

MINUTES
UTAH
ONLINE PRESCRIBING, DISPENSING
AND FACILITATION LICENSING
BOARD MEETING

October 5, 2010

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

CONVENED: 9:00 A.M.

ADJOURNED: 3:45 P.M.

Bureau Manager:

Noel Taxin

Board Secretary:

Karen McCall

Board Members Present:

Kathleen Littlefield, R.Ph.

Roger Fitzpatrick, R.Ph.

Michael Ross

Jennifer, R. Korb

Peter Ax

Mark N. Bair, MD

Board Members Absent:

John W. Bachman, MD

Guests:

Casey Hill, Utah Medical Association

Michelle McOmber, Utah Medical Association

Paul Rogers

DOPL Staff Present:

Mark B. Steinagel, Division Director

Karl Perry, AG

Blaine Ferguson, AG

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

Opening

Ms. Taxin opened the meeting until Board members have been sworn in and a Board Chairperson has been selected.

Swearing in of Kathleen Littlefield, R.Ph., Roger Fitzpatrick R.Ph., Michael Ross, Jennifer R. Korb, Peter Ax, Mark N. Bair, MD, and John W. Bachman, MD, as Board members.

Ms. Taxin conducted the swearing in of Ms. Littlefield, Mr. Fitzpatrick, Mr. Ross, Ms. Korb, Mr. Ax and Dr. Bair as Board members. Dr. Bachman will be sworn in when he attends a scheduled Board meeting.

Board Chairperson

Ms. Taxin explained the process of selecting a Board chairperson. She stated any Board member may chair the meetings and they are usually her contact person if she has any questions, although she could contact any Board member, they keep the order of the meetings, follow the agenda and be sure that any public person with questions is acknowledged. Ms. Taxin then opened the floor to the Board members for nominations.

Mr. Ax requested the selection of a Board chairperson be deferred to the end of the meeting to give the Board members time to know each other a little better.

Ms. Taxin chaired the entire meeting and at the end of the meeting Ms. Littlefield requested nominations be open.

Mr. Fitzpatrick seconded the motion.

The Board vote was unanimous.

Mr. Fitzpatrick nominated Dr. Bair.

Mr. Ax nominated Mr. Fitzpatrick.

Dr. Bair nominated Ms. Korb.

Mr. Fitzpatrick seconded the motions and moved for nominations to close.

The Board vote was unanimous and nominations were closed.

For the voting, Lt. Ross, Ms. Littlefield, Mr. Fitzpatrick and Dr. Bair voted in favor of Dr. Bair for chairperson.

Mr. Ax and Ms. Korb voted in favor of Mr. Fitzpatrick for chairperson.

There were no votes for Ms. Korb as chairperson.

By majority vote, Dr. Bair will be the Board

Introductions

chairperson.

Ms. Taxin requested each Board member to introduce themselves.

Ms. Korb stated she is an attorney in the Salt Lake area in private practice.

Mr. Ax stated he is involved in various ventures and the Board will be reviewing his application for licensure in Utah for KwikMed. He stated his home is in Phoenix, Arizona but he owns property in Park City, Utah.

Ms. Littlefield stated she is a Pharmacist who has worked in all types of Pharmacies and does a lot of work with mental health group homes.

Mr. Fitzpatrick stated he is a Pharmacist who practices in Ogden at a federally funded health center. He stated he just completed serving 8 years on the Pharmacy Board and was chairperson of that Board for 3 years.

Mr. Perry stated he works with the AG's office as counsel and has assisted Ms. Taxin with this new profession.

Ms. Taxin stated she is the Bureau Manager who regulates about 10 other professions of which medicine is the largest. She stated she is looking forward to working with this Board and voiced appreciation for their accepting to serve.

Dr. Bair stated he is a Physician but also graduated in Pharmacy and worked as a Pharmacist while going through medical school.

Lt. Ross stated he works for the Salt Lake Police Department and is involved with undercover work with drug related issues.

Mr. Steinagel stated he is the Utah Division Director. He stated when the Bill passed he knew he needed a strong team to work with this

profession and requested Ms. Taxin to be over the profession. He stated there have been only a couple of applicants so far but what he has heard is people are having a positive interaction with Ms. Taxin and her team. Mr. Steinagel stated in 2008 the Physicians, Osteopathic Physicians and Pharmacy Boards all met for discussion and input. He stated Online Prescribing, Dispensing and Facilitation are a controversial issue nationally so the eyes of the nation are on Utah, this Board and the licenses that are issued. He stated the Board has the expertise to provide balance along with great AG's to assist. Mr. Steinagel read the Division Strategic Plan and stated Board members should notify him if the Plan is not happening. He stated the guidance from the Governor's office is to regulate but not over regulate. Mr. Steinagel stated the creation of the applications are still a work in progress. He stated the primary purpose of the Board is to assist with the review of those applications as well. He stated there will be complaints and information brought before the Board to evaluate to be sure the needs of the profession and public are met. Mr. Steinagel stated he takes pride in what the Division and staff do. He stated we are not perfect but we are trying.

Mr. Ferguson stated he is with the AG's office as advisory counsel to the Division and Boards. He stated he has worked with Mr. Steinagel and Ms. Taxin as they have been involved in putting together this new profession.

Board Member Training

Ms. Taxin explained the Division manages about 182 thousand licensed individuals. She stated there are two units within the Division; the licensing unit and the investigative unit. She explained the licensing unit reviews applications to be sure the applicants meet qualifications for licensure based on the requirements in the Law and Rule. She stated if requirements are met the license is issued as licensees should not be held up from working if the Board meets monthly, quarterly or once a year for the applications to be reviewed by the Board. She stated if there is a question regarding the application that concerns her in

regard to the safety of the public or qualifications then the application is held for the Board to review.

Ms. Taxin stated this is a new profession and application review should be equitable across the Board for all applicants.

Ms. Taxin explained anyone can file a complaint and those go to the investigations unit. She stated an investigator reviews the information and, if appropriate, files a case. She stated the Division for example does not deal with marital issues but does deal with issues that are in violation of our Statutes in 58-1 and 58-83. Ms. Taxin stated the investigator will investigate the complaint and then review it with her and the investigator supervisor to determine the severity of the case. She stated she likes to keep the Board out of the investigation process so that if there is a hearing the Board can hear the case as the jury. Ms. Taxin stated if Board members know the case they may be requested to recuse themselves. She stated a quorum is needed for a hearing. She stated if Board members receive calls regarding complaints or licensure they should refer the caller to the Division.

Ms. Taxin stated she requested Mr. Ferguson to cover the role and duties of Board members and if they have questions, to write them down for discussion after Mr. Ferguson's presentation.

Mr. Ferguson gave each Board member a handout of information. He stated much of what the Division and Board do is under the Administrative Law. Mr. Ferguson stated the Board is involved with the process for licensing and if the Division goes against a company or an individual, that is disciplinary action.

Mr. Ferguson stated the Board will have different roles and need to remember what those roles are. He gave the example of a Board member being aware of a situation they want to report. He stated they should not bring that situation up in a Board meeting as decision makers need to be fair and impartial and discussing the situation in a Board meeting may taint the Board. He stated if a person disagrees with a

Division decision there is an appeal process which is administrative and if they are dissatisfied with the Department decision they may then appeal through the civil courts.

Mr. Ferguson then covered the general purpose in creating the Division and stated it is a balance on how much to regulate and how much to allow businesses to be run on their own. He stated the general public interest is the primary concern and priority.

Mr. Ferguson stated the Board is advisory to the Division as they are viewed as people in the field who are qualified to give recommendations. He stated the Legislature approves the Law and the Division in collaboration with the Board writes the Rules. He stated the Board is viewed as qualified people to give recommendations regarding the Rules for the profession.

Mr. Fitzpatrick commented one of the most difficult things for any Board member is to set aside the professional hat and wear the hat to protect the public. He stated it took him a few years to think about what the Board needs to do to protect the public. He stated it needs to be a different mind set when Board members meet as a Board.

Mr. Steinagel commented he has had to take action on well over 1300 recommendations and Rule recommendations from the different Boards and only once has he not supported the advisory Board recommendation.

Mr. Ax commented protecting the public could be taken to an extreme and shut everything down. He stated he believes his role is to do no harm but also try to help the citizens of Utah by building the economy. He stated there is a delicate balance.

Mr. Ferguson agreed in that the Board does have a need to help the citizens of Utah but also to protect the public.

Ms. Taxin stated sometimes Board members come in with their identity with the profession and the Board needs to make sure they make decisions/recommendations that are for the public and not for their own best interest or the best interest of someone they may know.

Mr. Ferguson stated the Online Board should keep in mind the statute was adopted by the Legislature as an approved way of doing business.

Mr. Ferguson explained the Open and Public Meetings Act and the importance of only closing meetings for specific reasons. He stated the Online Board meetings falls into the public meetings Act. Mr. Ferguson explained Board members may have chance or social meetings but an effort must be made not to discuss Board business at those meetings as public meetings must be recorded and open to the public. He stated there are times when someone does not want everyone to hear what they are saying in Board meetings and if that is the case the person should say nothing at all as copies of the tapes are frequently requested and the comments would be on tape. He stated this would not be a valid reason to close a meeting. Mr. Ferguson stated one-on-one discussions between Board members at a convention or meeting in which someone is asking their support or thoughts should be avoided and discussed as Board business in a formal Board meeting and on tape. He stated there must always be an agenda posted for the public.

Mr. Ferguson then covered the requirements of a closed meeting. He stated if the meeting is closed for the purpose of litigation strategy and the discussion is completed the meeting must be reopened prior to discussion of new business. He stated all motions and votes must be recorded during the open session of meetings and minutes and recordings are not required for certain closed sessions.

Ms. Taxin stated she recommends and has only closed meetings for review of character or competency and if the Board wants to close a meeting to let her know and she will walk them

through the process. She stated if there is someone meeting with the Board but Board members do not want to be honest with their comments in front of the person then Board members need to think of a different way to give their comments or not say anything as that is not a reason to close the meeting. She recommended Board members always comment in a professional manner and make their comments to applicants or probationers in a kind way.

Mr. Steinagel stated Ms. Taxin recently had an experience where a probationer left the meeting and then the Board started talking about the person. He stated the Board did not want their comments in the minutes so Ms. Taxin asked if they had made the comments and they confirmed they had. She informed the Board members the comments would be left in the minutes.

Mr. Ferguson explained Board meeting notices have to be given for the meetings and the last point to make changes on an agenda is 24 hours prior to commencement of the meeting.

Ms. Taxin suggested Board members contact Ms. McCall or herself if they have items to include on an agenda. She stated there are times when public people see the names of Board members on an agenda or in the minutes and they call to discuss something the Board member may have said. She stated the Board should inform the caller that they cannot discuss it outside a Board meeting and then contact her to include the information on the agenda for Board discussion. She stated Board members should never discuss or review qualifications, information or an application for licensure outside a Board meeting because if they verbally approve and then her staff finds there is an issue which requires the application to be denied it causes problems.

Mr. Ferguson stated if an applicant contacts Board members and wants to discuss their application or a disciplinary action the Board should not talk with the

individual as it would then be inappropriate for the Board member to be part of a discussion in a Board meeting or in a formal hearing with the individual.

Mr. Ferguson stated in the past there was an agenda item listed as “other business” only. He stated that is no longer acceptable and all reasonable agenda items must be specifically listed as a topic for discussion. He stated if something is not listed on the agenda it cannot be brought up and discussed at that meeting. Mr. Ferguson stated if a public person brings up something not on the agenda the Board should be respectful and let them know it could be discussed but not acted on in that meeting.

Mr. Ferguson reviewed the guidelines of emergency meetings and stated meetings could be electronic as long as proper procedures are followed but it is not recommended or ideal as it is hard to hear. He stated all meetings must be tape recorded with minutes typed up for a permanent record but certain closed sessions do not need to be recorded or notes taken.

Mr. Ferguson stated not following the guidelines for open and public meetings is a serious violation of a Class A Misdemeanor.

Mr. Ferguson stated there always must be a quorum to conduct Board business which means this Board must have a minimum of four members present as it is a Board of seven members. He stated if four Board members were present and one had to be recused then there would not be a quorum to conduct business. Mr. Ferguson stated if there is a vacant position it is still considered a position and counts as part of the quorum.

Mr. Ferguson stressed the importance of maintaining proper decorum during Board meetings. He stated there may be friendships and a relaxed feeling about being with each other but if someone comes in for an application review and the Board is joking and bantering it takes away from the process. He stated Board members are considered public officers and there can be actual or potential conflicts of interest

between public duties and private business. He stated Board members may see private information in the applications or private information may be brought up in an interview or discussion and the Board must use that information only for Board/Division business.

Ms. Taxin stated the Board will have to discuss information and they may be given the information to take home for review. She asked the Board to be sure to keep all application or probationary information they are given confidential and to bring it back to be shredded. Ms. Taxin stated the information should not be reviewed by anyone but the Board as they need to respect others privacy.

Mr. Ferguson stated there are situations where information may be faxed to Board members to review prior to a meeting and they should be sure they have some protocols in place to maintain privacy. He suggested the Division and Board be careful about e-mails as they are not always secure.

Mr. Ferguson cautioned the Board regarding the use of their Board position as a Board member and possible conflicts of interest.

Ms. Taxin discussed accepting gifts. She stated she had a situation where a Board member had said if the probationer brought donuts ... and the next probationer asked if he brought donuts would the Board be easier on him. She stated the Division or Board do not accept gifts. Ms. Taxin stated there are times when cookies, gift certificates, etc., are given to her or her staff and we all return the gifts and have to say thank you but we cannot accept gifts for doing our jobs.

Mr. Ferguson stated Governor Herbert has tightened the gift policy and it is safer not to accept any gifts.

Mr. Ferguson explained recusal or disqualification. He stated when Board members recuse themselves from an appointment or hearing they are disqualifying themselves. He stated they may also be disqualified if there is a conflict of interest such as a friend on

disciplinary action or a friend applying for a license as the friendship could make the Board member want to go easier or harder on that person. He stated in conflict of interest situations Board members should make a disclosure to Ms. Taxin and let her know you may not be able to participate prior to a Board meeting or hearing and she may request you to bring up the issue in the Board meeting or hearing. He stated someone else may also bring up a possible conflict regarding them not being comfortable with you sitting in on this specific issue or situation.

Mr. Steinagel stated there was one probationer who was in violation of the Order and the Division needed to do an Order to Show Cause. He stated the probationer believed over time there were some biases of Board members and he wanted the entire Board recused. Mr. Steinagel stated the Judge did not go with the probationers request but two Board members were recused.

Mr. Ferguson stated the public thought is that a body such as the Board is being honorable and wanting to do things the right way but over time biases can come up. He stated Board members should recuse themselves if they have a company where they have an interest in becoming licensed or their own application is being reviewed. He stated those Board members may be part of the discussion and give a presentation or leave the room to avoid a possible conflict of interest. He stated those Board members should not be part of the decision making process based on the conflict of interest.

Ms. Taxin stated she has discussed this issue with Mr. Steinagel and they determined it is a case by case basis. She stated the cleanest would be for a Board member who is an applicant to be sure there is no appearance of bias and she recommended they request another member of the company to meet, present and represent the company. Ms Taxin stated she has not found any authority requiring the applicant to leave the room but they should not vote or be part of the decision.

Mr. Fitzpatrick asked if some of the Rules of the Board need to be decided while the Board is here.

Ms. Taxin responded Mr. Ferguson is presenting the concepts for the Board to think about.

Mr. Ferguson stated Board members may call Ms. Taxin if they have questions regarding legal concepts. He then covered the Government Records Management Act, GRAMA. He stated some records are public and some are classified as private/protected records which would be trade secrets or confidential information. He stated if an applicant believes their information should be protected they must document why it should be classified as protected and private.

Ms. Taxin stated she believes this Board will have some classified/protected information to review, discuss and decide together so all applicants are treated fairly across the Board.

Mr. Ferguson stated if Board members are contacted by the news media they need to refer those calls to Jennifer Bolton or Ms. Taxin. He stated Board members may be approached in a meeting and asked to speak for the Board. Mr. Ferguson recommended Board members always remember that the Board acts as a collective body and they should refer those questions to the Division or to a Board meeting. He requested Board members to be careful when they speak for the Board outside a formal Board meeting. In conclusion he reminded Board members that the AG's office role is to assist the Division and Board. He stated the AG's are here to help within the bounds of the Law.

Application Process

Ms. Taxin reviewed the application process with the Board. She stated her staff do the first review and if the application is complete the license is issued but if incomplete a letter is sent requesting the deficiencies be submitted within 30 days. She stated if there are issues she does not know how to address then the application comes before the Board to review. Ms. Taxin stated there is no standard for the Online Prescribing profession as Utah is the only State that

has licensure. She stated she created the applications and believes they ask the questions needed. Ms. Taxin explained she had to start somewhere before the Board was formed and after the Board reviews the applications changes can be made quickly if necessary. She stated other States are not supportive as they believe online prescribing strays too far from traditional medicine and is not a safe practice but the Utah Legislature passed the Law and the Division was given the responsibility to enforce the Law and make it as safe a possible for the public. She stated if the Law needs some changes the Legislature will have to open it but the Board/Division amend the Rule if necessary. She stated as the profession is new it will grow and the Law and Rule will need updating accordingly. Ms. Taxin stated she cannot regulate inconsistencies so the Board will need to be sure to be equitable with all applicants.

She then turned the time over to Mr. Ax for his introduction on a branching questionnaire and the online process from his perspective.

Peter Ax Presentation

Mr. Ax explained Utah is currently the only State who has decided to regulate the Online Prescribing, Dispensing and Facilitation profession but he has been working with individuals in Utah for ten years and they understand the profession. Mr. Ax gave an overview of the profession and stated his organization purchased KwikMed in October 2001 as they believed there is delivery to be had online. He explained Dr. Bachman just published an 18 month study with online consultation through the Mayo Clinic. Mr. Ax stated his company is based in Utah and he has worked with the State of Utah for the last 14 months developing a standard. He stated in December 2002 his company created a consent Order with DOPL for online services to sell certain drugs, ie: Viagra, Cialis, Levitra, Chantix and Propecia. He stated patients are able to obtain these drugs with online consultation. He stated the company operated until 2010 when the new Law went into effect. Mr. Ax stated with the Legislation they have permission to work with specific Pharmacies, Physicians and Pharmacists.

Mr. Ax stated the new Law requires a branching questionnaire be completed by all patients and when a patient goes online for a drug or treatment they are asked specific health issues questions. He stated the answers to the questions move the patient to another branch of questions in order to create an electronic medical record for the Physician to determine the health of the patient. He stated the Physician has access to the information on new patients and any previous orders from patients and may also interact with the patients through e-mail or a phone call. He stated the Pharmacy also has an interface. Mr. Ax stated the Physician will have access to all patient information but the Pharmacist will only be allowed to view specific things.

Mr. Ax stated the Mayo Clinic and the University of Utah reviewed their patient medical records for several years and wrote peer review papers regarding how safe the online company is and how good they are about prescribing drugs that are information based.

Dr. Bair stated it is interesting to have Mr. Ax give a presentation on KwikMed as he has an application to be reviewed. He asked for a definition of online prescribing. He stated his concern is that practitioners are already doing things that could be considered online prescribing and MD's are sending prescriptions through to Pharmacies. He stated there are several States who use scanned prescriptions and patients receive their medications prior to the Pharmacy receiving the actual prescriptions.

Mr. Steinagel and Mr. Perry responded Dr. Bair is referring to e-prescribing.

Mr. Steinagel responded the Division believed it would be helpful to the Board if Mr. Ax explained the background for online prescribing but not discuss a particular application. He stated the authority for licensure was based on 58-1-501. He stated online prescribing is typically a prohibitive practice but Utah defines the practice by a scope rather than a definition as it is based on practice.

Mr. Perry stated the consent agreement went into effect prior to the Legislative Bill.

Dr. Bair commented the Board is defining what section of legend drugs are prescribed. He stated it is very limited and he wants to be sure information is very clear so the public understands.

Mr. Steinagel read the definition of online pharmaceutical services from the Law. He stated the only authority the Board/Division has to write Rules is set by the Legislature in the Law. He stated the Legislature wants a specific list in Rule and the current Rules are limited.

Mr. Ferguson stated Rules can be written only if the Law allows for them.

Ms. Taxin requested Board member to e-mail their suggestions to her and she will put the information together for the Board to review.

Mr. Fitzpatrick suggested Ms. Taxin contact Ms. Poe and Ms. Kimball regarding a possible model for her to review already created by NAPB.

Mr. Perry suggested a Rule distinguishing between eprescribing and online prescribing.

Ms. Taxin responded if people call the Division to inform them they do not need an additional license for e-prescribing.

Dr. Bair asked if a Utah Physician were to go with a group out of Utah but had an online facilitator in another State could Utah sanction their license.

Mr. Perry responded the Physician and Pharmacy must be licensed in Utah even when the company is located in another State.

Mr. Ax commented there might already be Utah Physicians prescribing out of Utah. He stated he does not believe there will be many applicants for the Online Prescribing as the requirements are quite strict.

Dr. Bair asked how Mr. Ax is defining patients in his system.

Mr. Ax responded each patient is given a specific ID number.

Dr. Bair stated he deals with a Master Patient index (MPI). He stated patients do not always use the same name. He asked how KwikMed deals with this issue.

Mr. Ax responded when a patient purchases from KwikMed they give their name, address, telephone number and social security number. He stated if someone calls in again KwikMed has identifiers in place that they use to get the right patient. He stated it is a check on the system so the patient does not order too often.

Ms. Taxin stated she believes the easiest way to review the applications is to review each separately, ie: the Facilitator application, the Physician or Osteopathic Physician application and the Pharmacy application.

Ms. Taxin stated her staff has found the Facilitators are filling out the applications for all three areas as they are the coordinator for the Pharmacy and the Physician. She referred the Board to the sheet her staff use to be sure all required information has been received. She stated the Board will only review the areas where she and her staff have questions not the complete areas.

Dr. Bair asked how an organization can complete all three applications.

Mr. Ax commented it is easier for the Facilitator to collect the information and submit it for the Physicians and the Pharmacy. He stated Facilitators are reimbursed by reading files. Mr. Ax stated there are also several Federal Rules they have to follow and the Facilitator makes sure there is no conflict of interest. He stated they do not necessarily take Medicare reimbursements.

Dr. Bair asked if patients pay for the services.

Mr. Ax responded yes. He stated the patient pays a single payment for the package.

Dr. Bair asked if the patient does not get the prescription is the physician reimbursed.

Mr. Ax responded no as there is no charge if no drug is given and when someone wants a refill they have to go through the whole process again.

Dr. Bair stated he wants to make sure the relationship is appropriate.

Ms. McOmer stated a patient is required to be 18 years or over to receive the drugs. She asked Mr. Ax how his company verifies the age.

Mr. Ax responded his company requires every medication packet to be signed for by an adult showing their ID on receipt of the drug.

Mr. Perry asked if the Board wants to see a demonstration of the branching questionnaire.

Mr. Steinagel responded the Statute requires the applicant to demonstrate to the Board's satisfaction that they meet requirements. He stated he believes a demonstration should be conducted to satisfy the Board.

APPLICATION REVIEW:

KwikMed Applications

Ms. Taxin explained the KwikMed applications were received and she believes they are now about 90% complete. She stated on initial receipt of the application information was about 50% complete so she met telephonically with Mr. Ax to review and he has submitted additional information. Ms. Taxin stated she made a copy of the 90% complete application only but could copy all the information if the Board determines it is necessary for the review. She pointed out the following deficiencies/questions for discussion:

1. Review the disciplinary actions from other States;
2. Dr. Chen still needs a verification;
3. Review the branching questionnaire;
4. Review the policy and procedures and FAQ – do they meet Statute requirements; and
5. Does the laboratory service fall within Statute authority.

Mr. Ax asked if the qualifying questionnaire questions are all standard questions.

Ms. Taxin responded yes and most States ask similar questions.

Dr. Bair stated he is not sure he has enough information regarding the standards definitions for the profession and Statute to review the application.

Ms. Taxin acknowledged Dr. Bair's concern and stated there is currently an application that has been received and the Board/Division have a responsibility to respond to the request for licensure in a timely manner.

Ms. Taxin stated it is important to maintain continuity in reviewing the applications and the Board needs to be equitable with each application.

Ms. Taxin stated the Division received a second application. She stated, due to the complexity of the applications, she believes the Board should meet again in November.

DISCUSSION ITEMS:

Discuss the request for Chantix and other approved Cosmetic Drugs to be added to the current approved list

Ms. Taxin explained Mr. Ax has requested Chantix be approved and Mark Taylor, MD (dermatologist) has requested the Board include Retinoids which helps fine lines and acne and Hydroquinone which lightens pigmentation.

The Board discussed the safety of legend drugs vs. over the counter drugs and what criteria should be in

place regarding approving additional drugs for online prescribing.

Mr. Ax distributed a handout for Chantix and an unnamed drug for the Board to review in considering approval for his company. He stated Chantix is used to assist people to stop smoking, has been out on the market about three years and has been very effective.

Mr. Fitzpatrick asked if Mr. Ax changed the branching questionnaire after the FDA placed a black box warning on Chantix.

Mr. Ax responded all questions are written and submitted from Alan Winter and Dr. John Bachman. He stated his company did make minor changes on their questionnaire. Mr. Ax stated his company needs formal approval from the Board to continue selling Chantix as that drug was not on the original list passed in the Law.

Mr. Fitzpatrick stated when the Physicians Board, the Osteopathic Physicians Board and the Pharmacy Board all met in 2009 they discussed Chantix and the drug being on the FDA black box warning list. He stated the Boards were charged at that meeting to come up with a formulary of accepted drugs and the consensus of all three Boards was not to include black box warning drugs.

Ms. Taxin concurred with Mr. Fitzpatrick. She stated the Boards spoke about Chantix and had said they did not believe Chantix was safe to put on the list as it is on the black box list and this decision was based on public safety.

Dr. Bair stated the Board now needs to discuss whether they are comfortable putting black box warning drugs on a new list as black box warnings have an effect on policy.

Mr. Ax responded black box warnings are just warnings and the individual needs to be aware and

make their own decision. He stated no such meeting occurred that included KwikMed in 2009.

Ms. Taxin stated when the Boards met with KwikMed representatives present Dr. Kristen Ries specifically addressed Chantix at the 2009 combined meeting by stating: “she believes black box warnings are important and no drug with the black box warning should be prescribed from online prescribing. She stated Chantix has a black box warning.”

Ms. Littlefield asked if the Board could recommend Chantix be grandfathered on to the list.

Ms. Taxin reminded the Board that the drug list is not just for KwikMed but will be for all companies who apply and receive licensure. She stated she believes the Board has to look at each drug and require a process to be in place to assure safety to the public.

Mr. Ax reminded the Board of the Law requiring the Board/Division deciding on black box warning drugs after January 1, 2010. He stated the FDA may have a different level of standards and requested the Board to discuss the issues and standards.

Mr. Ax then requested the Board to review the unnamed drug. He stated this drug is a plan B emergency contraceptive which is already being distributed in 22 foreign countries. He stated the drug will require a prescription and will be sold by Physicians prescribing and Pharmacies selling. Mr. Ax stated by being approved to sell this drug online it will eliminate embarrassment and judgment for patient.

Dr. Bair asked for clarification from Mr. Ax as he is requesting the Board to approve Chantix to be on the list and he says he has years of safety and now he is requesting an unnamed drug which has no track record to be approved. He stated the Board should not get into the habit of approving new drugs that have not been launched without a track record. He stated the discussion comes back

to what will the parameters be to include drugs on the approved list. He voiced concern regarding hearing arguments to include several legend drugs.

Dr. Bair made a motion to table the review of specific drugs until the Board establishes criteria to be followed and at least one meeting to review with studies on the drugs presented for further discussion.

Mr. Fitzpatrick seconded the motion.

Mr. Ax requested the Board to continue the discussion as the Board is charged with reviewing, discussing and approving additional drugs for the list.

Ms. Taxin recommended the discussion be tabled until the November meeting.

Ms. Taxin asked for a Board vote on the motion.

Ms. Littlefield abstained from voting.

Mr. Ax voted against the motion.

Mr. Fitzpatrick, Ms. Korb, Dr. Bair and Lt. Ross voted in favor of tabling further discussion to the November meeting. The motion passed with a simple majority.

Mr. Ax stated his business is based on public safety.

Lt. Ross responded he believes Mr. Ax but if the public comes back and said there are no statistics regarding the unnamed drug as it has not been tried and Mr. Ax has been approved to sell it to the public there could be a problem. He stated he believes the Board should not discuss black box warning drugs right now.

Ms. Littlefield explained she abstained from voting as the agenda had listed we would discuss Chantix today and we could have completed that discussion. The agenda did not list discussion of an unnamed drug. She stated for the open meeting discussion the unnamed drug should have been listed in order

to discuss it. Ms. Littlefield stated the Board was appointed to protect the public.

Ms. Taxin stated the Board may not personally agree with the online prescribing philosophy of medicine but they need to be sure it is managed in a safe way as the Legislature has decided online prescribing will be in Utah. Ms. Taxin stated Chantix has been sold by KwikMed and Physicians may still sell it out of their offices. She suggested the Board consider if Chantix should be on the list and be prepared for further discussion in November. She stated maybe the Board could require the patient to sign a waiver acknowledging they have been warned of the side effects of Chantix.

Mr. Ax commented there has to be a level of reasonableness. He stated Viagra is safely prescribed online and he could provide a safe study about Chantix. He stated the Board was not created to make decisions in this manner and Utah needs a Board who is willing to move forward and not be so cautious.

Review of Future Applications

Ms. Taxin asked Mr. Ax if there are areas of the application that would be proprietary and should not be shared.

Mr. Ax responded yes.

Ms. Taxin reminded Mr. Ax, as a Board member, he would have access to other applicant's information. She stated she has reviewed Mr. Ax's application and the other application and believes there is information that should not be shared.

Dr. Bair suggest Mr. Ax label the proprietary areas but have that information available in case it should be needed during the review/discussion.

Ms. Taxin agreed and stated the Law says the individual has to notify the Board/Division what is proprietary. She stated the application information is public information but if the company asks for specific information to be private she will need clarification on

what those items are and will let the Board know the decision regarding releasing. She asked if the Board wants to take the application information to review for discussion in November.

Ms. Taxin then asked Mr. Ax if he is comfortable with the Board taking his application to review and he voiced he is not comfortable with the Board having and reviewing his information. Ms. Taxin stated she will honor Mr. Ax's request for information to remain with the Division but the Board will review all information in November.

Ms. Taxin requested Board members to review the Law, specifically 58-83-302, qualifications for licensure. She stated there were five applications for Physicians who have all paid their fees; the verifications were clean or resolved. She stated the branching tool will be presented in November. Ms. Taxin stated KwikMed made several changes in their policies and procedures manual and the Board will need to review those documents to approve if the policies and procedures address confidentiality, accuracy of personal information and Statute requirements. She continued by stating KwikMed offers additional services beyond prescribing online. Ms. Taxin stated one such service is lab testing and she questioned if the Utah Online Statute allows for additional services.

Mr. Ax responded his company sells five drugs and offers 15 lab tests only. He stated the Physicians are not reimbursed based on the lab tests.

Mr. Perry stated lab tests are the practice of medicine and the patient is required to be seen before prescribing lab tests.

Ms. Taxin stated one profession cannot practice another profession unless they have the authority. She stated the profession needs to be careful not to cross over into the practice of medicine or pharmacy.

Mr. Ax stated if legal issues are going to be discussed he would prefer his legal counsel to be

present. He stated the drugs for online services are regulated by the Division but the lab tests are not.

Mr. Perry responded lab tests might be regulated in other Statutes.

Ms. Taxin commented she believes lab tests are part of the practice of medicine.

Ms. Taxin stated if Online Prescribing applicants do not want information sent out to Board members to review for discussion at Board meetings then the Board will have to review all information during the Board meeting. She stated some questions she thought were not clear have been amended but she is not confident enough yet to issue a license on her own. She stated she may have made some mistakes or overlooked something as the applications are complicated. She stated she is also not sure how much of the applications the Board will want to review. Ms. Taxin stated she believes most of the information for the KwikMed application has been received but she is still waiting on a verification from California for one Physician application. She stated the Board will have to review and decide if the disciplinary actions are a concern. She stated the AG's Office needs to review the information and provide an opinion. Ms. Taxin stated in other professions a Cease and Desist Order is disciplinary action and for other professions she would do a probationary license with conditions.

Ms. Littlefield asked if all the cases were for the same issue.

Mr. Ax responded yes, they were all in Oregon. He explained KwikMed tried to obtain licensure in Oregon and was denied and informed if they decided to fight the decision they would be fined a huge amount.

Mr. Ax explained KwikMed always used third party fulfillment for shipping medications. He stated they bought a website but contract with outside Pharmacies and when DOPL voiced concerns about some of the Pharmacies they were

using they purchased their own Pharmacy and became a target for attack by several States. He stated in all cases they were transparent and tried to win the day.

Ms. Taxin explained KwikMed was prescribing in other States without their permission. She stated Utah does not regulate other States and each one has differences in their Laws.

Mr. Perry stated the Utah Law allows KwikMed to prescribe in Utah only.

Ms. Taxin suggested the Board review the policies and procedures first at the November meeting.

Mr. Fitzpatrick asked in how many States KwikMed's Pharmacy is currently licensed.

Mr. Ax responded he believes they now have licensure in about 30 States. He stated some States do not require licensure and others allow them to ship to their States.

Dr. Bair commented he believes the Board should follow the policy of other professions for reviewing the applications and review all information.

Mr. Ax responded that Dr. Bair and other Board members may believe the whole application is public but he does not agree. He stated he did not sign anything giving permission for anyone to review the whole application, just the Division to review. He stated KwikMed is a business and he does not need to follow the same requirements as Physicians/practitioners as he is not a Physician/practitioner.

Mr. Perry responded yes, Mr. Ax did agree to his application being reviewed by the Board as per the Division umbrella and GRAMA Statutes where the issue is addressed (58-1-202. Boards – Duties, functions, and responsibilities. (1) The duties, functions and responsibilities of each board include the following: (d) screening applicants and

recommending licensing, renewal, reinstatement and relicensure actions to the director in writing;...). In addition Mr. Perry stated the **Physician/practitioner is also a business person.**

Ms. Taxin requested Mr. Ax and other Board members to remember the Online Prescribing profession is new and all involved need to understand the profession as information is going to need to be provided and reviewed.

Mr. Ax reminded the Board/Division that he is trying to run a business and has run this business for ten years. He stated he believed Utah was moving forward but is now being informed he has to take away part of his business. He stated that was not the intention of the legislation or the creation of the Board.

Tentative Board Meeting Dates

Following discussion the Board determined to meet again November 9, 2010, from 9:00 am to 1:00 pm in addition to the following tentative dates: December 7, 2010 and March 1, June 14, September 20 and December 6, 2011.

NEXT MEETING SCHEDULED FOR:

November 9, 2010

ADJOURN:

The time is 3:45 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 and
Facilitation Licensing Board

November 9, 2010
Date Approved

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