

MINUTES

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

November 9, 2010

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

CONVENED: 9:04 A.M.

ADJOURNED: 1:22 P.M.

Bureau Manager:
Board Secretary:

Noel Taxin
Karen McCall

Board Members Present:

Mark N. Bair, MD, Chairperson
Kathleen Littlefield, R.Ph.
Roger Fitzpatrick, R. Ph.
Peter Ax
Jennifer R. Korb

Board Members Absent:

Lt. Michael Ross
John w. Bachman, MD

Guests:

Brian Ackley
Kevin Marino
Richard J. Holmes, MD
Mark Brinton, UMA Legal Counsel
Lisa Dimick
Hailey Black
Paul Rogers

DOPL Staff Present:

Mark B. Steinagel, Division Director
Blaine Ferguson, Assistant Attorney General, Division
Chief
Karl Perry, Assistant Attorney General
Francine Giani, Department Director
Thad Lavar, Department Deputy Director

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

MINUTES:

The minutes from the October 5, 2010 Board meeting were read.

Board members made minor revisions.

Mr. Ax made a motion for the amended minutes to be resent for the Board to review again prior to approving. Ms. Littlefield seconded the motion. The Board vote was unanimous.

Peter Ax Comments

Mr. Ax apologized to the Board for his comments and actions at the October 5, 2010 Board meeting. He stated he does not normally conduct himself in that manner. He then introduced the individuals he brought with him today for his presentation. Mr. Ax stated he will recuse himself from participating as a Board member during the review of his applications for licensure.

APPOINTMENTS:

9:30 am

COMPLETE REVIEW OF KWIKMED APPLICATIONS:

1. Review and Discuss Branching Questionnaire Presentation to Determine if it Meets Requirements as per 58-83-302(1)(f) and 58-83-305

Dr. Bair stated he discussed the application/approval process with Ms. Taxin and the Board needs to discuss applications here in formal Board meetings with no discussion between meetings. He then turned the time over to Mr. Ax to present the branching questionnaire for the Board to review.

Mr. Ax then walked the Board through the branching questionnaire process from logging onto their website through the medical records to the accepting or denying an order for medications to be sent. He also reviewed the various disclosures to ensure customers that their information is secure. Mr. Ax reviewed the section regarding medications, allergies and any other health problems. He stated when the order is completed the customer receives a receipt for their order.

Mr. Ax then reviewed the information the Physician views. He stated the Physician is able to review the

questions and the answers that are given and there is an automated summary that rates the level of ED. He stated, based on the questions and answers, the Physician is able to give the patient guidance regarding their health. Mr. Ax stated all e-mails are sent through secure links. He stated the subsequent orders are more complicated with alerts regarding when the last order was requested and if the order was denied. He stated the Physicians do not send or approve an order without some type of interaction with the patient by e-mail or telephone contact.

Ms. Taxin asked if someone was previously denied does the Physician go through the information then contact the patient to determine if they should be denied again or does the Physician automatically deny again.

Mr. Ax responded there is a red alert on a denied patient's information and if the patient tries again to obtain the medications the Physician contacts the patient.

Dr. Holmes responded if the patient indicates the answers are not truthful it will put in an alert and the Physician then contacts the patient.

Dr. Bair asked if the red answers indicate the patient answered yes to questions.

Dr. Holmes responded yes. He stated anything in red means it is something the Physician needs to address. He stated he can ask if the patient has seen their primary Physician recently and can recommend they do see their primary Physician. Dr. Holmes stated he may also address nitrates and poppers with the patients and give the recommendation they never use them with ED medications as it is dangerous. He stated he has never asked that question to any patient he sees face to face. He stated there are questions that identify areas that are risky to the patients.

Dr. Bair commented nitrate bases could come from using fertilizers on farms or by working in an

explosive plant.

Mr. Ax stated he will check into environmental issues for appropriate questions.

Mr. Steinagel asked what happens if the patient is kicked out of the questionnaire.

Mr. Ax responded the patient is allowed to complete the process before they are denied and then the information is retained in the database for future reference.

Mr. Fitzpatrick asked what information the Pharmacist sees regarding recommendations or counseling and if there is information to caution the patient to not use any poppers or nitrates while using ED medications.

Ms. Dimick responded there is a drug utilization file which shows the medications each patient is currently taking and the answers they have given, especially on the nitrates and poppers. She stated it is the same as any other database and does have cautions to inform patients not to use poppers or nitrates while using ED medications.

Dr. Bair voiced concern regarding making sure computer programs for the Physician and Pharmacist are interconnected so either are able to review the database to be sure what medications each patient is taking.

Mr. Ax stated the company could write a program for interfacing.

Mr. Bair asked if Board members had any questions regarding the information Mr. Ax provided at the October 5, 2010, meeting.

Board members had no additional questions.

2. Review and Discuss How the Division will Receive the Audit as per 58-83-308 and R156-83-308

Ms. Taxin asked if Mr. Ax could show the information the Division will receive quarterly for the required audit and how it will work.

Mr. Ax responded the Division has been given a user name and password for staff to review/audit the reports. He stated Ms. Taxin's staff will log in and review detailed patient data and the medications given.

Ms. McCall clarified the staff reviews everything online and KwikMed sends nothing to the Division.

Mr. Ax responded yes. He stated KwikMed will have the reports required by Law and Division staff will review the information online.

Mr. Marino stated the audit feature was developed when KwikMed started with DOPL.

Ms. Taxin asked if every patient in Utah will be listed for each quarter as there may be some questions after the first audit.

Mr. Ax responded yes, all Utah patients will be listed.

Mr. Perry asked if the declined patients will also be on the list.

Mr. Ax responded yes.

Dr. Bair stated accountants have access to all information and pull specific random files. He asked how the Board/Division ensures they have access to all data versus specific data.

Mr. Ax responded KwikMed could write attestation that the information provided is the full report for each file for that quarter.

Ms. Taxin asked if the staff will see everything.

Mr. Ax responded yes. He stated DOPL used to want a random sampling and KwikMed provided the random sampling.

Mr. Steinagel stated DOPL is a covered entity under HIPPA so all patient information can be reviewed.

Ms. Taxin stated she will probably have one staff person conducting the audits but could have up to three and the review is no different than staff looking at medical records. She stated it would probably be easiest to see all the raw data so staff knows what the Physician is seeing.

Ms. Giani commented it is great that KwikMed will provide this information to the Division for the audits.

Ms. Korb asked if DOPL will also have access to any complaints.

Mr. Ax responded there is a link available for DOPL to review any complaints. He stated there is a link for regulatory concerns.

Ms. Taxin commented her concern is if someone sees there is a DOPL link they may not submit their complaint because of concern that KwikMed will track or review the complaint. She stated she requested KwikMed to make a change on the website to ensure it is not tracked.

Mr. Steinagel stated he likes the idea of the link so complaints have to come through DOPL.

Mr. Marino stated KwikMed does not track the complaints and separating them out makes sense.

Dr. Bair stated the link says regulatory complaints and should say Utah regulatory complaints. He stated the link also says “license to prescribe online” and should say “Utah licensure” if approved. He stated he believes it is a little misleading for the public regarding which States they are licensed in to offer online services.

Mr. Ax responded there are a lot of disclosures in place regarding being a provider for Utah.

Mr. Fitzpatrick suggested using a field at the top as it could be a pop up field listing the States where

KwikMed is licensed. He stated they could use the same terminology but allow for a list of the States where they are licensed.

Mr. Ax responded he will need to think about the suggestion as additional pop ups slows down the processing and he believes the disclosure should be enough.

Mr. Marino commented it would be misleading to say all 50 States but a tag stating licensed by Utah DOPL might work.

Mr. Ax asked if including the language above the FAQ questions would work.

Mr. Marino stated he believes language above the FAQ questions would meet the Truth in Advertising Law.

Mr. Steinagel stated he has had numerous discussions over the last year regarding KwikMed. He stated the Utah Legislature has passed the Law to allow KwikMed to practice in Utah and there has been a lot of give and take on both sides in regard to the application. Mr. Steinagel stated Governor Herbert has said to protect the public but not to hinder commerce. He stated the Board should not worry about what happens in other States as we regulate only Utah.

Dr. Bair commented because KwikMed is allowed to be licensed in Utah they could use that information to obtain licensure in other States.

Ms. Taxin informed the Board she talked with Mr. Ax regarding changing the dates on the website and documents from 2000 to 2002 as that is when they were first given permission to practice in Utah.

Mr. Ax responded the date is changed in the body of the document. He asked if it also needs to be changed at the top of first page.

Ms. Taxin responded yes. She then asked if the Board could review the window the Pharmacist sees.

Mr. Ackley responded they were not prepared to show the Pharmacist page today.

Ms. Taxin asked how the prescription is transferred to the Pharmacy.

Mr. Ax responded the Pharmacist logs into the patient history for prescriptions.

Ms. Taxin asked Ms. Dimick if she believes the process works for her pharmacy functioning.

Ms. Dimick responded yes. She stated if there are any changes she needs KwikMed has made the changes to make the program and process better.

Mr. Ax stated they install updates about each quarter.

Ms. Littlefield asked why there is a question to the patient on the website regarding it being ok to use a safety vial.

Mr. Ax responded the packaging is flat packing and if the patient requests a safety vial they need to give direction.

Ms. Dimick stated they also ask for childproof packing.

Ms. Littlefield commented the bubble packing is child proof.

Mr. Marino stated Ms. Littlefield is correct but there are times when the patient wants the medication packaged different.

Mr. Fitzpatrick asked if they have a sample of what the packaging looks like and if the system integrates to the pharmacy system.

Mr. Ackley showed a picture of the container and

packaging.

Mr. Ax stated the system is all the same. He stated they have no inventory and errors are substantially below a regular pharmacy but there are only five drugs.

Mr. Fitzpatrick asked how frequently there is telephone consultation.

Dr. Holmes responded he does not call patients often but sometimes he does call patients or the Pharmacist will call him and ask him to call a patient as per the patient's request.

Mr. Fitzpatrick asked how a patient reports an adverse event.

Mr. Ax responded the patient can call KwikMed and either Ms. Dimick or a Physician will follow up with the patient. He stated the patient may also call Pfizer.

Ms. Dimick commented Pfizer is finding there are some women who have had problems taking Chantix. She stated one of her patients contacted Pfizer and was given a form to complete and send back to Pfizer.

Mr. Fitzpatrick asked how patients are notified regarding how to deal with adverse incidents.

Mr. Marino responded they could include a statement for patients to contact their Physician if there an adverse incident.

Dr. Holmes stated the Physician's site automatically flags him each day if there are questions and he receives e-mails all the time with questions. He stated there has not yet been a question he was unable to address.

Dr. Bair asked how after hours emergency complications are handled. He stated he believes there should be a notification giving the hours of availability as there may be some patients who do

not have a primary Physician.

Mr. Ax responded patients are directed to contact their own primary Physician or go to the emergency department for after hours care.

Mr. Marino stated their concern is patients will not seek emergency care.

Dr. Bair stated in traditional care there is always someone available for patients after hours.

Mr. Marino responded he believes the site could be changed slightly to cover Dr. Bair's concerns.

Mr. Perry asked how many patients are typically reviewed by each Physician.

Mr. Ax responded the reports from 2003 indicate there where hundreds each day. He stated they are load balancing now and add a Physician if the volume goes over 75 per Physician per day.

Mr. Perry asked if the Physicians also have their own practices.

Mr. Fitzpatrick asked what the prescription volume is in Utah each day.

Mr. Ax responded there are about 5,000 to 7,000 shipments each month.

Mr. Brinton, UMA Legal Counsel, asked if a Utah licensee violates Utah Law for an out-of-State individual would that be a concern.

Mr. Steinagel responded Utah would need to review what Utah Law and/or Rule provision was violated. He stated if a Utah licensed Pharmacy violated the Utah record keeping requirement then DOPL would have authority to take action. Mr. Steinagel stated if someone holds a Utah license and violates another State's Law it does not necessarily mean Utah would take action against their license. He stated this has been an area of

great confusion and since Utah is one of the only States to license online prescribing the conduct would still need to be illegal in Utah.

Mr. Brinton commented the Utah Laws would still need to be followed. He asked if it is relevant for Utah to audit KwikMed's out of State patients to be sure KwikMed is complying with Utah Law. He stated if KwikMed filled a prescription for a patient in New York for Oxycontin it would be unlawful in Utah.

Mr. Steinagel responded that a Utah Pharmacy filling a prescription for a New York patient would still be required to abide by Utah Law. He stated he is not sure whether the Audit should include patients outside of Utah but if the underlying license has some problems the Division may want to review those problems. He stated it would depend on whether there is a violation or not and on a case by case situation would review. He stated there is an unprofessional conduct section in the Division Umbrella Law and if the conduct would constitute unprofessional conduct in Utah then Utah may take action.

Mr. Brinton stated the list reviewed was only of patients in Utah. He stated he believed the Division would audit all patients.

Mr. Ax responded there is a list for Utah patients only and another list with all patients.

Ms. Taxin clarified she understood Utah could randomly pick any patient and audit that medication and that she believes the audit should include all patients that receive prescriptions from a Utah licensed Pharmacy.

Mr. Ax responded yes, DOPL could randomly audit any patient medications.

3. Review and Discuss Policies and Procedures Manual as per 58-83-302(1), (4)(d), (e) and (f)

Ms. Taxin stated at the October meeting the Board talked about reviewing the Policies and Procedures and then discussing them together. She stated she has

reviewed them and requested Mr. Ax make some revisions. Ms. Taxin stated Mr. Ax made the requested revisions which better clarify the information and she has the latest version of the Policies and Procedures. She stated there will be one other change in regard to a disclosure on lab testing. Ms. Taxin stated she believes the Policies and Procedures are clear and well written but if the Board wants to review they may take the time to review.

Mr. Fitzpatrick stated the minutes from the October meeting indicate the Board would review the Policies and Procedures to be sure they meet and address specific concerns. He asked Ms. Taxin if they now meet those concerns.

Ms. Taxin responded she believes some of the unclear language was clarified and that Mr. Ax is working on a few more corrections.

Dr. Bair asked if they now address how they determine the person ordering is the person receiving the medication, if they are age appropriate, etc.

Ms. Taxin responded the screen disclosure has that information on it.

Mr. Ax responded every new patient is contacted by telephone for a conversation. He stated they match the credit card numbers to the person, they check the addresses and use some other processes to confirm the identity of the patient. Mr. Ax stated a signature is required upon delivery and a picture ID of the person receiving FEDEX delivery is required which confirms the patient is over 18. He stated the package is not delivered if the person receiving the package is under 18.

Dr. Bair stated the Law requires a patient relationship be established and maintained. He asked if that is happening.

Mr. Ax responded every patient establishes an electronic medical record. He stated they always

have the right to contact the Physician and Pharmacist through that record. Mr. Ax stated they also have some follow up e-mails they send out. He stated they could follow up with patients regularly but have left it up to the Physician regarding how they want to follow up with their patients.

Dr. Holmes responded there are some patients he believes he should follow up with and he has the capability to retain their e-mails forever for periodic follow up. He stated he can look at an order any time by the order number or patient name.

The Board thanked Mr. Ax and Dr. Holmes for the explanations.

4. Review and Discuss Online FAQ as per 58-83-302(1)(h), (4)(g) and (i) and 58-83-305

Ms. Taxin stated she combined numbers 4 and 5 as they are connected. She stated she did not believe there was a term called U.S. regulated so she requested anything that said U.S. regulated be taken out and "Licensed Utah Pharmacy" be inserted. She stated she believes it is now correct in both documents.

5. Is it Acceptable for Policy and Procedures, FAQ's and/or Information to the Public to State U.S. Regulated or Direct Information to the Residents of the United States vs. the State of Utah as per 58-83-302(3)(a)

The Board thanked Ms. Taxin for clarifying.

6. Review and Discuss Administrative Sanctions as per 58-83-302(1)(e), (3)(a), (4)(i) and 58-83-302(2)

Ms. Taxin stated since the October meeting the AG's office and the Division have reviewed the actions taken.

Mr. Perry stated at the October meeting the Board discussed how the Law requires the Pharmacy to have no restrictions or actions within the last 3 years. He stated based on that requirement the AG's office and the Division have determined by Utah Law the disciplinary actions in other States with KwikMed are not an issue for this application.

Ms. Littlefield stated the Administrative Sanctions under 58-83-302 require they discuss the issues. She stated she believed since the applications are a trio they are linked together. She asked if a licensed Physician could use other Pharmacies.

Mr. Steinagel responded the Physician and Pharmacy have to be linked together with the Facilitator. He stated the question was asked at the Legislative meeting and the intent is they want a higher bar for this profession and want all three licenses linked.

Mr. Fitzpatrick asked if the Pharmacist ever transfers a prescription or if the patient contacts the Pharmacist and tells them they want the prescription filled at a specific Pharmacy.

Ms. Dimick responded yes, she has transferred prescriptions. She stated each prescription is a new prescription and if the patient wants it filled at a specific Pharmacy she will call the Pharmacy.

Mr. Fitzpatrick asked if the patient could still contact the Pharmacy and ask the prescription be filled elsewhere.

Dr. Holmes responded yes.

Mr. Perry asked if there is a box the patient clicks on for a different Pharmacy to fill the prescription.

Mr. Ax responded there is not a box to click on but the patient may fill in an area for a transfer of the prescription for a different Pharmacy to fill.

Dr. Bair asked if all three licenses are linked is a condition of licensure to have a contract with all three entities and if the Facilitator lost their license would it affect the others or is there a grace period.

Mr. Perry responded all would not automatically loose their licenses but they could not continue to practice until all three are connected again.

12:00 pm to 1:00 pm

WORKING LUNCH

GENERAL QUESTIONS FOR ONLINE APPLICANTS:

1. Discuss Performing Lab Work and Other

Ms. Taxin explained there was a question regarding if

Medical Procedures Online – Is it within the Scope of Online Prescribing as per 58-83-102(1) and (3) and 58-83-305(b)

it is ok for KwikMed to promote lab work on their website.

Mr. Perry stated lab work sought by the patient is allowed. He stated there are two types of lab work that almost never get the Physician involved, ie: STD tests and pregnancy tests. He stated medical practice is then in effect and online does not have medical practice as part of their scope. He stated if it comes to an interpretation of the lab test the patient would have to contact their own Physician.

Mr. Ax stated KwikMed has a contract with Labcorp for lab testing and they have Physicians who are allowed to requisition for lab tests. Mr. Ax stated Mr. Perry is saying lab testing is not in the online legislation and there should not be a Physician interacting in Utah for lab tests. He stated KwikMed could turn off that information for Utah but will need to go through Labcorp as they have a contract with Labcorp. He stated if lab tests came through KwikMed they would not have their Physicians review the results.

Mr. Steinagel stated ordering a lab test is not required by a Physician but reading it for the patient would have to be done by their own Physician.

Dr. Bair stated he is not concerned with some basic lab tests. He stated there are federal policies which are audited by federal people. He stated he is uncomfortable with ordering lab tests online and not receiving feedback on those tests.

Ms. Taxin asked if the patient could get the lab result and the online Physician refer them to their own Physician.

Mr. Perry stated the online Physician would then be getting into diagnosing.

Mr. Ax asked what if the Physician had a disclosure that they are not diagnosing but the patient should see their own Physician as soon as possible.

Dr. Bair responded a patient might think if no one followed up they might not see their own Physician.

Mr. Marino stated he does not believe the patient would not see their own Physician if counseled to do so.

Ms. Taxin responded the Division receives malpractice complaints and notifications all the time.

Dr. Bair stated there is case precedence, if you order the lab work you are responsible for it.

Ms. Taxin suggested KwikMed not offer the lab testing for Utah at this time.

Mr. Ax stated he could have the information for lab testing shut off for Utah for now and then the Board and AG's office make a determination later.

Ms. Taxin stated KwikMed will also have to take out anything on labs for Utah in their Policies and Procedures and FAQ's.

Dr. Bair suggested KwikMed have a statement that lab tests are not currently offered in Utah.

Mr. Ax agreed to make a change on their online site.

Application Approval

Ms. Taxin asked the Board if they are comfortable approving KwikMed's applications based on the reviews. She stated Mr. Ax will need to make all corrections prior to issuing the license but the Board could make a motion to issue the license upon receiving confirmation of the corrections requested.

Mr. Fitzpatrick made a motion to approve the KwikMed's application pending receiving a clean copy of the documents with the changes that were recommended and requested.

Mr. Perry reminded the Board that there are three applications, the Facilitator, the Physicians and the Pharmacy.

Mr. Fitzpatrick amended his motion to include approving the three applications through PCM pending receipt of documentation with the requested changes.

Ms. Littlefield seconded the motion.

The Board vote was unanimous.

Mr. Ax thanked Ms. Taxin, Mr. Steinagel, Mr. Perry, Mr. Ferguson and the Board for their questions, the effort put into reviewing and improving the application and the website.

Mark Steinagel

Mr. Steinagel requested the Board to separate the drug Chantix from the rest of the list of drugs being discussed. He stated he went back to the meeting held last year with the combined Boards and the meeting held with Legislators and reviewed the list of drugs that would be approved, which were four drugs and Chantix. Mr. Steinagel stated the Legislative intent was that Chantix would be included and therefore, he needs to pull off the list the hormonal contraceptives and put Chantix on the list. He stated the Board should start from the corrected baseline regarding their discussion of approving additional drugs.

Dr. Bair stated he believes the Board should start fresh on the discussion of which drugs to include.

Ms. Littlefield stated the list of approved drugs is in the Rule. She asked if that list can be changed by the Board.

Mr. Steinagel responded the Rules can be changed by the Board but the Division tries to be respectful of Legislative intent.

Dr. Bair asked if the public has already received the Rules and are aware of the listed drugs. He stated his understanding was the list in the Rules was approved and stand regardless of the intent.

Mr. Steinagel responded the Rules have been approved

and published for the public. He stated the Division tries to ensure the Law and Rules are administered according to the language and also with the Legislative intent. He stated the list, including Chantix, came from a meeting with one of the three readings of the Bill.

Ms. Taxin clarified she would file an amended Rule to put in the Legislative intent to include Chantix, then the Board would discuss the process.

Dr. Bair asked if Ms. Taxin and Mr. Steinagel mean the Board will have no input regarding including Chantix on the list of approved drugs as he is hearing the Legislative intent was to approve Chantix without any Board discussion.

Ms. Taxin responded Mr. Steinagel has suggested to the Board that the Legislative intent was for Chantix to be included on the original list.

Mr. Ax asked why the starting point would not be what was presented to the public and keep the hormonal drug on the list. He stated the discussion should be if the Board wants to include the other drugs.

Ms. Littlefield voiced her opinion that the hormonal drug should stay on the list.

Mr. Marino commented he heard the hormonal drug would be on the list and KwikMed has acted on that as part of their business. He stated Chantix was an approved drug for KwikMed but he heard the concerns from the last meeting. He stated he believes it is within the power of the Division to make the decision in consultation with the Board but KwikMed would like to see both Chantix and the hormonal drug to be on the approved list.

Dr. Bair responded he believes the Board needs to discuss both today. He voiced being uncomfortable with DOPL putting the list out to the public prior to discussion and a recommendation from the Board.

Mr. Ferguson stated DOPL made a decision to write and publish the Rules based on their understanding and this was done prior to the Board being established. He explained the Rules needed to be in place in order for applications to be submitted and reviewed. Mr. Ferguson stated there were five drugs put on the list in the Rules. He stated DOPL is the entity authorized to write the Rules and those Rules are in effect, however, it is appropriate for the Board to make comments and recommendations.

Create and Review Criteria to Approve
Additional Drugs as per 58-83-306, 85-83-307
and R156-83-306

Dr. Bair read the Law and asked the Board what criterion they believe is necessary to add drugs to the list.

Ms. Littlefield stated she believes the Board should consider if the drug requires lab testing or a physical assessment and if the answer is no, then the Board should consider the drug.

Mr. Marino stated the Board needs to get away from the idea of face to face medicine and get into an evidence base of what drugs are appropriate. He stated they should consider if the drug can be prescribed without a physical. Mr. Marino stated Chantix was approved by the Legislation and it was not a willy/nilly approval. He stated historically DOPL has approved Chantix and KwikMed has had no adverse experiences. Mr. Marino stated once there is a negative experience KwikMed has pulled that drug.

Mr. Perry commented Celebrex was taken out and Chantix was put in as Chantix did not have an FDA black box warning at the time. He stated hormonal contraceptives came from Planned Parenthood who met with DOPL. He stated they had a model which included a physical consultation with the patient.

Mr. Ax and Mr. Marino clarified Chantix did have the FDA black box warning when it was originally included.

Dr. Bair requested the Board not focus on Chantix.

Ms. Littlefield commented she believes the criterion should consider drugs that would be used only for their intended purpose and not for recreational purposes.

Mr. Brinton stated another criteria should be a drug for which close monitoring of the patient is required or useful. He stated KwikMed has many things in place for monitoring but some drugs need to have the patient seen by a Physician within a specified time for monitoring. He stated in regard to Chantix the FDA states the patient should be monitored for any behavioral problems when using the drug. He suggested the Board discuss what KwikMed will do on their website to ensure the monitoring if Chantix is included.

Mr. Marino commented Mr. Brinton's suggestions are excellent and monitoring Chantix more closely is an excellent idea. He stated Mr. Brinton has not suggested face to face follow up but a follow up. Mr. Marino suggested the Board consider a sliding scale for drugs and monitoring as the FDA black box warnings raise many concerns.

Mr. Ax stated KwikMed has inserted material they include when Chantix is sent out to the patient. He stated they have been able to determine which patients open their e-mails and have called those patients who do not open their e-mails. He stated Chantix is a drug they are very careful with. He stated they could have more follow up on their patients and have them contact KwikMed if there are any adverse reactions.

Mr. Fitzpatrick asked if KwikMed follows up with the mental health side effects and asked if there is another set of questions for that.

Mr. Ax responded when a patient reorders then they would do the follow up. He then showed the Board what the patient sees on the website when they reorder and the list of information on the drug.

Dr. Bair stated there is a black box warning under the drug when it is listed.

Ms. Taxin asked if KwikMed has something to warn the patient the drug has a black box warning and what that warning means.

Mr. Ax responded KwikMed does not have the warning listed at this time.

Mr. Fitzpatrick suggested Mr. Ax include the warning on the first page.

The Board requested the black box warning be at the top of the home page and include a box for the patient to check acknowledging have read the warning.

Mr. Ax stated there are several levels of black box warnings and some are substantial enough that KwikMed would never want to sell them online. He stated they can sell Chantix but warn the patient to be careful with depression.

Ms. Littlefield suggested the Rules include requiring black box warnings to be on the home page.

Ms. Taxin suggested the categories of drugs be explained to the Board and guests.

Dr. Bair explained the controlled substances (CS) are a way to categorize drugs. He stated Schedule I (one) drugs are not intended for public consumption, Schedule II (two) are the Opioids, Oxycodone, Oxyconton drugs and Schedule III through V (three through five) are the drugs which have the potential for abuse and are compound drugs. He stated everything else is listed as legend drugs. Dr. Bair stated Ultram and Tramadol, are pain relievers and are now being considered for the CS list.

Ms. Taxin stated the Board would only be

reviewing and considering legend drugs.

Dr. Bair asked if Ultram and Tramadol are moved to the CS list then the Board could not consider them.

Mr. Steinagel and **Mr. Ferguson** responded yes.

Mr. Fitzpatrick stated Spice is also being considered for CS listing.

Ms. Taxin clarified the Board has determined the criterion will be the following for consideration:

1. If the drug does not require lab tests or close monitoring;
2. The drug must be used for the intended purpose only;
3. The drug should not have an addictive quality;
4. If there is an FDA black box warning on the drug there must be an attestation box documenting the patient has read the warning.
5. There cannot be any compounded drugs.

Ms. Taxin stated she could write the Rule with the above criterion for the Board to review. She stated the benefit of having the criterion in the Rule is that it can be changed as needed and applicants will know they cannot request a drug if it does not meet the criterion.

Mr. Fitzpatrick suggested **Ms. Taxin** put the criterion under R156-83-306 (1) and (2) with (1) being the list of approved drugs and (2) the criterion. He suggested the Board review the criterion from time to time to update. **Mr. Fitzpatrick** suggested the language be sent to the Pharmacy Board, the Physicians Board and the Osteopathic Physicians Board for review.

Mr. Brinton stated the UMA could also prepare some language in regard to the criterion for the Board to review.

Dr. Bair requested the language be reviewed for further discussion at the next Board meeting.

3. Further Discussion

- Chantix

Dr. Bair stated Chantix will not be discussed for approval for the list but KwikMed will need to put in an FDA black box warning with an attestation on their website.

Ms. Taxin stated the Board will also need to be sure any other applicant also includes the warning and attestation on their website if they will be offering Chantix.

Ms. Littlefield commented smoking cessation would be one of her top five goals for protecting the helping the public.

Mr. Fitzpatrick asked if KwikMed would need to cease and desist selling Chantix until the Rule has been changed.

Mr. Brinton commented KwikMed is already operating under a consent agreement which is still in effect until their applications are approved. He stated the Board could adopt a Rule that any Online licensed group may sell Chantix with specific conditions. He stated the Legislature would never expect or require someone to stop selling a product for a period of time and then start selling it again to give time for a Rule to be approved and he would never imagine an enforcement action if KwikMed continues to sell Chantix.

Ms. Taxin stated a motion for approval would be appropriate so Chantix is included in the Rules and in order for other companies who are licensed to also sell the drug.

Mr. Ax made a motion to add Chantix to the list of approved drugs subject to conditions established by DOPL.

Mr. Fitzpatrick seconded the motion.

The Board vote was unanimous.

Ms. Taxin stated she will make the Rule change to include Chantix and then allow approved companies to dispense it even though the Rule is not yet approved based on the Legislative intent.

- Hormonal Based Contraceptives

Mr. Marino stated selling contraceptives was an overwhelming approval at the meeting last year.

Dr. Bair stated he believes the Board needs to narrow contraceptives down to oral contraceptives only and not injections or implantable contraceptives.

Ms. Taxin stated there should also be clarification regarding what a contraceptive is and if the morning after pill is a contraceptive.

Dr. Bair stated the definition of a contraceptive is to be used prior to the act and not after. He stated the Board would need to be assured the contraceptive is going to actually be used appropriately. He stated the timeline for use is within 72 hours of having sexual relations and if used differently it creates a different set of liability.

Mr. Ax stated clinic studies document emergency contraception's are not effective and should not be used to avoid pregnancy. He stated a patient would have to take substantial doses similar to birth control pills to abort. Mr. Ax stated contraception and birth control pills are the same hormones doing effectively the same thing, stopping the sperm from entering the egg. He stated the Board/Division would approve oral contraceptives. Mr. Ax explained the KwikMed system allows for monitoring if a patient orders a second time and would have greater protections instead of fewer.

Dr. Bair stated KwikMed would need to ensure the emergency contraception's were not given after a 48 hour time frame. He stated he works in

emergency with rape and incest victims and if the incident happened 2 weeks or more prior to the patient coming to emergency he, Dr. Bair, will not write a prescription. He stated if the patient comes in and says the incident happened yesterday he will write a prescription as he has verbal information and he documents the visit. He stated Mr. Ax mentioned KwikMed looks at abuse issues. He stated when a Physician has a face to face with the patient the Physician can tell within a few minutes if the situation is beyond their care and needs additional help.

Mr. Marino stated KwikMed is developing the system at this time for screening.

Dr. Bair asked if the online system for contraceptives has been completed.

Mr. Ax responded no, KwikMed is in development now.

Dr. Bair stated, if he reads the Law correctly, the online system for contraceptives must be complete prior to approval by the Board.

Mr. Marino stated KwikMed wants the Board to have the knowledge but the content of the system does not have to be completed prior to approval. He stated he does not believe every time someone meets with a drug to be approved that the Board has to review the whole questionnaire.

Dr. Bair voiced feeling uncomfortable with approving a drug without reviewing the branching questionnaire for that drug.

Mr. Ferguson stated KwikMed might consider one criterion would be to gather information by using the online branching questionnaire to glean the necessary information.

Mr. Marino suggested Mr. Ackley pull up a development site for the Board to review. He stated the development site is not approved as it is still being

developed.

Mr. Ax assisted in presenting the information to the Board. He stated questions can be added regarding if the patient was raped, if they are a victim of abuse, etc.

Ms. Littlefield commented she would think the patch or the ring would be accepted.

Ms. Taxin stated the Board could limit the types of contraceptives or be more open. She stated right now it is fairly open.

Mr. Ax made a motion to approve hormonal based contraception's with the exception of injections or implantable methods.

Ms. Littlefield seconded the motion.

Mr. Fitzpatrick, Ms. Littlefield, Ms. Korb and Mr. Ax voted in favor of the motion. Dr. Bair opposed the motion. The motion passed with a simple majority.

- Retinoid/Hydroquinone

Ms. Taxin explained she received a letter from Dr. Mark Taylor requesting Retinoid and Hydroquinone be added to the approved list of online drugs. She explained Hydroquinone is a skin lightener and Retinoid is to soften lines and at times used for acne.

Dr. Bair commented these drugs are cosmetic. He stated Retinoid is used for acne and other types of spots which is a strong astringent on the skin and dries up skin problems. Dr. Bair stated it can cause burns and rash.

Ms. Littlefield asked if Ms. Taxin could respond to the request that the Board is considering to include these drugs to the list of online drugs with the caveat that the Board would need to see their branching questionnaire prior to approval.

Dr. Bair stated he believes the person requesting approval should meet with the Board and present their branching questionnaire as the other

applicants are required.

Mr. Brinton stated there is information available regarding deforming fetuses due to the use of Retinoids and there have been some serious complications for pregnant women. He stated the Board needs to be sure there are safeguards in place for these patients.

Mr. Fitzpatrick stated one of the concerns of the combined Boards was the drugs should not be compounded drugs. He stated some of the drugs listed in the letter can be compounded.

Ms. Taxin asked if the Board wants only drugs that are not and cannot be compounded.

The Board responded yes, they do not want any compounded drugs or drugs that could be compounded.

- Other Drugs

4. Web Conferencing

This item was deferred to a future Board meeting.

Ms. Taxin explained she and the AG's office are still going through the other application. She stated they inquired if their Facilitator could attend a meeting and walk the Board through their process and branching questionnaire. She stated Board members would be able to talk with the Physician, Pharmacist and IT staff live by web conferencing when they present their branching questionnaire. Ms. Taxin stated it appeared to be a reasonable plan but if enough information is not presented the Board could then ask them to meet in person.

Dr. Bair responded he likes to work through technology. He asked if web conferencing would meet the open meeting policy.

Mr. Brinton responded the Board would all be at the origin location so he believes it would qualify.

Mr. Ferguson stated this is the first time he has heard of the request and would need to do some research.

Ms. Taxin responded the Board could let Mr. Ferguson do his research and get back to her or request they attend in person.

The Board requested they meet in person and that they would consider web conferencing in the future.

Board Meeting Schedule

The Board noted meetings will be scheduled for:
December 7, 2010
January 22, 2011
February 22, 2011
March 22, 2011
June 7, 2011
September 20, 2011
December 6, 2011

NEXT MEETING SCHEDULED FOR:

December 7, 2010

ADJOURN:

The time is 1:22 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.

February 22, 2011
Date Approved

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

December 2, 2010
Date Approved

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