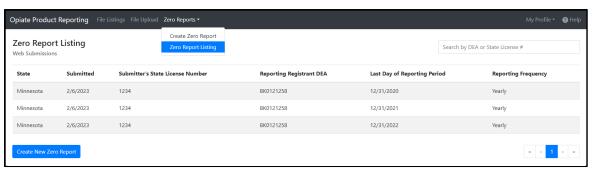


- 3. Populate all required fields noted with an asterisk (*) as outlined below:
 - a. *State Select the State to which you are submitting the Zero Report.
 - b. *Submitter's State License Number Enter your Minnesota Board of Pharmacy issued license number. The license number should be the submitter's (aka central reporter) state license number. If your entity possesses multiple license numbers from this state, please enter the license number most closely associated with the DEA number entered.
 - *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 this Zero Report. For example, when trying to report 2022 transactions (by March 1, 2022), the last day of reporting period would be 12/31/2022.
 - e. *Reporting Frequency The Reporting Registrant DEA's reporting frequency to the State selected. This should always be entered as "Yearly".

4. Once all fields are populated, click *Submit Zero Report*. Confirm you are submitting the correct information and click *Submit*.



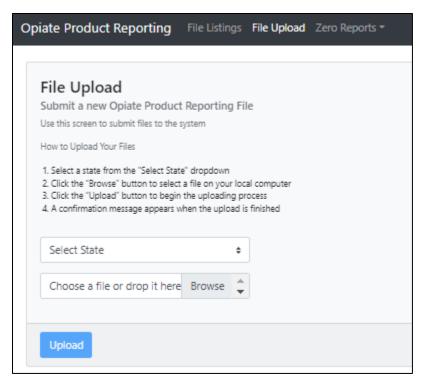
5. Zero Reports submitted through quick entry can be viewed within the application. From the menu bar click *Zero Reports*.



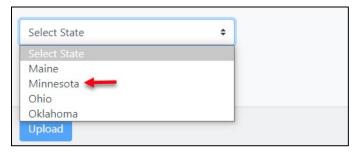
6.2 ARCOS File Zero Report

- Open an internet browser window and navigate to the Opiate Product Reporting log in page located at https://pmpclearinghouse.net/opiatereporting.
- 2. Click **File Upload**.

The File Upload page is displayed.



3. Select Minnesota from the **Select State** dropdown.

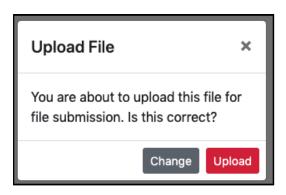


4. Click **Browse** and select the report file.

Notes:

- Please refer to Appendix B of this document for information on zero report requirements for MN OPR.
- 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.

7 Changing Your Password

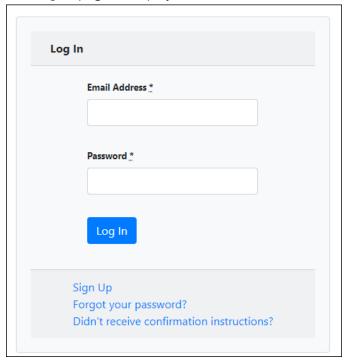
There are two ways you can manage your password:

- 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

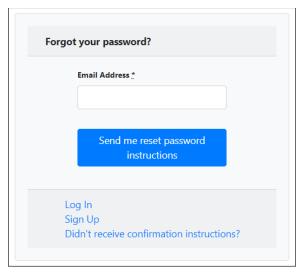
 Open an internet browser window and navigate to the Opiate Product Reporting log in page located at https://pmpclearinghouse.net/opiatereporting.

The **Log In** page is displayed.



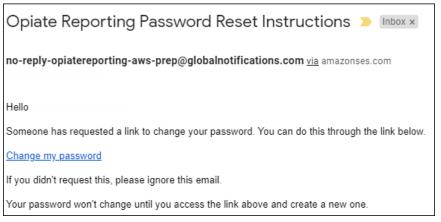
2. Click the Click your password? link.

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

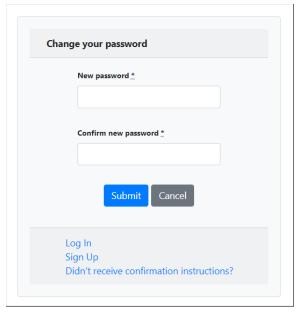


3. Enter the email address for your account in the **Email Address** field, then click **Send me reset password instructions**.

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.



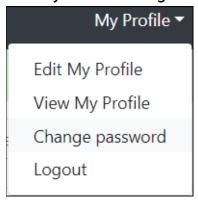
- 5. Enter a new password in the **New Password** field, then re-enter it in the **Confirm new password** field.
- 6. Click **Submit**. Your password is updated, and you will use the new password the next time you login to the system.

7.2 In Application Password Change

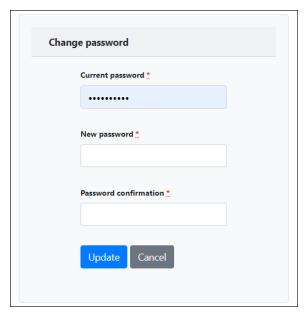
If your password has not expired, but you would like to proactively reset it, you can do so within the application at any time.

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.

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

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 Opiate Product Registration and Fee Program (OPRFP), please contact:

MN Board of Pharmacy – Attn OPRFP 335 Randolph Ave., Suite 230 St. Paul, MN 55102

Email: opiateproductregistrationfee@state.mn.us

Phone: 1-651-201-2845

Website: https://mn.gov/boards/pharmacy/opiateregistrationfee/

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
1.1	1 11/05/2021 Appendix A/Repo Requirements for ARCOS		Added Appendix A
		Section 5/Email Reports	Replaced information contained within Section 5 to address failed reporting
		Appendix B/Zero Report Requirements for ARCOS	Added Appendix B
1.2	1/17/2022 General F		Rebranded the guide from Appriss branding to Bamboo Health
		5.3/Error Corrections	Add additional sentence in the bulleted list
1.3	.3 12/29/2022 3 and 4		Account Creation and File Upload screenshot and process changes
		5.3/Error Corrections	Add additional bullets to address uploading file names
1.4	02/08/2023	3.1 Creating Your Account	Removal of DEA requirement in account creation text and screenshots.
		Section 6/Zero Report Quick Entry	Added new chapter

Appendix A: ARCOS Report Requirements for MN OPR

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	0					

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	0	1	11			
NDC Number	R	11	12-22			

Quantity	R	8	23-30	
Unit	0	1	31	
Associate Registrant DEA	R	9	32-40	
Order Form Number	0	9	41-49	
Transaction Date (MMDDYYYY)	R	8	50-57	
Correction Number	0	8	58-65	
Strength	0	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.



Appendix B: Zero Report Requirements for MN OPR

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

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	0				

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.

