

## **BACKGROUND**

The Maryland Prescription Drug Affordability Board may request information to conduct a cost review study under Health-General Article, §21-2C-09(a)(2), Annotated Code of Maryland, and COMAR 14.01.04.04.A.(2). The data points requested in the manufacturer data submission request form (excel) are in accordance with COMAR 14.01.04.04.B.(1).

## **MANUFACTURER REQUEST INSTRUCTIONS**

Manufacturers are encouraged to provide information on as many data elements for all applicable 11-digit National Drug Codes (NDC-11). If the submitter completing this file opts to only submit information at the aggregate level for the drug product under review, please check the box below.

### *Submission of Aggregate Information Only*

Respondents may provide the requested information via the following:

- a. Utilizing the tables provided at the end of this form in appendices A-E.
- b. Utilizing the supplemental excel file provided with this form.
- c. Directly typing data in each applicable section.
- d. Providing documentation in any form that the respondent deems suitable.

For any questions regarding the data submission request form, please reach out to support.pdab@maryland.gov.

## **Part 1: Contact and Drug Information**

Please provide the name and contact information of an individual who will be able to answer questions regarding the information submitted in this form.

<b>Contact Information</b>	
Name of Manufacturer	
Contact Name	
Contact Title	
Email Address	
Telephone Number	
Street Address	
City	
State	
Zip Code	

Provide the information requested in the table below about the prescription drug product under review. In this table, submitters should provide the non-proprietary and brand name of the drug selected for Cost Review. Additionally, submitters should provide all applicable 11-digit National Drug Codes (NDC-11), Healthcare Common Procedure Coding System (HCPCS) J Code(s) or Q Code(s), and indications related to the selected drug. When populating the form, each NDC-11, HCPCS code, and indication should be separated with a semicolon.

<b>General Drug Information</b>	
Non-Proprietary Drug Name	
Brand Name	
National Drug Code(s) (NDC-11)*	
Healthcare Common Procedure Coding System (HCPCS) J Code(s) or Q Code(s), if applicable	
List of U.S. Food and Drug Administration (FDA)-Approved Indications	
*If there are multiple NDC-11s, please provide a description of each, including information on dosage and package size. Please separate each NDC with a semicolon.	

## Data Dictionary

The following table reflects the requested data elements along with their respective regulatory authority. The table also notes the applicable section where each data element should be populated.

<b>Requested Data Points</b>	<b>Regulatory Citation</b>	<b>Applicable Section</b>
Net average price in the State	14.01.04.04(B)(1)(a)(ii)	Pricing
Prices charged to purchasers in the State, including but not limited to pharmacies, pharmacy chains, pharmacy wholesalers, and other direct purchasers	14.01.04.04(B)(1)(j)	Pricing
The invoice price per unit for the prescription drug product charged to purchasers in the United Kingdom, Germany, France, and Canada, reported in U.S. dollars;	14.01.04.04(B)(1)(i)	Pricing
The units of the prescription drug product sold in the State	14.01.04.04(B)(1)(e)	Utilization
The units of the prescription drug product sold nationally	14.01.04.04(B)(1)(f)	Utilization
The total dollar amount of sales of the prescription drug product into the State	14.01.04.04(B)(1)(g)	Revenues

The total dollar amount of sales of the prescription drug product nationally	14.01.04.04(B)(1)(h)	Revenues
Maryland and national gross and net manufacturer revenues for the prescription drug product under review for the most recent tax year	14.01.04.04(B)(1)(l)	Revenues
The average profit margin of the prescription drug product over the prior 5-year period and the projected profit margin anticipated for the current year for the prescription drug product	14.01.04.04(B)(1)(k)	Revenues
The net price received by manufacturers for the drug product in the State accounting for all price concessions, discounts, and rebates	14.01.04.04(B)(1)(d)	Rebates
The total amount of the price concessions, discounts, and rebates provided to each payor type operating in the State	14.01.04.04(B)(1)(b)	Rebates
The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to each payor type	14.01.04.04(B)(1)(c)	Rebates
The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment that are specific to the prescription drug product under review	14.01.04.04(B)(1)(p)	Marketing and R&D
The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal Securities and Exchange Commission	14.01.04.04(B)(1)(o)	Marketing and R&D
Life cycle management	14.01.04.04.B(1)(a)(i)	Submit as supplemental document
The estimated value or cost-effectiveness of the prescription drug product	14.01.04.04(B)(1)(a)(iii)	Submit as supplemental document
Information concerning all authorized generics as defined by 42 CFR §447.502 for the prescription drug product	14.01.04.04(B)(1)(m)	Submit as supplemental document
Information concerning all other ANDAs, BLAs, and NDAs that pertain to the same active moiety and the same manufacturer	14.01.04.04(B)(1)(n)	Submit as supplemental document
Any additional factors or information the manufacturer proposes that the Board consider	14.01.04.04(B)(1)(q)	Submit as supplemental document

## Part 2: Pricing

Provide best estimates for the pricing elements listed below:

1. Net Average Price in Maryland
2. Prices Charged to Pharmacies in Maryland
3. Prices Charted to Pharmacy Chains in Maryland
4. Prices Charged to Pharmacy Wholesalers in Maryland
5. Prices Charged to Other Direct Purchasers in Maryland
6. The Invoice Price per Unit for the Prescription Drug Product Charged to Purchasers in the United Kingdom, Reported in U.S. Dollars
7. The Invoice Price per Unit for the Prescription Drug Product Charged to Purchasers in Germany, Reported in U.S. Dollars
8. The Invoice Price per Unit for the Prescription Drug Product Charged to Purchasers in France, Reported in U.S. Dollars
9. The Invoice Price per Unit for the Prescription Drug Product Charged to Purchasers in Canada, Reported in U.S. Dollars

A table template for populating the requested information can be found in **Appendix A**.

## Part 3: Utilization

Provide best estimates for the utilization-based data elements listed below:

1. The Units of the Prescription Drug Product Sold in Maryland
2. The Units of the Prescription Drug Product Sold Nationally

A table template for populating the requested information can be found in **Appendix B**.

## Part 4: Rebates

Provide best estimates for the rebate-based data elements listed below:

1. The Net Price Received by Manufacturers for the Drug Product in Maryland Accounting for All Price Concessions, Discounts, and Rebates
2. The Total Amount of the Price Concessions, Discounts, and Rebates Provided to Commercial Payors Operating in Maryland
3. The Total Amount of the Price Concessions, Discounts, and Rebates Provided to Medicaid Payors Operating in Maryland
4. The Total Amount of the Price Concessions, Discounts, and Rebates Provided to Medicare Payors Operating in Maryland

5. The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Commercial Payors
6. The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Medicaid Payors
7. The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Medicare Payors

A table template for populating the requested information can be found in **Appendix C**.

## **Part 5: Revenue**

Provide best estimated for the revenue-based data elements listed below:

1. The Total Dollar Amount of Sales into Maryland
2. The Total Dollar Amount of Sales Nationally
3. Maryland Gross Manufacturer Revenues for the Most Recent Tax Year
4. Maryland Net Manufacturer Revenues for the Most Recent Tax Year
5. National Gross Manufacturer Revenues for the Most Recent Tax Year
6. National Net Manufacturer Revenues for the Most Recent Tax Year
7. The Average Profit Margin Over the Prior 5-Year Period
8. The Projected Profit Margin Anticipated for the Current Year

A table template for populating the requested information can be found in **Appendix D**.

## **Part 6: Research and Development and Marketing**

Provide best estimates for the data elements related to (a) research and development or (b) marketing, listed below:

1. A Description of the Tax Year (i.e., The Annual Accounting Period for Record Keeping)
2. The Manufacturer's Research and Development Costs, as Indicated on the Manufacturer's Federal Tax Filing or Information Filed with the Federal Securities and Exchange Commission
3. The Portion of Direct-to-Consumer Marketing Costs Eligible for Favorable Federal Tax Treatment that are Specific to the Prescription Drug Product Under Review

A table template for populating the requested information can be found in **Appendix E**.

## **SUBMISSION OF ADDITIONAL DOCUMENTATION**

Manufacturers completing the Maryland PDAB's data submission requests should provide additional documentation for additional factors included in the regulations which do not have corresponding tables in this form:

1. Information on the life cycle management of the prescription drug product under review (COMAR 14.01.04.04.B(1)(a)(i))
2. The estimated value or cost-effectiveness of the prescription drug product under review (COMAR 14.01.04.04(B)(1)(a)(iii))
3. Information concerning all authorized generics as defined by 42 CFR §447.502 for the prescription drug product under review (COMAR 14.01.04.04(B)(1)(m))
4. Information concerning all other ANDAs, BLAs, and NDAs that pertain to the same active moiety and the same manufacturer (COMAR 14.01.04.04(B)(1)(n))

Manufacturers completing the Maryland PDAB's data submission requests are also encouraged to provide additional documentation for other factors that they believe are relevant and that the Board should consider.

**Appendix A. Pricing Information**

<b>Maryland Pricing</b>					
NDC-11*	Net average price in the State	Prices charged to pharmacies in the State	Prices charged to pharmacy chains in the State	Prices charged to pharmacy wholesalers in the State	Prices charged to other direct purchasers in the State
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.					

<b>International Pricing</b>				
NDC-11*	The invoice price per unit for the prescription drug product charged to purchasers in the United Kingdom, reported in U.S. dollars	The invoice price per unit for the prescription drug product charged to purchasers in Germany, reported in U.S. dollars	The invoice price per unit for the prescription drug product charged to purchasers in France, reported in U.S. dollars	The invoice price per unit for the prescription drug product charged to purchasers in Canada, reported in U.S. dollars
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.				

**Additional Information**

In a narrative format, use the space below to provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section of the appendix.

**Appendix B.** Utilization Information

<b>Utilization</b>		
NDC-11*	The units of the prescription drug product sold in the State	The units of the prescription drug product sold nationally
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.		

Additional Information

In a narrative format, use the space below to provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section of the appendix.



**Appendix C. Rebate Information**

<b>Rebates Received and Provided in Maryland</b>				
NDC-11*	The net price received by manufacturers for the drug product in the State accounting for all price concessions, discounts, and rebates	The total amount of the price concessions, discounts, and rebates provided to Commercial payors operating in the State	The total amount of the price concessions, discounts, and rebates provided to Medicaid payors operating in the State	The total amount of the price concessions, discounts, and rebates provided to Medicare payors operating in the State
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.				

<b>Expected Rebates</b>			
NDC-11*	The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Commercial payors	The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Medicaid payors	The total amount of the price concessions, discounts, and rebates the manufacturer is expected to provide to Medicare payors
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.			

**Additional Information**

In a narrative format, use the space below to provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section of the appendix.

**Appendix D. Revenue Information**

<b>Revenues – Part 1</b>				
NDC-11*	The total dollar amount of sales of the prescription drug product into the State	The total dollar amount of sales of the prescription drug product nationally	Maryland gross manufacturer revenues for the prescription drug product under review for the most recent tax year	Maryland net manufacturer revenues for the prescription drug product under review for the most recent tax year
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.				

<b>Revenues – Part 2</b>				
NDC-11*	National gross manufacturer revenues for the prescription drug product under review for the most recent tax year	National net manufacturer revenues for the prescription drug product under review for the most recent tax year	The average profit margin of the prescription drug product over the prior 5-year period	The projected profit margin anticipated for the current year for the prescription drug product
*If submitting aggregate information, please provide the non-proprietary drug name in place of the 11-digit NDC. If submitting information by NDC-11, please insert as many rows into this table as needed.				

**Additional Information**

In a narrative format, use the space below to provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section of the appendix.

**Appendix E.** Research and Development and Marketing Information

<b>Research &amp; Development and Marketing</b>			
<b>Tax Year*</b>	<b>Tax Year Description</b>	<b>The portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment that are specific to the prescription drug product under review</b>	<b>The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal Securities and Exchange Commission</b>
*Please insert as many rows as needed to provide the requested information for each year since the drug product under review received FDA-approval.			

Additional Information

In a narrative format, use the space below to provide additional information on the calculation methods, assumptions, interpretations, and caveats related to the data requested in this section of the appendix.