ALABAMA STATE BOARD OF PHARMACY

BUSINESS MEETING

Wednesday, February 25, 2015

9:21 a.m.

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

REPORTER: Sheri G. Connelly, RPR

APPEARANCES

BOARD MEMBERS:

Dan McConaghy, President
Tim Martin, Vice President
Buddy Bunch, Treasurer
David Darby, Member
Donna Yeatman, Member

ALSO PRESENT:

Susan Alverson, Executive Secretary
Eddie Braden, Chief Inspector
Steven Wade
Brenda Carlisle
Sue Esleck
Bill Maguire
Roger Bates
Bruce Harris
Cherry Jackson

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MR. MCCONAGHY: Now we will open the

regular business session for the State Board of Pharmacy, February 25, 2015, the public meeting and I lost my agenda there. Do we have -- well, number one we need to adopt the agenda. Has everybody looked over the agenda or got any problems with the way it's laid out there?

MS. YEATMAN: No.

MR. DARBY: I move we adopt the agenda.

MS. YEATMAN: Second.

MR. BUNCH: Second.

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

MR. MCCONAGHY: It is adopted. If we have any presentations.

DR. ALVERSON: Yes, from Brookwood, Mitzi put it on the agenda yesterday.

MR. MCCONAGHY: That's fine. That's good. We'll start with Brookwood.

MR. WADE: Okay. My name is Steven Wade. I'm the director of pharmacy at Brookwood

Medical Center and this didn't make your packets and what I want to do is to present Brookwood's plans for pharmaceuticals to be handled at a freestanding emergency department.

The Alabama Department of Public Health has granted two, as far as I am aware, has granted two facilities in the State of Alabama the right to open freestanding emergency departments. Brookwood is one of those two and one of the -- one of the issues is making sure that on my behalf is that we meet the pharmaceutical regulations and so what I wanted to do is present what our plans are at Brookwood to meet what we feel -- to do what we think will meet the Board of Pharmacy regulations on pharmacy distribution at the freestanding emergency department.

One of the things that we want -- a separate location -- by definition, a freestanding emergency department is part of the facility just like a department -- just like the emergency department is attached to the facility. I think one of the regulations or one

of the rules is that it be within 35 miles of the parent facility. Brookwood plans to open a freestanding emergency department very close to here, right across the street actually practically, and it is a separate, licensed provider-based department of Brookwood Medical Center.

So we intend to request a -- since it is a different physical location, we intend to request an institutional license for that facility and going through the Alabama law or regulations I should say, I've looked at points that are there to make sure that we meet those standards and our freestanding emergency department, or FED, THE pharmacy will be under the supervision of a pharmacist in and control of a registered pharmacist who will be the supervising pharmacist at that facility. The pharmacy will not provide any outpatient services. This is strictly to serve the FED.

The oversight for the FED pharmaceuticals will receive the same oversight and follow the same policies and procedures as

other departments at Brookwood Medical Center, so they'll be in compliance with us. The anticipated hours for the FED pharmacy will be Monday, Wednesday, and Friday from 8:00 until noon and that's anticipated based on the fact that we'll be needing to fill some automated dispensing devices in the FED and also receive orders from prime vendors and from other sources.

We plan to use a Pyxis or automated dispensing devices at the FED. The supervising pharmacist -- one of the places in the regulations say the supervising pharmacist will need to be there 50 percent of the open hours and of course we'll comply with that. The pharmacy access will be restricted to pharmacy access at the FED -- it will be restricted to pharmacy personnel. No technicians will be accessing the FED pharmacy without a pharmacist present -- the pharmacy technicians.

The logistics of it is all pharmaceuticals will be secured, monitored, and controlled in the same manner they do with the

pharmaceuticals at the regular facility. All C-II controlled substances will be received at the FED with a DEA-222 and accountability of the inventories will be the same as it is at other departments of the facility.

We will use automated dispensing devices at the FED and the monitoring and oversight of those automated devices will be the same as it is performed at the main facility. The source of pharmaceuticals will come from a prime vendor or wholesaler as well as in direct orders and from the main facility and the decision of where we will get those will be based on the package sizes that are available and the package labeling because everything will have to be bar coded for administration. All pharmaceutical inventory accountability will be the same as it is at the main facility.

MR. WARD: So it's going to be transfer of drugs from the hospital to you -- to this place?

MR. WADE: To the FED, there will be transfer of drugs from the hospital to there.

MR. WARD: You'll have a separate DEA there?

MR. WADE: We will have -- that's the goal is to get a separate DEA. Anything that's C-II will have to be transferred on 222s on a separate -- with a separate DEA number. And one of the things we want to disclose is that the remote processing -- there will be remote processing of orders. Pharmacists at the main facility will process some orders at the FED and pharmacists at the FED may be processing orders at the main facility and that is to kind of balance out of the workload between the two.

The FED will be on the same computer system as the facility physician ordering. The Pyxis machines -- it happens to be Pyxis machines. There are also some Omnicells used for supplies but the automation will be on the same computer system and monitored through the same process, same oversight. So it's really just like a facility that's attached to the hospital electronically, it just happens to be down here and it is under the authority of the

Alabama Department of Public Health.

So really what I want to do is present to you what as the oversight for pharmacy, how we anticipate meeting your expectations and give you the opportunity before we open because we are just now breaking ground so we have several months before I would actually get an institutional license, pharmacy license, and apply for a DEA. So this is the request for you to oversee our process and concur that we are moving in the right direction.

MR. WARD: Do you also have to get a -- a CON for this?

MS. CARLISLE: We did.

MR. WADE: Two were granted in the state, yes, we did.

MR. WARD: Will you submit that to us as well?

MR. WADE: I have two people with me that will.

MS. ESLECK: We can, yes. We can get you a copy of the certificate of need, not a problem.

MR. WADE: And I unfortunately didn't make your packet but we do have a copy of the rules of the -- Alabama Department of Public Health's rules for freestanding emergency departments and we can provide you with that link.

MS. CARLISLE: Basically it states that we comply with the Alabama State Board of Pharmacy.

DR. MARTIN: Are you going to be the director of both?

MR. WADE: I don't -- if I could I would but right now I have a pharmacy manager who either -- we will either hire a pharmacy manager to be the supervising pharmacist or one of my current pharmacy managers will become a supervising pharmacist. I have -- when it comes to the automation and stuff, while I don't personally do the automation stuff, the person who does the automation stuff will be down there a lot, so they will likely be the supervising pharmacist; however, I will be over -- oversight on everything just like now.

MR. DARBY: That was really my question.

DR. MARTIN: Steve, we knew when the Alabama Department of Public Health passed the rules related to freestanding emergency departments that we sooner or later would have someone wanting to put a pharmacy in one and we would have to cross this bridge. So as far as you know, this is the first FED in Alabama where we have -- where we see a pharmacy in the FED?

MR. WADE: There are two granted in the State of Alabama. One is I think Med West here in Birmingham and I don't know their exact plans but what I tried to do was look at the regulations and design my plans around to meet the regulations and not ask for anything uniquely special.

DR. MARTIN: Okay. Well, we appreciate you cracking the ice and we -- I appreciate you taking the position of coming to the Board ahead of time and laying out your plan and trying to make sure you've got all your bases covered.

MR. WADE: I have talked to a DEA inspector and told him what my plans were and he pointed out that we will have to have a DEA license and we will have to transfer products in and out based on 222s. And just for what it's worth, I said we'll do the same oversight as we do at the facility. We have a perpetual inventory on all controlled substances, not just C-IIs.

MR. WARD: Will you be -- will you be subject to the five-percent transfer rule?

MR. WADE: Based on my interpretation of even Alabama regulations, we are the same facility under the same ownership so that shouldn't apply -- the five percent shouldn't apply to that.

MR. WARD: Maybe not but see we don't know that you're the same facility under the same ownership.

MR. WADE: Well, we are and actually the Public Health Department definition of granting us an FED indicates that it would have to be a part of it. The FED is just like a

department of the facility -- of the parent facility.

MR. WARD: I'm the Board's lawyer, so you've brought me something else I'm going to have to learn. Thank you.

MR. WADE: Probably so. It's the Public Health Department's.

MR. WARD: Who's the owner? Is Affinity the owner?

MS. ESLECK: No, we're Tenet Healthcare is our upline parent company but we're Brookwood Health Services doing business as Brookwood Medical Center.

MR. WARD: Dallas?

MS. ESLECK: Dallas, yes, sir.

DR. ALVERSON: Are there going to be products that will -- that will be there under lock and key other than in the automatic dispensing device?

MR. WADE: Not by plans, not pharmaceuticals.

DR. ALVERSON: All right.

MR. WADE: And I think I might have --

IV add mixtures, I don't think I mentioned that. In compliance with USP 797, we do not -- we will not be doing any anticipatory compounding at the FED. All IV compounding -- there will be -- all IV compounding will be done for immediate use at bedside and we will try to purchase as many commercially products -- made products as possible for that facility and we will not transfer compounding products from the main facility down there for that purpose because that would not be compliant with USP 797, I don't think.

DR. MARTIN: Do you know if there is -- I'm more or less addressing the Board members at this point to say that I think Steve has done a pretty thorough job of getting his plan together and if there are gaps there, I don't know what they are but now I'm guessing that in the process of getting it up and running and having some additional discussions, we're going to find some gaps and we'll have to address them along the way but it certainly looks like at least the large visible issues

have been addressed. I don't know what kind of feedback the Board wants to provide Steve with today other than proceed. We don't see any reason not to proceed and as we uncover -- if we uncover additional issues, we'd certainly let you know those and we'd ask that you do the same.

MR. WARD: Well, we don't have an application yet so it's going to be the issue of -- it's going to be the issue of not only that but of processing and there's a bunch of moving pieces and I've got to read these rules to make sure they're --

DR. MARTIN: I think what we're going to find is that the ADPH rule is going to be silent on the issue of permitting the pharmacy. That's my recollection when I looked over it.

MR. WADE: It does -- there is a statement in there that says that there will be pharmaceutical services on site at the facility and I think that's the main thing, the pharmacy services.

DR. MARTIN: Yeah.

MR. WADE: And as far as the regulatory portion, they kind of left it up to the existing regulatory boards except it did define the facility as a department of the hospital; therefore, we would see it as an -- I interpret that and request that y'all interpret that as an institutional pharmacy because not being an institutional pharmacy would be a -- would open another bag of worms. There will not be any outpatient services prescription wise from the FED.

DR. MARTIN: So currently, again as far as I know, this Board has granted institutional permits to three off-site facilities that are connected in this fashion back to the hospital and the Board's decision up and to this time has been for those facilities, namely UAB's Comprehensive Cancer Care Center on Acton Road, Montgomery Cancer Center that's affiliated with Baptist in Montgomery, and the Mitchell Cancer Center affiliated with the University of South Alabama at Mobile was that the Board agreed that facilities of that nature

would qualify themselves as an institutional -- qualify for an institutional practice permit, so this will be the first time we've seen an FED and the first time we've seen anything beyond a cancer care clinic seeking an institutional permit. It seems to me to fall in line with the president of the Board has -- we'll have to continue to flesh that out and if we come up with difference -- differences of opinion on that, we'll have to deal with it.

MR. MCCONAGHY: I just think the fact that you're applying for a separate permit at a separate location makes it --

MR. WARD: A lot easier.

MR. MCCONAGHY: -- makes it a lot easier on everybody and the inspectors included that they can do that and I know you and I talked and the way you've put it together, you can't ask for any more from that from the Board or the regulatory board that you have anticipated this much stuff and I can't imagine as things come up that you won't notify the Board and say, hey, this is what we'd like to do

and hopefully it will fit in.

MR. WADE: Absolutely. Thank you very much.

DR. MARTIN: I think what I heard out of that is proceed with the application as soon as you're ready.

MR. WADE: Thank you.

DR. ALVERSON: They have stayed in touch with our office also, so they really have made every possible effort to keep us in the loop.

MR. WADE: Thank you.

MS. ESLECK: So we need to supply CON copies and the ADH rules for each Board member -- a copy?

DR. ALVERSON: If you'll get it to me, I'll get it to the Board.

MR. MCCONAGHY: Just one.

MR. WARD: Ownership, anything that the -- anything that the -- that those rules provide. I don't need to know everything but you know, those commonality things, same ownership, CON, if you would provide that, that

would be great.

MR. WADE: Thank you.

MR. MCCONAGHY: We're going to need to get y'all to tell us who you are again so Sheri can have it on the record there. Roger Bates, Alabama Pharmacy Association.

MR. BATES: Roger Bates, Alabama Pharmacy Association.

MR. HARRIS: Bruce Harris, APCI.

MS. JACKSON: Cherry Jackson, ALSHP.

MR. MAGUIRE: Bill Maguire, Omnicell.

MR. MCCONAGHY: Buddy, are you prepared to do the treasurer's report?

MR. BUNCH: I am fully prepared this time. You've got it in the Dropboxes this month and even got a printout so we're good.

Treasurer's report, I'm happy to report it looks good from what I can tell. The expenses are on budget. We have 95 percent of the income that we'll get is in. This is the year where we have money but we have to live off of that money for another year so Dan left us in good shape. Any questions? Got any questions,

Dan?

MR. DARBY: I will point out, it's not really a question but on the data processing if anybody asks, we're significantly over budget for the year but that's because we've made a payment to our new computer people.

MR. BUNCH: Yeah.

MR. DARBY: But other than that, all the expenses look in line.

DR. MARTIN: When will the expenses to the current but soon previous data processing company fall off?

DR. ALVERSON: Right now we must keep the present company until August 31. We will begin installing the new company August 1 and the changeover date will be September 1.

DR. MARTIN: Great, thank you.

DR. ALVERSON: Our contract with the present company is due for annual renewal in April and so we plan to go to the lowest possible cost. I've also been working with our other lawyer, Joe Wilson, and I had an email this week from him outlining all the things we

did not receive on this contract and he's been talking to the CEO of the present company to say we should receive a reduced rate or money back or stop paying because you didn't deliver on what was promised even within these time frames.

MR. BUNCH: Need to move for treasurer's report.

DR. MARTIN: I move we accept the treasurer's report as submitted.

MS. YEATMAN: Second.

MR. MCCONAGHY: Any discussion?

(No response.)

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MS. YEATMAN: Aye.

MR. BUNCH: Aye.

MR. MCCONAGHY: Any volunteers to do the Board of Pharmacy Wellness Committee report?

DR. MARTIN: Do you just need it read?

MR. DARBY: It's in the Dropbox here.

DR. MARTIN: Yeah, I'll be glad to

read it. Let's see, Susan, would you want to read it?

DR. ALVERSON: No, that's okay. It would be great if you would read it.

DR. MARTIN: Okay. I'm going to read this as if I know what I'm doing.

DR. ALVERSON: You do.

DR. MARTIN: This is a report from Dr. Michael C. Garver, program administrator of the Alabama State Board of Pharmacy Wellness Committee. It's dated February 19, 2015.

Gentlemen and Ladies, There are presently 144 people in our screening program with signed contracts and orders. This number includes any individuals on a DMC, that's a diagnostic monitoring contract, but does not include any of the professionals listed below.

Under current work Dr. Garver lists there's one pharmacist in inpatient treatment. There's 16 pharmacists who are either being held out for some reason or are in the process of being investigated, evaluated, or made ready for presentation to the Board. There's also one

technician in treatment. There are ten technicians who are either being held out for some reason or are in the process of being investigated, evaluated, and may be ready for presentation to the Board.

In addition there is one student who is in inpatient treatment. There is one student who has completed outpatient treatment who refused recommendations and wants to get an extension and be monitored. There is one student who has relapsed, has been withdrawn from school, and may not be able to return and this individual will need a disposition. All of the individuals who are in treatment or in evaluation or undecided are presently out of the workplace and without license. There are 85 individuals in facility-driven aftercare.

The completed work portion of the monthly report is as follows: We've met personally with all licensees returning to work to sign contracts and explain how monitoring works. All returning licensees have been placed in a caduceus, either pharmacy or a health

profession.

Thank you for letting me serve recovering pharmacy professionals. Reports for the inspectors and attorney on current recommendations for Wellness folks that you are seeing this meeting have been emailed to the Board's office and that concludes Dr. Garver's report.

DR. DARBY: I move we accept the Board of Pharmacy Wellness Committee report.

MR. BUNCH: Second.

MR. MCCONAGHY: Any discussion?

(No response.)

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

DR. MARTIN: Aye.

MR. BUNCH: Aye.

MS. YEATMAN: Aye.

MR. MCCONAGHY: Next on the agenda we have the Board minutes from the January meeting and we need to approve them individually so I need a motion.

MR. DARBY: Move to approve the

minutes of the January 14, 2015, Board business meeting.

MS. YEATMAN: Second.

MR. MCCONAGHY: Any discussion?

(No response.)

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

DR. MARTIN: Aye.

MR. BUNCH: Aye.

MS. YEATMAN: Aye.

MR. MCCONAGHY: Opposed?

(No response.)

MR. DARBY: I move we approve the minutes of the January 14, 2015, interview meeting.

MS. YEATMAN: Second.

MR. MCCONAGHY: Any discussion?

(No response.)

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

DR. MARTIN: Aye.

MR. BUNCH: Aye.

MR. MCCONAGHY: Opposed?

(No response.)

MR. MCCONAGHY: Okay. Eddie, you're up next with the inspector report.

MR. BRADEN: Yes, sir, Mr. President, if you look at the Dropbox, you'll see the statistics for the month of January, how many inspections were completed, which also included USP 795 and USP 797 inspections. We had the number that you will see, the received complaints that we actually received, the completed investigations that we did on complaints, which is the bottom number, and then we also have several investigations ongoing that are intense investigations from 2014 but we've almost completed all investigations that were initiated in 2014. You'll see we assisted some agencies and met with several agencies in regard to issues that we both have mutual interests in.

MR. MCCONAGHY: Thank you.

Susan, have you got a secretary's report today?

DR. ALVERSON: I do. I'm going to curtail a few of the things that I was going to

say because I could go on for a period of time as you know. We received a notice this week that the State financial auditor will be here on Monday at nine o'clock and about three pages of information which we will have to have available. They're auditing 2011, 2012, 2013, and 2014. There will be nothing from the beginning of this fiscal year, which was October, nothing from that point forward.

A lot of the information are things like all the minutes from all four years of every meeting and they check to make sure all of those statements that you have to read when you break to go into private -- we have all of those, that all of them are signed. They said they will be here for a period of weeks.

We had met with the gentleman who is in charge of that office previously. We asked him here and explained that there's been a turnover in who manages that, we're under a new system, there are new people here, we do understand there were some issues previously. We can do nothing about 2011 or any part of 2012

other than to provide documentation that we have corrected all things that were found wrong on the previous audit and when that gentleman was here he said, you know, we can expect nothing -- nothing else. You can't fix what wasn't under your control. We will be looking to make sure you've corrected -- you've put in place things to make sure that those kind of things don't happen again.

It's unfortunate that it's during tax season because that will put added pressure on Blake, our CPA, but he has worked out methods to be here. He'll be working from here rather than his office at times.

We are not expecting any problems and we feel pretty good about where we stand about everything that's been put in place but of course, an audit is an audit and you never know until the auditor gets here and you go through things. I will be glad to send you an email as often as you want -- daily, weekly, you know. They'll take days just reading all the minutes. So you know, I can send you an email, keep you

up to date every time I think there is something -- we've learned one more thing. Is that all right with everybody? They'll be gone by the time you get back.

MR. MCCONAGHY: Maybe.

DR. ALVERSON: Maybe, right.

MR. MCCONAGHY: The last time they were here for several --

DR. ALVERSON: My guess is they may want some board members here, if not all board members, for the exit interview and I will keep you apprised of everything I know about that and give you as much lead time as I can, all right.

MS. YEATMAN: We're very confident.

DR. ALVERSON: The gentleman who is managing our new computer program was going to be doing a presentation today but driving from Atlanta and back with the weather was iffy for him and so we have moved that to the next meeting. So you know, they have already put all of our inspection forms into the new computer system. They've put a good part of our renewal systems into the computer already. So what

we've seen -- they have shown us screenshots of what they're doing and we've been very pleased so far, again.

All right. I guess the next big thing is to let you know that we received or we downloaded information from the FDA. I gave you a binder yesterday. So the FDA has sent a draft of the memorandum of understanding that they will ask each state to sign and if you sign it, then pharmacists in your state will be allowed to compound without submitting a new drug application for every compound. I don't know how the State could function if we don't sign the memorandum of understanding. I personally have some issues with it.

There will be a meeting in Washington March 18 and 19. Eddie is going and I'm going. Cristal is going. Dan is going. Jim -- I believe Jim is going. I think David is going also, so we really want to be represented and have our position heard but these are the high points in it and I would really like -- I'm just going to give you my opinion but I want to

represent the Board when we're there, all right.

So all 503A pharmacies, which are -- we would call a traditional pharmacy will be under the jurisdiction of the State Board of Pharmacy and those are called 503A pharmacies. They may only fill prescription -- only compound based on a prescription for an individual and there must be a doctor-patient-pharmacist relationship.

The new category, the 503B pharmacies, are really a version of a manufacturer and they will be inspected by the FDA. We will also be inspecting them, but they will come under FDA and they will have to comply with good manufacturing practices.

DR. MARTIN: Is that the full GMP or --

DR. ALVERSON: As I understand a full GMP.

DR. MARTIN: I thought it was abbreviated GMP for some reason.

DR. ALVERSON: It turns out they have not trained any of their inspectors yet. We

have spoken with their inspectors and -- to try to get some answers on questions, so we'll have to see when they train them how they train them, all right. So here are the things that I -- that I personally would question.

MR. WARD: Susan, wait a minute. We have -- we're required, however, to inspect 503A pharmacies that compound and ship over state lines.

DR. ALVERSON: We're required to inspect all compounding pharmacies that are 503A.

MR. WARD: The way I read it only interstate, the way I read it.

DR. ALVERSON: Okay. Well, we would be inspecting them anyway but we have to report on the ones that ship interstate.

MR. WARD: Right. The MOU requires only all of that as to interstate.

DR. ALVERSON: Okay. That's one of my first concerns -- if a pharmacy is restricted to ship no more than 30 percent of their products over state lines. At the last meeting they said

they will make an exception of about a 50-mile radius for a pharmacy that is on the state line, all right.

MR. DARBY: That's not in the MOU though, is it, the 50-mile radius?

DR. ALVERSON: No, it is not.

MR. DARBY: Okay.

DR. ALVERSON: And so, you know, I think it should be added because someone could interpret it to say, it's not the law, we don't do it. My concern is this: I don't see where shipping 25 percent, 35 percent speaks to the quality of a pharmacy, and what we're seeing happen already is pharmacies are buying small, ready-to-go-out-of-business pharmacies. They're really not treating them as a -- they want to develop this business. They're just using it as a place to get another 30 percent out of it, so if you put enough business in there, you can use that site as a method to increase what you can ship.

DR. MARTIN: And avoid coming under 503B.

DR. ALVERSON: Correct, all right. We've seen one pharmacy that has now purchased four such pharmacies that have just become a place with a license. We've spoken to Mississippi and the same thing is happening in Mississippi also.

MR. WARD: Plus it doesn't define, it says 30 percent in any month. How many months do you go back? I mean, if you -- if you look at 24 months and one month they were 30 and then they qualify, I mean, it's so poorly written.

DR. ALVERSON: Right, right. So I don't know where you stand on that. I'd like your opinion.

The second is we have to send inspections of compounding pharmacies that ship across state lines to the FDA and as I read it, and Jim, maybe you have a different interpretation, it sounds as though anything we find wrong, we have to report to the FDA. Now, in my opinion, if the compounding pharmacy is compounding beyond the rights of a 503A or their sterile technique is atrocious or something of

that nature, but you know, if they didn't get their techs registered on time, I don't see where the State needs to be reporting every possible violation or every part of an inspection report to FDA.

MR. WARD: I just read it as having to report adverse events and quality, those two terms. That's all. That's how I read it.

DR. ALVERSON: I just don't know how they're going to interpret that quality. I mean, what -- what are they going to say?

MR. WARD: Well, they define it -- that's what I'm trying to say. They define it as an actual event occurring, not the possibility of an event, an event occurring.

DR. MARTIN: Like an untoward outcome.

MR. WARD: It has to be something has to happen, so like I said the other day, that would be like a DUI law saying you can drive as drunk as you want as long as you don't hit anybody, which is kind of stupid.

DR. MARTIN: Yeah.

DR. ALVERSON: You know, they can define an event. Like I said, if it's a compounding event that would change their status, I understand that. In some ways, I feel the FDA said we want the right to supervise people who manufacture. They have that right and they've stated the rest remain with the State. So I think there's an issue of whether or not the FD -- how far the FDA can go in monitoring pharmacies that are state pharmacies.

MR. WARD: Well, what's going to be skillful about this I think is be careful not to ask certain questions and just interpret it the way you think rather than ask and get an answer you don't want.

DR. ALVERSON: And the last thing that concerns me is on every document they've sent, it says, in cooperation with NABP. I actually talked to FDA yesterday and raised that. I said, do you plan on sharing our inspection reports with NABP and they said, oh, no, we would never do that but NABP has gotten information and they openly admit it and I think

my -- in my opinion again, I don't know if the State has the right to send information which would be shared with a body that does not have legislative authority, so that's my concern on that.

DR. MARTIN: There was some discussion earlier about the definition of interstate commerce and what that might entail. Has that been resolved or is that a nonissue?

MR. WARD: Yeah, they call it inordinate amounts. An inordinate amount is defined as more than 30 percent. That's going to be their cutoff of whether it should be a 503A or (b).

DR. MARTIN: Yeah, that's how I read it. So if a patient comes from Florida to David's pharmacy and has a prescription filled.

MR. WARD: That doesn't count. They address that.

MR. DARBY: They address that. They do have it in their -- for serious product quality issue, which I think would go to maybe

your point.

MR. WARD: But if a patient comes from Florida, goes to Dave's store, Dan's store, Buddy's store, and takes it back across state lines, that does not count.

MR. DARBY: It's the point of dispensing but I think they do hit on the product quality issue in the inspection you reveal a problem with the quality of somebody's product, then that's reportable.

DR. MARTIN: That's reportable.

MR. WARD: It makes no difference how much they're doing. If they are sending it interstate and there's an adverse action, then there's a problem.

DR. MARTIN: Correct. So if filling a prescription for someone in another state when they travel over to your pharmacy and go back is not interstate commerce.

MR. WARD: It's not distribution as they define it.

DR. MARTIN: What is distribution?

DR. ALVERSON: If you mail it.

MR. WARD: Mail it.

DR. MARTIN: Put it in the United States Postal Service, FedEx, UPS is considered --

DR. ALVERSON: Delivered by truck or a courier.

MR. DARBY: Wherever the patient receives it at determines if it's interstate or not.

MR. WARD: If it's distribution or not.

MR. DARBY: Yeah.

DR. MARTIN: Will the decision about whether they fall into 503 -- I'm trying to put myself in a position of a facility that compounds and I may be right on the 30-percent line, how do I know if I need to submit an application for 503B?

DR. ALVERSON: All right. Well, I was going to tell you that -- what would make you 503B.

DR. MARTIN: Okay. Sorry, got ahead of you.

DR. ALVERSON: No, no, no. There's a document that says these are the people that should apply to be a 503B, all right. If you wish to compound and you wish to sell those compounds without a prescription, so if you wish to sell to a physician or to a hospital. Now, the regulation states that when you transfer it, it cannot be transferred again, so a physician could not then sell those products to a patient and what we have been telling people is the physician cannot have a program in place such as a weight loss program and the injections are part of the overall charge for that program because you are then selling those injections.

DR. MARTIN: If they're obtained from the 503 source.

DR. ALVERSON: If they're obtained from the 503B.

DR. MARTIN: If they're obtained from the commercial source, they couldn't.

DR. ALVERSON: Right, but a 503B must label their products not for resale, for office use only, all right.

DR. MARTIN: Okay.

DR. ALVERSON: And so when we've inspected pharmacies, we've seen where physicians write a prescription but they want a prescription delivered to the office and they will pay for it and then they will bill the patient, so that can't occur with the 503B. All right. A 503B --

MR. DARBY: How would -- how would the 503B facility know what happens to it once it left their control?

DR. MARTIN: Yeah, who would get dinged?

MR. DARBY: Do you know what I'm saying?

DR. ALVERSON: Right. I would think that they would have to have something to say we've informed whoever purchased this that --

MR. DARBY: Do they have to be the terminal user?

MR. WARD: Well, better yet, what about someone who wants to do that, they follow -- they follow GMP, do everything, but

they want to be able to do exactly what you can under 503B, what are they?

DR. ALVERSON: You mean if they want to sell it to someone who will resell it?

MR. WARD: Yeah.

MR. DARBY: They have to be a manufacturer.

DR. ALVERSON: They have to become a manufacturer in the full sense of the word.

DR. MARTIN: Or a byproduct of --

MR. WARD: How is that going to be different than a 503B? They still have to follow GMP. They aren't going to have to have them -- how is it different? That's what I don't get.

DR. ALVERSON: A manufacturer can prepare a product. They're inspected under GMP.

MR. WARD: So is the 503B; right?

DR. ALVERSON: Right, but a --

MR. DARBY: Aren't there some labeling issues that a manufacturer has to go through that a 503B would not?

DR. MARTIN: Register.

DR. ALVERSON: A manufacturer has to -- if they create a compound, they have to apply for a new drug application.

MR. WARD: What if I'm doing the exact same thing that a 503B is, exactly, but instead of writing office use, the physician is going to sell it. It's the exact same drug. Everything is exactly the same except he's going to sell to his patient.

DR. ALVERSON: Well, the pharmacy is going to have to protect -- the 503B is going to have to protect itself.

MR. WARD: That's what I mean. How would they do it? That's the thing.

DR. ALVERSON: Well, they're going to have to notify them and I would think maybe get a signed contract with the physician.

MR. WARD: Isn't that kind of stupid that you have to do a whole different set of rules doing the exact same thing? It depends on what the end user is going to do with it. You're manufacturing it. What's the difference

between manufacturing something for office use and manufacturing for the doctor to use in the office but sell to the patient. That's what I don't know. I'm not fussing at you. I don't understand that.

DR. ALVERSON: Right.

MR. WARD: I don't know what the right answer is.

MR. BRADEN: My understanding is they don't have to go through the new testing procedures.

MR. WARD: Well, why would they have to go through new testing procedures? It's exactly the same. Think about it.

MR. BRADEN: If they're a manufacturer, they have to do that.

MR. WARD: But it's exactly the same. It is exactly the same. They're doing the exact same thing except instead of writing office use on it, they're selling it to the doctor with an invoice. It's exactly the same drug made the exact same way.

DR. ALVERSON: Well, that's what

they're saying, it's not made the same way and if I'm a manufacturer, I can sell it all over the United States and if something goes wrong --

MR. WARD: You sell it to doctors all over the United States.

DR. ALVERSON: Right, but manufacturers are under much stricter control than 503B is.

MR. WARD: I know but you could manufacture -- someone who wants to do this could manufacture gobs and gobs and gobs of it, more than -- as much as any manufacturing, just sell it to physicians for office use all day long.

DR. ALVERSON: Well, and it's our job to make sure they're not selling that quantity.

DR. MARTIN: I think you're right. I think the 503B pharmacy would have to --

MR. WARD: But there's no limit on quantity. They can do -- they can make as much as they want.

DR. MARTIN: They would have to engage

in some kind of a written understanding with the physician's office or whoever they're selling to if it was not available for resale.

DR. ALVERSON: And we -- we saw the order sheet that our one 503B was using and it was pretty obvious when we saw their order sheet, you're selling this to the doctor to resell because the doctor wouldn't go through two dozen jars -- four-ounce jars for office use of a pain cream.

DR. MARTIN: Yeah.

DR. ALVERSON: I mean, a physician wouldn't be doing that.

MR. MCCONAGHY: Guys, we all know we could discuss this for the next three days.

MR. WARD: Yeah.

MR. MCCONAGHY: And I think we really do need to set up either one of our work sessions or Susan like one of the -- where we invited folks here to just go through that full discussion part of it but with the weather coming in, I think we need to move on today.

DR. ALVERSON: All right. Let me just

mention the last thing and we're having trouble enforcing this but we are enforcing it, we're getting a lot of pushback, which is you may not make a copy of a drug that's already on the market, whether it's brand or generic. If it's on the market as a generic and you make a copy, you have to apply as a generic manufacturer. I received a call from Mississippi last night from Sherry and apparently the Mississippi legislature has a product that's being pretty frequently compounded and somebody came out with a brand name of this product and of course the price went way up and so there's a bill in the Mississippi legislature that's moving through pretty quick and they're voting to say, well, we don't care if there's a brand name product on the market or not, our pharmacists can compound it and sell it to Medicaid at a lower price, so it will be interesting to watch that legislation.

DR. MARTIN: That flies in the face of existing federal directives.

DR. ALVERSON: Right, I think that

it's not going to work but it's going to be fun watching.

MR. WARD: You're telling me you're surprised Mississippi won't follow federal regs. That's such a shock.

MR. DARBY: And I'm sure we're going to be a long way behind that too.

MR. WARD: Yeah, I know. I know.

MR. MCCONAGHY: Kind of like on a lot of the stats, thank God for Mississippi --

DR. ALVERSON: Right.

MR. MCCONAGHY: -- we're not number 50.

DR. ALVERSON: That's primarily what I needed y'all to know.

DR. MARTIN: That's very good, Susan.

MR. WARD: I'm with you, I don't understand it. I'd like to be able to figure it out but it makes no sense to me.

MR. MCCONAGHY: Jim, have you got an attorney's report that applies to anything other than 503?

MR. WARD: No, no, I have -- it's

in -- it's in the executive session, a couple of cases we need to talk about.

MR. MCCONAGHY: Okay.

MR. DARBY: Do we need to act on any of this?

MR. MCCONAGHY: Do we have any old business?

DR. ALVERSON: I'd like to act on it in -- well, I guess we have to vote on it. Do you want this in executive session? We have a pharmacist who has sent a letter asking to be able to be a supervising pharmacist.

MR. WARD: Yes, this needs to be in executive session.

DR. ALVERSON: All right.

MR. MCCONAGHY: Moving into old business, is there any old business?

(No response.)

MR. MCCONAGHY: New business?

MR. DARBY: This council, do we need to appoint --

DR. ALVERSON: Pardon?

MR. DARBY: Do we need to appoint

somebody to the Southeast Alabama EMS Council?

DR. ALVERSON: Yes.

DR. MARTIN: Southeast Alabama EMS Council. What areas does that serve, Dan?

MR. DARBY: Dan doesn't know geography in this state.

DR. MARTIN: Oh, this is southeast, not southwest.

DR. ALVERSON: It's in Dothan.

DR. MARTIN: David, do you know what area this is?

MR. DARBY: I don't know the exact counties. They say it's I think 18 counties. I would guess that it would be -- my guess it will be -- it would probably go up towards Lee County over to Montgomery and down through Covington. That's a general definition of Southeast Alabama.

MR. MCCONAGHY: And by the way, I do know the geography. It's David that says he lives in south Alabama and this is the correct terminology. You live in southeast Alabama.

MR. DARBY: Actually south central.

DR. ALVERSON: Thank you, James Spann.

DR. MARTIN: I think we should take advantage of the opportunity to appoint someone to the -- to the EMS council and it seems to me it most likely should be someone living in that area.

MR. DARBY: Thank you. I'd be willing to serve on it if that was the Board's pleasure.

MR. WARD: Is he in the correct geographical area, Dan?

MR. MCCONAGHY: Yes, absolutely.

DR. MARTIN: And I guess we should anticipate there could be other EMS councils across the State that requests participation in the future.

DR. ALVERSON: Could be.

DR. MARTIN: I have one item of new business, Mr. President.

MR. MCCONAGHY: All right, Tim.

DR. MARTIN: This goes back to the rule that was read today for the changes in

680-X-2-.18 on Institutional Pharmacies. So it's my understanding that this rule has been -- this change has been properly logged with the State and now proper action has been taken to make the change that was discussed earlier today in the session -- in the rulemaking session prior to this meeting and I'm in support of those changes and appreciate moving forward with those.

There are some additional changes that I think need to be made and if I'm understanding Mr. Ward correctly, those will need to be considered as a separate topic and possibly at a separate time. I don't know what all of those are going to be but I can tell you at least one of those is dealing with the first page under definitions, so that's number 2.8, institutional facility.

It currently reads, "Institutional facility means any organization whose primary purpose is to provide a physical environment for inpatients -- to obtain, rather, healthcare services including but not limited to," and then

it's laundry list of places considered institutional settings and part of that sentence I read has become problematic, particularly the word inpatients and I believe that what we'll see is a request to drop the word inpatients and allow that to say patients, because institutional facilities on a daily basis commonly provide care for patients who are, in fact, not inpatients at that location.

MR. WARD: We have to use the word patients because you can -- you're talking about in the pharmacy, so you're going to have to come up with a different word than patients.

DR. MARTIN: So that -- for those of you who were here during the earlier portion today, the rulemaking portion, that's what I was pointing at and so I -- with your understanding and I guess with your permission, I'll forward this document back to the ALSHP group who will probably have the most interest in addressing that point and possibly some other points in the document and that's all I needed to say about that.

MR. MCCONAGHY: Any other new business?

(No response.)

MR. MCCONAGHY: No new business. Then at this time we will go into executive session for the purpose of discussing the competencies of professionals, permit holders, registrants, and other legal matters. We will start the executive session at 10:30 and probably end it by 10:45. At that time there will be no further business but we'll have to come back into session to read into the minutes any decisions that were made during the executive session.

You're welcome to come back but there won't be any further business other than hearing some numbers that are to be written in. In order to go into executive session, we're going to need to take an individual vote.

MR. WARD: Mr. President, excuse me, I've got to say though that as an attorney licensed to practice law in the State of Alabama, one of the purposes of executive session will be to consider the resolution of

pending cases, which is under legal matters.

MR. MCCONAGHY: Have you got that clarification, resolution of legal cases falls under legal matters.

MR. WARD: Correct.

MR. MCCONAGHY: We'll spell that out in the future if we need to.

MR. WARD: You know, the auditors will look for that -- that little blurb. Why, I don't know. That's the only reason I said it.

MR. MCCONAGHY: Yeah, we'll definitely add that to it so -- that part of it. So, let's see, Buddy, yea or nay going into executive session?

MR. BUNCH: I say yea.

MR. MCCONAGHY: Donna?

MS. YEATMAN: Yea.

MR. MCCONAGHY: Tim?

DR. MARTIN: Yes, sir.

MR. MCCONAGHY: Dave?

MR. DARBY: Yea.

MR. MCCONAGHY: Dan is yea. We are adjourned for executive session and we'll return

at 10:45.

(Whereupon, a recess was taken for executive session. Member Buddy Bunch left the meeting when it was recessed for executive session.)

MR. DARBY: On request of the license number 13688 that she be granted to be a supervising pharmacist, the request is granted.

On case number 14-0120, case number 14-0141, case number 14-0155, case number 14-0156, case number 14-0157, case number 14-0167, and case number 14-0184, case number 14-0028, case number 15-0015, recommendation of no violation.

MR. WARD: Motion.

MR. DARBY: I make a motion that -- of no violation.

MR. MCCONAGHY: Second. All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MS. YEATMAN: Aye.

MR. DARBY: Case number 14-0190, case number 14-0118, case number 14-0135, make a motion that those be sent to the Board's attorney.

MS. YEATMAN: I move that those be sent to the Board's attorney. Second.

MR. WARD: You second.

MR. DARBY: Yeah, you second.

MS. YEATMAN: I second.

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

MR. MCCONAGHY: Aye.

MR. DARBY: Case number 14-0006, I make a motion that we have a -- accept a permanent surrender.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MS. YEATMAN: Aye.

MR. DARBY: Case number 14-0177, make a motion that a letter of warning and corrective

action plan.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

MR. MCCONAGHY: Aye.

MR. DARBY: Case number 14-0162, make a motion that a letter of concern restating HIPAA laws and a letter to complainant referring him to HHS.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

MR. DARBY: Aye.

Case number 15-0001, I make a motion that a letter of concern and warning be sent.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

MS. YEATMAN: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye. Case number 15-0003, I make a motion that a letter of concern and

corrective action -- corrective action plan to the pharmacy, refer responsible physician to the Alabama Board of Medical Examiners.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

MS. YEATMAN: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye. And case number 15-0018, I make a motion that a letter of concern to improve communications with patients and need to cancel on any change on a prescription be made.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

MS. YEATMAN: Aye.

DR. MARTIN: Aye.

MR. DARBY: I think that's all. Did I miss one?

MR. BRADEN: 0196, did we include that on no violation? I know you just decided on it.

MR. DARBY: On case number 14-0196, I

make a motion for no violations.

MS. YEATMAN: Second.

MR. MCCONAGHY: All in favor?

MR. DARBY: Aye.

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

DR. MARTIN: I move we adjourn.

MR. DARBY: Is that all?

MR. BRADEN: Yes, sir.

MR. DARBY: I make a motion we adjourn.

DR. MARTIN: Second.

MR. MCCONAGHY: All in favor?

DR. MARTIN: Aye.

MS. YEATMAN: Aye.

MR. DARBY: Aye.

MR. MCCONAGHY: Adjourned.

(Whereupon, the meeting was adjourned.)

CERTIFICATE

STATE OF ALABAMA

SHELBY COUNTY

I, Sheri G. Connelly, RPR, Certified Court Reporter, hereby certify that the above and foregoing business meeting 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

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