CONSENT CALENDAR

February 8, 2023

HOUSE OF REPRESENTATIVES

REPORT OF COMMITTEE

The Committee on Health, Human Services and Elderly
Affairs to which was referred HB 223,

AN ACT relative to prescription refills. Having considered the same, report the same with the recommendation that the bill OUGHT TO PASS.

Rep. Gary Merchant

FOR THE COMMITTEE

Original: House Clerk

Cc: Committee Bill File

COMMITTEE REPORT

Committee:	Health, Human Services and Elderly Affairs
Bill Number:	HB 223
Title:	relative to prescription refills.
Date:	February 8, 2023
Consent Calendar:	CONSENT
Recommendation:	OUGHT TO PASS

STATEMENT OF INTENT

The committee finds that increasing the state limitation of 34-day supply to a 90-day supply does not violate Federal law, and that topically-applied testosterone medications have minimal potential for abuse. Requiring the prescriber to specify the medication is being used for the treatment of chronic low testosterone replacement therapy notifies the pharmacist of the reason for the prescription assist in their compliance with the corresponding responsibility requirement of the Drug Enforcement Agency (DEA).

Vote 20-0.

Rep. Gary Merchant FOR THE COMMITTEE

Original: House Clerk

Cc: Committee Bill File

CONSENT CALENDAR

Health, Human Services and Elderly Affairs

HB 223, relative to prescription refills. OUGHT TO PASS.

Rep. Gary Merchant for Health, Human Services and Elderly Affairs. The committee finds that increasing the state limitation of 34-day supply to a 90-day supply does not violate Federal law, and that topically-applied testosterone medications have minimal potential for abuse. Requiring the prescriber to specify the medication is being used for the treatment of chronic low testosterone replacement therapy notifies the pharmacist of the reason for the prescription assist in their compliance with the corresponding responsibility requirement of the Drug Enforcement Agency (DEA). Vote 20-0.

Original: House Clerk

Cc: Committee Bill File

BILL TITLE: relative to prescription refills.

DATE: February 8, 2023

LOB ROOM: 210-211

MOTIONS: OUGHT TO PASS

Moved by Rep. Merchant Seconded by Rep. Layon Vote: 20-0

CONSENT CALENDAR: YES

<u>Statement of Intent</u>: Refer to Committee Report

Respectfully submitted,

Rep Bill King, Clerk

HOUSE COMMITTEE ON HEALTH, HUMAN SERVICES AND ELDERLY AFFAIRS

EXECUTIVE SESSION on Bill # 223

BILL TITLE:			
DATE: 2/8/23			
LOB ROOM: 210-211			
MOTION: (Please check one box)		
☐ OTP ☐ ITL	☐ Retain (1st year)		Adoption of
	☐ Interim Study (2nd year)		Amendment # (if offered)
Moved by Rep. MERCHANT	Seconded by Rep. Layon	<u> </u>	Vote: <u>20-0</u>
MOTION: (Please check one box)		
□ OTP □ OTP/A □ ITL	☐ Retain (1st year)		Adoption of Amendment #
	☐ Interim Study (2nd year)		(if offered)
Moved by Rep	Seconded by Rep.		Vote:
MOTION: (Please check one box)		
□ OTP □ OTP/A □ ITL	☐ Retain (1st year)		Adoption of Amendment #
	☐ Interim Study (2nd year)		(if offered)
Moved by Rep.	Seconded by Rep.		Vote:
MOTION: (Please check one box)		
□ OTP □ OTP/A □ ITL	☐ Retain (1st year)		Adoption of Amendment #
	☐ Interim Study (2nd year)		(if offered)
Moved by Rep.	Seconded by Rep.		Vote:
Minority Report?Yes	No	N	
Respectfully submitte	ea:		



STATE OF NEW HAMPSHIRE OFFICE OF THE HOUSE CLERK

1/6/2023 12:36:33 PM Roll Call Committee Registers Report

2023 SESSION

Health, Human Services and Elderly Affairs

Bill #:	223	Motion:	OTP	AM #:	Exec Session Date:	2	18,	123	
	~ ~ ~		0) •	1,0101 110			-/		

<u>Members</u>	YEAS	<u>Nays</u>	NV
MacDonald, Wayne D. Chairman	20		
Layon, Erica J. Vice Chairman	ì		
Cushman, Leah P.	2		
King, Bill C. Clerk	3		
Kofalt, Jim NOMER, JEANINE	A		
McLean, Mark	5		
King, Seth	6		
Mazur, Lisa R	7		
Nagel, David J	8		
Polozov, Yury	9		
Weber, Lucy M.	lo		
MacKay, James R.	10		
Freitas, Mary C.	12		
Cannon, Gerri D.	13		
Nutter-Upham, Frances E.	14		
Schapiro, Joe	15		
Merchant, Gary	16		
Murphy, James Michael	17		
Palmer, William S	18		
Tellez, Trinidad Parge, David	19		
TOTAL VOTE:			

HOUSE COMMITTEE ON HEALTH, HUMAN SERVICES AND ELDERLY AFFAIRS

PUBLIC HEARING ON HB 223

BILL TITLE: relative to prescription refills.

DATE: January 25, 2023

LOB ROOM: 210-211 Time Public Hearing Called to Order: 11:25 AM

Time Adjourned: 11:45 AM

<u>Committee Members</u>: Reps. W. MacDonald, Layon, B. King, Cushman, Kofalt, S. King, Mazur, Nagel, Polozov, Weber, Freitas, Cannon, Nutter-Upham, Schapiro, Merchant, J. Murphy and Palmer

Bill Sponsors:

Rep. D. McGuire Rep. Merchant

TESTIMONY

* Use asterisk if written testimony and/or amendments are submitted.

Rep. Dan McGuire - Epsom - Supports - Prime sponsor

- Bill offers an exception to current law
 - Q: Rep. Cannon Is this bottle for 30 days?
 - A: Depends on pumps per day 20 days for him because he pumps 3 times a day
 - Q: Rep. Nagel Why is this not a schedule 3 drug?
 - A: This is in the steroid category

*Rep. Gary Merchant -Supports

- Q: Rep. Schapiro Do we have the means of determining other drugs?
- A: Study yes, but don't hold this bill up as a result
- Q: Rep. Nagel What makes this product different from other topicals
- A: Puts onvs on prescriber
- Q: Rep Nagel Should we be providing information for patient responsibilities
- A: Pharmacies give out necessary paperwork
- Q: Rep. Murphy Way specific for this diagnosis only
- A: Way to differentiate

Rep. Merchant will be offering an amendment

Respectfully submitted,

Rep. Bill King, Clerk

SIGN UP SHEET

To Register Opinion If Not Speaking

Bill #: HB223	Date: <u>1/25/23</u>
Committee: HHS & EA	

** Please Print All Information **

Name		Address		Phone	Representing	Pro	Con
Rap	DANIEL	Palalle	- MV(Lie D	603 767 6147	Representing ROCKINGHAM (7	X	COM
D (2 .4.1	19/10/00	0 10 10	0)	11-44-1	-	
USB-	75145			693660-0653	Hallsh.		
		*					

House Remote Testify

Health, Human Services and Elderly Affairs Committee Testify List for Bill HB223 on 2023-01-25

Support: 0 Oppose: 0 Neutral: 0 Total to Testify: 0

Export to Excel

223

Drug Enforcement Administration Pharmacist's Manual

Refills

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required. 21 U.S.C. 829(b) and 21 CFR 1306.22(a).

When a prescription for any controlled substance in schedules III or IV is refilled, the following information must be entered on either the back of the prescription, another appropriate document, or an electronic prescription record: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. 21 CFR 1306.22(b) and (c). If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription. 21 CFR 1306.22(d).



State of New Hampshire

REPRESENTATIVE GARY MERCHANT SULLIVAN, DISTRICT 6

Testimony HB 223 House Health, Human Services and Elderly Affairs January 25, 2023

Good morning, mister Chairman, members of the Health, Human Services and Elderly Affairs committee, and members of the public. For the record, I am Representative Gary Merchant for Sullivan County, District #6, Claremont, and Croydon.

I come before this committee today in support of HB 223. HB 223 will allow prescriber to write for a 90-day supply of a topical androgen and for a patient to obtain a 90-day supply of a topical androgen. A common topical androgen is testosterone. This bill addresses two interrelated regulatory concerns – abuse and pharmacist's corresponding responsibility.

Abuse - Androgens are potent drugs requiring a prescription for valid medical indications or offlabel reasons as well as being abused without prescription for illicit nonmedical application for performance or image enhancement. Androgen abuse originated during the Cold War as an epidemic of androgen doping among elite athletes for performance enhancement before the 1980s when it crossed over into the general community to become an endemic variant of drug abuse in sufficiently affluent communities that support an illicit drug industry geared to bodybuilding and aiming to create a hypermasculine body physique and image. For these reasons, Congress passed the Anabolic Steroids Act of 1990 that placed these drugs in Schedule III of the Controlled Substances Act regulated by the Drug Enforcement Agency (DEA).

Illicit use and abuse of androgens typically occurs with the injectable form of a drug.

DEA Corresponding Responsibility – Drug Enforcement Agency Pharmacist's Manual 2022

A pharmacist has corresponding responsibility for the proper dispensing of controlled substances. An order purporting to be a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the Controlled Substance Act. The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. 21 U.S.C. 841(a)(1), 21 U.S.C. 842(a)(1), and 21 CFR 1306.04(a).

A pharmacist is required to exercise sound professional judgment, and to adhere to professional standards, when making a determination about the legitimacy of a controlled substance prescription. 21 CFR 1306.04(a) and 1306.06. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious medical legitimacy. To the contrary, the pharmacist who deliberately ignores the high probability that a prescription was not issued for a legitimate medical purpose and fills the prescription, may be prosecuted along with the issuing practitioner. for knowingly and intentionally distributing controlled substances. United States v. Veal, 23 F.3d 985 (6th Cir.1994). Such action is a felony offense, which upon conviction, may result in a term of imprisonment and a fine. 21 U.S.C. 841(b). Unlawful dispensing of controlled substances by a pharmacist may also be subject to criminal actions against the pharmacy or pharmacist, and to civil enforcement actions against the pharmacy or pharmacist for money penalties or injunctions. 21 U.S.C. 842 and 843. Moreover, DEA may revoke a pharmacy's registration based on a finding that its pharmacists have violated the corresponding responsibility rule and both the pharmacy and pharmacists may be the subject of proceedings against their state licenses. Jones Total Healthcare, L.L.C., v. DEA, 881 F.3d 823 (11th Cir. 2018).

The Federal 1970 Comprehensive Drug Abuse and Control Act limits the number of refills to 5 within 6 months. It does not limit a day supply of a prescription; however, state law does limit the day supply to 34-days. A pharmacist may question the legitimacy of a single prescription for greater than 180 days or combination of first and subsequent refills exceeding 180 days under DEA corresponding responsibility.

By requiring a prescriber to include this phrase on a prescription for a quantity greater than 34-day supply – "for use to treat chronic low testosterone replacement therapy associated with a medical condition" it informs the pharmacist that the prescription is for a legitimate medical reason, alleviating most of this concern related to DEA corresponding responsibility.

This bill addresses these two related regulatory concerns while allowing a patient to obtain a cost effective and practical 90-day supply of a topical testosterone. I support HB 223 for these reasons.

Respectfully submitted,

Gary Merchant

HB 223 - AS INTRODUCED

2023 SESSION

23-0392 05/08

HOUSE BILL 223

AN ACT relative to prescription refills.

SPONSORS: Rep. D. McGuire, Merr. 14; Rep. Merchant, Sull. 6

COMMITTEE: Health, Human Services and Elderly Affairs

ANALYSIS

This bill creates an exception to the 34-day limit on prescription refills of schedule III topical androgens if the prescription specifies it is being used for the treatment of chronic low testosterone replacement therapy.

.....

Explanation: Matter added to current law appears in **bold italics**.

Matter removed from current law appears [in brackets and struckthrough.]

Matter which is either (a) all new or (b) repealed and reenacted appears in regular type.

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty Three

AN ACT relative to prescription refills.

1

2

3

4

5

6 7

8

9

10

11

12

13

14

1516

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 Controlled Drugs; Sale by Pharmacists. Amend RSA 318-B:9, IV to read as follows:

IV. No prescription shall be filled for more than a 34-day supply upon any single filling for controlled drugs of schedules II or III; provided, however, that for controlled drugs, in schedules II or III, that are commercially packaged for dispensing directly to the patient, such as metered sprays and inhalers, liquids packaged in bottles with calibrated droppers, and certain topical preparations packaged with metered dispensing pumps may be filled for greater than a 34-day supply, but not more than 60 days, utilizing the smallest available product size, in order to maintain the dosing integrity of the commercially packaged containers; and, provided that:

- (a) With regard to amphetamines and methylphenidate hydrochloride, a prescription may be filled for up to a 90-day supply if either such prescription specifies it is being used for the treatment of attention deficit disorder, attention deficit disorder with hyperactivity, or narcolepsy; and
- (b) With regard to a topically applied androgen, a prescription may be filled for up to a 90-day supply if the prescription specifies it is being used for the treatment of chronic low testosterone replacement therapy.
 - 2 Effective Date. This act shall take effect January 1, 2024.