ALABAMA STATE BOARD OF PHARMACY

BUSINESS MEETING

Wednesday, December 17, 2014

9:05 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:

Susan Alverson, Executive Secretary, Board of Pharmacy
Donna Yeatman, Incoming Board Member
Cristal Anderson, Board of Pharmacy
Terry Lawrence, Board of Pharmacy
Seth Feldman
Frank Petrillo
Sherry Mauldin
Carey McRae
Tammie Koelz
Paul Rengering
Matthew Muscato
Cynthia Ransburg-Brown

Bart Bamberg
Bruce Harris
Steve Bethea
Jim Easter
Julie Hunter
Louise Jones
Rick Stephens
Tracy Davis
Eddie Vanderver
Krista Pederson
LaDaria Hartley
Lauren Barron
Cherry Jackson
Ronda Lacey

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MR. CONRADI: Good morning, welcome to the December '14 meeting of the Alabama Board of Pharmacy. As usual, I'd like for us to start off here on the front row, if you'd stand up, tell this lady who you are, who you represent so she can get it down for the record.

MR. FELDMAN: Hi, I'm Seth Feldman. I represent Fresenius Medical Care.

MR. PETRILLO: Hi, my name is Frank Petrillo. I also represent Fresenius Medical.

MS. MAULDIN: I'm Sherry Mauldin and I represent Fresenius Medical Care.

MR. MCRAE: I'm Carey McRae. I'm a healthcare lawyer with Bradley Arant and I'm Fresenius' lawyer.

MS. YEATMAN: I'm Donna Yeatman and I'm with CVS.

MS. ANDERSON: Cristal Anderson with the Alabama State Board of Pharmacy.

MS. KOELZ: Tammie Koelz, Walgreens Pharmacy.

MR. RENGERING: Paul Rengering, Walgreens Pharmacy.

MR. MUSCATO: Matthew Muscato, Walgreens Pharmacy.

MS. RANSBURG-BROWN: Cynthia Ransburg-Brown, Sirote and Permutt.

MR. LAWRENCE: Terry Lawrence, Alabama Board of Pharmacy.

MR. BAMBERG: Bart Bamberg, Publix Supermarkets.

MR. HARRIS: Bruce Harris, APCI.

MR. BETHEA: Steve Bethea, University of South Alabama Medical Center.

MR. EASTER: Jim Easter, Baptist Health System.

MS. HUNTER: Julie Hunter, Omnicare.

MS. JONES: Louise Jones, Alabama Pharmacy Association.

MR. STEPHENS: Rick Stephens, Senior Care Pharmacy.

MS. DAVIS: Tracy Davis, attorney for Alabama Pharmacy Association.

MR. VANDERVER: Eddie Vanderver, CAPS, Incorporated.

MS. PEDERSON: Krista Pederson, Harrison School of Pharmacy.

MS. HARTLEY: LaDaria Hartley, Harrison School of Pharmacy.

MS. BARRON: Lauren Barron, Harrison School of Pharmacy.

MS. JACKSON: Cherry Jackson, ALSHP.

MR. CONRADI: Thank you. I think we've got one presentation this morning. We'll get started with Fresenius if y'all want to take over.

MR. MCRAE: Yes, sir, good morning. It's a pleasure to be before the Board this morning. I mentioned before, I'm Carey McRae. I'm a lawyer for Fresenius Medical Care North America.

We've got a presentation that we want to give you but I'm going to step -- on advice of your sound -- very sound counsel, I'm going to step out of the way. He said, the Board doesn't want to hear from a bunch of lawyers, so I totally understand that.

So I'm going to introduce our speakers this morning if y'all will stand up. Starting here, this is Seth Feldman. He is the pharmacist in charge of Fresenius' Waukegan, Illinois, pharmacy, so he's down from right outside of Chicago. Frank Petrillo is both an attorney and a pharmacist and I don't know if that's a lethal combination or what.

MR. CONRADI: It's a great combination.

MR. MCRAE: I figured you might like that. But Frank is from the Waltham, Massachusetts, headquarters of Fresenius and he heads up all the regulatory and licensing issues for the pharmacy operations for the company around the country. And then Sherry Mauldin, y'all might know Sherry. She is the pharmacist in charge of our Alabaster pharmacy, which is a licensed, closed-door pharmacy here obviously in Alabaster.

And we've got a presentation. I will just tell you briefly it's for a pharmacy services permit that would allow our Waukegan facility, which is a licensed pharmacy in Illinois, to do remote order entry processing on new prescriptions for home dialysis patients and we can explain it more as we go through the presentation but Seth, why don't I turn it over to you and here is a -- the clicker. Yeah, and I told you all of this for the most part already but Fresenius is the world's largest owner and

operator of dialysis services. It also is -- does drugs and supplies for dialysis patients.

There are two types of dialysis. I won't get into it a great deal but there's the in-center hemodialysis, which we're all familiar with. There's also home dialysis. There's home hemodialysis but that's a very small percentage of dialysis patients. The vast majority, I'd say probably 99 percent, is what's called peritoneal dialysis, and that's a process through which fluids are put into the abdomen and through the process of osmosis, the particles in the -- in the blood that need to be filtered out go into this solution and then the solution is washed from the body and that is the type of patient that we're here about today.

Fresenius has over 2,000 clinics nationwide. The home market for Fresenius is about 15,000 patients nationwide. We have about 470 home dialysis patients in Alabama.

I'll turn it over to Mr. Feldman.

MR. FELDMAN: Thank you. Thank you, Gentlemen, for seeing us. We're staffed by

myself and another pharmacist and we also bring in pharmacists as we need for coverage. We have several technicians who take care of order entry.

We're a central order entry pharmacy, only. We have no drugs, no controlled substances. We don't deal in controlled substances. We don't do any compounding, no inventory. All we're really doing is order entry receiving prescriptions, transcribing them into the pharmacy system.

We are broken up into eight service teams. There are actually six teams that take care of pharmacy patients and two other teams that just take care of the wholesale side of our business. All our pharmacy technicians that we've hired are in the process of becoming nationally certified by PTCB.

The team of technicians that take care of the Alabaster region is called team 15. There are ten technicians that work in that group to cover the patients out of the Alabaster pharmacy and only those ten technicians will

have any sort of access to enter healthcare information from these patients. The rest of the system is blocked and no one else will be able to see it but those particular patients and the pharmacists and like I said before, there are only 470 patients that Sherry handles out of that facility and by doing this, we're just looking to really improve patient safety by getting more eyes on checking prescriptions and improve patient compliance by getting their customer service and helping the patients, you know, know their products.

MR. CONRADI: Now, what do the technicians do at the Alabaster location? Do they actually dispense?

MR. FELDMAN: At the Alabaster location or Sherry -- they do not dispense. Sherry does all the dispensing at the Alabaster location.

MR. CONRADI: How many other pharmacists are there?

MR. FELDMAN: Sherry.

MS. MAULDIN: There's me and one other

and there's two technicians, so one-to-one ratio right now.

MR. CONRADI: I just saw ten technicians, so.

MR. FELDMAN: No, that's in Illinois. That's in Waukegan. That's the ten technicians that will be handling the order entry for the pharmacy.

MR. CONRADI: I see it now.

MR. FELDMAN: Okay. Unless you have any questions for me, I'm just going to turn it over to Sherry.

MR. DARBY: Seth, how many pharmacists work on team 15?

MR. FELDMAN: There's two.

MR. PETRILLO: So what's unique about our company here is that we have an extremely limited proprietary formulary. Like Seth mentioned, no controlled substances of any kind, no compounding, and the bulk of our prescriptions are made up of Delflex, which is a peritoneal dialysis solution, some saline. You see Heparin there but out of the Alabaster, I

1 believe Sherry yesterday we calculated yesterday
2 she has about five patients who require Heparin,
3 and those patients are doing the home hemo,
4 which again is very rare, and it's just for a
5 flush to clean out the machine.
6 Everything else would be sterile
7 water, also very benign, needles, syringes, the
8 tubing sets that connect to the machines, and we
9 also supply all of the ancillary OTC items --
10 gloves, gauze. We give them antibacterial soap.
11 We give them soup to nuts so they can dialyze at
12 home.
13 This is a screen shot of our PDX,
14 which is the pharmacy computer system that we're
15 implementing, and the reason why I put this up
16 here is to show you that if we were to put in --
17 I put in Amoxicillin here. If we were to put in
18 a drug that we simply do not carry or ever
19 dispense, we would get the error message of no
20 products found, so it is -- I can say this with
21 confidence, it is impossible for us to enter,
22 process, even print the label for a drug that we
23 don't carry or dispense. It's like going to

Burger King and asking for a Big Mac. It just won't happen. And Sherry is going to take Alabaster.

MS. MAULDIN: I believe you kind of answered what I'm supposed to say but -- or asked the question but there are two pharmacists, myself, and one other out in the Alabaster facility, and we have two technicians at the moment and they are -- one is certified and one is not, so the one-to-one ratio and right now currently, you know, we handle all the orders, entering the prescriptions. No one else in the company can see the prescriptions but us. They are faxed to us and that's the way it -- you know, that's just the way it is.

Let's see, only one pharmacist is needed to verify the prescriptions before dispensing under the current procedure. What -- I guess to kind of explain that a little bit is right now I enter the prescription, our technician enters the prescription, and I verify it. In the proposed process, they would enter the prescription in Waukegan. Seth would -- or

the other pharmacist would verify it, then it would come to Alabaster, okay.

Then whenever they got an order, I would pull it up, I would verify it, so there would be two eyes on the actual transcribing of the prescription, okay. There would be another set of eyes just like now on the part of checking the product versus the label once it got out into the warehouse, so you know, I have been to the Waukegan facility and if I did not think it was a good idea, I wouldn't be here, you know. You know, I just -- I'm very strict when it comes to patient safety and some things out there it seems like people are trying to get through loop holes and things but this, I have no -- no qualms about it. It is safe.

MR. BUNCH: How many prescriptions do you think you'll do a day? Is this a big volume thing? I wouldn't think it would be big volume.

MS. MAULDIN: I'm sorry?

MR. BUNCH: How many prescriptions would you do a day?

MS. MAULDIN: Probably, and you'll see the size of an order, you know, some are refills, you know. You've got your, you know, majority of them every day is refills but I would say we dispense about 70, 80 orders a day so -- that meaning a patient's order, you know, like if you go into the drug store --

MR. BUNCH: Right.

MR. WARD: -- and Ms. Whoever gets three medications every 30 days. We're kind of set up on the same thing on a 28-day cycle if that is feasible for some patients. Some patients, you know, says I don't have storage for 28 days, I do for 14, or the physician says, you know, we're still working with this patient, this is, you know, likely to change so let's -- let's hold off and do seven days for a while. Whatever, you know, we're accommodating and then some 56 days if they're on a very low, you know, doesn't dialyze as large of quantities, you know, so that varies too but yeah.

MR. FELDMAN: Might I add though most of the prescriptions are of the ancillary type,

1 the gloves, the tubing.
2 MS. MAULDIN: Right.
3 MR. FELDMAN: Most of it is not
4 prescriptive items.
5 MR. CONRADI: Dialysate and things
6 like that?
7 MR. PETRILLO: Yeah.
8 MS. MAULDIN: I'm sorry?
9 MR. CONRADI: Dialysate and things
10 like that?
11 MS. MAULDIN: Yes, yes.
12 DR. MARTIN: So the way it's working
13 now is the order or the prescription comes to
14 you, you process it. It results in product,
15 supplies, whatever they could deliver.
16 MS. MAULDIN: Correct.
17 DR. MARTIN: So the difference is
18 instead of the order just coming to you, the
19 order will come to you and it will go to your
20 facility in Waukegan, was it?
21 MS. MAULDIN: Yes.
22 DR. MARTIN: And so the bottom line is
23 what you're accomplishing are two sets of eyes?

MS. MAULDIN: That is correct.

DR. MARTIN: I mean, you could do the two sets of eyes with the two pharmacists you have in Alabaster, right, you have one enter it and one review it but -- so there's an additional benefit -- help us understand that, an additional benefit of having that done in a remote fashion.

MR. FELDMAN: Right, and also -- it also frees her up to check to find it better if you've got a pharmacist somewhere else doing the verification.

DR. MARTIN: So it takes some order processing pressure off of the pharmacists at the Alabaster site?

MR. FELDMAN: Right, so she could do more DUR with the patient, that kind of thing.

MS. MAULDIN: Yeah, because right now the technician there does all the -- you know, we are the only ones that can see the prescription, so you know, we're talking to the nurse, you know, calling and you know, it's constant, you know, just like in a drug store

pretty much, you know, all day, lots of interruptions. But you know, the -- there it would -- like setting up the -- even calling because even though the patient knows every fourth week on Thursdays they're supposed to get an order, we still call the day before and make sure. And then even say a week before that, we call and check your inventory level to see, you know, how many of this do you have, how many of that do you have.

So we can kind of check their compliance and see if, you know, she may say, oh, no, I'm not using so much of that anymore. I don't need all of that, you know, or I'm going to be out of town next Thursday, can you do it, you know. So all of that right now, you know, since we are the only ones that have access to her information and we're doing all of that now.

DR. MARTIN: So you're just essentially asking the Board to grant a pharmacy services permit for the site in Waukegan?

MS. MAULDIN: That is correct, remote,

yes, entry.

DR. MARTIN: Remote, okay. So it will be remote order processing done through a pharmacy service permit in Waukegan; correct?

MS. MAULDIN: That is correct.

MR. MCRAE: Correct.

MR. PETRILLO: We're extending the bench all the way up to Illinois just so that --

MR. CONRADI: Make a gap in there so they can't come down here.

MR. PETRILLO: But the processing will occur -- the entry will occur there but everything else will flow through Alabaster and it's the new patient orders that will be entered in Waukegan rather than here in the VIP system, which is a -- it's an older system. The nice thing about PDX is -- and the process that we designed up in Waukegan is no prescription can leave Waukegan, can't even get here until Seth or the other pharmacist clearly puts their thumb or finger onto a biometric device to say, yes, I am the pharmacist, I approve of this DUR, this allergy, this dosage.

MR. DARBY: Are y'all using that PDX system already in Waukegan?

MR. FELDMAN: We have just rolled it -- yes, we have rolled it out.

MR. PETRILLO: The Alabaster pharmacy will then receive a prescription and process the prescription for dispensing and labeling, so that part won't change and at all times, Sherry is able to view an actual image of the signed doctor's prescription in the patient's profile anytime she wants. If she wants to check is this dose right, is that for five or 15, she can pull it up at any time and the refill requests also go through Waukegan but Seth can also check the DUR and check the refill before he then sends it down for Sherry in much the same way.

Some of the highlight advantages of this center or the processing that was mentioned before was it allows the -- this greater number, this team approach of technicians, you know, you'll see later that these are large orders and these patients -- they're on the phone quite a bit and we find out whether they've been

1 hospitalized, whether they've been sick, whether
2 they've changed modalities. That comes out
3 during a longer phone call and that can't happen
4 sometimes with -- with fewer people and we're
5 able to catch any compliance issues. If we see
6 that they haven't ordered a certain strength of
7 Delflex, we can say, well, don't you need this
8 and if they're not using it, we're in touch with
9 their clinics as well to go back and forth with
10 the patient.
11 The other beauty of PDX is it's tied
12 into our warehouse inventory system, which is
13 SAP, and it allows us to respond to any out of
14 stock. If there's a natural disaster, an
15 emergency, we can quickly replenish that supply
16 from another distribution center that is
17 licensed in Alabama. We have double or triple
18 coverage in every state and the highlight that
19 Sherry had mentioned, it will now require two
20 pharmacists to put their thumb, finger down to
21 okay a prescription rather than one, and that's
22 a patient safety concern and it frees Sherry up
23 to do more pharmacy-related items.

DR. MARTIN: Sherry, you're the supervising pharmacist of record at the Alabaster site?

MS. MAULDIN: Yes, sir.

MR. PETRILLO: So I have to remind people when I talk about Fresenius and dialysis that it's not a little bag with 30 pills in a vial that you can walk out and put in your car. This is a distribution center that we have 14 of all around the country, one of which is here in Alabaster. Here's a patient order and maybe we should have done this at the beginning but this is a prescription. So when Sherry said 70 orders, this is one order.

MR. BUNCH: That's what I was wondering. I didn't expect it to be such a small volume. I see what you're saying now.

MR. PETRILLO: So each one of these cases is a case of Delflex, different strengths. There's your pharmacy label on each box. Here's a box of tubing. There's another box of a different type of tubing and you'll see some unlabeled boxes up here. Inside those

boxes are your gloves, your gauze, your Band-Aids. We give them bathroom scales. We give them heating pads, everything. It gets shrink-wrapped, put on a pallet.

There's your 30 pills going into your car. This is all our staff. We have our own fleet of logistic trucks that hand-carry every order to every patient's home. We do not leave it on the porch. We hand-carry it in. The driver will actually scan the inventory, which reports back to Seth to say, well, this patient should based on their usage should only have 20 cases left but they have 40, what's going on.

And you look, it doesn't say Fresenius on there. It says TruBlu. That's our service brand for our logistics.

MR. CONRADI: So they scan what's left at the patient's house?

MR. PETRILLO: Correct.

MR. CONRADI: Okay.

MR. PETRILLO: We just didn't want the patient's privacy to be affected that says a Fresenius dialysis truck is in my neighbor's

1 driveway once a month, so that's when people say
2 what's TruBlu, that's our own delivery and
3 that's it.
4 DR. MARTIN: So if a patient has -- I
5 know you've gotten the patient referral,
6 possibly out of the hospital or some facility.
7 You've assessed the patient. You know what the
8 prescription is going to be. You've gone into
9 the home environment. You've assessed the
10 environment. Somebody has educated the patient.
11 Now you've dropped the drug off, fluid,
12 whatever. If the patient has a problem, who do
13 they call?
14 MR. PETRILLO: Every label and every
15 delivery order comes with an invoice that has a
16 phone number on it. The phone number -- Seth
17 has a phone in his pocket right now. The other
18 pharmacist has a phone. They switch off 24/7.
19 A lot of patients have a very good relationship
20 with the clinic that they go to and the nurse
21 that they see and it's often, you know, either
22 the clinic or Seth that they call saying, you
23 know, I've had the flu, I'm using less solution

or I'm using more solution, how do I accommodate --

DR. MARTIN: So I'm the patient. I call that number. Am I talking to the pharmacist primarily in Alabaster or in Waukegan?

MR. PETRILLO: Sherry is available when the pharmacy is open but the 24-hour line goes to Seth in Waukegan.

DR. MARTIN: So it goes to you if you're open. If you're not open, it goes to Seth.

MS. MAULDIN: Right, unless the patient, you know, wants to call their clinic during normal hours and a lot of times they will because that is where they -- they went and they got set up, they got stabilized to determine if they were a candidate for home dialysis. Some just aren't, you know, because it is -- it's a process but -- made sure that everything is okay, the doctor followed them, and then, you know, so they got a relationship with the nurse there and so a lot of times they will call the

nurse, of course, but -- you know, and then the nurse will come out, train them, make sure that it's sanitary, that kind of thing.

DR. MARTIN: And that relationship already exists --

MR. PETRILLO: Yes, sir.

DR. MARTIN: -- from a phone backup standpoint?

MS. MAULDIN: Right.

MR. FELDMAN: And I do have Sherry's cell phone number and we communicate. If something needs to be gotten to her, I'll get to her after hours.

MR. PETRILLO: And my phone is always on too.

DR. MARTIN: Mark, I don't have any other questions.

MR. CONRADI: And y'all are doing this just for home dialysis, right, not for your clinics?

MR. PETRILLO: Only for home dialysis, correct.

MS. MAULDIN: Right.

MR. PETRILLO: Clinics are a different business. We service Fresenius patients that go to Fresenius clinics who then send the prescriptions to us. We also service non-Fresenius patients at DaVita clinics and other -- other dialysis clinics.

MS. MAULDIN: We have a DaVita right up here on the corner behind CVS.

MR. PETRILLO: Right, we fill --

MR. CONRADI: They're sending regular prescriptions there too, which is illegal.

MS. MAULDIN: Are they?

MR. CONRADI: Yeah.

MS. MAULDIN: Really?

MR. CONRADI: Yeah, but anyway. I just want to make sure y'all are not doing it.

MS. MAULDIN: No, no.

MR. CONRADI: Y'all do a good job. I have a friend of mine that's on home dialysis in Clanton -- hemo dialysis and y'all really do a great job on keeping him supplied.

MS. MAULDIN: Good.

MR. CONRADI: I appreciate y'all being

here.

MR. PETRILLO: Thank you for having us.

MS. MAULDIN: Thank you.

MR. CONRADI: We've got one question.

DR. ALVERSON: I have a couple of questions if you don't mind. Is the Delflex -- you mentioned different strengths, so are there any additives ever added to that?

MR. PETRILLO: No.

MR. FELDMAN: No.

DR. ALVERSON: And who makes it?

MR. PETRILLO: Fresenius.

DR. ALVERSON: And where is that made?

MR. PETRILLO: Delflex is made in Ogden, Utah, and we dispense -- you've seen those -- those boxes of Delflex. We don't even open the boxes. We send the patient a box of --

DR. MARTIN: Made in a GMP facility?

MR. PETRILLO: What's that?

DR. MARTIN: It's made in a GMP?

MR. PETRILLO: Yes.

DR. ALVERSON: You're a manufacturer?

MR. PETRILLO: Correct.

DR. ALVERSON: You're licensed as a manufacturer?

MR. PETRILLO: Correct, Fresenius from the first slide manufactures the machines for home dialysis and handles over 2,000 clinics in the country but also makes all the solutions that are required similar to Baxter. So one of our competitors is Baxter. So Baxter makes machines and solutions.

DR. ALVERSON: Right.

MR. PETRILLO: They don't have any clinics. DaVita has clinics. They don't make machines or solutions. Fresenius does all three.

DR. ALVERSON: All right. You mentioned nurses who go out. Are they your nurses or do you contract out?

MR. PETRILLO: They're the clinic's nurses, so if they're Fresenius nurses, they're our nurses. If they're DaVita nurses, they're DaVita nurses.

DR. ALVERSON: I ask that because --

1 and I was going to mention this to the Board
2 today and we're going to have to get a memo out
3 to pharmacists around the State. We were with
4 the Board of Nursing this past week and they
5 said, you know, some of the nurses that you send
6 out have not applied through us to approve their
7 processes and I said, I had never heard of that.
8 So I've never advised a home health pharmacist
9 to have their nurses submit data to the Board of
10 Nursing --
11 MS. MAULDIN: Right.
12 DR. ALVERSON: -- to approve their --
13 the various things that the nurses do in the
14 home and they said that's actually a law in
15 Alabama that if the -- if you're contracting
16 with the nursing agency and you're a pharmacy,
17 you don't have to worry about it. That's the
18 nursing agency's responsibility but if they are
19 your nurses and the nurse is being asked to do
20 something that --
21 MR. MCRAE: Outside their scope.
22 DR. ALVERSON: Out of the scope of
23 what you would get if you got a B.S. degree. If

you're doing something that --

MR. MCRAE: Right.

DR. ALVERSON: -- you didn't learn in school, then you have to submit a full description of that process --

MS. MAULDIN: Uh-huh.

DR. ALVERSON: -- how people are trained, A fairly in-depth document to the Board of Nursing. So for instance, putting in a PIC line.

MS. MAULDIN: Oh, yeah.

DR. ALVERSON: They said that would not have been taught in school, not that you're putting in a PIC line.

MS. MAULDIN: Right.

DR. ALVERSON: But that kind of thing and so we told the Board of Nursing we would most certainly cooperate with them and try to inform people of that, so that's why I'm asking the question.

MS. MAULDIN: Of course, yes.

DR. ALVERSON: You may be getting something from us.

MS. MAULDIN: All right.

DR. ALVERSON: And two more: The trucks are temperature controlled?

MR. FELDMAN: Oh, yes.

DR. ALVERSON: Because in Alabama --

MS. MAULDIN: Yes.

DR. ALVERSON: -- well, it's just as bad in Waukegan but the other way.

MR. PETRILLO: Yeah, we ship. Our trucks go -- they're in Alaska. They're in Hawaii. They're in Florida. They're in Minnesota. They're in Texas.

DR. ALVERSON: So when patients need IV antibiotics or that kind of thing, is that through the clinic? They would go into the clinic for that?

MR. PETRILLO: They would go into their clinic and that would be completely different. We don't have any of those supplies.

MS. MAULDIN: No.

DR. ALVERSON: Okay.

MR. PETRILLO: You saw what happened when I tried to fill an Amoxicillin

prescription. We don't have that.

DR. ALVERSON: And I assume the Utah plant is licensed to ship into Alabama?

MR. PETRILLO: All of our manufacturing plants are registered with the FDA and hold resident and nonresident wholesale licenses where they ship to.

DR. ALVERSON: That's it.

MR. PETRILLO: Great.

DR. ALVERSON: Thanks.

MR. MCCONAGHY: I've got one more.

MS. MAULDIN: Okay.

MR. MCCONAGHY: Do you have any process by which you notify the patients that their prescriptions may be processed at another location?

MR. MCRAE: Yes, sir, that's a good question. We submitted some written materials and in one of the indices was a notice that we would propose to send but we can send any kind of notice that y'all would want but assuming y'all would approve of this, we would notify them -- I think the rule requires it to let them

know that their prescription for a new order might be processed in Waukegan.

MR. MCCONAGHY: Okay.

MR. MCRAE: Yes, sir.

MR. CONRADI: Any more questions?

DR. MARTIN: I move we approve the request for a pharmacy services permit and remote processing for the Waukegan location for Fresenius.

MR. DARBY: I'll second that.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. MCCONAGHY: Aye.

MR. DARBY: Aye.

MR. CONRADI: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Thank y'all for coming.

MR. PETRILLO: Thank you very, very much.

MR. MCRAE: Oh, one question, I -- think I didn't mention it but we will not probably start this process until early in the next quarter because it will take a little while

to roll it out and I assume that that's okay. We could begin maybe January 1 with our permit, is that okay, rather than today, I guess.

DR. ALVERSON: Oh, certainly.

MR. CONRADI: Well, they'll have to have an Alabama registered pharmacist.

MR. DARBY: He's in the process.

MR. FELDMAN: I've done all the requirements. We're just waiting to see if I had to apply for this year or for next year.

MR. DARBY: Yeah, I would wait a couple of weeks.

MR. FELDMAN: Make sure it's okay with you. That's right.

MR. DARBY: Although our treasurer would like for you to do it today.

MR. MCCONAGHY: Do both.

MR. CONRADI: Thank y'all.

MR. FELDMAN: Thank you.

MR. MCRAE: Thank y'all very much. I will say one last thing which will make him mad but --

MS. MAULDIN: Well don't do it.

MR. MCRAE: No, they've already voted. I just want to tell y'all --

MR. WARD: Get in line. Bye, good to see you.

MR. MCRAE: I have worked a lot with Mr. Ward and I would just like to publicly say how appreciative we are of the work that he does for the Board and Jim could beat me up later.

MR. WARD: No, come on.

MR. MCRAE: Anyway, thank you.

MR. CONRADI: Out of order.

MS. MAULDIN: Thank you.

MR. CONRADI: Thank y'all for coming.

MR. CONRADI: Treasurer's report. I guess we need to approve the agenda, how about that.

MR. MCCONAGHY: Yeah, we need to do that, don't we?

MR. CONRADI: Do I have a motion to approve the agenda?

MR. BUNCH: I'll make a motion that we approve today's agenda.

MR. CONRADI: Second?

MR. DARBY: Second.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. MCCONAGHY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Now treasurer's report. I'm sorry. Dan, you're still treasurer.

MR. MCCONAGHY: Not for long. The -- we are two months into our fiscal year and we have currently collected a little over two million dollars of our four million dollar budget, which is about right on pace for a licensing agency and by the end of this month, probably 80 percent of it will already be in the bank as far as what you have to work off of but as far as the Board goes, you have to keep in mind this is to cover that deficit from last year where we have a lower income year plus the current year.

So it may look like a big number sitting in there but you can't spend it because

it's going to come up where actually when you -- we look at the expenses that have been budgeted versus the income, the ideal number would be 100 percent and we're at 100.45 percent, so that's about as close as you can get on the budgeting end of it but it just tells you where that four million dollars at the end of the year is not going to be there so -- it's there but it's not there to spend on other things other than the budgeted items, so.

If you looked at -- David, if you're looking at your business right now, you'd have a $1.5 million net income. You'd be a happy man.

MR. DARBY: I'd be smiling.

MR. MCCONAGHY: You'd probably spend it and then you wouldn't be able to pay the bills for the end of the year.

That's -- I would just -- my report would say we're in real good shape, that I don't know on the licensing end if we're -- if everybody is -- we're going to have a big rush at the end of the year again this year or not

but the -- have y'all got any --

DR. ALVERSON: Well, of course we're having a lot of push with nonresident pharmacists trying to get licensed, so it's been a lot for Lynn right now and GLS isn't working as well as we would like it to, especially for businesses, for pharmacies, and so that's taken a little extra work also that we hadn't anticipated but we don't anticipate at all having a rush or a backup or anything of that nature at the end of the year.

MR. MCCONAGHY: Well, I --

DR. ALVERSON: We plan to finish -- right now, we're probably turning licenses out within 48 hours of when we get the application.

MR. DARBY: And we can get into that in your report later but I renewed mine a couple of weeks ago and I got mine within two days.

MR. MCCONAGHY: And percentage wise I've been -- as long as I've been doing the treasurer report, it's -- we're way ahead at the end of November than where we have been in past

years as far as percentage of folks that have already registered by that point.

DR. ALVERSON: Right.

MR. MCCONAGHY: So it should be --

DR. ALVERSON: The computer renewals have definitely helped us. I mean, it's made things a lot easier. It's just not as smooth as it could be or we anticipate it being.

MR. MCCONAGHY: That's all I've got, Mark.

MR. CONRADI: All right. Any questions?

(No response.)

MR. DARBY: I move we accept the treasurer's report.

DR. MARTIN: Second.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. MCCONAGHY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

Have you got the Wellness report?

DR. ALVERSON: I do. From Dr. Garver, Gentlemen, we presently have 143 people in screening program with signed contracts and orders, two pharmacies in inpatient -- pharmacists in inpatient treatment, 20 pharmacists are being held out for some reason or process of being investigated, evaluated.

We have one tech in treatment, ten techs who are in the process of being investigated or evaluated. We have one student in inpatient treatment and that student should be out within -- before the first of the year, one student who has completed outpatient treatment and refused recommendation and needs disposition. I know Jim is aware of that.

MR. WARD: I prepared that. It's been prepared and sent.

DR. ALVERSON: Okay. It's not -- it's not urgent I would say but.

MR. WARD: No, but it's done.

DR. ALVERSON: All of those individuals in treatment or evaluation or undecided are presently out of the workplace and

are without a license. We have 83 individuals in facility-driven aftercare.

If you remember, we discussed briefly at the last meeting Dr. Garver meeting with the schools of pharmacy and he says, I've sent an email to the schools outlining standard protocols concerning students and I've spoken to representatives of both. There was a misunderstanding which has now been cleared up and I have copied the email to Ms. Alverson so that she may have it for a January meeting.

We have also set up a meeting with a representative of the two schools and Dr. Garver for immediately after he gives his report at the next meeting, so they'll have an opportunity to sit down face to face and continue with their discussion but I've spoken to the schools and both schools are really very happy with the way things are going. The summary report for 2014 will be available at the January meeting.

Finally, in wishing you all a safe and happy holiday season, I want to extend that from my mother as well. She wishes you to know she's

ordered fruit cakes and will be sending each of you one for the holidays. Though she does not know who you are or your addresses, I can only hope the poor soul that receives one somewhere in the USA will have the good sense not to eat it. And as far as I can recall, Mr. Ward is the only person here whose name she actually knows.

MR. WARD: Well, she knows --

DR. ALVERSON: So you may get a fruit cake.

MR. WARD: You can tell him that she produced the biggest fruit cake I know.

DR. ALVERSON: I will send that back.

We have personally met with all licensees returning to work to sign contracts and explain how monitoring works. All returning licensees have been placed in the caduceus, either pharmacy or health professional. Thank you for letting me service recovering pharmacy professionals. Reports for the inspectors and the attorney on current recommendation for Wellness folks that you are seeing this meeting have been emailed to the Board's office.

Signed, Dr. Garver.

MR. CONRADI: Thank you.

DR. MARTIN: So if I heard the numbers right, Susan, there were 143 in some stage of screening and 83 in some stage of aftercare?

DR. ALVERSON: Yes.

DR. MARTIN: And those are separate numbers, that means we have 226 in the process in some form; am I correct?

DR. ALVERSON: I wasn't sure if some of the 143 --

DR. MARTIN: Could be in screening and aftercare at the same time.

DR. ALVERSON: Right, in screening that in.

DR. MARTIN: Yeah.

DR. ALVERSON: Yes, but I think that number is very close.

DR. MARTIN: Yeah, 226. I think that's important for pharmacists and techs and others that interface with the Board understand that, you know, it's a good program. I wish we didn't need it. It's great that we have it and

today there are 226 individuals in our state that are involved in the program in one form or another -- 226 pharmacists and technicians and students.

DR. ALVERSON: I was -- with your permission, I'd like to ask Dr. Garver for the annual report if there's any way he could tell us how many people with whom he actually makes contact.

DR. MARTIN: You can ask him anything you want to.

DR. ALVERSON: Okay. Because I'd like to know of those people that we contact or suggest treatment, how many -- where do they all go, how are they all parsed out, so. Thank you.

MR. CONRADI: Any more questions?

(No response.)

MR. CONRADI: We need to approve the last board meeting minutes and interview minutes. Have y'all got any corrections to any of those?

DR. MARTIN: My folder is empty.

MR. DARBY: Yeah, I didn't -- there

were none in my folder.

DR. MARTIN: We could probably if somebody will give us the date so we can cite the --

MR. CONRADI: November 19.

DR. ALVERSON: Mitzi handles all of that setting it up and she's been out sick, so I assume that's why.

MR. CONRADI: Do you want to just roll those over to next month?

MR. DARBY: Yeah, do you want to do that?

DR. MARTIN: I think that's probably the most appropriate thing to do.

MR. CONRADI: Eddie, inspector report?

MR. BRADEN: Yes, sir, Mr. Conradi, as you see in your Dropbox, the inspections that were completed by the inspectors and how many complaints we received and how many complaints we completed. There's also a number of complaints still being investigated that's not included in that. We had training for five of the inspectors that occurred in November and we

had one assist for inspection by NABP inspector and we also have some items to go over in executive session.

MR. CONRADI: Do y'all have any questions?

DR. MARTIN: No questions.

MR. DARBY: No.

MR. CONRADI: - secretary's report?

DR. ALVERSON: All right. Cristal is going to add something to this also because there's a section of work that she did this -- this month.

As I mentioned earlier, we were in Montgomery and we met with the Board of Nursing. Three or four of us went and we asked the chief inspector from the Board of Medical Examiners to go with us so everybody heard what was said and there would be no misunderstandings. We talked to the Board of Nursing about handling chemotherapy and what protection nurses need.

I'd say we had excellent reception. They've asked us to write for their journal -- their newsletter. They've asked us to be

speakers for their CE programs and their annual meeting. They said they really look forward to working with the Board of Pharmacy, so we're hoping we have made friends at the Board of Nursing and that we'll be working cooperatively on some issues and that's when the issue came up about if you are a pharmacy and you employ a nurse and that nurse goes beyond the usual scope of practice, that procedure has to be submitted to the Board of Nursing.

MR. MCCONAGHY: Did they tell you where that law was?

DR. ALVERSON: They emailed it to me. I don't have it with me but.

MR. WARD: There's something in our law about that if you're working for a physician but I'm not --

DR. ALVERSON: The way this happens, a pharmacy from Tennessee was doing home health in Alabama and they had sent a nurse to -- to do some work and they brought products in and somehow this person contacted the Board of Nursing, at which time the Board of Nursing

1 realized that there were some home health nurses
2 that weren't having their processes approved by
3 the Alabama Board of Nursing. So like I said,
4 I -- I was not aware of that regulation.
5 DR. MARTIN: Who did you meet with at
6 the Board of Nursing?
7 DR. ALVERSON: We met with Peggy who
8 is the second in line. Apparently --
9 DR. MARTIN: Yeah, Genell.
10 DR. ALVERSON: Genell Lee.
11 DR. MARTIN: Genell Lee.
12 DR. ALVERSON: Genell Lee has been
13 sick. Twice that we've been there recently
14 she's been out sick and I've been told she's
15 having health issues.
16 MR. WARD: Was that in the -- was the
17 nurse -- the nurse came from where, Tennessee?
18 DR. ALVERSON: Tennessee.
19 MR. WARD: Were they licensed in this
20 state? So doesn't that end the inquiry if they
21 weren't licensed?
22 DR. ALVERSON: She was going to get me
23 the information on who the agency was and what

they were doing coming into Tennessee and the name of the pharmacy.

DR. MARTIN: So this was a pharmacy in Tennessee?

DR. ALVERSON: Right, that had a patient in Alabama.

DR. MARTIN: Providing home care to a patient in Alabama?

DR. ALVERSON: Correct.

DR. MARTIN: Asking a nurse who's licensed in Tennessee to provide --

DR. ALVERSON: Well, I don't know -- I don't know yet if the nurse was licensed in Tennessee.

MR. WARD: Then the nurse would have to be licensed in both.

DR. MARTIN: Well, I would think as formal as the Board of Nursing has been for some time on get this approved and get that approved before you do it kind of stuff, that they would be equally as attentive to nurses needing to be licensed in the proper state as well. That was a good initiative on y'all's part to do that. I

1 think it's a good thing to come out of it.
2 So while we were in Montgomery, we met
3 with the staff at the Board of Medical Examiners
4 and again got a very warm reception. We've set
5 up a meeting for January 27 here in this
6 building so all of the inspectors for the
7 Medical Board and their director will be coming
8 here. They want to discuss compounding issues,
9 they said. We said we most certainly did too.
10 The issue of physicians setting up compounding
11 pharmacies, buying things from heaven only knows
12 where is -- is becoming huge and they're
13 interested in finding out how big that is just
14 as we are. We have offered to do some training
15 for them and they've taken us up on that, that
16 they would like us to train some of their
17 inspectors, which I took as a good sign.
18 We met with one of their lawyers. We
19 have an issue of a company coming into the state
20 that I think will be under a physician's license
21 but we're very concerned about it and so they
22 said they'd work with us on looking into that,
23 so we were also very pleased with how things

1 went with the Board of Medicine.
2 DR. MARTIN: So I'm assuming that some
3 of those same topics related to chemo and chemo
4 preparation you discussed with Nursing, you also
5 discussed with the BME and their staff?
6 DR. ALVERSON: Well, that's why we
7 took their chief inspector with us so he could
8 hear what we said.
9 DR. MARTIN: Yeah, yeah.
10 DR. ALVERSON: And I talked to him
11 afterward and said, would you like us to -- that
12 was one of the training topics we offered, that
13 your inspectors understand the issues with
14 chemo.
15 DR. MARTIN: Yeah, we still encounter
16 physicians who don't understand it, you know,
17 they're subject to 797 and 800 just like we are.
18 DR. ALVERSON: And their lawyer
19 mentioned to us that, you know, gees, it would
20 be great if there was something that would
21 impact physicians but there is nothing and I
22 said no, no, no, there is something that does
23 impact you, so we will definitely be talking

about that on the 27th.

MR. MCCONAGHY: Will we be billing them for that training that we're doing for them or are you going to trade out?

DR. ALVERSON: I think we're going to trade out.

DR. MARTIN: I think we'll get some in-kind out of that.

MR. BRADEN: We work well with them. They help us. We help them.

DR. MARTIN: Who is them?

MR. BRADEN: The investigators with the Board of Medical Examiners.

DR. MARTIN: BME?

MR. BRADEN: Yes, sir.

DR. ALVERSON: They seem to be open to the idea that when we have pharmacy kinds of things going on in a physician's office that they would consider when they go in taking one of us with them. So if we got that kind of cooperation, I'll train all day long for free.

DR. MARTIN: That's exceptional.

DR. ALVERSON: We did a CE program at

1 Samford, a three-hour live CE about what's going
2 on at the Board and an update about the Board.
3 I did part of it and Scott did the other part of
4 it. We had about 160 pharmacists and it seemed
5 to be well received.
6 We have spoken to two pharmacies now
7 who are doing fairly large scale compounders but
8 who are selling to physicians and we've told
9 them that that -- that has to stop, both because
10 of the FDA and because of our law so -- and so
11 we've told both of them in a very friendly and
12 cooperative way that they have three choices.
13 They can stop doing business. They can become
14 an outsourcer or they'll have to begin doing
15 everything on prescription and so we've given
16 them about a month to think about it, talk with
17 the owners, make that decision but we are going
18 to be going back to them to say what's the
19 decision.
20 MR. CONRADI: What are they making?
21 DR. ALVERSON: Pardon?
22 MR. CONRADI: What are the products?
23 DR. ALVERSON: IV products, a lot of

vitamins that are used in injection programs for weight loss.

MR. DARBY: With this --

DR. ALVERSON: Hormones.

MR. DARBY: With this topic being like it is, how would they not have already known that?

DR. ALVERSON: I think everybody does know it. Were you on the Board --

MR. CONRADI: If you call --

DR. ALVERSON: Right, it's like, you know, until the FDA shows up.

DR. MARTIN: Well, that's their fourth option, continue to do what you're doing and experience the consequences.

DR. ALVERSON: Correct.

DR. MARTIN: You said they had three but they really had four.

DR. ALVERSON: They really have four, right.

MR. CONRADI: I don't believe we'd let it go on, I hope.

DR. MARTIN: I think we'd help them

experience the consequences.

DR. ALVERSON: And I think Eddie would probably say we've -- are working well with the various federal agencies and -- so just having spoken to them, they are on that path of going into large compounders and making that decision.

DR. MARTIN: So I understand 503(b) went out for comment, was going out for comment a second time, still not out for real.

MR. DARBY: Are you talking about --

DR. MARTIN: No, 503(b).

DR. ALVERSON: 503(b) is done.

DR. MARTIN: I thought -- I thought it was out for a second round of comment.

DR. ALVERSON: They -- they have sent out some guidance for industry and just recently three new documents came out --

DR. MARTIN: Yeah.

DR. ALVERSON: -- about outsourcing facilities.

MR. WARD: Has the MOU come out yet?

DR. MARTIN: That's the question I

have. There were some -- when I met at the ASHP meeting -- the ASHP clinical meeting with other members of boards of pharmacy from around the nation, some of them say they have signed the MOU.

DR. ALVERSON: You're kidding.

DR. MARTIN: No. And I'm like, well, we're still waiting on the MOU and so either we're --

DR. ALVERSON: We have asked FDA people what about the MOU and they go --

DR. MARTIN: It is possible that they were confused but I just wanted to let you know.

DR. ALVERSON: Oh, I don't doubt that. It's just I'm -- I had the impression when we went to the meeting in Washington that when it came out, it was --

MR. MCCONAGHY: Everybody.

DR. ALVERSON: -- everybody is getting one of these and --

MR. CONRADI: I don't think it's out yet.

DR. MARTIN: I'll try to give you --

let me follow up on that because I think I wrote the name down of the Board member and what state it was.

DR. ALVERSON: Yeah, I would love -- I'd love to get a copy of it and see what their -- I did not think they would do them individually from state to state. I thought it was going to be one MOU or that was my guess.

MR. CONRADI: That is going to be just one MOU, take it or leave it.

DR. ALVERSON: That's what I thought.

DR. MARTIN: Well, we don't know if it's going to be offered to everyone at the same time or offered -- we don't know. We just assumed it was all going to be the same MOU offered to everybody at the same time. I'll follow up with you on that.

DR. ALVERSON: I'd really appreciate that. We are also in the process of setting up a meeting with the gang from the Board of Pharmacy investigators and staff from Mississippi and Georgia to talk about what

1 things are going on across state lines, what
2 problems are you running into, you know, are
3 some businesses moving back and forth and trying
4 to play us one against the other. We are also
5 going to offer a sterile compounding training
6 for the first half day or so if any of them need
7 that so.
8 And the last thing is the computer.
9 We have met with Cyber Best Technologies, which
10 is the group that did the Board of Nursing's
11 data system and the Board of Nursing continues
12 to rave about how good the system is and how
13 cooperative they are. We met with their CEO and
14 the person who handles health system -- health
15 programs. We brought everybody in the building
16 in to ask any questions that they wanted.
17 It turns out they are one of the
18 companies that have also developed some of the
19 police systems in the state and I had heard that
20 those work extremely well, so I was kind of
21 shocked to find out it -- what is it, LETS --
22 MR. BRADEN: LETS and AlaCOP that we
23 have access to that we utilize and it's very

user-friendly and I was very excited when I found out they were a part of that too.

DR. ALVERSON: So they're in the process of trying to nail down everything that we want. So we're still talking back and forth about getting everything we want identified so we don't have to hear, well, you didn't tell us that up front so you're not going to get it.

I talked to Joe Wilson last night about looking at the contract to make sure we get out of GLS cleanly and that this contract is well written. I would anticipate we would stay with GLS up through maybe July because this company will have everything done rather than just move data and then begin to build systems. But when we looked at it, they've already built -- they already have the ability to renew a license, to apply for an original license. This -- their system holds CE hours, holds all the data about proof of citizenship, schooling, just about any kind of background you would want. They have the ability to do that for people and for businesses already.

They have a legal system built in that documents who gets the complaint at the first step. When that complaint moves up the line to the next person, there's a place to document that and a place for -- to document notes or comments, so it's a step-wise process that's completely built in, a place for lawyers' comments, a place for SOCs, all of that is already built which, you know, we haven't even started talking about that yet. They have a place for investigations to be documented, so it sounds like there are a lot of things that are already in place.

MR. BUNCH: Are we going to be live on them before we drop GLS? Is that what you're saying?

DR. ALVERSON: Yeah, I don't -- I don't want to drop one --

MR. BUNCH: Right.

DR. ALVERSON: -- without having the other one.

MR. WARD: Can we negotiate the contract you think that payments will depend on

time of installation and --

DR. ALVERSON: Yes.

MR. WARD: -- and it working so they have an incentive to come back?

DR. ALVERSON: In fact, they said, you know, we need to get -- if you do contract with us, we need to get going so this is ready by the time you want it. It has to be in place by the time we renew technicians next and they said, we will work with no payment if that's what you want while you have the GLS system in place.

MR. WARD: We'll see if they'll sign a piece of paper that says that.

DR. ALVERSON: Well, I understand but.

MR. WARD: Because that's what happens every time, we pay them everything and then things go wrong and there's no incentive for them to come because they won't -- you know, when you build a big house, you hold back -- you hold back some to -- complete the building.

DR. ALVERSON: And that's why I want to be sure this contract is well written that we

have everything that -- that you all think should be in there.

DR. MARTIN: And Joe is in the middle of all of this?

DR. ALVERSON: Yes.

MR. CONRADI: Good.

DR. ALVERSON: I also think we should negotiate the GLS contract down because we have the Cadillac system right now. Right now they are just finishing projects from --

MR. CONRADI: But we're still driving a Pinto; right?

DR. ALVERSON: We sure are. I'll give you one small example. When we designed renewal for pharmacists, we explained that the people who get a license are: All active pharmacists can renew online, any pharmacist on probation can renew online. Nobody else can just automatically go through. We put that in writing. We told them, when we saw it when we would work here.

So now the -- when we print licenses, it won't print licenses for probationary people

and they said, well, you didn't tell us you wanted it to print a license for those people. So why would we have set it up to renew but not print the license and they said, well, if you want to pay us $550, we'll tell you how to print the license so -- but I mean, that's what it's like to -- to work with them. We -- we said when can you have it done, sometime in January. We won't need it in January but we haven't started on this year's projects, so why should we pay for the Cadillac number of projects going forward when we'll never even finish this year's projects.

DR. MARTIN: Sure.

MR. CONRADI: Get Joe working on that.

DR. ALVERSON: That's my report.

MR. CONRADI: It sounds like an active month.

DR. ALVERSON: Yeah, it's been -- Jim will tell you that we've kept him busy.

MR. WARD: It's the busiest month we've had this year without question.

MR. CONRADI: Mr. Ward, do you have an attorney's report?

MR. WARD: Yeah, I want to ask y'all something. You know, it's -- human nature being what it is, we're getting a lot of last-minute applications and renewals. Most of them are fairly straightforward. Some are not and require some further investigation or finding out other things and what I'm asking if you all would consider, this has been done in the past, assuming it's not something awful like a person under -- you know, it's pretty clear that you ought to have a hearing first just to send a letter that says, we're granting your application or your -- your renewal without a waiver of a disciplinary proceeding in the event that becomes necessary. That way the person gets licensed or the entity gets licensed and you haven't given up -- if not, you've got to wait until you get -- a lot of these folks don't submit what we ask them to to submit and asking other boards or entities, especially this time of year to get it, it takes a long time. So

rather than -- than not doing anything at all and waiting until a month or two, sending that letter. Is that -- what do y'all think about that?

MR. CONRADI: I think that's good -- a good approach.

MR. DARBY: I think that's fine.

MR. WARD: Is that okay with everybody?

DR. MARTIN: Yes.

MR. WARD: Dan?

MR. MCCONAGHY: I'm good.

MR. CONRADI: Do you want a motion on that or are you okay?

DR. ALVERSON: Cristal also has something she wanted to talk about.

MS. ANDERSON: After the fact. I was just -- would y'all like a paper copy or do you want me to have Terry Dropbox you or both?

MR. CONRADI: A paper copy would be great.

MS. ANDERSON: As you know, nurse practitioners, certified nurse midwives, and

physician assistants are going to be -- have limited writing abilities for C-II prescriptions starting January 1, 2015. I just wanted to let y'all know what the criteria was and hopefully we can put a little piece in it -- in the actual website for frequently asked questions. Not any midwives or nurse practitioners can do this but they have to go through multiple steps, have their own DEA number, have their own qualified Alabama Controlled Substance Certificate, and then also, thirdly, apply for the limited purpose Schedule II permit. They also must have an agreement -- a contract agreement with a collaborating physician.

I know we're going to get a lot of questions about this so I wanted to go ahead and introduce it and then also one of the things that the Medical Board wanted us to mention is the PDMP and that we need to make sure the pharmacists are actually submitting this under the nurse practitioner or physician assistant's name as opposed to their collaborating physician so -- because the collaborating physician will

be monitoring their nurse practitioner or physician assistant using the PDMP website.

MR. WARD: Okay. Are those -- are those other practitioners registering with the PDMP so they know?

MS. ANDERSON: Yes.

MR. WARD: So they'll have their own --

MS. ANDERSON: The collaborating physicians?

MR. WARD: No, the -- how do you know -- how does the pharmacist know --

MS. ANDERSON: The pharmacist can go into the Board of Medical Examiners' website and actually look up numbers. They can look up their LPSP, which is Limited Purpose Schedule II permit number or they can look it up by their qualified Alabama Controlled Substance Certificate.

MR. WARD: Yeah, but -- okay.

MR. CONRADI: Who's going to have time to do that while you're trying to fill prescriptions?

MR. WARD: Yeah, I mean, how --

MR. CONRADI: Isn't it on them, the physician, to --

MR. WARD: I mean, that's awful nice for them to be that concerned but I mean, how busy a pharmacy is, you're going to have to stop and have to --

MS. ANDERSON: Well, I think --

MR. WARD: And then what's going to happen is you don't do it and then some third party is going to come along and say you aren't entitled to reimbursement because you don't have the right -- and that's bull. That's not -- that's not fair. That's not right to do.

MS. ANDERSON: I did ask them about third party and paid claims and they said that, you know, processing it under these --

MR. WARD: Well, let me ask you this: The PDMP gets their information from -- through -- from the practitioner or the pharmacy; right?

MS. ANDERSON: Correct.

MR. WARD: That's how we're

identified?

MS. ANDERSON: Correct.

MR. WARD: Everybody -- the Pharmacy Board has to send to the PDMP some identification of all pharmacies filling controlleds; correct?

MS. ANDERSON: Correct.

MR. WARD: Okay.

DR. ALVERSON: Or not filling controlleds.

MR. WARD: Or not filling controlleds. And the doctors, the physicians, have to send something in with their information; correct?

MS. ANDERSON: Correct.

MR. WARD: And the dentists have to send in something with their information; correct?

MS. ANDERSON: Yes.

MR. WARD: So why can't the nurse practitioners and midwives and everybody else do the exact same thing?

MS. ANDERSON: Well, they will be but this is just -- basically we're kind of talking

about two things first and as we're talking about the licensure and then secondly --

MR. WARD: Right, I get that part.

MS. ANDERSON: -- we're reminding pharmacists that they need to be submitting under the nurse practitioner or physician assistant as opposed to the collaborating physician.

DR. MARTIN: So you're saying that when the pharmacy sends in the PDMP information today, and let's say it's a physician who wrote the controlled substance, that the pharmacy submits that under that physician's name?

MS. ANDERSON: Correct.

DR. MARTIN: And now in the future, maybe even now or beginning January 1, I guess, when the pharmacist goes to submit that prescription that's written by one of these middle-level people, their name will already be there for us to submit that on?

MS. ANDERSON: Yes, they -- they were confident that third parties should accept the nurse practitioner/physician assistant as the

primary caregiver for that prescription.

MR. WARD: Are they going to have their own pad? Are they going to have their own prescription pad or is it going to be identified under the physician?

MS. ANDERSON: They will have to put their own DEA number on there, their own qualified Alabama Controlled Substance Certificate, and their limited purpose Schedule II.

MR. WARD: It's going to be the doctor -- the physician's prescription.

DR. MARTIN: Their information is going to -- I mean, I don't do PDMP but I would assume that you need some numbers on that mid-level practitioner; right?

MR. DARBY: Yeah, you'll have to have their DEA number.

DR. MARTIN: Their DEA number.

MR. DARBY: That's what is submitted.

DR. MARTIN: So that should be a requirement that their LPSP --

MS. ANDERSON: Uh-huh.

DR. MARTIN: -- is printed on the prescription blank they're using to write the prescription?

MS. ANDERSON: That would definitely help, which we -- we probably need to touch base with them again to see how they are going to do that as far as a prescription.

MR. WARD: I'm just going to say something: Which number are they supposed to submit? They're going to have a DEA number. They're going to have a medical board issued number.

MS. ANDERSON: Two medical board issued numbers.

MR. WARD: So which number are -- which number is it going to be -- that PDMP is going to have?

MR. BRADEN: PDMP operates off of DEA.

MR. WARD: So then -- so then the prescription then will have to have the mid-level practitioner's DEA number --

MS. ANDERSON: Correct.

MR. WARD: -- in order for the pharmacist to do it?

MS. ANDERSON: To -- yes.

MR. WARD: Okay. And when it doesn't -- okay.

MS. ANDERSON: It's going to be just like a physician that doesn't put their DEA number on there.

MR. WARD: I know. I agree but the point is that before it was just one person not doing it, now you may have five people not doing it. Okay.

MR. MCCONAGHY: The third parties are going to be billing off their NPI, not their DEA or state number. They're going to be billing off their NPI, so they need to put that on there too.

MR. CONRADI: Is this going to be on our website?

MS. ANDERSON: Yes, I --

MR. MCCONAGHY: They want our input. We want that on there too.

MS. ANDERSON: Before the end of the year, Susan and I will get together and I will see if we can't put -- and I also talked to Amy. She is the nurse practitioner that works at the Medical Board and she's the one that's heading this up, so it's really the Medical Board, not the Nursing Board, that's taking care of this aspect.

DR. ALVERSON: There's another -- correct me if I'm wrong here -- complicating factor. These practitioners cannot write for all C-IIs.

MR. WARD: Right.

DR. ALVERSON: They can --

MR. CONRADI: We'll have to just trust that that's the right C-II.

DR. ALVERSON: Right.

MR. WARD: No, what the Medical Board wants you to do is go to their website every time and look.

DR. ALVERSON: They do. That's exactly what they want you to do.

MR. CONRADI: They'll have to monitor

that themselves. I mean, the pharmacist hasn't got time to check every prescription to see if it's under --

MR. WARD: Wait until the third-party payer comes in and says, oh --

MR. BUNCH: The physician should be held if he writes a C-II that he's not supposed to write instead of us policing what he's writing.

MR. CONRADI: They will start catching him.

MR. BUNCH: Well, that's what I meant. It could be their fault, not our fault.

MS. ANDERSON: And I'm hoping there's only going to be --

MR. CONRADI: Just like on a prescription, we have to assume it's within the scope of the collaborative --

MR. BRADEN: That's what I understood the problem with the Medical Examiner's office is that the doctors were going to be responsible and that's what they were going to have to monitor that PDMP problem.

MR CONRADI: It would be nice for as many as you can get --

MR. WARD: Well, they have a collaborative practice -- they have some sort of collaborative agreement --

MR. BRADEN: Yes.

MR. WARD: -- with -- with the physician, so ultimately he's responsible.

MR. BRADEN: Right. And the Board of Medical Examiners --

MR. WARD: So as usual, they want the pharmacy to correct the doctor's mistakes. Isn't that the way it always works?

MR. BUNCH: Yeah.

MS. ANDERSON: I think just so they can have the collaborating physician check behind their mid-level practitioners. That's why they want us to use their DEA and have their name on the prescription as opposed to the physicians.

MR. CONRADI: I'm sure they put it on there.

MR. WARD: Well, aren't you doing that

now?

MS. ANDERSON: It was supposed to be.

MR. MCCONAGHY: I think we need to make some kind of statement that just says it's the physician's responsibility or we're going to run into a lot of the -- especially the young pharmacists that are not going to fill it unless they can verify everything as said and if they think they're going to be held responsible for it. So if we're going to say, you know, we're not going to cause you a problem if you fill one that's not on their formulary, then they --

MR. WARD: Maybe they should hire Fresenius. If it's Amoxicillin it kicks out, maybe they could -- the PDMP should be able to do that for the Schedule II. Wouldn't that be great?

MR. BUNCH: Hey, Susan, on this new system coming out, you know, you get things like this that are -- I get a lot of calls in my pharmacy from other pharmacists, you know, asking a question about rules and all of that. Do we have a system that we pretty much I assume

have everybody -- kind of pharmacists' email address, they send that in on their -- it is on the application, isn't it, where we could -- where we can just kind of blast -- hit one button and everybody gets an email?

DR. ALVERSON: And I was going to ask you if that would be okay with you that we send an email to every pharmacy and every pharmacist.

MR. BUNCH: Right.

DR. ALVERSON: We could do a mailing but that's going to take us longer.

MR. BUNCH: Yeah, the email would be great.

MR. CONRADI: A lot of people doesn't -- as I understood from yesterday it just -- you may just set it in the trash pile.

MR. BUNCH: Yeah.

DR. ALVERSON: All right.

MR. MCCONAGHY: I don't ever get the mail.

DR. ALVERSON: Oh, that's right. But yes, we -- Cristal has already written up a lot of this.

DR. MARTIN: Yes.

DR. ALVERSON: So we'll put it in an email and do an email blast for pharmacies and pharmacists.

MR. CONRADI: And on the website too.

DR. ALVERSON: And on the website, yes. And we're not planning on doing --

MR. CONRADI: Put something in there about it's their responsibility to write them right. I don't think we've got time to -- now, I know I don't have time to look at the regular prescriptions they write. I assume what they're writing is --

DR. ALVERSON: And we figure we won't any work January 2 and 5, we'll just answer phone calls, so. And I think Cristal had one more thing.

MR. CONRADI: All right.

MS. ANDERSON: That was it.

DR. ALVERSON: Oh, that's it. Thank you.

MR. CONRADI: Anything else?

MR. WARD: Cristal, this looks good.

Thank you.

MR. CONRADI: Mr. Ward, do you have any attorney report?

MR. WARD: No, sir, no, I just gave it about the -- about the letter.

MR. CONRADI: Have you got anything for executive session?

MR. WARD: No, sir.

MR. CONRADI: Okay.

MR. WARD: Well, I may have one thing, one thing.

MR. CONRADI: Okay. Old business? Got any old business, Dan or David?

MR. MCCONAGHY: Yeah, I guess one item that we had -- we had been talking about the automated dispensing rules for long-term care and that's not finalized but one of the things Susan -- wasn't it in a meeting and I know in that group session we had, we had agreed that we would -- to abide by the federal rules on the limitations in the stat cabinet of 50 drugs, that the feds don't have a limitation on that.

DR. ALVERSON: They don't.

MR. MCCONAGHY: And I'd like to suggest in lieu of not having the long-term care automated dispensing rule finalized yet -- we had some new ideas that came into the process and we were going to redo and are going to come back with that hopefully next month but on -- I think to solve that one problem because it looks like -- I talked with Jim and we both read it and it looks like this section was written and then that one line was gone back and added in there and under the rules of the State Board of Pharmacy.

MR. CONRADI: What rule number is it, Dan?

MR. MCCONAGHY: In Chapter 680-X-2.18. It's on page 44. It's number 4(e)(3). It says, "The number of drugs provided by a pharmacy to a long-term care facility shall be limited to 50," and I would propose that we just omit that line in the rules.

MR. WARD: Just amend the rule by deleting that line.

MR. DARBY: That's a motion; correct?

MR. MCCONAGHY: That's a motion.

MR. DARBY: I'll second the motion.

MR. CONRADI: Any discussion?

(No response.)

MR. CONRADI: That will still have to go through the regular rules process, Jim?

MR. WARD: Yeah, I guess, it's 680-2.18(4)(e)(3).

MR. MCCONAGHY: Yeah. And I know Tim had -- he and I had discussed some of the other wording in there that potentially needs to be reworded but I just suggest we do that when we do the automated rule.

MR. WARD: I agree.

MR. MCCONAGHY: And just do this one action at the moment.

MR. CONRADI: So get Susan to put this up to read next month or to delete it?

MR. MCCONAGHY: Uh-huh.

MR. WARD: We need to prepare the papers so that will --

DR. ALVERSON: I'll ask Mitzi to do that. She's really good at that.

MR. WARD: Yeah, she knows how to do that.

DR. ALVERSON: Yes.

MR. CONRADI: All in favor of the motion?

DR. MARTIN: Aye.

MR. MCCONAGHY: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. WARD: Eddie, do you remember that email from that Mr. Jordan and I sent it to ask Mitzi to put on the agenda, and Susan, I don't know if you've read it yet, about the disposing of controlleds at nursing home facilities using a --

DR. ALVERSON: A distributor.

MR. WARD: No, some sort of a box.

DR. MARTIN: A little mail in.

MR. WARD: And whether or not -- what he wants to know is who needs to be involved in the destruction process or putting it in the box or whatever they are going to do with it because it had to be both -- does the pharmacist have to

be involved in it.

DR. ALVERSON: Yes. Well, right now federal law says that the consultant pharmacist must be present for all destruction and the director of nursing or that person's representative and you must make a list of all C-IIs documenting name, dose, type, quantity.

MR. WARD: So I told them that I would ask y'all but it seemed to me that would be up to the pharmacist's responsibility --

MR. CONRADI: They would have to do that.

MR. WARD: -- to know that -- to know that -- how to do it; right?

DR. MARTIN: I think it spells out in the federal drug law that -- what options are available, right. There's not just one. There's a couple of ways.

MR. WARD: There's some new -- there's some new technology.

DR. MARTIN: I know the new rules came out on take back.

MR. BETHEA: There's some rules on the

Board of Public Health side too that the facility had to abide by.

MR. WARD: Hold on one second. Let me see if I can find it. Hold on a minute.

DR. MARTIN: Public health?

MR. WARD: Hold on one second.

MR. BRADEN: There has to be a DEA-41 form also for destruction of controlled substances.

MR. WARD: A DEA?

MR. BRADEN: Forty-one.

MR. WARD: Forty-one/2X, division four one.

MR. BRADEN: We call it a 41.

DR. ALVERSON: Does the nursing home have to fill that out though or doesn't the reverse distributor have to fill that out?

MR. BRADEN: The reverse distributor if it's done by a reverse distributor does that.

MR. WARD: Yeah, but I don't think this is a reverse distributor. Here it is. Can I just read it to you real quick?

MR. CONRADI: Yeah.

MR. WARD: "I am Joe Jordan with Sharps Compliance. We manufacture the Med Safe, a DEA-compliant collection receptacle for use in retail and long-term care for the collection and transport by common carrier and destruction of controlled and noncontrolled alternate user unused medications. I'm emailing to request information to best advise customers registered as authorized collectors. In Alabama it is required that both a pharmacist and a nurse/employee from a long-term care facility destroy the controlled substances together." Then the answer is yes.

DR. ALVERSON: Yes, that's who has to do it.

MR. WARD: Huh?

DR. ALVERSON: That's who has to be present.

MR. WARD: Okay. And they both -- they have to do it together.

DR. ALVERSON: They must do it together, right.

MR. WARD: All right.

MR. CONRADI: Any more old business?

(No response.)

MR. CONRADI: Any new business? We've got election of officers.

DR. MARTIN: Do you want them all in one or do you want them one at a -- I guess you want them one at a time?

MR. CONRADI: I think we can do the whole slate.

DR. MARTIN: I think I'd rather do them one at a time.

MR. CONRADI: Okay. Do one at a time.

DR. MARTIN: So I move that Dan McConaghy be elected as president of the Board for next year.

MR. DARBY: Second.

MR. CONRADI: All in favor?

MR. DARBY: Aye.

MR. BUNCH: Aye.

DR. MARTIN: Aye.

MR. CONRADI: Aye.

DR. MARTIN: All right.

MR. CONRADI: Have you got another one?

MR. MCCONAGHY: I move Tim Martin be vice president.

MR. CONRADI: Second. All in favor?

MR. MCCONAGHY: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. MCCONAGHY: I move Buddy Bunch be treasurer.

MR. CONRADI: Second. All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. CONRADI: Aye. All right.

MR. BUNCH: With assistance from Dan McConaghy.

MR. CONRADI: There we go.

MR. DARBY: Mark, I want to make a motion that Wednesday, December 24, the State Board office be closed and that the employees be paid for that day.

MR. CONRADI: I'll second that.

MR. WARD: I'm not sure you can do that but I mean, you should, but I'm not sure.

MR. CONRADI: We'll let the auditor tell us next year.

DR. ALVERSON: You are so wonderful.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. CONRADI: Aye.

MR. MCCONAGHY: Aye.

MR. BUNCH: Aye.

DR. ALVERSON: Actually, I'm the one who's working the 24th manning --

MR. WARD: Manning the post.

DR. ALVERSON: -- 12 phones or something like that, so I'm planning to use the day to clean off my desk because that's a day-long project.

MR. DARBY: I would think that phone wouldn't be ringing a lot that day.

DR. ALVERSON: That's what I'm thinking too.

MR. CONRADI: If it is, have you got

Eddie on speed dial?

MR. BRADEN: I live right over the hill.

MR. WARD: Hanukkah will be over so I'll be at the office so you can call me.

MR. CONRADI: We'll let you come over here and handle it.

DR. ALVERSON: Why don't you come here and answer the phone.

MR. CONRADI: Any other new business?

MR. WARD: I'm not sure you want me to do that.

MR. DARBY: I've got one more. In order to keep up with the compensation for relief pharmacists, I would make a motion that we increase the Board member salary to $600 a day.

MR. BUNCH: Second.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. MCCONAGHY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

Any other new business?

DR. ALVERSON: Mark.

MR. CONRADI: Yes.

DR. ALVERSON: I remember this happening last year, the Board being reminded about voting for the secretary and it turned into THAT just because I did it for last year, do we have to do that?

MR. CONRADI: We do. Do we want to vote for a secretary at this time?

MR. DARBY: I make a motion that Susan Alverson be the Secretary of the Board.

MR. BUNCH: Second.

MR. DARBY: All in favor?

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. MCCONAGHY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

We do have executive session. Before we go in, I just want to tell you it's been a pleasure serving the Board for the past five

1 years. I'm going to miss it. I appreciate the
2 opportunity and the honor to do this. It's been
3 fun. It's been bad at times but it's a great
4 opportunity, so I appreciate that. I appreciate
5 y'all putting up with me for five years in the
6 audience there, so anyway.
7 DR. ALVERSON: We hope you'll come
8 back and visit anytime you want.
9 MR. CONRADI: Not as much as Charlie
10 but maybe. Oh, he's not here, but anyway. All
11 right.
12 At this time, we will retire into
13 executive session at -- for the purpose of
14 talking about the competencies of professionals,
15 permit holders, registrants, and other legal
16 matters. We'll go in at 10:20 and we'll come
17 out at 11 o'clock. When we come out, all we
18 will do, we will vote on -- huh?
19 DR. ALVERSON: 10:40?
20 MR. CONRADI: 10:40, I mean. We'll
21 vote on anything that we discussed in executive
22 session. That will be all the business we will
23 conduct at that time. I need a voice vote.

Mr. McConaghy?

MR. MCCONAGHY: Aye.

MR. CONRADI: Mr. Darby?

MR. DARBY: Aye.

MR. CONRADI: Dr. Martin?

DR. MARTIN: Aye.

MR. CONRADI: Mr. Bunch?

MR. BUNCH: Aye.

MR. CONRADI: And I vote aye.

So y'all have a great holiday.

(Whereupon, a recess was taken for executive session beginning at 10:32 a.m. to 11:25 a.m.)

MR. CONRADI: Case number 12- -- that's an old one, isn't it?

MS. ANDERSON: Yes, we're cleaning up some -- some ones that were just still sitting out there.

MR. CONRADI: Case number 12-0427, letter of concern to the pharmacist and copy to the nurse practitioner in M.D.'s office. How do

y'all vote?

DR. MARTIN: I move we accept the recommendation as submitted.

MR. CONRADI: Okay.

MR. MCCONAGHY: Second.

MR. CONRADI: All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

Case number 13-0515, letter of concern to the pharmacist and a copy to the complainant.

DR. MARTIN: I move we accept the recommendation as submitted.

MR. CONRADI: All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

14-0083, 14-0084, 14-0114, 14-0140,

and 14-0159, no violation.

DR. MARTIN: I move we accept the recommendation as submitted.

MR. MCCONAGHY: Second.

MR. CONRADI: All in favor?

DR. MARTIN: Aye.

MR. MCCONAGHY: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Case number 14-0126, letter of concern and recommendations to continue to monitor medication.

DR. MARTIN: I move we accept the recommendation as submitted.

MR. MCCONAGHY: Second.

MR. CONRADI: All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Aye.

DR. MARTIN: You don't need anything on the surrenders?

MR. CONRADI: Yeah, we do. Case number 14-0149, hold for further investigation.

DR. MARTIN: I move we accept the recommendation as submitted.

MR. MCCONAGHY: Second.

MR. CONRADI: All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: Case number 14-0105, 14-0113, 14-0165, accept permanent surrender.

DR. MARTIN: Propose -- I move that we accept the recommendation as submitted.

MR. MCCONAGHY: Second.

MR. CONRADI: All in favor?

MR. MCCONAGHY: Aye.

DR. MARTIN: Aye.

MR. DARBY: Aye.

MR. BUNCH: Aye.

MR. CONRADI: All right. That completes -- the Board of Pharmacy, 12/17/14, is

1 officially dismissed.
2
3 (Whereupon, the meeting was adjourned
4 at 11:27 a.m.)
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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

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