



West Virginia State Auditor's Office

**Pharmaceutical Manufacturers'
Compliance Manual**

December 7, 2020

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Part I

Introduction and Overview

A. Program Overview

Welcome to the West Virginia State Auditor’s Office Manufacturer’s Reporting Manual. The goal of this manual is to assist pharmaceutical manufacturers with submitting data to our office.

In 2020, the West Virginia Legislature passed Senate Bill 689, the Requiring Accountable Pharmaceutical Transparency, Oversight, and Reporting Act. This legislation added a new article, Article 54, to Chapter 33 of the West Virginia Code.

Chapter 33, Article 54 requires pharmaceutical drug manufacturers annually report to the West Virginia State Auditor’s Office the current wholesale acquisition cost (WAC) of U.S. Food and Drug Administration-approved drugs sold in or into West Virginia that exceed \$100 for a 30-day supply. Pharmaceutical drug manufacturers are also required to separately report specific information related to WAC increases exceeding a certain threshold and drugs losing patent exclusivity during a certain year. Certain research and development costs are also collected. All information collected will be available to the public on the statewide West Virginia Checkbook transparency site (<https://www.wvcheckbook.gov>).

Senate Bill 689 also made changes to West Virginia Code regarding health and pharmacy benefit plan issuers. These entities are required to report the 25 most frequently prescribed prescription drugs across all plans, the percent increase in net spending for prescription drugs across all plans, the net increase in premiums attributable to prescription drugs across all plans, the percentage of specialty drugs with utilization management requirements across all plans, and premium reductions attributable to specialty drug utilization management. Pharmaceutical manufacturers will not report any data pertaining to this portion of the legislation.

B. Important Dates

| Date | Activity |
|-------------------------|--|
| December 7, 2020 | Collection of annual pharmaceutical data begins |
| January 15, 2021 | Deadline for manufacturers to submit 2020 data reports to our office |
| July 1, 2021 | Deadline for our office to display live pharmaceutical data on West Virginia Checkbook transparency site |

C. Reporting Packet

Our office has placed a reporting packet on our website, <https://www.wvsao.gov>.

Click on the “Budget Analysis” tile, then click 2020 Pharmaceutical Manufacturer’s Reporting Packet.

This packet contains the following:

- A copy of this manual.
- A copy of West Virginia Code §33-54, the statute setting forth the requirements for drug manufacturers.
- A blank Attestation form for completion, fillable with Adobe Acrobat.
- Manufacturer Information Report Template spreadsheet: ManufacturerInfo_Report.xlsx
- Annual Wholesale Average Cost Report Template spreadsheet: WAC_Report.xlsx
- Drug Price Increases Report Template spreadsheet: WACIncreases_Report.xlsx
- Drug Patent Exclusivity Report Template spreadsheet: PatentEx_Report.xlsx
- Research and Development Report Template spreadsheet: RAD_Report.xlsx

D. What Must Be Reported

Manufacturer Information and Contact Information

West Virginia Code §33-54 requires drug manufacturers to submit address and contact information to our office on an ongoing basis.

Annual Wholesale Average Cost Data

West Virginia Code §33-54 requires drug manufacturers to disclose information about generic, brand-name, or specialty drugs with a wholesale acquisition cost of \$100 or greater for a 30-day supply.

The wholesale acquisition cost, or WAC, is the manufacturer’s list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates, or reductions in price. The current or proposed WAC is the amount that prompts reporting under this act. If reported by a drug group, it is the average WAC weighted by the relevant number of WAC units. (*West Virginia Code §33-54-2*)

Loss of Patent Exclusivity Information

West Virginia Code §33-54 requires the disclosure of information about a manufacturer’s pharmaceutical drugs losing patent exclusivity in the last three calendar years.

Research and Development Costs

West Virginia Code §33-54 requires the disclosure of aggregate, company-level research and development costs.

Wholesale Average Cost Increases

West Virginia Code §33-54 requires the disclosure of information about generic, brand-name, or specialty drugs whose wholesale acquisition cost increased 40 percent or greater over the preceding three calendar years, or 15 percent or greater in the previous calendar year.

A calendar year is the period from January 1 through December 31. For example, for the year 2021, the prior calendar year is the period between January 1, 2020, and December 31, 2020.

| | WAC on December 31, 2018 | WAC on December 31, 2019 | WAC on December 31, 2020 | 15% Reporting Required For 2020 Reporting Year? | 40% Reporting Required For 2020 Reporting Year? |
|--------|--------------------------|--------------------------|--------------------------|---|---|
| Drug A | \$45 | \$60 | \$75 | Yes | Yes |
| Drug B | \$100 | \$105 | \$105 | No | No |
| Drug C | \$50 | \$75 | \$80 | No | Yes |
| Drug D | \$140 | \$140 | \$180 | Yes | No |
| Drug E | \$55 | \$85*; \$55 | \$55 | No | Yes |

**Denotes a drug price increase during calendar year 2019*

Drug A's WAC increased greater than 15% from the previous reporting year to the current reporting year, so a 15% reporting requirement would apply. The WAC also increased 40% or greater over the preceding three years, so the manufacturer would submit another record to report a 40% increase.

Drug B's WAC did not increase by 15% or greater in the preceding calendar year, nor greater than 40% in the preceding three calendar years, so this drug would not require reporting.

Drug C's WAC did not increase by 15% or greater in the preceding calendar year. However, Drug C experienced an increase by 40% or greater in the preceding three calendar years. So, the manufacturer would report this drug to our office as a 40% increase.

Drug D did not experience a 40% increase in the preceding three calendar years. However, it did increase by 15% or greater in the previous year. Thus, the manufacturer would report a 15% increase.

Drug E did not experience a price increase of 15% or greater in the previous calendar year. However, Drug E experienced an increase of 40% or greater during the 2019 calendar year. Though the drug price on December 31, 2020 is the same as the WAC on January 1, 2018, an increase of 40% or greater occurred in calendar year 2019. Thus, the manufacturer would report a 40% increase.

Does the manufacturer use the WAC on December 31 or throughout the year?

In the table on page 3, we've used the WAC at the end of each year to simplify the table and the examples shown. The manufacturer should consider the WAC throughout the entire year for reporting purposes.

If a manufacturer is unclear whether a prescription drug should be reported, our office suggests reporting the drug. For each reported drug, the manufacturer is permitted to explain their justification for a cost increase and provide their viewpoint. Should a manufacturer determine a drug was reported in error in the future, they can contact our office and request the revision or removal of the reported drug from the dataset.

E. Differences Between Texas and West Virginia

The below table shows the material differences between the pharmaceutical transparency legislation passed in the State of Texas and the State of West Virginia. Some requirements must be fulfilled by the manufacturer, while some requirements apply to our office.

| <i>Legislative Requirement</i> | State of Texas (Health and Safety Code Title 6, Chapter 441) | State of West Virginia (West Virginia Code Chapter 33, Article 54) |
|--|---|--|
| <i>Manufacturer must report drugs receiving FDA approval within statutory timeframe</i> | Required | Not Required |
| <i>Manufacturer must report drug price increases meeting a specific threshold throughout the year</i> | Required | Not expressly required on an ongoing basis, but implied/strongly encouraged |
| <i>Manufacturer must report annual United States sales/revenue of drugs losing patent exclusivity</i> | Not required | Required |
| <i>Manufacturer must report the introductory price of the drug when approved by the FDA</i> | Not required | Required |
| <i>Government timeframe for publishing updated information on government website</i> | 60 days | 30 days |
| <i>Manufacturer must continually provide government agency with contact information for manufacturer</i> | Not required | Required |
| <i>Government must publish identities of manufacturers failing to comply with statute</i> | Not required | Required |
| <i>Government must compile an annual report and present report to State legislative body</i> | Not required | Required |

F. Contacting the West Virginia State Auditor's Office

Via Mail:

West Virginia State Auditor's Office
Attn: Program Oversight and Budget Analysis
1900 Kanawha Boulevard, East
Building 1 Room W-125
Charleston, WV 25305

Via Telephone:

Local: (304)-558-2251
Toll Free: (877)-982-9148

Website:

<https://www.wvsao.gov>
<https://www.wvcheckbook.gov>

For questions specific to this legislation and data reporting requirement please contact a member of our staff:

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Part II

Annual Reporting Instructions

A. General Instructions for Using the Reporting Templates

Our office provides reporting templates to assist manufacturers with submitting data. Here are some tips to keep in mind:

- **Some columns and rows are hidden.** These rows contain metadata that assists us with importing data into our database. Please do not delete, enter data into, or modify the data in these rows.
- **Data formatting and types have been preformatted into the spreadsheet.** Textual fields are formatted as text strings. Currency and date information has been preformatted.

B. Reporting Manufacturer Information

About This Report

This report should be submitted to the West Virginia State Auditor's Office with each submission of data to our office. This report collects information about the manufacturer. This information is due to the West Virginia State Auditor's Office by January 15, 2021 and within 30 days of any changes.

Per West Virginia Code §33-54-5(c), any changes to this information should be reported to our office within 30 days of the change. This allows our office to effectively contact the manufacturer if needed.

This information will not be published on the transparency website; rather, it is for our office's records.

Steps for Submitting the Manufacturer Information Report

This template for the manufacturer information report is titled ManufacturerInfo_Report.xlsx.

Please submit only one manufacturer information report CSV file per manufacturer. Please prefix your CSV files with an entity name. To illustrate, a file submission from Example Laboratories, Inc. may be named ExampleManufacturerInfo_Report.CSV or Example-ManufacturerInfo_Report.CSV.

Entering Information into Fields

A. Reporting Year

Enter the reporting calendar year. For the submission due January 15, 2021, this should be calendar year 2020. Please do not enter any dates, only a year.

INCORRECT: 12/31/2020

INCORRECT: 12/2020

CORRECT: 2020

B. Manufacturer Name

Enter the name of the manufacturer. Please do not include any special characters such as ® or ™. Please include corporate suffixes such as “Inc.” or “LLC” when applicable. The manufacturer name field is limited to 255 characters.

INCORRECT: Examplex Laboratories®

INCORRECT: Examplex Laboratories™

INCORRECT: Examplex Laboratories

CORRECT: Examplex Laboratories, LLC

C. Manufacturer Address – Line 1

D. Manufacturer Address – Line 2

E. Manufacturer Address – Line 3

Enter the address of the manufacturer’s corporate headquarters. Three fields are provided to allow the manufacturer to split address lines, if desired. The maximum amount of characters is 100 for each line.

F. Manufacturer City

Enter the city of the manufacturer’s corporate headquarters. Maximum characters 100.

G. Manufacturer State

Enter the state (postal abbreviation) of the manufacturer’s corporate headquarters. Maximum characters 2.

H. Manufacturer Zip

Enter the postal ZIP code of the manufacturer’s corporate headquarters. Five-digit ZIP and ZIP+4 acceptable. Maximum characters 9.

- I. Manufacturer Mailing Address – Line 1**
- J. Manufacturer Mailing Address – Line 2**
- K. Manufacturer Mailing Address – Line 3**
- L. Manufacturer Mailing City**
- M. Manufacturer Mailing State**
- N. Manufacturer Mailing ZIP**

The information collected and character limits of these fields are identical to fields C-H. These fields only need completed if the manufacturer's preferred mailing address for communications differs from the address information collected in fields C-H. If the preferred mailing address is identical to the manufacturer address, these fields can be left blank.

O. Contact Name

Please provide a contact name for a manufacturer representative should our office need to contact the manufacturer. Maximum 80 characters.

P. Contact Title

Please provide the corporate title of this contact person, such as Chief Counsel, Chief Compliance Officer, etc. Maximum 80 characters.

Q. Contact Phone

Please provide a telephone number where this contact person can be reached. Maximum 20 characters.

R. Contact E-Mail

Please provide an e-mail address where this contact person can be reached. Maximum 80 characters.

S. Manufacturer Website

If desired, provide the manufacturer's corporate website or leave blank. Maximum 80 characters.

T. Manufacturer Stock Ticker

If the manufacturer is publicly traded in the United, please provide the ticker name used for reporting with the U.S. Securities and Exchange Commission. Privately held companies or non-public companies can leave this field blank. Maximum 10 characters.

C. Reporting Data for the Annual Wholesale Average Cost (WAC) Reporting

About This Report

This is an annual report. Pharmaceutical manufacturers with U.S. Food and Drug Administration-approved prescription drugs sold into West Virginia are required to submit their January 1 WAC cost information for the 2020 calendar reporting year. This information is due to the West Virginia State Auditor's Office by January 15, 2021.

Steps for Submitting the Annual WAC Report

This template for the annual WAC report is titled WAC_Report.xlsx.

Please submit only one annual wholesale average cost report CSV file per manufacturer. Please prefix your CSV files with an entity name. To illustrate, a file submission from Example Laboratories, Inc. may be named ExampleWAC_Report.CSV or Example-WAC_Report.CSV.

Entering Information into Fields

A. Reporting Year

Enter the reporting calendar year. For the submission due January 15, 2021, this should be calendar year 2020. Please do not enter any dates, only a year.

INCORRECT: 12/31/2020

INCORRECT: 12/2020

CORRECT: 2020

B. Manufacturer Name

Enter the manufacturer name. Please do not include any special characters such as ® or ™. You may include any corporate suffixes if desired. The manufacturer name field is limited to 255 characters.

INCORRECT: Example Laboratories®

INCORRECT: Example Laboratories™

CORRECT: Example Laboratories

CORRECT: Example Laboratories, Inc.

C. NDC-11 Code

Enter the NDC-11 code. Please do not include hyphens, spaces, or other punctuation. Concatenate all labeler, product, and package codes into one string. If the NDC-11 code includes leading zeroes, please include them. Maximum 11 characters.

INCORRECT: 97845-034-64

INCORRECT: 9874503464

INCORRECT: 97848 034 64

CORRECT: 09784803464

D. NDC Description

Enter basic information about the quantity, strength, and/or dose in this field (maximum 255 characters)

EXAMPLE: 125mcg 30 tablets

EXAMPLE: 2%, 10 mL

EXAMPLE: Oral tablet extended release 2.5 mg

EXAMPLE: 70 units / ml 30 units / 10mL in 1 vial in 1 carton

E. Trade or Generic

Either enter "T" or "G" (without quotes) to indicate a trade drug (T) or generic drug (G). Maximum 1 character.

INCORRECT: Any value other than the letters T or G.

CORRECT: The letter T or G.

F. Trade Name

If the drug is a trade/brand name drug, enter the brand name or trade name. Do not include any special characters such as ® or ™. If desired, this field can remain blank if the drug is a generic drug. (maximum 255 characters)

INCORRECT: Examplex®

INCORRECT: Examplex™

CORRECT: Examplex

G. Generic/Chemical Name

Enter the generic chemical name of the drug, regardless of whether a trade or generic drug. (maximum 255 characters)

EXAMPLE: oxycodone

EXAMPLE: dextrose injection USP

EXAMPLE: heparin sodium (porcine) injection solution

H. Market Introduction Price

Enter the introductory wholesale average cost of the drug when approved for marketing by the U.S. Food and Drug Administration. Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

INCORRECT: \$15.00

INCORRECT: 135

INCORRECT: 1,230.30

INCORRECT: 1,230

CORRECT: 2500.25

CORRECT: 2500.3 -OR- 2500.30

I. Wholesale Average Cost

Enter the wholesale average cost of the drug. Per West Virginia Code §33-54-2, the wholesale average cost is the manufacturer's list price to wholesalers or direct purchasers in the United States on December 31 of the reporting year, as reported in wholesale price guides or other publications of drug or biological pricing data. This cost does not include prompt pay or other discounts, rebates, or reductions in price. The current or proposed wholesale average cost is the amount that prompts reporting under this act. If reporting by a drug group, it is the average WAC weighted by the relevant number of WAC units. Maximum 11 digits including two decimal places. Refer to Item H for information on correct data entry into this field.

D. Reporting Data Regarding WAC Price Increases

About This Report

This is an annual report, though our office strongly encourages manufacturers to submit this information to us on an ongoing basis. Pharmaceutical manufacturers with U.S. Food and Drug Administration-approved prescription drugs sold into West Virginia are required to submit information about prescription drug price increases meeting a certain threshold.

Steps for Submitting the WAC Price Increases Report

This template for the WAC price increase information is titled WACIncreases_Report.xlsx.

Please submit only one WAC increases report CSV file per manufacturer. Please prefix your CSV files with an entity name. To illustrate, a file submission from Example Laboratories, Inc. may be named ExampleWACIncreases_Report.CSV or Example-WACIncreases_Report.CSV.

Entering Information into Fields

A. Reporting Year

Enter the reporting calendar year. For the submission due January 15, 2021, this should be calendar year 2020. Please do not enter any dates, only a year.

INCORRECT: 12/31/2020

INCORRECT: 12/2020

CORRECT: 2020

B. Manufacturer Name

Enter the manufacturer name. Please do not include any special characters such as ® or ™. You may include any corporate suffixes if desired. The manufacturer name field is limited to 255 characters.

C. NDC-11 Code

Enter the NDC-11 code. Please do not include hyphens, spaces, or other punctuation. Concatenate all labeler, product, and package codes into one string. If the NDC-11 code includes leading zeroes, please include them. To facilitate proper data entry into the spreadsheet, you may have to preface the NDC-11 code with an apostrophe (') to retain the leading zeroes.

D. NDC Description

Enter basic information about the quantity, strength, and/or dose in this field (maximum 255 characters)

E. Trade or Generic

Either enter "T" or "G" (without quotes) to indicate a trade drug (T) or generic drug (G).

INCORRECT: Any value other than the letters T or G.

CORRECT: The letter T or G.

F. Trade Name

If the drug is a trade/brand name drug, enter the brand name or trade name. Do not include any special characters such as ® or ™. If desired, this field can remain blank if the drug is a generic drug. (maximum 255 characters)

INCORRECT: Example®

INCORRECT: Example™

CORRECT: Example

G. Generic/Chemical Name

Enter the generic chemical name of the drug, regardless of whether a trade or generic drug. (maximum 255 characters)

EXAMPLE: oxycodone

EXAMPLE: dextrose injection USP

EXAMPLE: heparin sodium (porcine) injection solution

H. Effective Date

Enter the effective date of the price increase. Dates should be entered in MM/DD/YYYY format, including slashes.

INCORRECT: 3/4/2020

INCORRECT: 03042020

INCORRECT: 03-04-2020

INCORRECT: 3-4-2020

CORRECT: 03/04/2020

I. Purpose of Report

Enter 40 in this field to indicate a price increase of 40% or higher over the previous three years. Enter 15 in this field to indicate a price increase of 15% or greater over the previous year. Do not include decimal points or percentage signs. The reporting template allows the manufacture to select the value 15 or 40 from a dropdown, if desired, or the information may be typed in.

INCORRECT: 0.40

INCORRECT: 40.00

INCORRECT: 40%

CORRECT: 40

J. Market Introduction Price

Enter the introductory wholesale average cost of the drug when approved for marketing by the U.S. Food and Drug Administration. Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

K. Lowest WAC

Enter the lowest WAC price from either the last calendar year (if reporting a >15% increase) or the last three calendar years (if reporting a >40% increase). Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

L. WAC Increase Amount

This is calculated by subtracting field K, the lowest WAC price from either the last calendar year or the last three calendar years, field M, the current WAC. Maximum

11 digits including two decimal places. Please include cents, but no dollar signs or commas.

M. Current / New WAC Amount

Enter the new WAC amount after the increases. Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

N. Factor Statement

Please enter a statement describing the factors leading to the price increase of this drug. This field can accept a maximum 4000 characters.

E. Reporting Data Regarding Loss of Patent Exclusivity

About This Report

This is an annual report. Pharmaceutical manufacturers with U.S. Food and Drug Administration-approved prescription drugs sold into West Virginia are required to submit information about prescription drugs losing patent exclusivity in the United States for the three previous calendar years. For this current reporting period, the calendar years covered will be 2020, 2019, and 2018. Future reports will roll forward on this three-year basis. For example, the report to be submitted next year (on 1/15/22, covering the 2021 calendar year), will report data from calendar years 2021, 2020, and 2019.

Steps for Submitting the Patent Exclusivity Report

This template for the patent exclusivity report is titled PatentEx_Report.xlsx.

Please submit only one patent exclusivity CSV file per manufacturer. Please prefix your CSV files with an entity name. To illustrate, a file submission from Example Laboratories, Inc. may be named ExamplePatentEx_Report.CSV or Example-PatentEx_Report.CSV.

Entering Information into Fields

A. Reporting Year

Enter the year the drug lost patent exclusivity. For the submission due January 15, 2021, include data for calendar year 2020, 2019, and 2018. Please do not enter any dates, only a year.

B. Manufacturer Name

Enter the manufacturer name. Please do not include any special characters such as ® or ™. You may include any corporate suffixes if desired. The manufacturer name field is limited to 255 characters.

C. NDC-11 Code

Enter the NDC-11 code. Please do not include hyphens, spaces, or other punctuation. Concatenate all labeler, product, and package codes into one string. If the NDC-11 code includes leading zeroes, please include them. To facilitate proper data entry into the spreadsheet, you may have to preface the NDC-11 code with an apostrophe (') to retain the leading zeroes. If the drug losing patent exclusivity does not have a specific NDC-11 code, please leave the field blank.

D. Trade Name

If the drug is a trade/brand name drug, enter the brand name or trade name. Do not include any special characters such as ® or ™. If desired, this field can remain blank if the drug is a generic drug. (maximum 255 characters)

E. Generic/Chemical Name

Enter the generic chemical name of the drug, regardless of whether a trade or generic drug. (maximum 255 characters)

F. Annual Gross Sales Revenue

Enter the annual gross sales revenue for this drug. Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

F. Reporting Data Regarding Research and Development Costs

About This Report

This is an annual report. Pharmaceutical manufacturers with U.S. Food and Drug Administration-approved prescription drugs sold into West Virginia are required to submit information about aggregate, company-wide research and development costs for the most recent calendar year in which final audit data is available. Depending on the manufacturer's fiscal year, annual report issuance, and audit schedule, the time period of the research and development costs presented may not directly align with the other information the statute requires to be collected.

Steps for Submitting the Research and Development Costs Report

This template for the research and development costs report is titled RAD_Report.xlsx.

Please submit only one research and development costs report CSV file per manufacturer. Please prefix your CSV files with an entity name. To illustrate, a file submission from Example Laboratories, Inc. may be named ExampleRAD_Report.CSV or Example-RAD_Report.CSV.

Entering Information into Fields

A. Reporting Year

Enter the reporting year. For the submission due January 15, 2021, this value should be 2020. Please do not enter any dates, only a year.

B. Manufacturer Name

Enter the manufacturer name. Please do not include any special characters such as ® or ™. You may include any corporate suffixes if desired. The manufacturer name field is limited to 255 characters.

C. Financial Statement Issuance Date

Enter the issuance date of the most recent audited financial statements by the manufacturer. Generally, these financial statements will be the statements from which the manufacturer will obtain the aggregate, company-wide research and development costs. Enter dates in MM/DD/YYYY format.

D. Research and Development Costs

Enter the aggregate, company-wide research and development costs. Maximum 11 digits including two decimal places. Please include cents, but no dollar signs or commas.

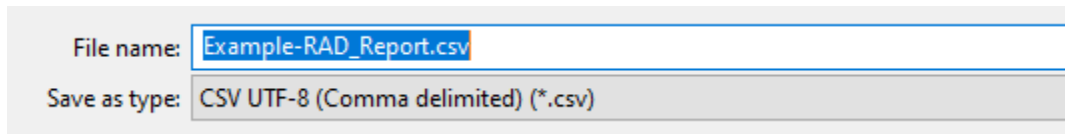
G. Compiling and Submitting Collected Data to the State Auditor

There are three steps to complete once a manufacturer compiles all data and is ready to submit to our office. Those steps are:

1. If using the spreadsheet templates, save the templates as a UTF-8 CSV file (instructions below). If a manufacturer is exporting data from a database, set your export utility to save as a UTF-8 CSV file.

To save as a UTF-8 CSV file in Microsoft Excel, select **File** → **Save As/Save a Copy**, then select “**CSV UTF-8 (Comma delimited) (*.csv)**” from the “Save as type” dropdown when saving your CSV file. Remember to use the proper prefix when saving your CSV file.

Your completed CSV file must be less than 40 megabytes in size. Please contact us if any file exceeds 40 megabytes in size.



The image shows a screenshot of a file save dialog box. The 'File name' field contains the text 'Example-RAD_Report.csv'. The 'Save as type' dropdown menu is open, showing the selected option 'CSV UTF-8 (Comma delimited) (*.csv)'. The dialog box has a light gray background and a blue border.

2. Complete and sign the Attestation form.
3. E-mail the data files and the Attestation form to BudgetAnalysis@wvsao.gov. In the subject line, please include the manufacturer's name. Please do not ZIP the files together into one file as our security software may block or reject the submission. Simply attach the multiple attachments to the e-mail and send.

That's it! You're all set.

What happens next?

The manufacturer will receive an e-mail within ten business days confirming a successful submission or requesting corrections to the data. Our office encourages manufacturers to retain a copy of this e-mail for their records to confirm their successful submission.

Data will be published on the transparency website, <https://www.wvcheckbook.gov>, within the timeframes set by statute.

H. Revising and Updating Data Submitted to the State Auditor

Once the initial annual data is received by our office, the manufacturer may have cause to update this data. The manufacturer may need to update contact information, for example, or identify errors or items requiring revision.

Should a manufacturer need to update contact information with our office:

1. The manufacturer should complete an updated ManufacturerInfo_Report.xlsx file, convert this to a UTF-8 CSV file, and e-mail the file to BudgetAnalysis@wvsao.gov.
2. No Attestation form is required when submitting updated manufacturer information.

Should a manufacturer identify an error in submitted data and wish to correct the error:

1. The manufacturer should identify the erroneous data in question. As data is uploaded to our wvcheckbook.gov website, each record receives a unique record number. The manufacturer can identify the specific record number needing revision and e-mail the needed changes to BudgetAnalysis@wvsao.gov.
2. Alternatively, the manufacturer can request we wipe all manufacturer data from our website and the manufacturer can submit new datasets. If the manufacturer has questions, they can e-mail our BudgetAnalysis@wvsao.gov e-mail or contact our office.
3. No Attestation form is required when submitting corrections to submitted manufacturer information.

Should a manufacturer wish to submit updated information regarding pharmaceutical drug price increases:

1. Submit an addendum WACIncreases_Report.xlsx report, converted to a UTF-8 CSV file, to BudgetAnalysis@wvsao.gov.
2. The manufacturer should submit an Attestation form to our office along with their data.

Part III

Frequently Asked Questions

Frequently Asked Questions

Our entity will not be able to submit the information requested by the January 15, 2021 deadline. Will there be fees, fines, or penalties levied against our company, or regulatory action taken?

No. West Virginia Code §33-54 does not provide for any fines, fees, penalties, or regulatory action for late reporting. We prefer all entities comply with the statutory January 15 deadline, but our office will accept late submissions/data after this date. Continued failure to report will result in our office publishing the identity of the manufacturer as failing to comply with the statute.

May we export information from a corporate database to fulfill the reporting requirements instead of using the provided templates?

Yes. Please see Appendix C, “Data Dictionary”, for information about how to effectively export data from a database for import into our system.

Are we required to submit research and development costs? May we decline to provide research and development costs?

West Virginia Code §33-54-3(b)(6) requires the disclosure of aggregate, company-level research and development costs. The costs should be derived from the most recent calendar year in which final audit data is available.

If a manufacturer declines to report research and development costs, please be aware that West Virginia Code §33-54 requires our office to publish the identity of manufacturers failing to comply with the provisions of the statute. If the manufacturer is a publicly traded entity, our office may obtain and publish research and development costs disclosed on the manufacturer’s most recent 10-K on file with the U.S. Securities and Exchange Commission.

Must we provide research and development costs for each drug, or may we aggregate total research and development expenditures for all drugs?

West Virginia Code §33-54 requires the reporting of aggregate, **company-level** research and development expenditures for each pharmaceutical drug. As this information is company-level information, it will be uniform across all records and collected once. The legislation does not require the disclosure of the separate research and development expenditures incurred to produce each reported pharmaceutical drug.

On what basis of accounting should we report research and development costs?

Report research and development costs consistent with the basis of accounting for the manufacturer. Information submitted must be consistent with the information that the drug manufacturer includes in the drug manufacturer's annual report submitted on Form 10-K to the Securities and Exchange Commission.

Are we required to submit pharmaceutical drug cost increase data on an ongoing basis throughout the calendar year? If not, may we submit this information to your office anyway?

West Virginia Code §33-54 does not explicitly require for the ongoing submission of drug cost increases throughout the calendar / reporting year, but the requirement is implied. We strongly encourage manufacturers who may have an ongoing reporting price increase requirement to other states to submit this information to us on an ongoing basis. West Virginia Code §33-54-5(b) states that as of July 1, 2021, our office shall update the information displayed on our searchable pharmaceutical price transparency website within 30 days of receiving updated or revised information from a drug manufacturer. Our office will accept this information throughout the year.

Are we required to report information regarding pharmaceutical drugs receiving U.S. Food and Drug Administration approval to your office?

No. Information about pharmaceutical drugs receiving U.S. Food and Drug Administration approval within a certain timeframe is not required to be reported to the West Virginia State Auditor's Office. Our office will obtain this data from the public FDA database and provide it separately.

Must we report two separate records if a drug experiences both a 15% increase from the previous year and a 40% increase over the previous three years?

Yes. Please report two separate records for this drug.

Will an audit or financial examination be performed of the submitted data?

No. Information will be reviewed for completeness and consistency. Each entity must attest to the accuracy and completeness of submitted data by completing the Attestation form.

What if we do not wish to participate?

Should a manufacturer refuse to submit information to our office, West Virginia Code §33-54 requires us to publish and identify the entities failing to fulfill the reporting requirements set forth in this act on our state transparency website, <https://www.wvcheckbook.gov>.

Where can I find the pertinent statutes pertaining to these reporting requirements?

Please visit <https://www.wvlegislature.gov>. Click "State Law" in the banner, then "West Virginia Code" to access the West Virginia Code applet. Select "Chapter 33 – Insurance" from the dropdown and select article 54 – "Requiring Accountable Pharmaceutical

Transparency, Oversight, and Reporting Act”. A copy of this chapter and article of the statute is provided in the Reporting Packet.

Our entity does not manufacture any prescription drugs that meet the reporting requirement thresholds. Must we still report data to your office?

You will not be required to report any pharmaceutical data, but West Virginia Code §33-54-5(c) requires us to collect contact information and an Attestation. The contact information allows us to contact the manufacturer in the future and the Attestation serves as the manufacturer’s confirmation that they have no data to report.

Will we receive notification that our submission has been received and approved?

Yes. Once a submission is received and approved the contact person you’ve designated for your entity will receive an e-mail from our office confirming your approved submission.

What happens if a submission is rejected?

If there exists an error or problem with your submission, our office will contact you within ten business days to resolve the problem. The manufacturer must correct the issues identified. Once the issues are corrected, the manufacturer will receive an e-mail from our office confirming an approved submission.

Who must sign the Attestation form?

If a manufacturer is submitting data on their own behalf, a representative from the manufacturer must sign the Attestation form. Should a third party submit data on behalf of the manufacturer, the third party should ensure a representative from the manufacturer signs the form.

Are electronic signatures acceptable for the Attestation form?

Adobe electronic signatures are accepted for the Attestation form provided the electronic signature clearly shows the name of the individual signing the form and the date. A title should also be provided for the individual completing the Attestation form.

Must the Attestation form be notarized?

There is no requirement for the Attestation form to be notarized.

In what format must we send the Attestation?

We prefer Attestations are sent via Adobe PDF -- either a scanned form that has been printed and hand-completed by the manufacturer or a digital document with an e-signature applied. Alternatively, paper copies of completed Attestation forms may be mailed to our office. Our mailing address can be found in Part I, Section F of this manual.

Our data exceeds the 40-megabyte limit for files. How do we submit the data to your office?

Should a specific file exceed 40 megabytes in size, please contact us at BudgetAnalysis@wvsao.gov to arrange for an alternate transmission method.

May a consultant or other external third-party submit data on our behalf?

Yes. Please see Appendix A, "Third-Party Reporting Guidelines", for more information on how the third-party should prepare the submission.

May we capitalize trademarks / registered trademarks when entering information?

Yes. A manufacturer can enter trademarks or registered trademarks in all caps if desired, but please do not include special symbols such as ® or ™ when entering information.

How will the data reported to your office be used or displayed to the public?

Data reported to our office will be displayed on the statewide West Virginia Checkbook transparency portal, <https://www.wvcheckbook.gov>. We will add a separate tile to the front page to allow the public to access the information. We encourage pharmaceutical manufacturers to visit this site and explore to obtain an example of the style of reporting used.

What other information will be disclosed to the public alongside the information manufacturers report?

In addition to the reported data, our office plans to present a variety of information and viewpoints regarding pharmaceutical drugs, including information obtained from the United States Food and Drug Administration, patient advocates, and pharmaceutical industry groups. Pharmacy benefit plan managers will also be responsible for disclosing pharmaceutical drug information which will also be presented.

Will the manufacturer's address and contact information be published on the transparency website?

No. This information is for our records and allows us to contact the manufacturer on an ongoing basis, if necessary.

Part IV

Appendices

Appendix A. Third-Party Reporting Guidelines

Our office accepts submissions from third parties representing a manufacturer (such as law firms, accountants, consultants, or lobbyists) provided the following guidelines are followed. To ensure successful data correction, it is important third parties submit information according to the below guidelines:

- If a third party submits data on behalf of multiple manufacturers, each manufacturer's submission should be a separate set of CSV files in separate e-mails. Please do not combine or comingle data from multiple manufacturers into one CSV file or e-mail.
- If a third party submits data on behalf of multiple manufacturers, the third party should complete a separate Manufacturer Information report for each manufacturer and submit this along with the reported data.
- If a third party submits data on behalf of multiple manufacturers, a separate Attestation form should be completed for each manufacturer. The Attestation form should be signed by a representative from the manufacturer.
- When completing an Entity Information report, the third party should provide the manufacturer's address information in the corporate address fields (fields B-H) and the third party's firm information in the mailing address fields (fields I-N). If desired, the third party may provide an individual from their firm to serve as the point of contact instead of the manufacturer in the contact information fields (fields O-R). (*See Part II, Section B, "Reporting Manufacturer Information"*).
- Parties should be aware the responsibility for compliance rests with the pharmaceutical manufacturer.

Appendix B. Definitions and Glossary

Trade or Brand-name drug -- a prescription drug approved under 21 USC §355(b) or 42 USC §262.

Drug or prescription drug refers to a brand-name, specialty, or generic prescription drug.

Drug manufacturer means any entity that holds the national drug code for a prescription drug and is engaged in the production, preparation, propagation, compounding, conversion, or processing of drug products; or is engaged in the packaging, repackaging, labeling, relabeling, or distribution of drug products, and is not a wholesale distributor of drugs or a retail pharmacy licensed under state law.

Generic drug means a prescription drug approved under 21 USC §355(j).

Market introduction means the month and year in which the manufacturer acquired or first marketed the drug for sale in the United States.

National drug code, NDC-11, or NDC means the numerical code maintained by the United States Food and Drug Administration that includes the labeler code, product code, and package code.

Wholesale acquisition cost or WAC is the manufacturer's list price to wholesalers or direct purchasers in the United States on December 31 of the reference year, as reported in wholesale price guides or other publications of drug or biological pricing data; it does not include prompt pay or other discounts, rebates, or reductions in price. The current or proposed WAC is the amount that prompts reporting under this act. If reported by a drug group, it is the average WAC weighted by the relevant number of WAC units.

Wholesale drug distributor means an entity licensed by the West Virginia State Board of Pharmacy that is engaged in the sale of generic, brand-name, or specialty drugs to persons other than a consumer or patient.

Appendix C. Data Dictionary

Should your entity wish to export information directly from a corporate database or other data source, please refer to the below information to assist you in reporting data. This data dictionary contains the field names, field conventions, and datatypes for the various fields used in data collection.

When submitting data, please submit in separate CSV files. CSV file sizes should not exceed 40 megabytes. If your CSV file size exceeds 40 megabytes, please contact our office for special transmission arrangements.

Please export separate CSV files for each report and utilize the naming conventions described in items B-F in Part II of this guide for each report.

General Conventions for CSV Formatting

| Item | Requirement |
|-------------------------|--|
| Field Delimiter | Comma (,) or pipe () |
| Field Encapsulation | Encapsulate all string data in double quotes ("") |
| Column Headers | First row of CSV file should include column headers whose names match the Field Database Title in the data dictionary for the respective report. |
| Empty fields | Please leave the field empty. Do not enter N/A, not applicable, or no/none. |
| Entering dates | Please use the following format: MM/DD/YYYY. Do not include spaces or additional characters. |
| Entering dollar figures | Whole numbers with two decimal places. (Example: xxxx.xx). Do not include dollar signs or commas. |
| Special characters | Do not include special characters such as ™ or ®. |
| File Encoding | UTF-8 |

Data Dictionary Structure for the Entity Information Report

| Field | Field Database Title | Data Type | Maximum Length |
|-------------------------------------|----------------------|-----------|----------------|
| Reporting Year | RPT_YEAR | Number | 4 |
| Manufacturer Name | MANUF_NM | String | 255 |
| Manufacturer Address Line 1 | MANUF_ADDR1 | String | 100 |
| Manufacturer Address Line 2 | MANUF_ADDR2 | String | 100 |
| Manufacturer Address Line 3 | MANUF_ADDR3 | String | 100 |
| Manufacturer City | MANUF_CITY | String | 100 |
| Manufacturer State | MANUF_ST | String | 2 |
| Manufacturer Zip | MANUF_ZIP | String | 9 |
| Manufacturer Mailing Address Line 1 | MANUF_MAIL_ADDR1 | String | 100 |
| Manufacturer Mailing Address Line 2 | MANUF_MAIL_ADDR2 | String | 100 |
| Manufacturer Mailing Address Line 3 | MANUF_MAIL_ADDR3 | String | 100 |
| Manufacturer Mailing Address City | MANUF_MAIL_CITY | String | 100 |
| Manufacturer Mailing State | MANUF_MAIL_ST | String | 2 |
| Manufacturer Mailing Zip | MANUF_MAIL_ZIP | String | 9 |
| <i>(continues next page)</i> | | | |

| | | | |
|---------------------------------|---------------|--------|----|
| Contact Name | CONTACT_NM | String | 80 |
| Contact Title | CONTACT_TTL | String | 80 |
| Contact Phone | CONTACT_PHN | String | 20 |
| Contact E-Mail | CONTACT_EMAIL | String | 80 |
| Website | MANUF_WEB | String | 80 |
| Manufacturer's Ticker Symbol | MANUF_TICKER | String | 10 |

Data Dictionary Structure for the Annual Wholesale Average Cost (WAC) Report

| Field | Field Database Title | Data Type | Maximum Length |
|---------------------------------|----------------------|-----------|---|
| Reporting Year | RPT_YEAR | Number | 4 |
| Manufacturer Name | MANUF_NM | String | 255 |
| NDC-11 Code | NDC11 | String | 11 |
| NDC-11 Description | NDC_DESC | String | 255 |
| Trade or Generic | DRUG_TYPE | String | 1 character. Values should be the letter T or G. |
| Trade Name | TRADE_NM | String | 255 |
| Generic Name | GENERIC_NM | String | 255 |
| Introductory FDA Approval Price | INTRO_PRICE | Number | 11 digits including 2 decimal places. |
| Wholesale Average Cost | WAC | Number | 11 digits including 2 decimal places. |

Data Dictionary Structure for the WAC Price Increases Report

| Field | Field Database Title | Data Type | Maximum Length |
|---------------------------------|----------------------|-----------|---|
| Reporting Year | RPT_YEAR | Number | 4 |
| Manufacturer Name | MANUF_NM | String | 255 |
| NDC-11 Code | NDC11 | String | 11 |
| NDC-11 Description | NDC_DESC | String | 255 |
| Trade or Generic | DRUG_TYPE | String | 1. Values should be the letter T or G. |
| Trade Name | TRADE_NM | String | 255 |
| Generic Name | GENERIC_NM | String | 255 |
| Effective Date of Increase | EFF_DT | Date | |
| Reporting Purpose | RPT_PURP | Number | 2 digits with no decimal places. Value should be either 15 or 40. |
| Introductory FDA Approval Price | INTRO_PRICE | Number | 11 digits including 2 decimal places. |
| Last Lowest WAC | LAST_WAC | Number | 11 digits including 2 decimal places. |
| WAC Increase Amount | WAC_INC_AM | Number | 11 digits including 2 decimal places. |
| New WAC Amount | NEW_WAC | Number | 11 digits including 2 decimal places. |
| Factor Statement | FACTOR_STMT | String | 4000 |

Data Dictionary Structure for the Patent Exclusivity Report

| Field | Field Database Title | Data Type | Maximum Length |
|---------------------------|----------------------|-----------|---------------------------------------|
| Reporting Year | RPT_YEAR | Number | 4 |
| Manufacturer Name | MANUF_NM | String | 255 |
| NDC-11 Code | NDC11 | String | 11 |
| Trade Name | TRADE_NM | String | 255 |
| Generic Name | GENERIC_NM | String | 255 |
| Annual U.S. Sales Revenue | ANNUAL_REV | Number | 11 digits including 2 decimal places. |

Data Dictionary Structure for the Research and Development Costs Report

| Field | Field Database Title | Data Type | Maximum Length |
|-----------------------------------|----------------------|-----------|---------------------------------------|
| Reporting Year | RPT_YEAR | Number | 4 |
| Manufacturer Name | MANUF_NM | String | 255 |
| Financial Statement Issuance Date | FIN_STMT_ISS_DT | Date | |
| Research and Development Costs | RND_COSTS | Number | 11 digits including 2 decimal places. |