ALABAMA STATE BOARD OF PHARMACY

WORK SESSION

Wednesday, July 16, 2014

8:13 a.m.

LOCATION: Alabama State Board of Pharmacy
111 Village Street
Hoover, Alabama 35242

REPORTER: Sheri G. Connelly, RPR

APPEARANCES

BOARD MEMBERS:

Mark Conradi, President
Tim Martin, Vice President
Dan McConaghy, Treasurer
Buddy Bunch, Member
David Darby, Member

ALSO PRESENT:

Henry Burks, Chief Inspector
Susan Alverson, Director of Professional Affairs and Secretary
Cara Léos
David Clark
Jim Easter
Julie Hunter
Karen Nishi
Rick Stephens
Louise Jones
Tracy Davis
Richard Lambruschi

DR. MARTIN: So today is one of those unusual days when we have a work session scheduled and no one sent in any topics, so guess what, we get to be as creative as we want to be. I have a couple of topics up my sleeve but I'm going to hold on those to wait and see if you guys have something you'd rather discuss. So we'll throw the floor open for comments from anybody, any direction you would like to take on the work session this morning. Jim.

MR. EASTER: Have we heard any further updates since the guidance from the FDA about compounding?

DR. MARTIN: I'm going to tell you what I know and it will take about 30 seconds, maybe less, and I think the answer is no. We're still -- we haven't heard anything on the verbiage on the MOU as far as I know.

MR. CONRADI: Well, they sent out a little verbiage last week.

DR. MARTIN: Proposed or is it that far?

MR. CONRADI: No, it wasn't that

far.

DR. MARTIN: So that seems to be the big deal on the 503B portion of it and we can't do anything until we hear what the MOU is. We know that it's going to be take it or leave it and we're inclined to take it. Until we see and see what it says, we don't know. A lot of people are in this same situation, I know that.

Not much activity on 503A, so we're still waiting on the FDA to flesh that out more and for those of you who don't know what those are, as I understand it, 503 has been on the books a long time, the FD&C and now it's -- there's going to be a 503A and there's going to be a 503B. What Jim is talking about is outsourcing compounders and this is the FDA's way of addressing that issue of if you are a manufacturer under GMP, you clearly fall into a category but if you are -- I should say and, if you are making compounds pursuant to a prescription and they're patient-specific, you clearly fall in that area.

The question came, well, what about

those who are in the middle that are making it in anticipation of in large quantities that's obviously not patient specific and so they're going to be calling those outsource compounders and they'll fall under this category called 503B, and as I understand it, they'll be required to comply with something that's kind of like GMP but it's not full GMP. Is that what y'all understand Mark, Susan?

DR. ALVERSON: Yes.

DR. MARTIN: Rick?

MR. STEPHENS: Tim, would CAPS and people that do TPNs, would they fall in that category?

DR. MARTIN: Yes, yes, I think your CAPS, your far mediums, and probably a dozen more that are out there would fall under that and they would choose to be registered with the FDA. They would pay a fee. I think that fee is, if I'm not mistaken, $15,000.

MR. CONRADI: Starting at the low end depending on volume.

DR. MARTIN: Yeah.

MR. STEPHENS: They want to be serious.

DR. MARTIN: So to get to play, the annie is 15 grand, the annie, and then you get to do something that's not full GMP but -- and I don't know how far it goes. So that's the 503B side. There's still a lot of questions on the way the wording was released. There's some people that claim you can't tell if it's sterile or nonsterile or both, so most of the people I've talked to thinks it was the intent of the FDA to say it was sterile but when the FDA people were sitting there at NABP in Phoenix, they wouldn't declare that it was only sterile. Is that your understanding, Susan?

DR. ALVERSON: Yes. Can I mention our experience two weeks ago?

DR. MARTIN: Yeah, please do.

DR. ALVERSON: We went in with the FDA just on something that had been on their books for a long time and they had postponed going into a pharmacy just because they weren't sure of what the law said and what ability they had.

So they now interpreted they could follow up on a complaint from a long time ago and when they went in, the inspector said we had no jurisdiction here because this pharmacy, there's a prescription for every single thing that goes out of here and I can't find that they're making an excess quantity. In fact, the majority they've made is the amount needed for the prescription and she kept calling Washington for confirmation and the more she looked, the more she was convinced that they had no jurisdiction.

On Thursday, and she had been there since Monday, Washington ruled they did have jurisdiction and to finish it as an inspection using GMP, they filed a 483. At the exit interview Washington called and said, well, we're not sure if we have jurisdiction but go ahead and file a 483. So that's our one experience with what Washington thinks about the situation.

MS. LÉOS: And was there anything there that you all saw that was --

DR. ALVERSON: There wasn't one single thing wrong according to 795 standards, nor did she find a single thing wrong with volume 795 standards.

MS. LÉOS: This was all -- so it was nonsterile?

DR. ALVERSON: It was all nonsterile but she did find things wrong according to GMP, which you would expect.

MR. EASTER: Yeah.

DR. ALVERSON: Because they're not at a GMP facility.

MS. LÉOS: Sure.

DR. ALVERSON: I haven't looked to see if it's posted yet.

DR. MARTIN: So that -- I don't mean to cut you off. Were you finished?

DR. ALVERSON: Pardon?

DR. MARTIN: Were you finished?

DR. ALVERSON: I am.

DR. MARTIN: Okay. So let me say one other thing about that and then I need to go back and correct a mistake I made earlier by not

allowing you to introduce yourselves for Sheri and the record, so sorry I missed that.

So that's 503B and you know, stay tuned and you can go out and Google it and you'll read a bunch of stuff and you know, most of it is spin and chatter and until -- until we get the real thing, we don't know what it is. 503A, on the other hand, gets more to the heart of what the act was that generated all of this and that's the Drug Quality and Security Act. You'll hear it referred to as DQSA and it will more or less establish a pedigree from the manufacturer to the pharmacy but it won't go beyond the pharmacy to the patient.

MR. CONRADI: Yet.

DR. MARTIN: Yet, Mark said yet. So the question is: What about from pharmacy to pharmacy, where does 503A fit and we don't know -- we don't know the answer to that yet. So we do know that there's been a bit of dialogue at the wholesaler level. Wholesalers appear to be preparing to help pharmacies out with the maintenance of the records and

requirements of the 503A portion. And I can't tell at this point if it's going to be as restrictive as Florida's pedigree law, so again, stay tuned, we'll see what comes out of that.

Was that -- that was a long answer to your question, Jim. I think we had some good dialogue there.

What other things are on your mind this morning?

MR. EASTER: Just -- can I say just following up with that, if we use the checklist that's on the Board web site --

DR. MARTIN: Yeah.

MR. EASTER: -- we ought to be in pretty good shape if we comply with that?

DR. MARTIN: The checklist for?

MR. EASTER: Compounding.

DR. MARTIN: I'm going to ask Susan to respond to that.

DR. ALVERSON: Our inspection forms are on the web site and we are putting up the new web site. We've changed inspection forms even for retail.

MR. EASTER: Okay.

DR. ALVERSON: And all inspection forms will be in one category. Meanwhile, 795 and 797 are posted on our web site and that is what we're using to inspect.

MR. EASTER: Okay.

DR. ALVERSON: We're not pulling anything else out of our hat.

MR. LAMBRUSCHI: And I just want to remind you the inspection form is a guideline. That's just not -- there are other things that can be checked other than specifically what's on that form. It's just a guide, you know, so don't think just you've got the 15 things on there that gets checked off, that that's all that's going to be looked at.

MR. EASTER: Right. But if I have those 15 things ready, plus the 795 checklist that's on there and I've got the 797 stuff in order, then I ought to be in pretty good shape?

MR. LAMBRUSCHI: Pretty good shape.

DR. MARTIN: Well, let's -- let's interrupt the discussion for just a minute and

ask you to tell us who you are and if you represent a group, tell us who you represent and we'll get that in the record so we'll have a record of your attendance and participation. Let's start with Cara and we'll just go back and forth.

MS. LÉOS: Cara Léos with ALSHP.

MR. CLARK: I'm David Clark with MediStat Pharmacy.

MR. EASTER: Jim Easter, Baptist Health System.

MS. HUNTER: Julie Hunter, Omnicare.

MS. NISHI: Karen Nishi, Cubex.

MR. STEPHENS: Rick Stephens, Senior Care.

MS. JONES: Louise Jones, Alabama Pharmacy Association.

MS. DAVIS: Tracy Davis, Alabama Pharmacy Association.

MR. LAMBRUSCHI: Richard Lambruschi, Alabama Board of Pharmacy, inspector.

DR. MARTIN: Thank you. So we heard a little bit on 503B, 503A. What else would you

like to discuss this morning? Louise?

MS. JONES: I have a couple of things. I received an email to APA's just general email inbox that I responded to the person and just advised them to contact the State Board of Pharmacy with the complaint or question but just wanted to just let you know in case they don't that this concern is out there. It was from a lady in Fairhope, Alabama, who had had an experience where she had someone at an ER down there with an accident and when they left, it was after hours for most of the -- or all of the pharmacies in the area to be open and so it was that issue that I know has kind of been talked about in the past year or so of hospitals being able to give outpatient meds to someone to get them through until the next day when pharmacies would be open.

DR. MARTIN: Uh-huh.

MS. JONES: So it's just an issue that's been brought up before so I just thought I'd just put it out there. I'm not saying we need to discuss it right now.

DR. MARTIN: Was she -- was she complaining that she did not get meds or that she did get meds?

MS. JONES: She did not.

DR. MARTIN: She was complaining that she could not get the medications.

MR. CONRADI: She didn't want to drive to Mobile?

MS. JONES: That's right. So I just wanted you to be aware that I asked -- just my advice to her was to contact the State Board with that complaint.

The other thing is I wanted to just let you know, and I believe most of you were able to attend our convention, but in case you didn't know, we announced at our house of delegates meeting the three names that were sent to the Governor. I hand-delivered that letter to the Governor earlier this week or actually, I take that back, I took it at the end of last week. And so the three names for the chain position to replace Mark when his term expires --

MR. CONRADI: You can't replace me.
MS. JONES: Well, you're right -- to fill the position that Mark will leave a huge hole in --
MR. STEPHENS: A huge hole.
MR. CONRADI: Huge hole.
MS. JONES: -- are Tammie Koelz and then -- let me think, gosh, my mind is blank -- Donna Yeatman and Joe Street, Junior. So those are the three names that went to the Governor and --
DR. MARTIN: Now the waiting begins.
MS. JONES: Yes, may the lobbying begin. It seemed like there was one other thing but I can't remember.
DR. MARTIN: Let's go back to your first topic for just a minute.
MS. JONES: Okay.
DR. MARTIN: And I know that occasionally I've had a conversation with a board member about how they think we should handle that and it tends to go back around to the issue of you can't regulate everything. You

can't anticipate all the situations that are going to come up and if you try to, you spend your life trying to identify compliance with things that are seldom if ever going to happen and so we're trying to find the balance between when is it time to step in and say something or do something and when do you just say reasonable and prudent people taking care of patients in the best way they can is the thing to do.

So if you have any comments about that, you know, we'd be glad to hear them but that's one of the handful of issues that I think all boards really -- really struggle with and if they don't, I think they're laboring under the misconception that they can regulate everything and make it make sense. We don't think that's the case. Well, I speak for myself, I don't think that's the case.

Pharmacists tend to be -- I think my niece calls them rules hotties, you know, we like to know the rules. We like to know what the rule involves. We like to know where the line is. We like to know that we're not

stepping over the line and if somebody else steps over the line, we like to let other people know somebody stepped over the line and sometimes that is a good thing and often it's not. I don't think -- I can't speak for the rest of the Board or for the inspectors but I don't think they're going to be requiring people to do something in this case like to give, sell, provide this lady her medications and I don't think they're going to forbid it. I think they're going to say, well, what was the situation, what were your thought processes, you know, what was the outcome, and -- and if there's no harm, no foul, but you know, that's -- that's my personal opinion. That's not the position of the Board.

MS. JONES: Let me ask you this: What are the current rules or statute that apply to that as far as an institutional pharmacy, hospital giving outpatient meds to someone in the ER as they leave that's after hours? What's currently on the books?

DR. MARTIN: It touches a lot of

differing areas and I think this is where it becomes a point of consternation with some people that they want to -- they want to be doing it right and they don't know what to do because nobody has told them what's right but it touches areas that are -- deal with billing and fraud. So for example, if you -- if a hospital fills a drug to a patient and it's assumed that the drug that was filled was administered on site but it wasn't, that could be considered fraud if there's not prior approval to do that.

When it comes to labeling, there's some issues. As I understand it, there are only two groups in this state who can dispense and those are pharmacists and physicians and pharmacists and physicians are required to comply with the laws on labeling and you can get in trouble in that area. There are some court cases that deal with antitrust and when a drug is bought under a contract but the drug is used in a manner not consistent with the contract, like own use is a term that particularly comes up in this discussion but I don't -- you know,

if a hospital was doing this day in and day out multiple scripts a day, clearly getting off into an area they shouldn't be getting off into, that's probably going to result in a bunch of complaints, not just an occasional complaint, and they probably need to be questioned about what they're doing. But for the occasional patient that just every now and then has a hardship, I don't -- I don't think anybody is going to do anything bad.

The thing in our mind, and let me own it, the thing in my mind is what if that patient was given those medications and then something bad happened -- they had a wreck on the way home after taking something in the car or there was some reaction to the -- who knows what and then that opens up, you know, to the legal system to question everything that happened and you find yourself having -- on your heels having to justify something that --

MS. LÉOS: I think one of the problems too that our institution ran into, Louise, is that a lot of complaints that kind of support

them and because obviously people who are in pain and have to wait until nine o'clock the next morning to take their pain meds. So our institution, despite the long fight from our director of pharmacy, was giving out little prepacks of Lortab and they were saying it was for patient satisfaction. I'd be satisfied too if I had Lortab walking out the door.

The other aspect of that though and where we got that stopped was the day the DEA came up here and we were talking to them about the PDMP because those drugs don't go through PDMP and that's how we got it stopped at our hospital because that's not going through a pharmacy system that's reporting to PDMP.

So a lot of times it depends on the medication. We get a lot of those orders that say, you know, like Levaquin, FirstDose Now, and One To Go, and most of us tend to turn an eye to it because we know it's technically not in those rules that way but a lot of times we'll just make sure that things are labeled appropriately so they know how to take it.

DR. MARTIN: Yeah, PDMP is another -- another one of those pieces that touches -- I would think that if a hospital is finding itself doing this multiple times a week that the hospital would be smart to develop its own guideline to protect itself to say, for instance, in the absence of any other direction, here's what our policy is going to be and state what you're doing and why you're doing it. At least in that position, you know, you're not -- you're not guilty of being arbitrary, you know, not using any specific logic in your -- in your decision making.

Some people regard you right the opposite. Some people would say the moment you put it down in policy, then you've got to be 100 percent consistent with your policy. So it's up to -- I think it's up to each institution to decide, you know, unless we get some clarity in the future on it.

MS. JONES: But there's nothing on the books that prohibits them from doing it --

DR. MARTIN: No, it's widely done.

MS. JONES: -- as far as state law?

DR. MARTIN: It's done by many hospitals. I think they do it -- I hope they do it with reservation, you know, that they are scrutinizing the processes and asking why are we doing it, are we violating something. So if anybody is doing it willy-nilly, that's a technical term -- if anybody is doing it quite often, then that's a different situation.

MR. MCCONAGHY: I think too you had that discussion a good while back where how many days would be appropriate and it never really went anywhere and I don't -- the best I remember, it was problems on both sides where, you know, even if you okayed it, then your hospital is going to have to properly label it and do all the other things that you're supposed to do to be able to dispense it and it just kind of never went anywhere and just stayed where -- where it had always been, just do whatever you need to do to take care of the patient.

DR. MARTIN: Do you know who it puts in the worst situation, and let's see if you can

guess this. Who do you think it puts in the worst situation and the answer is not the patient. And board members can't play, they know -- they probably know the answer.

The person it puts in the worst situation is sitting in the back of the room on the left side. It's the drug inspectors because they go into that environment and they see that activity and they don't know what to do with it. They don't know if it's a good thing or a bad thing or if it's this big, you know, they don't know, and so they are in a very uncomfortable situation. That was one of the reasons we tried to add some clarity to it but we just couldn't -- we didn't -- we felt like we were pushing a rock up the hill and we were about the only ones pushing it and at that point, you've got to ask yourself why are we doing this and you probably have to fall back on an individual situation for the institution.

Yes, sir, Rick.

MR. STEPHENS: Changing subjects, and I'll quickly defer to Dr. Alverson because I

think she's got some thoughts, but is the Board any closer to moving on some -- the proposed amendment on the institutional rule?

DR. MARTIN: Yes, and if we had been really prepared and had done all of our homework, we probably could have used this work session for that purpose.

DR. ALVERSON: We determined yesterday that at the next Board meeting on Wednesday after we interview students, and we think we'll only have one group at 11:30 next month, that after lunch we're going to hold a meeting for long-term care and I imagine it -- as that affects hospital people, that hospital people may want to be there because we -- I don't know if you want to limit this to discussion of automated dispensing devices but that's going to be our prime discussion, so let's say 1:30. Would that be good?

DR. MARTIN: I think 1:30 is reasonable. Board members, how do you feel about that?

MR. CONRADI: Yeah.

MR. DARBY: That's good.

DR. MARTIN: Okay.

DR. ALVERSON: Because we may not get done with interviews until 12:30.

DR. MARTIN: Yeah, give us some time to grab a sandwich.

DR. ALVERSON: Grab some lunch, all right, and that will be in this room. I would like -- I'm going to ask when we send out invitations if people could call us and tell us how many people they're bringing because obviously we can only hold about 80 people in this room, so we'd prefer not to have ten people from one organization. All right. So if you could just let us know, call Shirley -- I'll ask Shirley to take those phone calls or emails, let her know if you're coming and how many people you're bringing.

MR. STEPHENS: In addition to the automated dispensing discussion, will -- you know, we've got a proposal out there about some language change. You mentioned it a while ago about the quantity limitations and those kind of

things.

DR. ALVERSON: Right.

MR. STEPHENS: That's been --

DR. ALVERSON: I can't promise we'll get to that. I'm guessing that we're going to have a lot of variation on it. If we have time, we'll get to it.

MR. CONRADI: I just thought all of that to be in one deal.

DR. MARTIN: Well, I think it has -- it's kind of developed in two different places. You have the automated drug cabinets in the skilled nursing facilities and then you have the proposed change to the verbiage in the rule that is -- I forgot the number. Do y'all remember?

MR. STEPHENS: Dot 18.

DR. MARTIN: It's not 18?

MR. STEPHENS: No, I think it is.

DR. MARTIN: It is 18.

MR. CONRADI: 518, yeah.

DR. MARTIN: So I guess we need to be clear which one are we -- next month on Wednesday after the Board meeting, are we

talking about automated drug cabinets in skilled nursing facilities or are we talking about the proposed change to the verbiage in .18?

MR. MCCONAGHY: Well, primarily the automated dispensing but I don't think, Rick, on that box, I don't think there's a whole lot of, you know, opposition or --

MR. STEPHENS: Uh-huh.

MR. MCCONAGHY: -- discussion to go on that other than putting it in and that's what we had kind of discussed. We didn't want to go do that and then turn around and do this and we talked --

MR. STEPHENS: You're talking about moving them together as far as hearings go?

MR. MCCONAGHY: -- about three or four different things at the same time but let me just ask y'all from your point of view, all of that discussion on the box, do you have a number in mind or is there any reason to even put a number on it at all? I mean, that's --

MR. STEPHENS: I vote for that.

MS. HUNTER: Me too.

MR. MCCONAGHY: Is there some reason from the Board side that we would want to put a number on how many you can have?

DR. MARTIN: I think Susan has identified some verbiage in the existing federal document that we might want to consider.

DR. ALVERSON: Right, and I was going to bring it up today. I know we wouldn't vote on it today because we didn't publish that we were going to discuss it but I would like to propose that we follow federal guidelines. It's in the State operator's manual appendix PP, I think, A-425 if I'm not mistaken.

MR. MCCONAGHY: Yeah, that's it.

DR. ALVERSON: That's it.

MR. DARBY: What is the federal guideline?

DR. ALVERSON: But it says that they give no limit. What they say is that the pharmacist in cooperation with the medical director and the director of nursing, those three at a minimum must determine what medications are appropriate for that facility.

There's a difference between a hospice and what you need and long-term care and so that's to be determined by at least those three people. They suggest that it not be a quantity which becomes its own pharmacy. It should be an emergency stock, not enough to fill prescriptions and that it should be reviewed annually to see if it's still appropriate.

MR. DARBY: Reviewed by those same three people?

DR. ALVERSON: Yes, by those same three people.

DR. MARTIN: Whoever is in those positions at that time.

DR. ALVERSON: Whoever is in those positions. Now, the pharmacist is to take the lead on that. It also then specifies that it has to be locked, how it has to be stored, that you have to have a list of all medications inside that are -- is attached to the outside. You must have the expiration date of the first drug inside -- the expiration date of the first thing to expire, so it -- it goes into some of

that detail. It also says you may have a true emergency kit, something that you would use for pulmonary edema or heart attack, those kind of --

MR. STEPHENS: Right.

DR. ALVERSON: -- you know, start an IV, and that can be separate from -- some people call it a stat box or what you need just to cover until you can get the medication from the pharmacy with general meds and it also allows for there to be a kit on each nursing unit which is a big -- our law -- the Board of Pharmacy law limits you to one kit per facility, which, you know, if you're on the bottom floor and you've got to run up to the fourth floor or -- it's very inconvenient at times to have to run to find where the kit is.

MR. MCCONAGHY: Has that got to be confined to a box or could that develop into a room?

DR. ALVERSON: It could be in a locked cabinet. As I remember, it's not a room. It has to be a confined, locked space -- container.

MR. STEPHENS: Our law uses a cabinet.

DR. ALVERSON: Pardon?

MR. STEPHENS: I think our law uses cabinet is the word.

DR. ALVERSON: Cabinet, right. But it's such that every time you go into it, there's a way to record the fact like by breaking off the lock and putting on a lock with the new number, you actually have to record the number on the lock or there needs to be some way that someone couldn't go into that kit, enter it, take something out, and nobody would know that it had been entered, and that's in federal regulation.

MR. MCCONAGHY: Well, just for the enforcement side of it, Henry and Richard, you know, can you see something that that would be a problem for you when you're going in there that you're looking for a larger quantity of things, they have a larger quantity of things, but they should have it all laid out on a list.

MR. LAMBRUSCHI: It would all still be

part of the pharmacy inventory so we would have access to that.

MR. CONRADI: Do y'all go into nursing homes?

MR. LAMBRUSCHI: Those that have pharmacies.

MR. CONRADI: What if they don't have pharmacies, they're just doing what Rick and them do, they're delivering it out of a stat box, you don't go into those, do you?

MR. LAMBRUSCHI: No, sir.

MR. BURKS: No.

MR. LAMBRUSCHI: Now, the only time that we might go into something like that is if it's again part of an inventory supplied by an outside facility. I mean, I periodically will check ambulances for their narcotic boxes that's supplied by a local hospital.

DR. MARTIN: How do you know to do that?

MR. LAMBRUSCHI: I ask the pharmacy if they supply the local ambulance service with the meds and they typically do Valium, and what is

it, epinephrine, two or three things.

DR. MARTIN: Some of them do morphine.

MR. LAMBRUSCHI: Morphine.

DR. MARTIN: So then you go to the ambulance company to confirm?

MR. LAMBRUSCHI: Typically I go to the emergency room and if there's two ambulances there, I check with the two ambulances, and believe me, word gets around within two minutes, they're checking boxes.

DR. MARTIN: That's good to know. So that's a preview of what's going to happen next month --

MR. STEPHENS: Okay.

DR. MARTIN: -- on Wednesday afternoon.

DR. ALVERSON: Would you like me to prepare a regulation that reflects federal regulations?

DR. MARTIN: Yes.

DR. ALVERSON: Because it would be a lot easier if you weren't having to balance two laws.

DR. MARTIN: Yeah, yeah.

DR. ALVERSON: The other thing that's made a difference is it's been a couple of years now but they've added to the regulations that a resident may not go without their medication for any real period of time, so just because you admit somebody later in the day and maybe the pharmacy is even closed, you may not say, well, we'll get your medication in the morning. That is unacceptable.

MR. STEPHENS: Susan, on the -- particularly I guess the noncontrolled and this is based on discussions I had with the fellow that was at the Public Health Department, Rick Harris, who is retired now but narcotic kits or emergency kits as the Board of Public Health terms it, you can have multiples of those. Stat boxes, noncontrolled is confined to one. Now, our -- it is stated in our law but it also states in our rule that to have more than one, you petition the Board of Public Health, not the Board of Pharmacy, and the Board of Public Health has that in their rules as well. So I'm

just saying we've got to coordinate a little bit there.

DR. ALVERSON: Well, you know, that's interesting because at one time you had to petition the Board of Pharmacy because I remember Jerry Moore saying he always denied those petitions unless you had to go outside.

MR. STEPHENS: And Rick Harris told me he always denied those petitions.

MR. CONRADI: At least we're consistent.

MR. STEPHENS: So I don't know who's doing the denying but.

DR. MARTIN: At least we know nobody did anything.

MR. STEPHENS: Right.

DR. ALVERSON: There was actually a committee for it 15 years ago to look at changing that and I don't know if we have records of it but the committee wrote new regulations about that.

DR. MARTIN: And were the regulations adopted?

DR. ALVERSON: We just got a call from the Board of Pharmacy saying it got to Montgomery and they decided it was -- would give nurses too much leeway somehow and so it wasn't -- they didn't push it.

MR. MCCONAGHY: That was my next thing. When you're drawing up those things and on the automated stuff too, we need to define, I think, where that drug still belongs to the pharmacy and when it no longer belongs to the pharmacy or to the patient or the nursing home or whoever it's going to.

DR. ALVERSON: The regulations say it belongs to the pharmacy and I brought the DEA regulation with me this morning, which says it belongs to the pharmacy.

MR. MCCONAGHY: So in that case, if it belonged to the pharmacy, then if Richard wanted to go in there and look at that, he would have the jurisdiction to go in there and check a box --

DR. ALVERSON: Yes.

MR. MCCONAGHY: -- or whatever if he

felt the need to.

DR. MARTIN: Yeah.

MR. MCCONAGHY: I know the nurses are going to patrol your box anyway. They're not going to let you have anything out of date in there.

DR. ALVERSON: Right.

DR. MARTIN: Well, this is -- this is good discussion and to have been a work session we didn't have an agenda for, I think we've covered some really hot topics and especially those that are going to come up next month, this is a nice icebreaker to get ready for that.

I'm going to ask that we discontinue the work session. It's about seven or eight minutes to 9:00. We need to start promptly at nine o'clock so we'll have about a five-minute break between now and the nine o'clock session.

Thank you so much for being here.

(Whereupon, the hearing was adjourned at 8:52 a.m.)

CERTIFICATE

STATE OF ALABAMA
SHELBY COUNTY

I, Sheri G. Connelly, RPR, Certified Court Reporter, hereby certify that the above and foregoing hearing was taken down by me in stenotype and the questions, answers, and statements thereto were transcribed by means of computer-aided transcription and that the foregoing represents a true and correct transcript of the said hearing.

I further certify that I am neither of counsel, nor of kin to the parties to the action, nor am I in anywise interested in the result of said cause.

/s/ Sheri G. Connelly
SHERI G. CONNELLY, RPR
ACCR No. 439, Expires 9/30/2014

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