ALABAMA STATE BOARD OF PHARMACY

WORK SESSION

Wednesday, October 15, 2014

8:12 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:

Ronda Lacey

Rick Stephens

Dane Yarbrough

Jeff Freeze

Al Carter

Tammie Koelz

Matthew Muscato

Paul Rengering

Nancy James

Louise Jones

Tracy Davis

Gary Mount

Lindsay Leon

Clemice Hurst

Kelli Newman

Jim Easter

Julie Hunter

Sally Sims

April Marlin

Carly Rhodes

Pamela Jubach

Anita Pritchett

Jeanna Boothe

Chris Burgess

Melanie Smith

Scotty Armstead

Wendy Sprayberry

Leslie Payne

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MR. CONRADI: Welcome to the October work session. It looks like --

DR. MARTIN: Is it October? It is already October?

MR. CONRADI: I hope it is.

MR. BUNCH: There's a rumor to that effect.

MR. CONRADI: Sorry we're late getting started. We're waiting on Dan to get back in, since it looks like most of you are here for the automatic dispensing and Dan is here early so we're happy for that.

Before we get started, I'd like to start on the front row. If y'all would, stand up, talk loud enough for Ms. Sheri to hear you so we can get a count of who's in here and who you represent.

MS. LACEY: Ronda Lacey, McWhorter School of Pharmacy.

MR. STEPHENS: Rick Stephens, Senior Care Pharmacy.

MR. YARBROUGH: Dane Yarbrough, Turenne PharMedCo.

MR. FREEZE: Jeff Freeze, Turenne PharMedCo.

MR. CARTER: Al Carter with Walgreens.

MS. KOELZ: Tammie Koelz, Walgreens.

MR. MUSCATO: Matthew Muscato,

Walgreens.

MR. RENGERING: Paul Rengering, Walgreens Pharmacy.

MS. JAMES: Nancy James, PharMerica.

MS. JONES: Louise Jones, Alabama Pharmacy Association.

MS. DAVIS: Tracy Davis, Alabama Pharmacy Association.

MR. MOUNT: Gary Mount, Baptist Health Montgomery.

MS. LEON: Lindsay Leon, I'm a P4 student that's rotating with Medicaid.

MR. CONRADI: We're sorry.

MS. HURST: Clemice Hurst, Alabama Medicaid.

MS. NEWMAN: Kelli Newman, Alabama Medicaid.

MR. EASTER: Jim Easter, Baptist Health System.

MS. HUNTER: Julie Hunter, Omnicare.

MS. SIMS: Sally Sims, Baptist Health System here in Birmingham.

MR. MARLIN: April Marlin, Baptist

Health System.

MS. RHODES: Carly Rhodes, P4 rotating with Baptist Health System.

MS. JUBACH: Pamela Jubach, P4 rotating with Baptist Health System.

MS. PRITCHETT: Anita Pritchett, Southern Pharmaceutical Services.

MR. CONRADI: All right. We'll get started. I'm going to just quickly just punt the ball to Dan and -- to --

MR. MCCONAGHY: I don't know why he's doing that.

MR. CONRADI: Well, I think most -- how many people here want to talk about auto -- we don't have a subject today but want to talk about automatic dispensing systems?

MR. MCCONAGHY: First thing I was wanting to -- yeah, we're going to talk about that for sure but Jim Easter had brought something up in the last one to discuss that I don't think will be a big long discussion but we need to see if we can't clarify some stuff or get Eddie started on clarifying. Where did Jim

go?

MR. EASTER: The question was about three meetings ago, Tim called upon Inspector Lambruschi, who was at the back of the room, to talk a little bit about some inspections and how they were going. At that point he discussed being at facilities that supply ambulances and that we would go to the portico where ambulances arrived and check on the system of supply and kits and so forth and I just wanted to hear a little bit about what the Board or the inspectors were looking for in those cases.

When we sign our renewals, which are coming up this month or next, we sign on there that we're going to be responsible for them but Alabama Board of Health is less than direct in what they expect from us and I was just wondering if the inspectors were inspecting -- seeing what we could learn from what you've seen already.

DR. MARTIN: Yeah.

MR. BRADEN: Richard has interest in that because Richard has background in emergency

medical services so he -- he does that and he is probably the only one that actually does that. If it's outside the pharmacy facility, it's just like at the nurse's stations, we don't go and normally look at those. We primarily deal with the inspection within the pharmacy. Richard does have an interest in that and I'm sure that's why he does that.

MR. EASTER: And if Richard rotated to my area, and I know y'all do move around, do we have any idea what we're looking for or what somebody with his experience as a paramedic so that I might learn better to be prepared?

DR. MARTIN: I think we'll get that -- get something together along that but as far as, you know, what they're generally going to be looking for, it's going to be on your side on the hospital side how you're doing it and your recordkeeping and that kind of stuff.

MR. EASTER: Right.

DR. MARTIN: But I don't think there is anything written up as to what would be expected there. He's probably just trying to

assist them and make sure they're doing it correctly so.

MR. EASTER: I think we're fully compliant doing everything that you do down in Chatom, Dan, so I appreciate it. Thank you.

MR. BRADEN: Yes, sir.

MR. MCCONAGHY: And the next item that we've got on is -- I know most everybody wants to talk about with the nursing home and I have something on my computer here I'm trying to get up now that I haven't even read yet. So Tim, have you looked at that or any of the --

DR. MARTIN: No, I'm about the same point you are, Dan.

MR. MCCONAGHY: Do you want to open it up to discussion and Louise just kind of tell the process and what we've been through so far and who was with you on that?

DR. MARTIN: Yeah, yeah.

MS. JONES: Absolutely. We had a meeting here at the Board office at the Board's invitation on August 20 of interested parties who had a stake in the game so to speak for

automated dispensing in skilled nursing facilities and at that time, the Board, after hearing some of the discussion, asked that the group get together and consolidate thoughts and come up with a recommendation and an overview of what the desires were of the profession and present it to the Board.

And so Monday evening I -- oh, and during the process I worked with some of the pharmacists who volunteered their time, very appreciative of that, and also emails from the group. We've gone through a draft and comments came back. We've worked through those comments and then made adjustments based on those, some telephone calls.

So there's been a lot of interaction within the group and have come up with -- the cover letter I sent you outlines the three different approaches that I heard that vary distinctly from each other in how different groups would like to use this technology in skilled nursing facilities, the first being you have people that want to utilize it for

emergency, and I use that term loosely, but emergency medications, meaning could be first dose, immediate need, after hours, those things that are typically being used now with a stat box and if I state anything wrong, y'all please correct me, but mainly for those emergency need cases only.

The second approach I heard was basically the same technology, just more utilization of it where it's used for all doses and not strictly emergency cases. And the third approach I heard varied from the first two in that it wants to use it for all doses and it wants to use the machine and the technology on site at the skilled nursing facility and the packaging of the medications would be done there, not under the direct supervision of a pharmacist.

The first two would happen at the managing pharmacy and not away from that and then the third approach happens at the skilled nursing facility by the machine. So those are the three distinct ideas, approaches that kind

of came from the interested parties that were here at that meeting on the 20th.

So I've summarized those for you in the letter and then I went on to a second step to simply say where the numbers kind of fell out. Almost every group that I spoke with is interested in doing approach one.

DR. MARTIN: At least putting emergency meds through the process.

MS. JONES: That's correct. The second approach, I know I have at least one member that's interested in doing that, and I use the term at least because I don't know exactly everybody -- I don't think everybody that's interested in this may have been in attendance at that meeting, I don't know for sure, but that's what I heard at least from the discussion from the people that were there.

And then there is another group that's interested in doing approach three. Now, the groups that fall into one and two just for -- to make it easier to talk about are opposed to approach three because they feel like it needs

to happen, and I can let them tell you that during the discussion, but what I heard from them at least was they had safety concerns. They had quality concerns. They spoke from experience of seeing pills crushed in the technology, errors being made in how it's loaded at some point because you have humans involved, and so leaving all of that outside of a pharmacy on the packaging component they were not comfortable with.

So that's kind of how the different approaches shape up and then where the votes lie for -- and that's a very vague term but just where people kind of settle in on their comfort level is that you're going to see the majority of the comfort level falling in towards approach one. You're going to see a little bit of comfort level on approach two and you see very little comfort level from the masses within that group on approach three.

So that was kind of what I conveyed to you in the cover letter. I attached a draft that we had compiled and I had great intentions

of -- in my copy, actually the way it shows up on my computer and the way it prints for me, has the highlighted and the comments out in the bubbles and all of that. For some reason, I've heard from some of the group that when they pull it up, and I don't know how it shows up for you, the highlights and the bubbles don't show up. So I can get that to you again where hopefully it will show up, even if I have to do it in a printed copy. But what that does show is it shows the differences that would happen with this rule depending on which approach you went with. So if you went with approach one, it shows you what would happen -- this entire thing would happen and then if you go with approach two, some words are removed. If you go with approach three, further words are removed.

MR. CONRADI: Good explanation.

MS. JONES: Thank you.

DR. MARTIN: So this is spinning off of a statute that went through and do y'all -- do y'all know offhand what the statute of citation is? I want to look at it before we --

MS. JONES: I don't know if y'all's printed out or if you can even see it but this is the one with the bubbles and the comments. I don't know who needs that. Do you need it?

MR. CONRADI: Dan may.

DR. MARTIN: Yeah, Dan will be in.

MR. MCCONAGHY: Mine shows already.

MS. JONES: Yours shows, okay.

MR. MCCONAGHY: Give it to David.

DR. MARTIN: Does that cite the -- does that cite the statute?

MR. DARBY: No.

MR. MCCONAGHY: No, that's just the printed out part of it. Now, which part are you talking about where we talked about opening up the meds?

DR. MARTIN: I'm talking about the original -- it's 34 -- 34-23 something -- I can't remember the something.

MR. MCCONAGHY: Oh, yeah.

MR. CONRADI: Do one of y'all -- one of y'all three at the meeting, Rick and Dane?

MR. YARBROUGH: Yes, sir.

MR. CONRADI: What's y'all's feeling on the options?

MR. YARBROUGH: I represent Turenne PharMedCo obviously and we have packaging technology inside our pharmacy today and from my experience, if you don't have a pharmacist involved in the packaging and the labeling of those medications that come out of the machines -- when I say -- I mean direct involvement, physically there, it's very concerning. And so I know Turenne PharMedCo is 100 percent in support of option one and that's using it for emergency situations only and we are totally opposed to option three where the packaging is done on site at the nursing home.

DR. MARTIN: Talk to us a little bit more about the phrase that I -- there's a whole spectrum of technology out there that does different things. Talk to us a little bit more about what's meant when it's -- when it's packaging on site. Does that mean that there's a packaging mechanism built into the dispensing cabinet?

MR. FREEZE: That's correct.
MR. YARBROUGH: Yes, sir, it's where medications are generally kept in containers where there's technology that -- it's a vending machine -- the pills through chutes and ladders if you will --
DR. MARTIN: Yeah.
MR. YARBROUGH: -- end up in a location and this is a --
DR. MARTIN: Yeah, so I'll date myself when I say this but it's something that in the past we can an ATC 212 -- a Baxter ATC 212. Is that --
MR. FREEZE: This is multidose instead of single dose, I don't know, did you do single dose?
DR. MARTIN: You could do either one.
MR. FREEZE: Either way, the same.
DR. MARTIN: Yeah.
MR. CONRADI: The machine does that?
DR. MARTIN: Yeah.
MR. YARBROUGH: Yes, sir and in option -- in option three, which is the option

that we are opposed to, does something very similar to that on site in the nursing home without a pharmacist present.

MR. CONRADI: But the machine don't do it, it's a whole another machine that would package it?

MR. YARBROUGH: There's a machine that does that.

MR. CONRADI: Right, it's not located in the cabinet though.

MR. FREEZE: It's integrated.

MR. YARBROUGH: Yes, sir.

DR. MARTIN: It's in the cabinet. If all the cabinet -- if I understand -- if I understand it and I don't mean to be spending so much time on something that sounds like there's not a lot of support for but just so we'll understand, it sounds like it is a cabinet that is loaded with bulk containers.

MR. FREEZE: Correct.

DR. MARTIN: And then it is fed software -- it is fed information digitally and it says, okay, patient Conradi needs this and

this and this and it drops one of these, one of these, one of these, and it puts it in there and I think it has the potential to label it with that individual patient-specific name.

MR. FREEZE: It does.

DR. MARTIN: Yeah.

MR. FREEZE: Yes, sir.

MR. DARBY: How many states that y'all are aware use option two?

MR. FREEZE: I don't -- option two from my perspective, I'm not aware. I just don't know.

DR. MARTIN: So option two as -- I'm sorry, you've got --

MR. DARBY: No, Scotty.

MR. ARMSTEAD: Scotty Armstead. David, I believe that at least if you went on Louise's scale to say at least two is an option, it's in the neighborhood of at least 30 or something, I believe, in the country that at least allow that or maybe into three if you look at the far end of it.

MR. CONRADI: What part of this, Jeff,

on option three do y'all not like?

MR. FREEZE: The fact of where it's -- where it's happening, where the packaging is happening, and not having the pharmacist -- the integrity of what -- the pharmacist's involvement in --

MR. CONRADI: Checking it and making sure.

MR. FREEZE: -- in checking that and insuring that it's accurate. We have a machine like that in our pharmacy today. It is not perfect. It's very good but it's not perfect. It can leave pills out of the pouch. It can double them up. It can -- in the -- in the transformation or in the transfer of it going from that bulk container to that pouch can get broken. There's just some pretty big concerns not to have a pharmacist physically there inspecting the packages and making sure that they're accurate.

MR. STEPHENS: I think there's a lot of companies that have packaging like that that do it in the pharmacy, Jeff. We do, several

others, but we all have a pharmacist check on that package before it goes out.

MR. FREEZE: That's right.

MR. STEPHENS: And --

MR. CONRADI: How would the machine get bulk material in it -- a technician would come in and fill it up? That's another step for error.

MR. FREEZE: I suspect.

MR. YARBROUGH: We had that listed out in the actual -- if you read the options, I think we even say that it's a tech or I forget how we had that spelled out.

MS. JAMES: The licensed personnel.

MR. YARBROUGH: The licensed personnel that would help to place those canisters into the machine.

Another thing that we did -- we came to the agreement on this packaging is we kind of polled our pharmacists internally and said, if you had this ability remotely to send this package out with your initials on it and you're ultimately responsible, could you in good faith

conscience allow that to happen and let that go as the final check and we didn't have any pharmacists that weren't like I couldn't let that happen. While it's very good and probably 99.9 percent accurate, that .1 percent when you're filling as many prescriptions as we do, it's unacceptable and that's where we just don't have the comfort level today to let that go without that final check. Bottom line, that's where we came to our genesis on what we have.

MR. FREEZE: That's right.

MR. BUNCH: That's real good information. You guys are the ones out there doing that every day.

MR. YARBROUGH: Well, and there's a lot of us in the room that have this technology. Scott has it in his operation too in-house but to make it remote, we just don't feel comfortable with where we are here today to let that just go willy-nilly with my initials on it without that final check with my eyes.

MR. BUNCH: And you'd be more in favor -- in favor of just -- just doing the

emergency meds too as opposed to --

MR. YARBROUGH: I could speak to that too, Buddy. Dane Yarbrough, Turenne PharMedCo.

We're not strongly opposed to option two. We think that we need to table that for a later date. Really option one and option two are really one and the same. We just feel that we want to use it now just for first-fill emergency use, get the policies and procedures wrapped around it, make sure we vet it and it's right and it's in place and it works and we would hope that the Board would -- down the road would let us come to you as a group and say, we feel comfortable doing that now --

MR. BUNCH: Start out slow.

MR. YARBROUGH: -- could we consider using this as on ongoing maintenance therapy application. We can't really get our head around that part yet. All we can really get our head around now is the first part, so we feel more comfortable with option one today. Maybe down the road we can come back to you and talk about option two, which is that maintenance use

of that technology, but we're pretty firmly against, again Turenne PharMedCo, we're against option three. We just don't feel comfortable.

DR. MARTIN: So Jim, let me say one thing and I'll come back to you. I don't mean to be taking over your meeting here.

MR. CONRADI: It's a work session. It's wipe open -- wild wild west. That's when we let the audience participate.

DR. MARTIN: So under option one, there would be a patient profile. The patient profile --

MR. YARBROUGH: Yes.

DR. MARTIN: -- would have been updated to reflect the physician orders and the drugs that were stocked in the automated dispensing cabinet would only be emergency drugs and those drugs that were thought to be commonly needed as first doses of new orders?

MR. YARBROUGH: That's our intent, correct.

DR. MARTIN: And the difference in option one and option two is that in addition to

everything that it does by option one, also stocked in the automated dispensing cabinet would be an array of additional medications that should -- should the physician order the drug and the drug be placed in the profile by the pharmacist, the machinery would allow the nurse to access that drug.

MR. YARBROUGH: Correct.

DR. MARTIN: Okay.

MR. FREEZE: For every medication.

DR. MARTIN: For every medication that's in there. Of course there will be some you can't stock everything.

MR. FREEZE: That's right.

DR. MARTIN: There will be some that you would have to fulfill in some other manner and then, you know, it would run out and you know, you'd have to service it like a vending machine, you know, regularly. Is that the right picture?

MR. YARBROUGH: I would say so.

MR. STEPHENS: I think basically, yeah.

DR. MARTIN: I think Jim was chomping to say something over here.

MR. EASTER: Jim Easter, Baptist Health System, and because some of this crosses into the institutional side where we've used unit based cabinets for a long time.

Dr. Conradi asked about how this material gets into the cabinet. The ATC 212 that Tim and I came up through the system with would require about an hour's worth of downtime every day to clean the chutes and everything else and in the technology that most of us have moved to -- Pyxis, Omnicell and so forth -- we all use barcode scanning as a safety device. So if you want to open up any one of the CUBIEs that we use, you have to scan the CUBIE or go on the screen and then scan the product that you're going to put in there, which significantly increases the safety for our patients, so thank you.

MR. YARBROUGH: And that is the technology that we're looking at today is more like you've got. I think the one you alluded to

first was more that option three and he's right, there is a downtime maintenance that has to occur every day to make sure that it drops the right tablets but the ones we're talking about are very similar to what you are currently -- you had just mentioned.

DR. MARTIN: Under option -- just to be clear of that, under option one when the dose is (indicating quotes) dispensed from the cabinet, it is not patient specific.

FEMALE ATTENDEE: Yes, it is.

DR. MARTIN: It can be patient specific so all the -- it's hard to say this because we don't know what all the technology is but we're assuming that all the technology that's currently being considered has the capability of packaging the dose patient specific for that emergency dose.

MR. STEPHENS: No, the only -- the patient-specific part would be the patient's information would be integral to the system. It would pick it up from the MAR and the -- the eMAR, the pharmacy system.

DR. MARTIN: Right, so -- go ahead.
MR. STEPHENS: And that patient information would be input that we need a dose of this medication --
DR. MARTIN: Yeah.
MR. STEPHENS: -- for that patient.
DR. MARTIN: Yeah.
MR. STEPHENS: It doesn't come out packaged with anything that has that patient's name on it.
DR. MARTIN: Right, right. And so it comes out like perhaps as a unit dose of --
MR. YARBROUGH: That's correct.
DR. MARTIN: But not patient specific.
MR. FREEZE: That's correct.
DR. MARTIN: Not with an overwrap and I guess two comments there and maybe I shouldn't even be commenting because I wasn't part of the group but in other environments that there are a couple of concerns when that happens and one concern is that at least in the hospital setting, if the -- if the person, usually a nurse I guess, goes to the machine and all of

that other stuff has happened and it's proper and it drops the dose, then that dose needs to go -- that dose and any other doses for that patient need to then -- then the process stops, you go and you administer those doses. If you dispense doses for multiple patients, they have to be identified through baggies or boxes or something as belonging to that patient to prevent medication errors.

The second piece, and Dane, I think you were kind of getting toward this in a minute is the optimal system is when all of that happens and you scan it at the bedside and you're confirming against the MAR that that dose -- even if you did screw it up, it's going to get caught.

MR. YARBROUGH: That's right.

DR. MARTIN: Still if it's a facility that's looking at -- if it's a Joint Commission accredited facility, they're going to insist that there only be one patient's meds handled at one time.

MR. YARBROUGH: And that kind of fits

into what our -- our concern was about option two. We just didn't know when it's for multiple patients at multiple times --

DR. MARTIN: Yeah.

MR. YARBROUGH: -- the processes associated with that. In time, if we can educate ourselves to know -- when we feel better, I'm okay with it, but we just don't -- right now, it's kind of a one dose, one patient, one time, one administration for that moment at that time and not setting up a med pass.

DR. MARTIN: Yeah.

MR. FREEZE: It's basically taking the tackle box -- the emergency box today --

MR. YARBROUGH: That's right.

MR. FREEZE: -- and ramping that up to an electronic version that's much more, you know, where documents who access the medications over time --

MR. STEPHENS: More accountability there.

MR. FREEZE: -- where the meds were accessed and so forth whereas in today's system,

the manual systems with the tackle box, you would hope that someone has documented something properly on a piece of paper.

MR. DARBY: If I read the rule right now, a technician can fill the machine. Are y'all comfortable with that?

MR. FREEZE: We at Turenne PharMedCo are. We feel that that -- if they're under the auspices of us, we'll train them and we have accountability measures to make sure that there's some kind of check and balance in place.

MR. DARBY: Is there like bar scan capability there?

MR. YARBROUGH: Yes, yes.

MR. FREEZE: Yes, in fact we've already -- the technology that we're going to use won't allow you to put it in the wrong spot. It's not just going to barcode barcode and let you put it in the wrong place.

DR. MARTIN: It's like a lock that you --

MR. FREEZE: That's right. That's

right. There's technology that says, this can only go in this location.

MR. YARBROUGH: And we feel comfortable with that and we can let our techs do that.

MR. CONRADI: That doesn't mean everybody is going to use that technology; right?

MS. JONES: Right, but in the rule language, you'll see under that restocking note that I can tell you, it says that these are the people that can do it if the automated system utilizes technology to insure accurate restock and reloading. So in other words, when they present it to you for approval -- we kind of envision two different approvals by the Board. The first being for the technology itself, the machine, the system, whatever you want to term it, so either the companies that produce those products or the facilities that want to use them, the pharmacies or whoever, can bring that to the Board and get that technology approved. So that's kind of the first step, so that

technology has to be approved by you, how it works.

The second step would be an approval request from a pharmacy who wants to use approved technology and in that process of them applying to you saying, okay, you've approved this technology, we want to use it at this facility and here are our written policies and procedures of how we're going to use that technology and you need to approve those.

DR. MARTIN: It's a little bit -- I understand, it's very methodical. It's very laid out. It's safe and -- but it has not to this point been the interest of the Board to approve a particular technology one over the other but rather to put out, you've got to meet this standard and this standard and this standard and this standard and if you do, you're good to go. If you don't --

MS. JONES: And we're fine with that, however the Board wants to use it. Our thought in doing that was that once you've approved, you know, this widget --

DR. MARTIN: Right.

MS. JONES: -- you don't have to reapprove it every time.

DR. MARTIN: Right.

MS. JONES: And every pharmacy that wants to use that that's already been put in and approved for this place, they are already a step ahead and they can say, well, you've already approved this technology, we want to use that and this is how we want to use it.

DR. MARTIN: Well, I think one of the reasons -- one of the reasons we would -- I don't want to presumably speak for the other members of the Board but one of the reasons I would be reluctant to endorse a technology is because the technology may be used in one configuration in Dane's environment and it could be used in a completely different configuration in Rick's environment, which would pretty much say you've got to bring it back to the Board for every time you change configurations.

MS. JONES: Yeah, yeah. We're fine with however you want to approach that.

MR. YARBROUGH: That's right.

MR. DARBY: And also the number of quantity of medical centers could be unlimited. I mean, it would be up to the facility and the pharmacy to determine.

MR. CONRADI: How deep their pockets are.

DR. MARTIN: Well, I think -- I think that we put the caveat in there or I don't know if it's something that's been discussed here or if it's something that's in there that says there has to be a formulary and it has to be approved by a medical director.

MR. YARBROUGH: Yes.

DR. MARTIN: So there is some oversight to --

MR. FREEZE: That's in there. That's in the draft.

MR. YARBROUGH: We would want a formulary.

MR. DARBY: So y'all will still own the medicine until it's dispensed?

MR. YARBROUGH: Correct.

MR. FREEZE: Correct, it's an extension of our pharmacy is what it is.

MR. DARBY: Yeah.

MR. MCCONAGHY: Did you look at any of the -- if there were any current regulations or laws that this would affect, any of these processes -- any three processes, labeling laws, or -- that's right in effect? Are we going to have to change something else? I know that's our job but I was just curious if y'all looked at it, it would be handy to know that.

MR. FREEZE: We tried to be conscious of that but obviously, you know, we would need the Board to make sure that that doesn't conflict with something that's already standing, so we tried to be conscious of that.

MR. YARBROUGH: That's right. We were going back and forth with definitions trying to make sure to --

MS. JONES: Yeah, we did have one note in -- let's see where it is -- number eight under the general requirement says, "Nothing in this rule shall be interpreted to amend, alter,

or modify the provisions of Alabama Code Section 34 Chapter 23 or supporting regulations," meaning the rules and there may be better wording for that but our intent is not supercede obviously anything else. I'm not aware of anything that this conflicts with but it doesn't mean that Jim Ward's eyes certainly don't need to be on it. I don't know.

MR. MCCONAGHY: You did put in there somewhere we can't prescribe, didn't you?

MS. JONES: No.

MR. STEPHENS: Along with this, and I know it was discussed earlier but the -- the rules that we're talking about here are for the automated statute, a single statute, so they would be outside of the institutional rule but would -- would it be the will of the Board to make those rules more compatible, more similar when an automated -- automation rule comes about, there's no real limitation other than the medical director, DON, pharmacy, that same would apply under the institutional rule for manual systems as they have today.

DR. MARTIN: You know, I think, Rick, you bring up a very good point and again, I'm one out of five of these guys up here and I would think that the direction -- the direction I would support would be, one, to address automation in both environments. So you're talking about automated technology in the institutional environment and we would have a multitude of guidelines out there we can go by to say, it can do this, it can't do that, if it does this, it's got to have this safety net or whatever. I don't know if that's how it starts. I don't know if it morphs into that. I mean -- I'm trying to take the position a bit of an outsider. I mean, I know a considerable amount about the technology and its application but I don't know the application particularly in that environment. So I can express opinions about how we use it and maybe how I think it ought to be used but I'm trying to be -- I'm trying to not make my statements about how it works in a hospital, particularly apply to a nursing -- a skilled nursing facility. I need to hear what

the needs are there before I jump in and make some kind of conclusion.

MR. STEPHENS: Well, I just don't anticipate, at least our pharmacy throughout all of our facilities putting automated systems in, so what I was trying to I guess advocate is that the rules speak somewhat similar, particularly as it relates to pharmacy across manual systems as they are now and automated systems as you may develop rules for them.

MR. MCCONAGHY: Yeah, I had always thought that it should be more about the process -- the process if you can, no matter what the technology is, if the process is good and safe and the end user too. I mean, who's going to be getting this out of there. If it's in your pharmacy and it's the technology is one thing but if you put it out in a nursing home or in a hospital and you've got somebody totally different that's going to be getting it out, it may require a different level of sophistication or rule on that part but yeah, I'm with you on kind of having technology and one deal in the

process than the other so.

MR. CONRADI: Dane, how would y'all feel about instead of a regular technician, a certified technician, because I can just see somebody just registering their truck drivers to be -- you know, to be a pharmacy technician and sitting around getting them three hours CE every year and really not know anything about pharmacy to make it safe to fill the machines.

MR. YARBROUGH: We're not opposed to that. I think -- we'd like to have that dialogue if we could.

MR. CONRADI: Yeah. I mean, that's my heartburn is somebody is going to come up and get their truck drivers certified as a tech, you know, registered as a tech, excuse me, Mr. Vice President.

MR. MCCONAGHY: I believe we've had that come up.

MR. CONRADI: Get them registered as a tech and then they're filling up machines, they've never worked in a pharmacy and never plan on working in one and they get them three

hours of CE every year. I mean, that's my heartburn is that's a pretty critical point, filling that machine, and if they've never worked in a pharmacy -- I'm not saying somebody certified would necessarily work the pharmacy but I would hope somebody that is certified would have worked in a pharmacy.

DR. MARTIN: I would put that back -- I'm going to disagree with you a little bit.

MR. CONRADI: What's new?

DR. MARTIN: What's new, that's right. Like I told -- like I told the group yesterday, I've been known to have opinions and I've been known to disagree with them. I think we have to put a lot of that back on the supervisor and the supervisor has documented competency of people that's performing the job and if there's something that's not going right, that's -- that's the person we have main recourse for.

MR. STEPHENS: Many of the systems will have the stocking -- restocking mechanism is done by a container of some sort. It might be a CUBIE as one company calls it. Another

company may call it something else and I think that's where you want the technology -- the match-up to be. That container will be filled and checked at the pharmacy and so there will -- there will not be individual drugs I don't think being placed in anything under most of the technology I've seen at the site but there will be containers that contain drugs and it's how -- it's how that part of the checks and balances work.

DR. MARTIN: I think that likely the technology that's used in acute care has probably been -- and there is an opportunity for things to be put in wrong bins and stuff like that and so that's why you want -- you want that last person standing by the bedside.

MR. CONRADI: About three minutes left.

MR. DARBY: All right. This rule addresses the automatic dispensing systems but Dane, I think you made a comment not all facilities are going to -- you're not going to -- unless they have got money to be in every

facility. So it doesn't do anything to address the 50 drug quantity limit on the --

MR. YARBROUGH: It does not.

MR. STEPHENS: I think that's a separate --

MR. YARBROUGH: That is separate and we wanted to really kind of find out where that mark stands too.

DR. MARTIN: I think there's proposed verbiage already somewhere.

MS. JONES: I thought the Board had already voted on that at a meeting a couple of times ago.

MR. MCCONAGHY: Yeah, we were -- we were in agreement on that but decided to wait until hopefully we could push this on along with part of it, so it's never been written up and sent in. I checked with Mitzi yesterday.

MS. JONES: Okay.

MR. MCCONAGHY: And it hasn't been submitted as a -- on anything yet, so.

MS. JONES: But the Board has voted to do that, it's just the mechanism of how you are

going to do it has not been decided.

MR. MCCONAGHY: Yes.

DR. MARTIN: We're in agreement --

MS. JONES: We were writing this assuming that that's moving forward either on its own or conjunction or whatever but we -- that's why we put the number of products to be determined by -- we didn't put any limitations in here.

DR. MARTIN: We believe that's a good direction.

MR. CONRADI: We talked to Plano to see if they can get some real big tackle boxes.

MR. MCCONAGHY: And did y'all put any thought into -- I haven't always been real good at the regulatory side of things and trying to think of it in those terms but the way I think of it is almost like compounding versus manufacturing. If you're putting something out there -- nothing is going to be 100 percent. There's going to be a mistake somewhere along the line but some of the systems that could

potentially you put out there could make the same mistake over and over and over without anybody catching it versus ones that you might make one mistake but it gets caught on the next thing. Do you have any -- did we do any kind of data looking or anything like that on those kind of things?

MR. YARBROUGH: I could speak to that. If you look at the rules too, we talked about doing a quality assurance check. We could do reconciliations monthly remotely but we're thinking about going at least quarterly and doing a quality review check and I'll tell you, most of these technologies at least require twice a year preventative maintenance that comes out too for mechanical issues, so I think we're trying to address that, Dan. If we see that it's the same thing going on and on and on, we're going to contact the manufacturer and say, what's the deal. That's if it's mechanical. If it's an internal process, hopefully we'll catch that at least quarterly in a QA when we're there. Am I saying that correctly?

MR. FREEZE: I think so and the technology, I think once the Board looks at, you know, the accuracy of the technology in making sure that -- that when a nurse is pulling a Lasix 20, what she gets is a Lasix 20. I think when you see all the checks and balances just in the technology and the scanning -- barcode scanning and so forth, you'll see that, you know, it makes sense that -- you know, reasonably to say that it's going to be accurate.

MR. MCCONAGHY: That's kind of why I keep going back to the labeling thing and that may be a whole moot to you guys, I don't know, but that's why we wanted y'all to look at it too. If you've got a bin of medication out there and it's being labeled basically on site and you happen to get the wrong one -- medication in that bin, it -- it's going to be making the same mistake over and over is what I'm wondering.

MR. FREEZE: Right.

MR. MCCONAGHY: I understand if

there's check points to stop that kind of thing.

MR. FREEZE: And in option one, what we're suggesting is that labeling, that packaging happens in the pharmacy with the pharmacist with the last check.

MR. CONRADI: We're going to have to cut it off.

DR. MARTIN: I need to say --

MR. CONRADI: One minute.

DR. MARTIN: One minute, okay.

MR. CONRADI: And don't disagree with yourself.

DR. MARTIN: Did y'all discuss downtime?

MR. YARBROUGH: Downtime of the system itself for --

DR. MARTIN: When the system is down, you can't access it.

MR. YARBROUGH: Yes, actually that's addressed a little bit into -- well, two things, Tim. You're talking about downtime as what do you do?

DR. MARTIN: Yes, how does a nurse get

access to the medications they need for a patient.

MR. YARBROUGH: That would be in our policy and procedure I would assume as we would have sent that to you.

DR. MARTIN: Does it give the nurse carte blanche access to everything in the cabinet?

MR. YARBROUGH: It depends on the system that's out there, what you approved. There are some that don't. There's some that essentially if you get into it, I'm trying to think --

MR. FREEZE: I just don't --

DR. MARTIN: I mean, it would be real expensive if you had to keep a redundant system there.

MR. YARBROUGH: Tim, we didn't want to -- I think when we were helping Louise drafting -- we didn't want to get in the weeds on this too much.

DR. MARTIN: Yeah.

MR. YARBROUGH: We felt that a lot of

that would be hashed out on policies and procedures.

DR. MARTIN: Yeah, yeah, yeah.

MR. YARBROUGH: Again, that's a very good point.

DR. MARTIN: The last thing I just wanted to say for the record in case we ever go back and pull these minutes and try to decide what we talked about is we're talking about rules that are to be promulgated pursuant to 34-23-74 section B, so if somebody is trying to find out where all this came from, that's where it is. Thank you.

COURT REPORTER: I need everyone that came in after they introduced to introduce themselves.

MR. CONRADI: Whoever came in and did not introduce yourself, I don't know who came in last, but if y'all would, just stand up and say your name and who you represent.

MS. BOOTHE: Jeanna Boothe with Decatur Morgan Hospital.

MR. BURGESS: Chris Burgess, Heritage

Pharmacy.

MS. SMITH: Melanie Smith, BuzzeoPDMA.

MR. ARMSTEAD: Scotty Armstead, Turenne PharMedCo.

MS. SPRAYBERRY: Wendy Sprayberry, Calhoun Treatment Center.

MS. PAYNE: Leslie Payne, Calhoun Treatment Center.

MR. CONRADI: We'll take a five-minute break and then we'll come back and start our regular board meeting.

(Whereupon, the work session was adjourned at 8:57 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 9/30/2015