

**Awaiting Formal Approval
MINUTES**

**UTAH
ONLINE PRESCRIBING, DISPENSING
AND FACILITATION
LICENSING BOARD MEETING**

May 21, 2013

**Room 210 – 2nd Floor – 9:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111**

CONVENED: 9:10 A.M.

ADJOURNED: 11:45 A.M.

Bureau Manager:

Noël Taxin

Board Secretary:

Karen McCall

Board Members Present:

Mark N. Bair, MD, Chairperson

Michael Rapp, MD

Peter L. Ax

Jennifer R. Korb

Roger Fitzpatrick, R. Ph.

Board Members Absent and Excused:

Kathleen Littlefield, R.Ph.

Lt. Michael Ross

Guests:

Maria Vargas

Bill Rogers

Don Lineburg

DOPL Staff Present:

Mark B. Steinagel, Division Director

Joyce McStotts, Licensing Specialist

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

MINUTES:

The minutes from the November 6, 2012, Board meeting were read.

Mr. Ax made a motion to approve the minutes with minor revisions. Ms. Korb seconded the motion. **The Board vote was unanimous.**

APPOINTMENTS:

9:20 am

Audit Report/Review for KwikMed

Ms. McStotts reviewed the December and April audits. She stated she audited 35 files and the one file the Board requested at the last meeting be audited again.

Ms. McStotts reported on the file from the November 2012, audit and questioned again the large numbers of ED tablets ordered between April 2012 and September 2012.

Board members voiced concern regarding stocking up on the medications or possibly selling or giving tablets away to friends.

Mr. Ax explained what is being seen is not the whole situation and the KwikMed Physicians have determined the patient is being honest and is trustworthy so it is appropriate to fill the order requested.

Mr. Fitzpatrick commented in the community pharmacies this situation would be flagged and the patient would be counseled that they could not obtain a refill until a specific date. He stated the FDA guidelines for ED drugs are 365 tablets per year and this patient has obtained a considerable number over the 365 per year.

Following additional discussion it was determined the Board has a responsibility to protect the public and should follow the FDA guidelines. The Board recommended no more than 365 tablets per year be dispensed without the file being flagged and an explanation as to an exception to fill beyond the FDA recommendation. The Board again requested additional information on this file.

Ms. McStotts then reviewed the audit as follows:
1. She stated when she tried to start the KwikMed audit she could not get into the information. She explained upon contacting KwikMed she was informed that the information had not been

downloaded yet. She questioned if this meets the intent of the Law, 58-83-308, as the Law indicates she should be able to get into the files at any time as needed. Ms. McStotts explained she gives KwikMed the information she needs and they run a report for her instead of her being able to go the KwikMed website and open the files herself.

Following discussion, it was determined the Legislature approved the language as written in order for the auditor to have full, remote, read only access to the information.

Mr. Ax agreed to work with his IT people and have the information available for full, remote, read only access.

The Board requested an update at the next Board meeting.

2. Ms. McStotts reported this file was flagged for over ordering. She asked why the order was filled when it was documented the patient had already exceeded the FDA guidelines.

Mr. Ax explained the Pharmacist had talked with the patient and the Physician re-evaluated and approved the order due to the Pharmacist's recommendation.

Following additional discussion, the Board again recommended the Online Physicians write prescriptions and the Pharmacists fill them in accordance with the FDA guidelines.

The 1st Quarter Audit for 2013

Ms. McStotts reported she audited 35 files and had the following comments/questions:

1. Ms. McStotts reported seeing new drugs ordered through BellaRX.

Mr. Ax explained BellaRX is the Pharmacy adjacent to KwikMed but they do not write online prescriptions, that the information was provided in

error.

2. Ms. McStotts reported speaking to Brian Ackley from KwikMed IT and requesting the name of the drug be included in the list of items on the Order History. She stated Mr. Ackley stated it will be available for the next audit.

3. and 4. Ms. McStotts reported the majority of files audited appeared to be appropriate with appropriate amounts dispensed for a one year period.

5. Ms. McStotts asked how frequently Ella may be taken, how it is tracked and is it used for birth control as there was an order in December and again in March.

Mr. Ax responded he has been informed that it would take large quantities of Ella to be used for birth control and it has not yet been approved for that purpose.

6. Ms. McStotts asked how KwikMed addresses a file when the treatment appears not to be working, i.e., Chantix.

Mr. Ax responded the process would be evaluated again.

7. Ms. McStotts stated she was unable to view the detailed notes from the doctors.

Mr. Ax responded all the notes are available but he will check and get back to Ms. McStotts.

8. Ms. McStotts asked if the Board wants a report documenting all the websites the drugs are being ordered through. She stated Secure Medical has the information on each file audited.

Dr. Bair requested Mr. Ax to provide the website information.

Dr. Bair summarized the following for Mr. Ax:

1. Mr. Ax, Mr. Steinagel and Ms. McStotts to

- work with IT on obtaining full, remote, read only access of KwikMed for audit purposes.**
- 2. Adhere to the 365 tablets for a year, place a flag and be prepared to justify why more may have been prescribed and dispensed.**
 - 3. Place hard stops where necessary and provide justification when over-riding them.**
 - 4. Add the list of websites the drugs are ordered from to each file.**

The Board thanked Ms. McStotts for the audit reports.

10:45 am

Audit Report/Review for Secure Medical, Inc

Ms. McStotts reviewed the December and April audits for Secure Medical, Inc., due to the absence of Ms. Bolinder.

Ms. McStotts reported the paperwork has been submitted for the transition of the CEO position with Secure Medical, Inc. from Joel Korsunsky to Don Lineburg.

Ms. McStotts reported Ms. Bolinder audited 35 files for the 4th quarter of 2012. She stated Ms. Bolinder had the following questions/comments:

1. An order was placed and the patient agreed to get approval from his primary care practitioner (PCP) to continue ED drugs, however, the notes do not mention any approval.

Dr. Rapp responded he spoke with the patient and determined it was appropriate to fill the order as the patient promised to inform his PCP.

2. There is no reason mentioned regarding why an order was cancelled.

Dr. Rapp responded there was a duplicate order and one was cancelled. He stated the call center has been requested to follow proper procedure by including duplicate order in their comments.

3. Why was Propecia for 30 units shipped on December 5, 2012, and again December 31, 2012, as

that is prior to the 30 days.

Dr. Rapp responded the second order was delayed by the Physician until four days prior to the 30 day period as it is to be taken every day.

4. This patient was audited again due to the Board requesting follow up. Ms. McStotts stated it appears the patient is in the military and there were no obvious concerns with the file.

Dr. Rapp responded the patient is active military and ordered within the normal limits and the order was approved and sent.

5. This patient had a new approving Physician who was not licensed in Utah to prescribe in Utah.

Dr. Rapp responded this Physician is licensed in California and prescribes for California only.

Ms. McStotts reported Ms. Bolinder audited 35 files for the 1st quarter of 2013. She stated Ms. Bolinder had the following questions/comments:

1. This patient exceeded the 365 day period limit and had another order sent.

Dr. Rapp responded the customer explained his medication was stolen with his luggage. The Physician noted the patient was within limits and approved a one-time exemption.

2. This product was shipped to London, Utah. Should the address be Lindon, Utah?

Dr. Rapp responded the patient travels frequently from Utah to the United Kingdom and the billing address was mixed up and should have been the United Kingdom. He stated the address has been corrected.

3. There were no comments in regard to red flags.

Dr. Rapp responded this patient forgot his

medications when he traveled out of Utah and medication was sent to him, then the red flag tripped on his next order. He stated the combined orders were within acceptable standards.

Dr. Rapp explained the next patient was allowed to reorder after the Physician reviewed the history and status and determined the velocity was acceptable. He stated this Physician was reminded to be more diligent in making notes related to red flags.

4. This patient ordered Cialis, Viagra and Cialis within a short period of time. Is this appropriate?

Dr. Rapp responded as the patient was not exceeding the product velocity or cumulative annual limit it was appropriate to fill the orders.

5. Should a man be allowed to order a stimula for a woman?

Dr. Rapp responded yes, that this is an OTC product and men will purchase for their female partner to enhance sensitivity and a better experience for the woman, whereas, the man may use it for desensitizing to avoid premature ejaculation and completion.

Ms. McStotts stated Ms. Bolinder observed that out of the 35 files audited there were seven patients in their 30's and two were 28. She stated seven of the nine were not in the military.

Dr. Rapp responded a little more leeway is given if there is an APO address and the men are younger.

Dr. Rapp stated he believes both companies are trying to prescribe appropriately but sometimes people lose their focus and miss the soft stops accidently.

The Board thanked Ms. McStotts for delivering the reports.

FYI

Ms. McStotts informed the Board of her distributing the renewal forms to Mr. Ax for KwikMed and to Mr. Lineburg for Secure Medical, Inc.

DISCUSSION ITEMS:

Discuss the Proposed Rule and Stendra
(Avanafil)

Ms. Taxin stated she printed out avanafil drug information in case there are any questions.

The Board and guests commented the FDA approved avanafil last year but the manufacturer is not introducing it into the US at this time.

Mr. Fitzpatrick made a motion to approve the proposed Rule to include avanafil on the ED list and to audit all new Online licensees quarterly for the first 2 years and then the Board/Division may reduce the frequency to bi-annually for January 15 and July 15. He recommended the Proposed Rule be filed.

Mr. Ax seconded the motion.

The Board vote was unanimous.

Ms. Taxin stated she will file the Rule in order for avanafil to be filled when it becomes available.

Legislative Update

Ms Taxin reviewed the following legislative Bills with the Board:

HB51, HB120, SB20, SB77, SB214 and SB 270.

Ms. Taxin stated tramadol was put on the Schedule 5 list for controlled substances with some spice bath salts. She informed the Board that the mandated 4 hours of Opioid training has been postponed until the 2014 to 2016 renewal dates.

FYI

Ms. Taxin informed and provided hand outs to the Board of the Electronic Prescribing Requirement.

2013 Board Meeting Dates

The Board noted the dates scheduled for the remainder of 2013 are August 6 and November 5, 2013.

Ms. Taxin stated Mr. Ax may email the information he

was requested to provide and she will forward it to all Board members. She stated if everything is in order the August meeting will be cancelled and the Board will meet again November 5, 2013.

Board members concurred.

NEXT MEETING SCHEDULED FOR:

August 6, 2013

ADJOURN:

The time is 11:45 am and the Board meeting is adjourned.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

11.19.2013

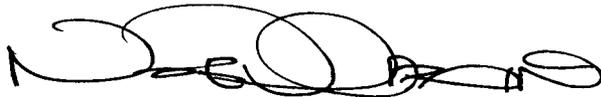
Date Approved



Chairperson, Utah Online Prescribing, Dispensing and
Facilitation Licensing Board

6/3/13

Date Approved



Bureau Manager, Division of Occupational &
Professional Licensing

Agenda

UTAH ONLINE PRESCRIBING, DISPENSING AND FACILITATION LICENSING BOARD

May 21, 2013

Room 210 – 2nd Floor – 9:00 am
Heber M. Wells Building
160 E. 300 S. Salt Lake City, Utah

This agenda is subject to change up to 24 hours prior to the meeting.

ADMINISTRATIVE BUSINESS:

1. Call Meeting to Order
2. Sign Per Diem
3. Read and Approve the November 6, 2012 Minutes

APPOINTMENTS:

- 9:20 am** – Audit Report/Review for KwikMed
10:45 am – Audit Report/Review for Secure Medical, Inc.

DISCUSSION ITEMS:

- Discussion Regarding Stendra (avanafil) for Approved ED List
- Legislative Update
- FYI – Electronic Prescribing
- Audit Dates and Frequency
- 2013 Board Meeting Dates: August 6 and November 5, 2013

CORRESPONDENCE:

NEXT SCHEDULED MEETING:

August 6, 2013

Note: In compliance with the Americans with Disabilities Act, individuals needing special accommodations (including auxiliary communicative aids and services) during this meeting should notify, Carol Inglesby, ADA Coordinator, at least three working days prior to the meeting. Division of Occupational & Professional Licensing, 160 East 300 South, Salt Lake City, Utah 84115, 801-530-6628 or toll-free in Utah only 866-275-3675.

Posted to Web 4/25/2013 12:36 PM

Posted to Bulletin Board April 25, 2013

2nd Agenda

UTAH ONLINE PRESCRIBING, DISPENSING AND FACILITATION LICENSING BOARD

May 21, 2013

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DISCUSSION ITEMS:

- Discussion Regarding Stendra (avanafil) for Approved ED List
- Legislative Update
- FYI – Electronic Prescribing
- Rule on Audit Dates and Frequency
- 2013 Board Meeting Dates: August 6 and November 5, 2013

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