State of Utah
Administrative Rule Analysis
Revised November 2021

NOTICE OF PROPOSED RULE		
TYPE OF RULE: New _x_; Amendment ___; Repeal ___; Repeal and Reenact ___		
	Title No. - Rule No. - Section No.	
Utah Admin. Code Ref (R no.):	**R590-287**	**Filing ID (Office Use Only)**
Changed to Admin. Code Ref. (R no.):	**R**	

Agency Information

1. Department:	Insurance	
Agency:	Administration	
Room no.:	Suite 2300	
Building:	Taylorsville State Office Building	
Street address:	4315 S. 2700 W.	
City, state and zip:	Taylorsville, UT 84129	
Mailing address:	PO Box 146901	
City, state and zip:	Salt Lake City, UT 84114-6901	
Contact person(s):		
Name:	**Phone:**	**Email:**
Steve Gooch	801-957-9322	sgooch@utah.gov
Please address questions regarding information on this notice to the agency.		

General Information

2. Rule or section catchline:

R590-287. Manufacturer Data Reporting

3. Purpose of the new rule or reason for the change (Why is the agency submitting this filing?)**:**

This rule adopts changes and implements drug manufacturer reporting requirements as provided in Utah Code Section 31A-48-103(5).

4. Summary of the new rule or change (What does this filing do? If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule)**:**

The rule provides specific guidance on how drug manufacturers should report pharmacy drug information to the Utah Insurance Department as required by Utah Code Section 31A-48-103(1).

Virtual Meeting ID:
April 13, 2022, 10:00 a.m.
meet.google.com/rhc-myae-uit
Phone: 503-917-5650
PIN: 786 418 143#

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:

A) State budget:

Implementation of this rule is anticipated to add an estimated one-time cost of $12,500 to the state budget. The work will be performed by the Division of Technology Services, so the net cost to the state will be $0. The Utah Insurance Department has already created the UID Pharmacy Web Portal for drug manufacturer reporting; however, it needs to be updated to gather the information required by this rule. Analysis of the information gathered from drug manufacturers will be performed by employees as part of their regular workload and will not have an ongoing cost.

B) Local governments:

There is no anticipated cost or savings to local governments. This rule only has requirements for certain non-small businesses, and will not affect any other persons.

C) Small businesses ("small business" means a business employing 1-49 persons)**:**

There is no anticipated cost or savings to small businesses. This rule only has requirements for certain non-small businesses, and will not affect any other persons.

D) Non-small businesses ("non-small business" means a business employing 50 or more persons)**:**

Non-small businesses that manufacture pharmaceutical drugs may see added minimal costs under this rule. The Insurance Department estimates that this rule could affect approximately 700 drug manufacturers that have a drug product available for sale in Utah that could potentially fall under the reporting requirements of Subsection 31A-48-103(1). Drug manufacturers already produce this information as part of their normal business operations and are already providing similar information to other state drug transparency programs. There may be minimal costs associated with compiling and submitting the required information to the Insurance Department, but this cannot be quantified because they would be business costs specific to each insurer, and the Department has no way to estimate them.

E) Persons other than small businesses, non-small businesses, state, or local government entities ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization of any character other than an ***agency***)**:**

There is no anticipated cost or savings to any other persons. This rule only has requirements for certain non-small businesses, and will not affect any other persons.

F) Compliance costs for affected persons (How much will it cost an impacted entity to adhere to this rule or its changes?)**:**

This rule is expected to have minimal compliance costs for affected persons. Drug manufacturers already produce this information as part of their normal business operations and are already providing similar information to other state drug transparency programs. There may be minimal costs associated with compiling and submitting the required information to the Insurance Department, but this cannot be quantified because they would be business costs specific to each insurer, and the Department has no way to estimate them.

G) Comments by the department head on the fiscal impact this rule may have on businesses (Include the name and title of the department head):

After conducting a thorough analysis, it was determined that this proposed rule may result in a fiscal impact to some businesses. Drug manufacturers already produce the required information as part of their normal business operations, and already provide similar information to other states. A business may have an additional cost due to submitting the information to an additional state, but the process is similar to other states and the costs are expected to be minimal. — Jonathan T. Pike, Insurance Commissioner

6. A) Regulatory Impact Summary Table (This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they will not be included in this table. Inestimable impacts will be included in narratives above.)

Regulatory Impact Table

Fiscal Cost	**FY2022**	**FY2023**	**FY2024**
State Government	$12,500	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Cost	**$12,500**	**$0**	**$0**
Fiscal Benefits			
State Government	$12,500	$0	$0
Local Governments	$0	$0	$0
Small Businesses	$0	$0	$0
Non-Small Businesses	$0	$0	$0
Other Persons	$0	$0	$0
Total Fiscal Benefits	**$12,500**	**$0**	**$0**
Net Fiscal Benefits	**$0**	**$0**	**$0**

B) Department head approval of regulatory impact analysis:

The Commissioner of Insurance, Jonathan T. Pike, has reviewed and approved this fiscal analysis.

Citation Information

7. Provide citations to the statutory authority for the rule. If there is also a federal requirement for the rule, provide a citation to that requirement:		
Section 31A-2-201	Section 31A-48-103	

Incorporations by Reference Information

(If this rule incorporates more than two items by reference, please include additional tables.)

8. A) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	First Incorporation
Official Title of Materials Incorporated (from title page)	
Publisher	
Date Issued	
Issue, or version	

B) This rule adds, updates, or removes the following title of materials incorporated by references (a copy of materials incorporated by reference must be submitted to the Office of Administrative Rules; *if none, leave blank*)**:**

	Second Incorporation
Official Title of Materials Incorporated (from title page)	
Publisher	
Date Issued	
Issue, or version	

Public Notice Information

9. The public may submit written or oral comments to the agency identified in box 1. (The public may also request a hearing by submitting a written request to the agency. See Section 63G-3-302 and Rule R15-1 for more information.)

A) Comments will be accepted until (mm/dd/yyyy)**:**	05/02/2022

B) A public hearing (optional) will be held:

On (mm/dd/yyyy)**:**	**At** (hh:mm AM/PM)**:**	**At** (place)**:**
04/13/2022	10:00 AM	See details above in Box 4

10. This rule change MAY become effective on (mm/dd/yyyy)**:**	05/09/2022

NOTE: The date above is the date the agency anticipates making the rule or its changes effective. It is NOT the effective date. To make this rule effective, the agency must submit a Notice of Effective Date to the Office of Administrative Rules on or before the date designated in Box 10.

Agency Authorization Information

To the agency: Information requested on this form is required by Sections 63G-3-301, 302, 303, and 402. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin* and delaying the first possible effective date.

Agency head or designee, and title:	Steve Gooch, Public Information Officer	**Date** (mm/dd/yyyy)**:**	03/15/2022

R590. Insurance, Administration.

R590-287. Manufacturer Data Reporting.

R590-287-1. Authority.

This rule is promulgated by the commissioner pursuant to Sections 31A-2-201 and 31A-48-103.

R590-287-2. Purpose and Scope.

(1) The purpose of this rule is to establish the:

(a) method for reporting information, and

(b) information required to promote comparability of the information reported to the department.

(2) This rule applies to a manufacturer.

R590-287-3. Definitions.

Terms used in this rule are defined in Sections 31A-1-301 and 31A-48-102. Additional terms are defined as follows:

(1) "Drug product" means the finished dosage form of a drug that contains a drug substance, in association with other active or inactive ingredients, and that has a unique NDC.

(2) "FDA" means the United States Food and Drug Administration.

(3) "National Drug Code" or "NDC" means a three-segment code maintained by the FDA that is converted to an 11-digit format and includes a:

(a) labeler code;

(b) product code; and

(c) package code.

(4) "WAC" means wholesale acquisition cost.

R590-287-4. Manufacturer Reporting and Submission.

(1) For each drug product that experiences a wholesale acquisition cost increase, a manufacturer shall submit the following information to the department:

(a) WAC history;

(b) approval history; and

(c) patent history.

(2) The reported information shall comply with the instructions provided by the Utah Insurance Department Pharmacy Web Portal User Guide available at https://insurance.utah.gov/consumer/other/pharmacy.

(3) The information required under this rule and Subsection 31A-48-103(1) shall be submitted electronically at https://pharma.utah.gov/.

R590-287-5. WAC History.

The reported WAC history shall include the following information:

(1) the name of the manufacturer;

(2) the drug product's NDC;

(3) a description of the drug product that includes the;

(a) name;

(b) strength;

(c) dosage form; and

(d) package size;

(4) the FDA classification of the drug product as brand or generic;

(5) the effective date of the WAC increase for the drug product;

(6) the amount of the WAC increase for the drug product;

(7) the WAC resulting from the reported cost increase for the drug product;

(8) the WAC one calendar year prior to the effective date of the reported cost increase of the drug product;

(9) the WAC two calendar years prior to the effective date of the reported cost increase of the drug product;

(10) a written description, suitable for public release, of the factors that led to the increase in the WAC of the drug product and the significance of each factor; and

(11) the manufacturer's aggregate company-wide research and development costs for the most recent year for which final audit data is available.

R590-287-6. Approval History.

The reported approval history shall include the following information for a manufacturer's drug that was approved by the FDA during the three calendar years prior to the effective date of the reported cost increase for the drug product reported in Section R590-287-5:

(1) the name of the drug; and

(2) the date when the drug was approved by the FDA.

R590-287-7. Patent History.

The reported patent history shall include the following information for a manufacturer's drug that lost patent exclusivity in the United States during the three calendar years prior to the effective date of the reported cost increase for the drug product reported in Section R590-287-5:

(1) the name of the drug; and

(2) the date when the patent expired.

R590-287-8. Severability.

If any provision of this rule, R590-287, or its application to any person or situation is held to be invalid, such invalidity does not affect any other provision or application of this rule which can be given effect without the invalid provision or application. The remainder of this rule shall be given effect without the invalid provision or application.

KEY: data, data reporting, insurance, pharmacy manufacturer
Date of Last Change: 2022
Authorizing, and Implemented or Interpreted Law: 31A-2-201; 31A-48-103

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