North Dakota Insurance Department

Drug Cost Transparency Manufacturer's User Guide

September 2021

Table of Contents

Program Overview

During the 67th Legislative Assembly the North Dakota Legislature passed HB 1032, relating to drug cost transparency. HB 1032 created Chapter 26.1-36.10 of the North Dakota Century Code. Chapter 26.1-36.10 requires pharmaceutical drug manufacturers (manufacturers) to file quarterly reports with the North Dakota Insurance Department (the Department) containing the current wholesale acquisition cost (WAC) of U.S. Food and Drug Administration (FDA)-approved drugs sold in or into North Dakota. Manufacturers also are required to separately report specific information related to significant WAC increases and the WAC for certain prescription drugs being introduced to the market. Drug cost information will be available to the public on the Department's Drug Cost Transparency website.

At the time of issuing this guidance, the Department does not anticipate manufacturer reports related to drugs specifically manufactured solely for animal use. If at a later time the Department modifies reporting expectations related to drugs specifically manufactured solely for animals, the Department intends to issue updated reporting guidance.

Important Dates for 2021

Date	Activity
October 1, 2021	Collection of Third Quarter 2021 WAC Reporting Begins
October 15, 2021	WAC reporting submissions for Third Quarter 2021 Due
January 1, 2022	Collection of Fourth Quarter 2021 WAC Reporting Begins
January 15, 2021	WAC reporting submissions for Fourth Quarter 2021 Closes

Reporting Method

The Department will be conducting a phased implementation of HB 1032. Until further notice, manufacturers will be submitting the required reports by filling out spreadsheet templates and sending the report to the Department via email. The email address to be used is drugtransparency@nd.gov.

During this phase of implementation, a complete filing can occur in one of two ways. The first is to send a message directly to the email address containing everything required in a report. The second, is to utilize a secure file transfer system and send an invitation to download the spreadsheet to the email address and then send a second message to the email address to complete the submission.

Quarterly WAC Reporting Data

About this report

This is a quarterly report. Manufacturers with FDA -approved prescription drugs sold in or into North Dakota are required to submit their quarterly WAC report to the Department, using the provided template, no later than the fifteenth day of January, April, July, and October.

Steps for Submitting Quarterly WAC Reports

Submit only one CSV file per manufacturer.

Step 1: Download the template.

Step 2: Enter and Save Your Data

1. Edit the file using Microsoft Excel to add your data.
2. When you are finished editing your file, go to **File** > **Save As**.
3. Make sure the file type selected is **CSV UTF-8**.
4. Save your file with this file name: **nd_wac_report**.
5. Your save screen should look like this:

Screenshot of WAC Template

	A	B	C	D	E	F	G
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	WAC
2							
3							

Below is a list of descriptions for what data should be entered into each field and the format for that data.

Variable	Description
NDC11	National Drug Code; code must be 11 digits; **do not include hyphens.** If the NDC has leading zeros, start the leading zeros with an apostrophe. Example: ‘00289865020 Consult the section on Tips for Submitting Data in a CSV File
NDC Description	Option to provide information about quantity, strength, and dose; 255 characters max
Trade or Generic	**T** for Trade **G** for Generic (includes biosimilar drugs) T or G; 1-character max
Trade Name	Also known as Brand Name; 255 characters max
Generic Name	Also known as Chemical Name, includes biosimilar drugs; 255 characters max
Manufacturer	Name of Manufacturer; 255 characters max
WAC	Wholesale Acquisition Cost per NDC11; 10 digits max. Include the decimal point No $ sign, ***NO COMMAS*** **Example format**: 10.00

Below is a screenshot of the report with sample data entered demonstrating proper data formatting.

	A	B	C	D	E	F	G
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	WAC
2	12345678901	5 MG tablet	G		Generic X	Example Co	5.00
3	'00008675309	40 mg/mL, 1 mL vial	T	Trade X		Example Co	15.78

Step 3: Follow the steps below to submit data in one of two ways.

1. As an email attachment:

   a. Attach the file nd_wac_report.csv to an email addressed to drugtransparency@nd.gov

   b. In the body of the email, state the manufacturers name and attest to the fact that the report contains no confidential information or trade secrets.

   c. Send the email.

   d. Please note that emails that do not contain either the report or attestation will not be considered filed.

   e. The Department will respond to submitted reports to confirm receipt. If the Department does not respond within one business day, please send a follow up message to confirm that the message was received.

2. Secure File Transfer

   a. Manufacturers may submit the completed template via secure file transfer. If this method is selected, it is the manufacturers responsibility to properly upload the file nd_wac_report.csv to the system of their choice and invite drugtransparency@nd.gov to receive the file.

   b. After utilizing uploading the secure file transfer system to send the completed template, the manufacturer must send an email to drugtransparency@nd.gov, state the manufacturers name, and attest to the fact that the report contains no confidential information or trade secrets.

   c. The Department will respond to submitted reports to confirm receipt. If the Department does not respond within one business day, please send a follow up message to confirm that the message was received.

Submitting Data for WAC Price Increase Reporting

About This Report

Chapter 26.1-36.10 of the North Dakota Century Code requires manufacturers to, in certain circumstances, submit a supplemental report within thirty days after an increase in the WAC. This report contains additional information that is not required in the quarterly WAC report. The quality and types of information and data a manufacturer submits to the Department pursuant the increase WAC reporting requirement "must be the same as the quality and types of information and data the drug manufacturer includes in the drug manufacturer's annual consolidated report on securities and exchange commission form 10 - K or any other public disclosure."

Determining Whether a WAC Price Increase Report is Required

Reporting is required if a drug's WAC is greater than $70, and the WAC for the drug has increased by:

- 40% or more above the lowest WAC of the preceding 5 calendar years, where a calendar year is January 1 through December 31; or
- 10% or more above the lowest WAC of the preceding 12 consecutive months.

Steps for Submitting the WAC Increase Report

Step 1: Download the template.

Step 2: Enter and Save Your Data

1. Edit the file using Microsoft Excel to add your data.
2. When you are finished editing your file, go to **File** > **Save As**.
3. Make sure the file type selected is **CSV UTF-8**.
4. Save your file with this file name: **nd_wac_increase**.
5. Your save screen should look like this:

Screenshot of WAC Increase Template

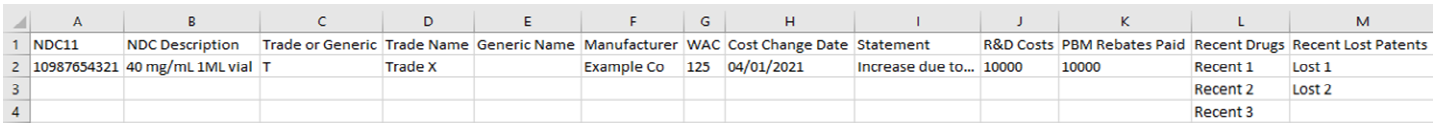
	A	B	C	D	E	F	G	H	I	J	K	L	M
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	WAC	Cost Change Date	Statement	R&D Costs	PBM Rebates Paid	Recent Drugs	Recent Lost Patents
2													
3													

Below is a list of descriptions for what data should be entered into each field and the format for that data.

Variable	Description
NDC11	National Drug Code; code must be 11 digits; **do not include hyphens.** If the NDC has leading zeros, start the leading zeros with an apostrophe. Example: ‘00289865020 Consult the section on Tips for Submitting Data in a CSV File
NDC Description	Option to provide information about quantity, strength, and dose; 255 characters max
Trade or Generic	**T** for Trade **G** for Generic (includes biosimilar drugs) T or G; 1-character max
Trade Name	Also known as Brand Name; 255 characters max
Generic Name	Also known as Chemical Name, includes biosimilar drugs; 255 characters max
Manufacturer	Name of Manufacturer; 255 characters max
WAC	Wholesale Acquisition Cost per NDC11; 10 digits max. Include the decimal point No $ sign, ***NO COMMAS*** **Example format**: 10.00
Cost Change Date	Effective date of the change in the WAC. Dates are to be entered in the mm/dd/yyyy format. For example, January 1, 2022 would be entered as 01/01/2022.
Statement	A concise statement of rationale regarding the factor or factors that caused the increase in the WAC, such as raw ingredient shortage or increase in pharmacy benefits manager rebates. 255 characters max.
R&D Costs	Aggregate, company-level research and development costs for the previous calendar year Include the decimal point No $ sign, ***NO COMMAS*** **Example format**: 10.00

PBM Rebates Paid	Aggregate rebate amounts paid to each pharmacy benefits manager for the previous calendar year Include the decimal point No $ sign, ***NO COMMAS*** **Example format**: 10.00
Recent Drugs	The name of each of the manufacturer's drugs approved by the FDA in the previous five calendar years. One name per row.
Recent Lost Patents	The name of each of the manufacturer's drugs that lost patent exclusivity in the United States in the previous five calendar years. One name per row

Below is a screenshot of the report with sample data entered demonstrating proper data formatting.



	A	B	C	D	E	F	G	H	I	J	K	L	M
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	WAC	Cost Change Date	Statement	R&D Costs	PBM Rebates Paid	Recent Drugs	Recent Lost Patents
2	10987654321	40 mg/mL 1ML vial	T	Trade X		Example Co	125	04/01/2021	Increase due to...	10000	10000	Recent 1	Lost 1
3												Recent 2	Lost 2
4												Recent 3	

Step 3: Submit data via email.

1. Attach the file nd_wac_increase.csv to an email addressed to drugtransparency@nd.gov

2. In the body of the email, state the manufacturers name and attest to the fact that the report contains no confidential information or trade secrets.

3. Send the email.

4. Please note that emails that do not contain either the report or attestation will not be considered filed.

5. The Department will respond to submitted reports to confirm receipt. If the Department does not respond within one business day, please send a follow up message to confirm that the message was received.

Submitting Data for New Drug WAC

About This Report

Chapter 26.1-36.10 of the North Dakota Century Code requires manufacturers to, in certain circumstances, submit a supplemental report within three calendar days of introducing a new prescription drug to market in North Dakota. This report is unique to the quarterly WAC report. This report may be submitted pending approval by the FDA if commercial availability is expected within three calendar days following the approval.

Determining Whether a New Drug Report is Required

Reporting is required if the new drug's WAC exceeds the threshold set for a specialty drug under the Medicare part D program.

Steps for Submitting the New Drug Report

Step 1: Download the template.

Step 2: Enter and Save Your Data

1. Edit the file using Microsoft Excel to add your data.
2. When you are finished editing your file, go to **File** > **Save As**.
3. Make sure the file type selected is **CSV UTF-8**.
4. Save your file with this file name: **nd_new_wac**.
5. Your save screen should look like this:

Screenshot of New Drug WAC Template

	A	B	C	D	E	F	G	H	I
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	Date Introduced	WAC	Reason for Exceeding Threshold
2									
3									

Below is a list of descriptions for what data should be entered into each field and the format for that data.

Variable	Description
NDC11	National Drug Code; code must be 11 digits; **do not include hyphens.** If the NDC has leading zeros, start the leading zeros with an apostrophe. Example: ‘00289865020 Consult the section on Tips for Submitting Data in a CSV File
NDC Description	Option to provide information about quantity, strength, and dose; 255 characters max
Trade or Generic	**T** for Trade **G** for Generic (includes biosimilar drugs) T or G; 1-character max
Trade Name	Also known as Brand Name; 255 characters max
Generic Name	Also known as Chemical Name, includes biosimilar drugs; 255 characters max
Manufacturer	Name of Manufacturer; 255 characters max
Date Introduced	Date on which the drug was, or will be, introduced in North Dakota. Dates are to be entered in the mm/dd/yyyy format. For example, January 1, 2022 would be entered as 01/01/2022.
WAC	Wholesale Acquisition Cost per NDC11; 10 digits max. Include the decimal point No $ sign, ***NO COMMAS*** **Example format**: 10.00
Reason for Exceeding Threshold	A concise statement of rationale regarding the factor or factors that caused the new drug to exceed the Medicare part D program price.

Below is a screenshot of the report with sample data entered demonstrating proper data formatting.

	A	B	C	D	E	F	G	H
1	NDC11	NDC Description	Trade or Generic	Trade Name	Generic Name	Manufacturer	WAC	Reason for Exceeding Threshold
2	10987654321	40 mg/mL 1ML vial	T	Trade X		Example Co	125.00	Exceeds threshold due to...

Step 3: Submit data via email.

1. Attach the file nd_wac_increase.csv to an email addressed to drugtransparency@nd.gov
2. In the body of the email, state the manufacturers name and attest to the fact that the report contains no confidential information or trade secrets.
3. Send the email.
4. Please note that emails that do not contain either the report or attestation will not be considered filed.
5. The Department will respond to submitted reports to confirm receipt. If the Department does not respond within one business day, please send a follow up message to confirm that the message was received.

Tips for Submitting Data in a CSV File

Below are some guidelines for entering and submitting data in a CSV file.

Entering Data

Data Entry Issue or Questions	Solution
Entering Leading zeros **If the NDC is: 00028030000**	Use an apostrophe (‘) Ex: ‘0002803000
Empty fields	Leave the cell empty Do not put NA, or not applicable, or No
Entering Dates	Use the following format: mm/dd/yyyy No spaces, no additional characters
Entering dollar figures in the CSV file	xxx.xx or xxxx.xx No dollar signs No commas
Entering Text Fields	No special characters or symbols such as: ®, TM, ©

Glossary of Terms

Generic Name

Chemical name or non-proprietary name of a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. These similarities help to demonstrate bioequivalence, which means that a generic medicine works in the same way and provides the same clinical benefit as its brand-name version.

Loss of Patent Exclusivity

Refers to the date on which a patent term ends.

Manufacturer

Name of pharmaceutical drug manufacturer. A person engaged in the business of producing, preparing, propagating, compounding, converting, processing, packaging, labeling, or distributing a prescription drug. The term does not include a wholesale distributor or retailer of prescription drugs or a pharmacist licensed under

The term also includes firms that hold the New Drug Application, Abbreviated New Drug Application, or Biologic License Application for a prescription drug.

The term does not include outsourcing facilities or manufacturers of United States Pharmacopeia-grade medical gases for which there is no new drug application.

At the time of issuing this guidance, the Department does not anticipate manufacturer reports related to drugs specifically manufactured solely for animal use. If at a later time the Department modifies reporting expectations related to drugs specifically manufactured solely for animals, the Department intends to issue updated reporting guidance.

NDC Description

National Drug Code description. Information about labeler, drug type, quantity, strength and dose.

NDC-11

The unique 11-digit National Drug Code that is a universal product identifier for human drugs in the United States.

Trade Name

Also known as brand name or proprietary name. A drug sold by a drug company under a specific name or trademark and that is protected by a patent.

Branded products are not generics. A brand can be first-in-class. It is protected by a patent or statutory exclusivity or has an expired patent or exclusivity. These are licensed under a New Drug Application by the U.S. Food and Drug Administration. Brand products are also generally referred to as innovator drugs.

Acronyms

CSV	comma separated value(s)
FDA	United States Food and Drug Administration
NDC	National Drug Code
R&D	research and development
WAC	wholesale acquisition cost