

State of Utah
Administrative Rule Analysis
 Revised November 2021

NOTICE OF PROPOSED RULE		
TYPE OF RULE: New ___; Amendment _x_; Repeal ___; Repeal and Reenact ___		
Title No. - Rule No. - Section No.		
Utah Admin. Code Ref (R no.):	R590-200	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:
R590-200. Diabetes Treatment and Management
3. Purpose of the new rule or reason for the change (Why is the agency submitting this filing?):
The rule is being changed in compliance with Executive Order 2021-12. During the review of this rule, the department discovered a number of minor issues that needed to be amended.
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 If this is a repeal and reenact, explain the substantive differences between the repealed rule and the reenacted rule):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 majority of the changes are being done to fix style issues to bring the rule text more in line with current rulewriting standards. Other changes make the language of the rule more clear, and update the Severability section to use the department's current language. The changes do not add, remove, or change any regulations or requirements.

Fiscal Information

5. Provide an estimate and written explanation of the aggregate anticipated cost or savings to:
A) State budget:
There is no anticipated cost or savings to the state budget. The changes are largely clerical in nature, and will not change how the department functions.
B) Local governments:
There is no anticipated cost or savings to local governments. The changes are largely clerical in nature, and will not affect local governments.
C) Small businesses ("small business" means a business employing 1-49 persons):
There is no anticipated cost or savings to small businesses. The changes are largely clerical in nature, and will not affect small businesses.
D) Non-small businesses ("non-small business" means a business employing 50 or more persons):

There is no anticipated cost or savings to non-small businesses. The changes are largely clerical in nature, and will not affect non-small businesses.

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. The changes are largely clerical in nature.

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

There are no compliance costs for any affected persons. The changes are largely clerical in nature.

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 amendment will not result in a fiscal impact to businesses. — 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	\$0	\$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	\$0	\$0	\$0
Fiscal Benefits			
State Government	\$0	\$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	\$0	\$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-22-626	

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	
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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):

10. This rule change MAY become effective on (mm/dd/yyyy): 05/09/22

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):	03/09/2022
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R590. Insurance, Administration.

R590-200. Diabetes Treatment and Management.

R590-200-1. Authority.

This rule is promulgated [pursuant to Subsections 31A-2-201(1) and 31A-2-201(3)(a) in which the commissioner is empowered to administer and enforce this title and to make rules to implement the provisions of this title. The authority to set minimum standards by rule for coverage of diabetes is provided in]by the commissioner pursuant to Sections 31A-2-201 and 31A-22-626.

R590-200-2. Purpose and Scope.

[The purpose of this rule is to establish minimum standards of coverage for diabetes. Diabetes includes individuals with:
 _____ (1) complete insulin deficiency or type 1 diabetes;
 _____ (2) insulin resistance with partial insulin deficiency or type 2 diabetes; and
 _____ (3) elevated blood glucose levels induced by pregnancy or gestational diabetes.
 _____ This coverage will be provided at the levels consistent with the coverage provided for the treatment of other illnesses or diseases.

R590-200-3. Applicability and Scope.

_____ (1) This rule applies to all health care insurance policies sold in Utah.
 _____ (2) This rule does not prohibit an insurer from requesting additional information required to determine eligibility of a claim under the terms of the policy, certificate or both, as issued to the claimant] (1) The purpose of this rule is to establish minimum standards of coverage for diabetes.
 _____ (2) This rule applies to each accident and health insurance policy that provides a health insurance benefit.
 _____ (3) This rule does not prohibit an insurer from requesting additional information to determine eligibility of a claim under the terms of a policy, certificate, or both.

R590-200-[4]3. Definitions.

[For purposes of this rule the commissioner adopts the definitions as particularly set forth in Section 31A-1-301 and in addition, the following] Terms used in this rule are defined in Section 31A-1-301. Additional terms are defined as follows:

~~(1) "Health care insurance" means insurance providing health care benefits or payment of health care expenses incurred, including prescription insurance. Health care insurance does not include accident and health insurance providing benefits for:~~

- ~~(a) dental and vision;~~
- ~~(b) replacement of income;~~
- ~~(c) short term accident;~~
- ~~(d) fixed indemnity;~~
- ~~(e) credit accident and health;~~
- ~~(f) supplements to liability;~~
- ~~(g) workers compensation;~~
- ~~(h) automobile medical payments;~~
- ~~(i) no fault automobile;~~
- ~~(j) Medicare supplement insurance plans;~~
- ~~(k) equivalent self insurance;~~
- ~~(l) any type of accident and health insurance that is a part of or attached to another type of policy; or~~
- ~~(m) long term care insurance.]~~

~~(2)(1)(a) "Diabetes" means diabetes mellitus, [which is] a common chronic, serious systemic disorder of energy metabolism [that includes] including a heterogeneous group of metabolic disorders [that can be] characterized by an elevated blood glucose level.~~

~~(b) The terms "diabetes" and "diabetes mellitus" are [considered] synonymous and defined to include [persons using insulin, persons not using insulin, individuals with elevated blood glucose levels induced by pregnancy, or persons with other medical conditions or medical therapies which wholly or partially consist of elevated blood glucose levels];~~

- ~~(i) a person using insulin;~~
- ~~(ii) a person not using insulin;~~
- ~~(iii) an individual with an elevated blood glucose level induced by pregnancy; and~~
- ~~(iv) a person with another medical condition or medical therapy that wholly or partially consists of an elevated blood glucose level.~~

~~(c) Diabetes includes an individual with:~~

- ~~(i) complete insulin deficiency, or type 1 diabetes;~~
- ~~(ii) insulin resistance with partial insulin deficiency, or type 2 diabetes; and~~
- ~~(iii) an elevated blood glucose level induced by pregnancy, or gestational diabetes.~~

~~(3)(2)(a) "Diabetes self-management training" means a program designed to help an individual[s to] learn to manage their diabetes in an outpatient setting. [They learn self-management skills that include]~~

~~(b) Self-management training topics include:~~

- ~~(i) making lifestyle changes to effectively manage [their] diabetes [and to avoid or delay];~~
- ~~(ii) avoiding or delaying the complications, hospitalizations, and emergency room visits associated with [this illness. This training includes] diabetes; and~~
- ~~(iii) medical nutrition therapy.~~

~~(4)(3) "Medical equipment" means non-disposable[?] or durable equipment used to treat diabetes [and will be treated per the standard deductibles, copayments, out of pocket maximums and coinsurance of the policy].~~

~~(5)(4) "Medical nutrition therapy" means the assessment and therapy of a patient's nutritional status [followed by therapy] including diet modification, planning, and counseling services [which are] furnished by a registered licensed dietitian.~~

~~(6)(5) "Medical supplies" means [the] a generally accepted single-use item[s] used to manage, monitor, and treat diabetes, and to administer [diabetes] diabetic specific medication[s. Medical supplies will be treated per the standard deductibles, copayments, out of pocket maximums and coinsurance of the policy].~~

R590-200-5. Minimum Standards and General Provisions.

(1) Coverage for [the] diabetes treatment [of diabetes] is subject to the deductibles, copayments, out-of-pocket maximums, and coinsurance of the [plan] policy.

(2)(a) [All health care insurance policies will] An accident and health insurance policy that provides a health insurance benefit shall cover diabetes self-management training and patient management, including medical nutrition therapy, when [deemed] medically necessary and prescribed by [an attending physician covered by the plan] a physician.

(b) The diabetes self-management training services must be provided by a diabetes self-management training program [that is accepted by the plan and is]:

- ~~(i) recognized by the Centers for Medicare and Medicaid Services; [or]~~
- ~~(ii) certified by the Utah Department of Health; or~~
- ~~(iii) approved or accredited by a national organization certifying standards of quality in the provision of diabetes self-management education.~~

(c) [Diabetes] A diabetes self-management training program[s] shall be provided upon [a health care insurance policyholder's/dependent's]:

~~(i) a diagnosis with diabetes[~~-upon~~];~~
~~(ii) a significant change in a [health care insurance policyholder's/dependent's]diabetes[~~-~~]-related condition[~~-upon~~];~~
~~(iii) a change in [a health care insurance policyholder's/dependent's]diagnostic levels[~~-or upon~~]; or~~
~~(iv) a change in treatment regimen[~~-when deemed medically necessary and prescribed by an attending physician covered by the plan. The plan must provide no less than the minimum standards required by the selected self-management training services provider program~~].~~

(3) ~~[All health care policies will-]~~An accident and health insurance policy that provides a health insurance benefit shall cover the following when [deemed-]medically necessary:

(a) ~~blood glucose monitors[~~-including commercially available blood glucose monitors~~] designed for diabetic patients[~~-use and for persons who have been diagnosed with diabetes~~];~~

(b) ~~blood glucose monitors [to-]for the legally blind [which includes commercially available blood glucose monitors-]designed for [patient-]use with adaptive devices[~~-and for persons who are legally blind and have been diagnosed with diabetes~~];~~

(c) ~~test strips for glucose monitors, [which include-]including test strips [whose performance achieved clearance-]cleared by the FDA[~~-for marketing~~];~~

~~(d) [visual reading and urine testing strips, which includes-]visual reading strips for glucose and ketones[~~-~~];~~

~~(e) urine testing strips for glucose and ketones[~~-or urine test strips for both glucose and ketones. Using urine test strips for glucose only is not acceptable as the sole method of monitoring blood sugar levels~~];~~

~~(f) lancet devices and lancets for monitoring glycemic control;~~

~~(g) insulin, [which includes commercially available insulin preparations including insulin analog preparations available including analog, in either vial or cartridge;~~

~~(h) injection aids, including those adaptable to meet the needs of the legally blind[~~-to assist with insulin injection~~];~~

~~(i) syringes, [which includes-]including insulin syringes, pen-like insulin injection devices, [pen-]needles for pen-like insulin injection devices, and other disposable parts required for insulin injection aids;~~

~~(j) insulin pumps, [which includes-]including insulin infusion pumps[~~-~~];~~

~~(k) ["]medical supplies["] for use;~~

~~(l) with insulin pumps and insulin infusion pumps, [to include-]including infusion sets, cartridges, syringes, skin preparation, batteries, and other disposable supplies needed to maintain insulin pump therapy; and~~

~~(m) "medical supplies" for use-]ii) with or without insulin pumps and insulin infusion pumps[~~-to include-~~], including durable and disposable devices [to assist with-]for the injection of insulin and infusion sets;~~

(l) prescription oral agents of each class approved by the FDA for treatment of diabetes, and a variety of drugs, when available, within each class; and

(m) glucagon kits.

(4)(a) ~~[As required by Subsections 31A-22-626(9) and 31A-22-626(10), no-]~~No later than June 1 each year, the department shall publish on the department's website at www.insurance.utah.gov:

(i) the price of insulin available under the discount program described in Section 49-20-421;

(ii) the insulin prescription caps for the following calendar year; and

(iii) the average wholesale price of insulin per milliliter, AWP/mL, for each calendar year 2019 and later.

(b) The insulin prescription caps ~~[shall be-]are~~ calculated using data provided by Public Employees Health Plan[~~-~~] (PEHP)[~~-~~] based on the annual change in the average AWP/mL.

(i) The calculation ~~[takes into account-]considers~~ the following initial reference values:

(A) PEHP's average insulin AWP/mL in 2019 of \$40.18, Base AWP/mL;

(B) the 2021 insulin prescription cap in Subsection 31A-22-626(4)(a) of \$30, Base Low Cap; and

(C) the 2021 insulin prescription cap in Subsection 31A-22-626(6)(b) of \$100, Base High Cap.

(ii) The insulin prescription cap ~~[will be-]is~~ rounded to the nearest dollar.

(c) The insulin prescription cap formula for years after 2021 for Subsection 31A-22-626(4)(a) is: Year X low cap = (Average AWP/mL for Year X-2 / Base AWP/mL) * (Base Low Cap) rounded to the nearest dollar.

(d) The insulin prescription cap formula for years after 2021 for Subsection 31A-22-626(6)(b) is: Year X high cap = (Average AWP/mL for Year X-2 / Base AWP/mL) * (Base High Cap) rounded to the nearest dollar.

(e) The adjusted insulin prescription cap posted on June 1 takes effect for a policy issued or renewed on or after January 1 of the following calendar year.

R590-200-6. Severability.

~~[If any provision or clause of this rule or its application to any person or situation is held invalid, such validity shall not affect any other provisions or application of this rule which can be given effect without the invalid provision or application, and to this end the provisions of this rule are declared to be severable]~~If any provision of this rule, Rule R590-200, or its application to any person or situation is held invalid, such invalidity does not affect any other provision or application of this rule that 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: insurance law

Date of Enactment or Last Substantive Amendment: June 22, 2021

Notice of Continuation: February 25, 2021

Authorizing, and Implemented or Interpreted Law: 31A-2-201; 31A-22-626

