

State of Utah
Administrative Rule Analysis

NOTICE OF PROPOSED RULE

- * The agency identified below in box 1 provides notice of proposed rule change pursuant to Utah Code Section 63G-3-301.
- * Please address questions regarding information on this notice to the agency.
- * The full text of all rule filings is published in the Utah State Bulletin unless excluded because of space constraints.
- * The full text of all rule filings may also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
State Admin Rule Filing Id:		Time filed:	
	Agency No.	Rule No.	Section No.
Utah Admin. Code Ref (R no.):	R 156	- 83	-
Changed to Admin. Code Ref. (R no.):	R	-	-

1.	Agency:	Commerce/Division of Occupational and Professional Licensing		
	Room no.:			
	Building:	Heber M. Wells Building		
	Street address 1:	160 East 300 South		
	Street address 2:			
	City, state, zip:	Salt Lake City UT 84111-2316		
	Mailing address 1:	PO Box 146741		
	Mailing address 2:			
	City, state, zip:	Salt Lake City UT 84114-6741		
	Contact person(s):			
	Name:	Phone:	Fax:	E-mail:
	Noel Taxin	801-530-6621	801-530-6511	ntaxin@utah.gov

(Interested persons may inspect this filing at the above address or at the Division of Administrative Rules during business hours)

2.	Title of rule or section (catchline):
	Online Prescribing, Dispensing, and Facilitation Licensing Act Rule
3.	Type of notice:
	New ___; Amendment XXX; Repeal ___; Repeal and Reenact ___
4.	Purpose of the rule or reason for the change:
	The Division and the Online Prescribing, Dispensing and Facilitation Licensing Board are proposing amendments to the rule to add a new erectile dysfunction drug, Avanafil, to the approved drug list and to amend audit report requirements to accommodate licensees who are in compliance.
5.	This change is a response to comments from the Administrative Rules Review Committee.
	No XXX; Yes ___
6.	Summary of the rule or change:
	Section 306: Proposed amendment adds Avanafil, an erectile dysfunction drug, to the approved list. Section 308: Proposed amendments allow for an Internet facilitator who has been licensed for two years to request the audit reports to be due biannually.
7.	Aggregate anticipated cost or savings to:
	A) State budget:
	Affected: No ___; Yes XXX

The Division will incur minimal costs of approximately \$50.00 to print and distribute the rule once the proposed amendments are made effective. Any costs incurred will be absorbed in the Division's current budget.

B) Local government:

Affected: No XXX; Yes ___

The proposed amendments only apply to licensed online prescribers, licensed Internet facilitators and persons who may receive prescriptions via online methods. As a result, the proposed amendments do not apply to local governments.

C) Small businesses ("small business" means a business employing fewer than 50 persons):

Affected: No ___; Yes XXX

The proposed amendments may affect online dispensing/facilitation small businesses by increasing revenue if the business sells the approved drug Avanafil. An exact amount of increased revenue cannot be determined by the Division to due a wide range of circumstances. Licensed Internet facilitators, who have been licensed in this state for at least two years and who may qualify as a small business, may also see a slight decrease in their costs relating to required audit reports that need to be submitted to the Division as a result of the proposed amendment with respect to the required audit reports. However, the Division is not able to determine an exact amount of potential decreased costs relating to audit reports due to a wide range of circumstances.

D) Persons other than small businesses, businesses, 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):

Affected: No ___; Yes XXX

The proposed amendments may affect other persons who are involved in online dispensing/facilitation by increasing revenue if the person sells the approved drug Avanafil. An exact amount of increased revenue cannot be determined by the Division to due a wide range of circumstances. Licensed Internet facilitators who have been licensed in this state for at least two years may also see a slight decrease in their costs relating to required audit reports that need to be submitted to the Division as a result of the proposed amendment with respect to the required audit reports. However, the Division is not able to determine an exact amount of potential decreased costs relating to audit reports due to a wide range of circumstances. Additionally, the proposed amendment adding the approved drug Avanafil increases the options of obtaining the approved erectile dysfunction drug for patients who utilize licensed online prescribing and dispensing companies which may result in lower costs than obtaining the drug through a pharmacy. The Division, however, is not able to determine the amount of potential lower costs in obtaining the newly approved drug.

8. Compliance costs for affected persons:

The proposed amendments may affect other persons who are involved in online dispensing/facilitation by increasing revenue if the person sells the approved drug Avanafil. An exact amount of increased revenue cannot be determined by the Division to due a wide range of circumstances. Licensed Internet facilitators who have been licensed in this state for at least two years may also see a slight decrease in their costs relating to required audit reports that need to be submitted to the Division as a result of the proposed amendment with respect to the required audit reports. However, the Division is not able to determine an exact amount of potential decreased costs relating to audit reports due to a wide range of circumstances. Additionally, the proposed amendment adding the approved drug Avanafil increases the options of obtaining the approved erectile dysfunction drug for patients who utilize licensed online prescribing and dispensing companies which may result in lower costs than obtaining the drug through a pharmacy. The Division, however, is not able to determine the amount of potential lower costs in obtaining the newly approved drug.

9. A) Comments by the department head on the fiscal impact the rule may have on businesses:

As stated in the rule analysis, no fiscal impact to business is anticipated from this rule filing, which adds a new drug to the list of medications that are approved for online prescribing, dispensing and facilitation; and allows an online facilitator that has been licensed for at least two years to request that its audit reports be due biannually rather than quarterly.

B) Name and title of department head commenting on the fiscal impacts:

Francine A. Giani, Executive Director

10. This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.

State code or constitution citations (required) (e.g., Section 63G-3-402; Subsection 63G-3-601(3); Article IV) :

Subsection 58-1-106(1)(a)	Subsection 58-1-202(1)(a)
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Section 58-83-101	
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11.	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 Division of Administrative Rules; <i>if none, leave blank</i>):		
		First Incorporation	Second Incorporation
	Official Title of Materials Incorporated (from title page)		
	Publisher		
	Date Issued		
	Issue, or version		
	ISBN Number (optional)		
	ISSN Number (optional)		
	Cost of Incorporated Reference		
	Action: Adds, updates, or removes		
(If this rule incorporates more than two items by reference, please attach additional pages)			
12.	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. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the Utah State Bulletin. See Section 63G-3-302 and Rule R15-1 for more information.)		
	A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy):	10/15/2013	
	B) A public hearing (optional) will be held:		
	On (mm/dd/yyyy):	At (hh:mm AM/PM):	At (place):
13.	This rule change may become effective on (mm/dd/yyyy):	10/22/2013	
	NOTE: The date above is the date on which this rule MAY become effective. It is NOT the effective date. After the date designated in Box 12(A) above, the agency must submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.		
14.	Indexing information -- keywords (maximum of four, in lower case, except for acronyms (e.g., "GRAMA") or proper nouns (e.g., "Medicaid")); may not include the name of the agency:		
	licensing	online prescribing	
	internet facilitator		
15.	Attach an RTF document containing the text of this rule change (filename):	R156-83.pro	
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 <i>Utah State Bulletin</i> , and delaying the first possible effective date.			
AGENCY AUTHORIZATION			
Agency head or designee, and title:	Mark B. Steinagel, Director	Date (mm/dd/yyyy):	08/27/2013

R156. Commerce, Occupational and Professional Licensing.

R156-83. Online Prescribing, Dispensing, and Facilitation Licensing Act Rule.

R156-83-306. Drugs Approved for Online Prescribing, Dispensing, and Facilitation.

In accordance with Subsection 58-83-306(1)(c), the following legend, non-controlled drugs are approved for prescribing by an online prescriber:

- (1) finasteride;
- (2) sildenafil citrate;
- (3) tadalafil;
- (4) vardenafil hydrochloride;
- (5) hormonal based contraception (except injectable or implantable methods); [~~and~~]
- (6) varenicline;
- (7) hydroquinone up to 4%; [~~and~~]
- (8) tretinoin up to 0.1%; and
- (9) avanafil.

R156-83-308. Audit Reports.

In accordance with Subsection 58-83-308(3), an initially licensed Internet facilitator licensed under this chapter shall provide quarterly reports to the Division containing the information listed in Subsection 58-83-308(3). The reports are [~~is~~] due on the fifteenth day of each quarter, i.e. January 15, April 15, July 15, and October 15. If the Internet facilitator has been licensed for two years, the Board and Division may reduce the audit reports to be due biannually, January 15 and July 15.

KEY: licensing, online prescribing, internet facilitator

Date of Enactment or Last Substantive Amendment: [~~February 21, 2012~~2013

Authorizing, and Implemented or Interpreted Law: 58-1-106(1)(a); 58-1-202(1)(a), 58-83-101