

MINUTES

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

**RULES HEARING
AND BOARD MEETING**

February 14, 2012

**Room 474 – 4th Floor – 9:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111**

CONVENED: 9:05 A.M.

ADJOURNED: 12:07 P.M.

**Bureau Manager:
Board Secretary:**

Noël Taxin
Karen McCall

Board Members Present:

Mark N. Bair, MD, Chairperson
Roger Fitzpatrick, R.Ph.
Peter Ax
Michael Ross
Jennifer R. Korb
Michael Rapp, MD

Board Members Absent:

Kathleen Littlefield, R.Ph.

Guests:

Julie Scott, U of U Pharmacy Student
Kevin Marino
Lisa Dimick, Pharmacist
Joel Korsunsky
Bill Stilling

DOPL Staff Present:

Mark B. Steinagel, Division Director
Karl Perry, Assistant Attorney General
Ray Walker, Compliance & Regulation
Joyce McStotts, Licensing Specialist
Julie Bolinder, Licensing Specialist

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

Swearing in of Dr. Michael Rapp as a Board Ms. Taxin conducted the swearing in of Dr. Rapp as a

Member

Board member. The Board welcomed Dr. Rapp.

MINUTES:

The minutes from the September 20, 2011 Board meeting were read.

Mr. Fitzpatrick made a motion to approve the minutes with minor revisions. Mr. Ross seconded the motion.
The Board vote was unanimous.

APPOINTMENTS:

9:00 am

Rules Hearing

Judge Eklund conducted the Rules Hearing. For information regarding the Hearing contact Judge Eklund's office directly.

9:30 am

Audit Report/Review for KwikMed

Ms. McStotts presented the third quarter audit report for KwikMed.

Ms. McStotts stated KwikMed has been very responsive in making corrections in their system when she has contacted them. She stated there are still some flag issues where she has not seen the comments or documentation from the Physician regarding whether or not the Physician has addressed the concerns raised by the flags.

Ms. McStotts then referred to a person who placed two orders within 14 days but she could find no documentation regarding the Physician addressing the issue.

Mr. Ax asked if Ms. McStotts knew what a flag is.

Ms. McStotts responded yes. She stated it is a concern or inconsistency that has come up or the branching questionnaire has put a stop in the file for the Physician to address.

Mr. Ax responded a flag is not always a medical issue that has been missed but could be a wrong address or social security number misstated. He stated most are administrative issues and are dealt

with at the customer service level. He stated if it is a medical flag there is always a response and perhaps Ms. McStotts is not reading the file correctly at times. Mr. Ax then read the concern Ms. McStotts had written on the audit and stated it could have been the patient did not complete the order as information was not complete.

Ms. McStotts pointed out the final information showed that both orders were fulfilled. She asked why one was not indicating it had been cancelled. She also asked why two different ED drugs were sent to the same patient

Mr. Ax again reviewed the audit information and stated Ms. McStotts may not have seen that one order was probably cancelled, however, this patient has ordered 20 pills of Cialis and 20 pills of Viagra for several years. He stated they were separate orders sent out to the patient at the same time. He stated this patient alternates the use of the ED drugs.

Dr. Bair stated the auditor should have the ability to access all information to view the comments Mr. Ax was referring to and Ms. McStotts could not see them. He voiced concern that Ms. McStotts is not allowed to see the full file.

Mr. Ax responded he is not seeing complete information and he asked if the information is the same patient.

Ms. McStotts responded yes. She stated she pulled down the links for that file but was unable to access all information.

Mr. Ax requested Ms. McStotts to call KwikMed and inform them what she is seeing and then request it be addressed and make the information available. He stated it also might be an error in reporting.

Dr. Bair requested Ms. McStotts to explain the concern.

Ms. McStotts explained a patient had indicated the use of a high frequency of alcohol consumption in one sitting. She asked if that would affect an interaction of the ED drug. She stated there were no Physician comments.

Ms. Taxin stated the branching question asked if alcoholic drinks were consumed in a specific period of time during the month and the patient responded yes and stated how many within the timeframe.

Mr. Ax responded he believes the Physician provided a response but Ms. McStotts must have not seen it.

Ms. McStotts stated yes, she had seen the response that the Physician stated six dinks in one month was not excessive. She stated the question is how many drinks in one sitting and the patient had responded six.

Mr. Ax responded the Physician must have misinterpreted the question.

Ms. Taxin stated there would an easy resolution if the Physician makes a note on each patient who has a flag.

Dr. Bair stated all appropriate fields need to be made available for the audit.

Mr. Ax responded it was a good catch on Ms. McStotts part and he will discuss it with IT to be sure there is a hard stop and the entire file is available. He asked if Ms. McStotts has accessed the link that says “notes”.

Ms. McStotts responded she has viewed order notes but many times that area is blank with no notes.

Mr. Ax explained if there is a flag there is a code number for what the flag means and if there is a hand written note it would go into that area.

Dr. Bair commented it appears there may be some notes and Mr. Ax needs to make sure the

Physicians are more diligent in putting notes in the hard stops. Dr. Bair explained that alcohol opens the blood vessels and Viagra or Cialis does the same. He stated the two combined could cause some concern. He stated the second concern on the audit appears to be a mailing address concern.

Ms. McStotts responded she believed if it was serious enough for there to be a question on the branching questionnaire then it should be addressed with a note from the Physician.

Mr. Perry commented if the issue is a customer service issue maybe customer service could address it with a comment.

Mr. Ax responded if the order was filled then the address issue was resolved.

Ms. McStotts stated the last concern she saw was the note that charting was not available. She then asked the Board if she should only look for the medical flags and not review the general flags.

Mr. Ax responded if the issue was administrative there would not be notes as they would understand the issue.

Mr. Perry commented on the second patient issue which says “order velocity too high”. He requested an explanation.

Mr. Ax responded the patient probably went to another KwikMed website which the system recognized and put in the comment. He stated this protects someone from using multiple sites and addresses to receive multiple medications. He stated the comment was this “patient orders a few pills every week” so there is no real concern.

Dr. Bair recommended the flags be set for the total amount ordered as one patient ordered one pill every day for two weeks.

Dr. Rapp commented there also may be someone

ordering 60 at one time for several times which would throw off the audit.

Mr. Ax responded he would get back to Ms. McStotts and the Board on that one.

Mr. Fitzpatrick commented each time there is a flag there should be a note that addresses the flag even if there is no change. He stated as a Pharmacist he receives these types of flags on several patients all the time and he writes his comments each time.

Ms. Taxin asked if the medication is shipped to someone is there a chance a different person would receive the medication.

Mr. Ax responded the person receiving the medication must sign for it and also verify that they are over 21.

Ms. McStott read the third concern regarding no note regarding the high blood pressure response.

Mr. Ax responded KwikMed has the ability to respond directly to the patient so sometimes the request goes to the Physician and the note would be in that file which would bypass the system file. He stated patients find out who the Physician is and will sometimes call them directly. He stated when this occurs the Physician tries to resolve the issue and notes it in the patient file.

Ms. McStotts responded there should also be a note in the system file so the auditor knows the concern has been addressed.

Ms. Taxin responded if the auditor sees high blood pressure there should be a note regarding the Physician addressing the issue and the issue being resolved.

Dr. Bair commented any time there is a complication with the interaction of medications it puts the Physician and KwikMed at risk. He stated it may take a few extra minutes to put in notes but

it would protect everyone and resolve the issue for the auditor. He stated the last concern in the audit shows a comment of no diagnostic output available. Dr. Bair asked what that comment means.

Mr. Ax responded at first it was a static consultation and did not branch out to additional questions. He stated notes of the static consultation would be in other files which did not synchronize into the current system and would depend on how it is interpreted on the database.

Ms. Taxin stated the issue occurred for the drug Ella which was a new drug. She stated if the auditor finds others Mr. Ax will be contacted to correct the comment.

Mr. Ax responded when Ella was launched it misfired but the situation is now fixed. He stated he is not sure if those older files can be integrated at this time as it is a complicated process.

Ms. Taxin explained that in the first audit a man was given Ella. She stated there are files that are incomplete. She stated this list is from the last quarter so it is recent. Ms. Taxin stated the charting system is inconsistent as there are files with comments and files without comments.

Mr. Ax responded he believed it was just at launch time but will find out and get back to Ms. Taxin.

Mr. Fitzpatrick asked what the number 14,684 represents.

Ms. Taxin responded it is the number of medications filled.

Mr. Fitzpatrick asked how many of that number were filled for Utah patients.

Ms. McStotts responded she has tried to pull a list of Utah patients but does not have a total per State as KwikMed does not have the breakdown but she is able to pull only Utah patients.

Ms. Taxin asked Ms. Bolinder if she is able to pull the number of Utah patients.

Ms. Bolinder responded yes.

Ms. Taxin stated the Utah Pharmacy fills for other States and Mr. Ax might want information on all the States they are filling for.

Mr. Fitzpatrick asked if the Pharmacy has been audited and if the Online Prescribing Board is reviewing the same information being noted by the Pharmacist audit.

Ms. McStotts responded she does not have access to the Pharmacy information.

Ms. Taxin stated she could ask investigations to go out and do a random audit of the Pharmacy as the Pharmacy Law allows for audits. She stated when Mr. Ax conducted the training program there was access to the Pharmacy information.

Ms. Bolinder commented she has access to what has been filled by the Secure Medical, Inc. Pharmacy.

Mr. Fitzpatrick commented the profession and audits are still in the infancy stage but he believes at some point the Board will need to review the whole process to be sure KwikMed and Secure Medical, Inc. are doing what needs to be done to protect the public.

Ms. Taxin responded Mr. Ax has the ability to review everything and maybe he needs it to be available for the Division to also review.

Dr. Bair asked Ms. Dimick when she received a prescription from a Physician and notices the Physician has approved the prescription even though the patient is on a nitrogen patch what does she do.

Ms. Dimick responded she receives the same flags

and section for comments. She stated she also documents any interaction with the patients in the history notes. Ms. Dimick stated she will go into the patient history and notes the Physician noted and approved the medication. She stated if she questions the approval she will contact the patient and Physician and make her own note.

Ms. Taxin stated in the initial training Ms. Dimick's notes were available for review. She stated KwikMed will need to make sure the auditor has access to review Pharmacy notes and flags.

Mr. Fitzpatrick stated the availability of the Physician flags and notes is a check and balance to protect the public. He stated in cases where patients may have been harmed it would be good to be able to review all the notes.

Mr. Ax responded he will make sure the Pharmacy notes are available.

Ms. Korb asked if the auditor also has access to any complaints.

Ms. McStotts responded no.

Ms. Taxin responded the tab for complaints refers the patient/auditor to contact the Division and/or the company.

Ms. Korb asked if complaints would be disclosed to the Board.

Ms. Taxin and Mr. Perry responded not necessarily but they could be disclosed.

Mr. Ax commented if KwikMed has a complaint it is usually the medications did not arrive on time. He stated medical complaints would go directly to the Physician and he is not aware of any complaints having been received.

Board members thanked Ms. McStotts for the audit report.

Ms. Taxin asked if the Board would like the same number of audits for the next report.

Board members responded yes.

10:45 am

Audit Report/Review for Secure Medical, Inc

Ms. Bolinder conducted the audit report for Secure Medical, Inc.

Ms. Bolinder stated she audited 38 files out of 9,552 files. Ms. Bolinder stated there was an IT problem which has now been corrected. She reported she was unable to view internal comments on a patient and was informed the patient cancelled the order as he did not want to complete the verification process. Ms. Bolinder then reported a patient was denied multiple ED medications at the same time and her understanding was that all three ED medications could be sent as samples. She stated Secure Medical, Inc. responded at the time of this specific order trial packages were not being sent to Utah patients but that has now been changed and the trial packages are now available to Utah patients. Ms. Bolinder reported an additional Physician prescribing who is not licensed in Utah and the response was this was an IT issue as the Physician prescribes internationally. She stated the IT issue has been resolved and the international information is no longer available to her. She asked if the Board had any concerns regarding products being sent internationally.

Board members did not respond to the subject of international services.

Ms. Bolinder then moved on to #4 regarding several files having an internal comment from Dr. Rapp stating “early, watch limit.” She stated Dr. Rapp’s response was the prescription request was ordered earlier than expected but does not exceed the annual limit of 180 tablets.

Dr. Rapp responded these patients are ordering the maximum at one time for a cost savings. He stated they are cutting the tablets down so they are not exceeding the annual limit of 180 tablets. He stated

they now hold the order for 10 days if the order has been placed early.

Mr. Ax asked if a hard stop was put in for the limit of 180 tablets per year.

Dr. Rapp responded no.

Mr. Fitzpatrick asked if a flag comes up to review for monitoring when the patient orders again.

Dr. Rapp responded no but he is always calculating the time between orders and checking the notes.

Ms. Bolinder stated the patients in number 5 are all under 30 years old. She stated there were notes that Dr. Rapp contacted one patient but there were no additional comments for the other two patients regarding if there is some underlying reason for ED frequency.

Dr. Bair asked Dr. Rapp if he had a discussion with the patient.

Dr. Rapp responded with military patients below 25 years of age he does not question but they must be at least 21 years of age. He stated if the patient is 21 years of age and in the military it is looked at; if out of the military and a civilian they require the patient to first see their Primary Care Physician. He stated if the patient is 25 years of age and a civilian they are required to see their Primary Care Physician for a prescription for one of the three ED medications. Dr. Rapp stated they do not mail out to APO addresses.

Dr. Bair commented not knowing the Secure Medical, Inc. policy makes the audit difficult. He stated the military have access to the Physicians where ever they are stationed. Dr. Bair asked Mr. Ax if KwikMed has a similar policy.

**Mr. Ax responded no. He stated it is up to the prescribing Physician at KwikMed.
Dr. Rapp agreed with Dr. Bair regarding military**

personnel having access to Physicians but he stated some of the small teams do not always have the time and when they have R & R they prefer to spend it other ways.

Ms. Taxin stated there should be something in the notes for clarification.

Dr. Bair stated any time the standard is not met there should be notes in the patient file.

Ms. Bolinder moved on to #6 which had a red flag for a patient but no internal comments. She stated Dr. Rapp had explained the patient only orders 30 tablets per year and internal comments were not necessary.

Dr. Bair asked why there was a red flag if the patient only orders 30 tablets per year.

Dr. Rapp responded when the order came in it was too early to fill them.

Dr. Bair recommended comments be entered for clarification and to avoid confusion.

Ms. Bolinder reviewed #7 regarding two orders placed and both indicated having been processed. She stated #8 was similar and #9 had no comment section.

Dr. Rapp responded they try to ship orders together as it is cost effective.

Mr. Fitzpatrick asked if #9 was the only file of the 38 audited that had no comment section.

Ms. Bolinder responded yes. She then reviewed #10 and stated the patient had a yes answer for the question regarding high blood pressure or enlarged prostate but she was unable to review any medications the patient is taking and there were no internal comments.

Dr. Rapp responded that the system will lump together the medications they are concerned with interacting with the ED medications. He stated the list of medications is listed above the question as

the patient has to type in all medications they are taking. He stated it needs to be two separate questions and it is helpful if the patient calls so someone can guide them through the questionnaire. He stated they tell the patients to take their time and not rush through so there are not problems in the future.

Mr. Fitzpatrick asked how many of the 38 files audited were Utah patients.

Ms. Bolinder responded five were Utah patients. Ms. Bolinder then stated she is able to view the prescriptions but cannot see the Pharmacy notes.

Mr. Korsunsky responded he will make sure the Pharmacy notes are available for the next audit.

The Board thanked Ms. Bolinder for the audit report.

DISCUSSION ITEMS:

Discuss Audit Expectations

Dr. Bair asked the Board members if anything has come to mind for them as they have gone through the audit process.

Ms. Korb responded she thought it would be helpful to see complaints that may have come to KwikMed and Secure Medical, Inc. She stated most might be administrative but they might be helpful to know about.

Mr. Korsunsky responded if patients are unhappy with the services they do not order again.

Dr. Rapp responded there are sometimes angry people when orders are delayed and sometimes patients will ask why they have to answer the same questions each time. He stated he does not hear patients calling with complaints. Dr. Rapp stated there have been patients who have said this will be their last order as they should not have to wait and then he has noticed some of those have come back again.

Ms. Korb asked if the interaction is like an email link.

Mr. Korsunsky responded no. He stated it is customer services interacting with the patients.

Ms. Taxin asked Mr. Ax if it is the same with KwikMed.

Mr. Ax responded yes.

Dr. Bair asked if there has ever been any complications, issues or legal issues where a mistake was made that caused a patient a problem.

Mr. Korsunsky responded no. He stated occasionally they have had a spouse try to find out if ED medications have been ordered and this is usually done through an attorney.

Mr. Ax responded KwikMed has never had litigation. He stated there were some issues with two patients who were in the process of divorce but to turn over patient information they would need a subpoena and authorized signatures. He stated all information would go into the patient medical record. Mr. Ax stated they do receive some calls asking if the drugs are real as periodically the medications do not work for the patient or they see so much negative advertising they want to be sure they are real medications.

Ms. Dimick commented that KwikMed offers a pedigree to prove purchases through a credible wholesaler and manufacturer. She stated ED medications do not work with about 20% of males and there is no guarantee any medication will work.

Mr. Ax commented both audits were well done and opened up thought. He suggested the audits be consistent, i.e.: here is what we focused on and both measured in the same way.

Ms. Taxin responded Ms. McStotts and Ms. Bolinder work together and review the same things in each file but they are finding different information as the companies are different and have different styles.

Mr. Fitzpatrick asked how prevalent ordering by military personnel is.

Dr. Rapp responded military personnel orders are about one to two percent but maybe not quite that high.

Mr. Ax responded KwikMed sees about the same.

The Board requested the same number of audits be completed and presented for the next audit.

Ms. Taxin commented it is expected that the list of concerns should be less in the upcoming audits. She stated the January and April audits will be presented at the May 22, 2012 Board meeting.

Board members concurred.

Legislative Update

Ms. Taxin reported SB88 is an amendment to the Pharmacy Practice Act at the Legislature. She then read the Bill and stated the part on cosmetic has been approved to be dispensed online.

Mr. Walker asked how many of the drugs on the list promote attractiveness or alters appearance.

Mr. Stilling responded he talked with Representative Vickers and was informed cosmetic is not a drug as drugs are for diseases. He stated he recommended the language be included in the Pharmacy Practice Act proposed changes. He stated an amendment was put in February 13, 2012 which opens the Law up for prescribing drugs and not just for cosmetic purposes. He stated the amendment will allow online prescribing and not just for Physicians.

Ms. Taxin stated the Online Prescribing profession is

included in adopting Administrative Rules but it is not quite clear on what is allowed. She stated the Board should review lines 45 and 46.

Mr. Stilling went on to say two years ago the Pharmacy Law was opened to allow for Lattise to be prescribed but this is a cosmetic medication and not a drug.

Mr. Walker commented HCG was also included at that time. He stated proposed Statute expansion would allow dispensing of oncology drugs.

Mr. Stilling stated the Pharmacy profession would not be happy about that change.

Dr. Bair stated the Physicians would not be happy about the changes either.

Mr. Ax commented the Physician who met with the Board for possible online licensure stated he dispenses out of his office.

Ms. Taxin clarified the Physician prescribes but does not dispense out of his office in Utah.

Dr. Bair stated if the bill were to pass then anything on the list could be dispensed out of the Physicians office. He voiced concern if the proposed change is for one Physician to be able to dispense out of the office medications that can be obtained online. He stated he believes it is all regulated by the Pharmacy Practice Act.

Mr. Marino commented he believes if these drugs can improve appearance the Physician could dispense them.

Dr. Bair stated he does not believe the Online Prescribing Board needs to be the approval Board for these drugs. He stated the Physicians Board reviewed the proposal and believes it is an exception and do not want Physicians to be acting as Pharmacies. He stated as a Pharmacist and a Physician he knows there is some overlap but if a

Physician does make a mistake in a prescription the Pharmacist will catch it as someone focused on medications will pick up on the medication interactions and provide the checks and balances.

Mr. Ax commented he would think the Physicians would be in favor of the change.

Mr. Stilling commented the proposed change would make it so Physicians could dispense anything that would change appearance. He stated it broadens the scope of practice and Physicians in Utah have never been able to dispense from their office except through samples.

Ms. Taxin stated the Online Prescribing Board would still be able to add to the list of approved online drugs.

Mr. Fitzpatrick stated the mitigating and treating language is back in the proposal. He stated if Physicians dispense medications they must abide by the Pharmacy Rules of labeling and storing.

Mr. Walker stated there is also H.B. 165 regarding Pharmacy/patient counseling amendments. He stated the language regarding the “Pharmacy shall orally offer counseling” has been taken out and “shall require face to face orally counsel and/or video conference for every drug in this State” has been put in. He stated the Class D Pharmacy will be required to offer oral counseling by telephone.

Mr. Stilling responded at this time the Pharmacy must offer to counsel in person unless the patient does not pick up the prescription. He stated the Pharmacy must provide a 24 hour line and written material with each prescription. He stated with the change the Pharmacist would have to call each patient or provide a video for counseling.

Mr. Ax asked if the changes are for Class D Pharmacies.

Ms. Taxin responded it would be for Class B Pharmacies.

In conclusion the majority of the Board and visitors voiced concern with the proposed Legislation.

Annual Board Member Training

Ms. Taxin conducted the yearly board member training.

Ms. Taxin reviewed the Open and Public Meetings Act guidelines with formal Board meetings for business and reminded the Board that all Board meetings are recorded with the recording being retained for a year.

Ms. Taxin reviewed the guidelines for Board meetings and explained that Board business must be conducted in the formal Board meeting with an agenda having been posted 24 hours in advance for any interested individuals to be able to attend. She explained additional agenda items cannot be added after the 24 hour deadline and will be on the next scheduled Board meeting agenda. She explained a quorum of Board members is required to make decisions with motions and votes.

Ms. Taxin explained the purpose for closing a meeting and stated with the Open Public Meetings Act there are very few reasons to close a meeting for the public to leave. Ms. Taxin reviewed electronic (telephonic) participation by Board members and for interviews. She stated Board members and public visitors may be requested to leave a Board meeting if they are being disruptive.

She stressed the importance of Board members being professional, remembering they are here to protect the public, to be fair, attentive and balanced in their comments and decisions. She stated Board members should be respectful to each other as well as any probationers or visitors. She stated they should listen and consider other view points; sometimes being creative but clear and open in communication and hold judgment until after all the facts have been presented.

Ms. Taxin recommended the Board review and be familiar with their Laws and Rules in order to make

correct decisions. She stated they should be positive role models.

Ms. Taxin covered the fire drill and her expectations for everyone to get out of the building and meet across the street in the parking lot to be accounted for. She asked the Board to let her know if they have any special needs and to be aware of any visitors who may have special needs in order for her to get assistance for Board members or visitors. Ms. Taxin reviewed the fire escape locations.

The Board thanked Ms. Taxin for the information.

2012 Board Meeting Schedule

The Board noted the following dates for the 2012 Board meetings: Tuesdays, May 22, August 21 and November 6, 2012.

NEXT MEETING SCHEDULED FOR:

May 22, 2012, the Board will review two quarterly audits.

ADJOURN:

The time is 12:07 pm 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.

May 22, 2012
Date Approved

(ss) Mark N. Bair, MD
Chairperson, Utah Online Prescribing, Dispensing
and Facilitation Licensing Board

March 1, 2012
Date Approved

(ss) Noël Taxin
Bureau Manager, Division of Occupational &
Professional Licensing