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ALABAMA STATE BOARD OF PHARMACY

WORK SESSION

Wednesday, October 15, 2014

8:12 a.m.

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

REPORTER: Sheri G. Connelly, RPR

1 APPEARANCES

2

3 BOARD MEMBERS:

4 Mark Conradi, President

5 Tim Martin, Vice President

6 Dan McConaghy, Treasurer

7 Buddy Bunch, Member

8 David Darby, Member

9

10 ALSO PRESENT:

11 Ronda Lacey

12 Rick Stephens

13 Dane Yarbrough

14 Jeff Freeze

15 Al Carter

16 Tammie Koelz

17 Matthew Muscato

18 Paul Rengering

19 Nancy James

20 Louise Jones

21 Tracy Davis

22 Gary Mount

23 Lindsay Leon

- 1 Clemice Hurst
- 2 Kelli Newman
- 3 Jim Easter
- 4 Julie Hunter
- 5 Sally Sims
- 6 April Marlin
- 7 Carly Rhodes
- 8 Pamela Jubach
- 9 Anita Pritchett
- 10 Jeanna Boothe
- 11 Chris Burgess
- 12 Melanie Smith
- 13 Scotty Armstead
- 14 Wendy Sprayberry
- 15 Leslie Payne

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

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

23 MR. CONRADI: I hope it is.

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

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

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

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

15 MR. STEPHENS: Rick Stephens, Senior
16 Care Pharmacy.

17 MR. YARBROUGH: Dane Yarbrough,
18 Turenne PharMedCo.

19 MR. FREEZE: Jeff Freeze, Turenne
20 PharMedCo.

21 MR. CARTER: Al Carter with Walgreens.

22 MS. KOELZ: Tammie Koelz, Walgreens.

23 MR. MUSCATO: Matthew Muscato,

1 Walgreens.

2 MR. RENGERING: Paul Rengering,
3 Walgreens Pharmacy.

4 MS. JAMES: Nancy James, PharMerica.

5 MS. JONES: Louise Jones, Alabama
6 Pharmacy Association.

7 MS. DAVIS: Tracy Davis, Alabama
8 Pharmacy Association.

9 MR. MOUNT: Gary Mount, Baptist Health
10 Montgomery.

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

13 MR. CONRADI: We're sorry.

14 MS. HURST: Clemice Hurst, Alabama
15 Medicaid.

16 MS. NEWMAN: Kelli Newman, Alabama
17 Medicaid.

18 MR. EASTER: Jim Easter, Baptist
19 Health System.

20 MS. HUNTER: Julie Hunter, Omnicare.

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

23 MR. MARLIN: April Marlin, Baptist

1 Health System.

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

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

6 MS. PRITCHETT: Anita Pritchett,
7 Southern Pharmaceutical Services.

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

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

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

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

1 go?

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

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

21 DR. MARTIN: Yeah.

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

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

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

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

20 MR. EASTER: Right.

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

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

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

6 MR. BRADEN: Yes, sir.

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

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

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

19 DR. MARTIN: Yeah, yeah.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 MR. CONRADI: Good explanation.

19 MS. JONES: Thank you.

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

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

5 MR. CONRADI: Dan may.

6 DR. MARTIN: Yeah, Dan will be in.

7 MR. MCCONAGHY: Mine shows already.

8 MS. JONES: Yours shows, okay.

9 MR. MCCONAGHY: Give it to David.

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

12 MR. DARBY: No.

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

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

20 MR. MCCONAGHY: Oh, yeah.

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

23 MR. YARBROUGH: Yes, sir.

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

3 MR. YARBROUGH: I represent Turenne
4 PharMedCo obviously and we have packaging
5 technology inside our pharmacy today and from my
6 experience, if you don't have a pharmacist
7 involved in the packaging and the labeling of
8 those medications that come out of the
9 machines -- when I say -- I mean direct
10 involvement, physically there, it's very
11 concerning. And so I know Turenne PharMedCo is
12 100 percent in support of option one and that's
13 using it for emergency situations only and we
14 are totally opposed to option three where the
15 packaging is done on site at the nursing home.

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

1 MR. FREEZE: That's correct.

2 MR. YARBROUGH: Yes, sir, it's where
3 medications are generally kept in containers
4 where there's technology that -- it's a
5 vending machine -- the pills through chutes and
6 ladders if you will --

7 DR. MARTIN: Yeah.

8 MR. YARBROUGH: -- end up in a
9 location and this is a --

10 DR. MARTIN: Yeah, so I'll date myself
11 when I say this but it's something that in the
12 past we can an ATC 212 -- a Baxter ATC 212. Is
13 that --

14 MR. FREEZE: This is multidose instead
15 of single dose, I don't know, did you do single
16 dose?

17 DR. MARTIN: You could do either one.

18 MR. FREEZE: Either way, the same.

19 DR. MARTIN: Yeah.

20 MR. CONRADI: The machine does that?

21 DR. MARTIN: Yeah.

22 MR. YARBROUGH: Yes, sir and in
23 option -- in option three, which is the option

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

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

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

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

11 MR. FREEZE: It's integrated.

12 MR. YARBROUGH: Yes, sir.

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

20 MR. FREEZE: Correct.

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

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

5 MR. FREEZE: It does.

6 DR. MARTIN: Yeah.

7 MR. FREEZE: Yes, sir.

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

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

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

15 MR. DARBY: No, Scotty.

16 MR. ARMSTEAD: Scotty Armstead.

17 David, I believe that at least if you went on
18 Louise's scale to say at least two is an option,
19 it's in the neighborhood of at least 30 or
20 something, I believe, in the country that at
21 least allow that or maybe into three if you look
22 at the far end of it.

23 MR. CONRADI: What part of this, Jeff,

1 on option three do y'all not like?

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

7 MR. CONRADI: Checking it and making
8 sure.

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

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

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

3 MR. FREEZE: That's right.

4 MR. STEPHENS: And --

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

9 MR. FREEZE: I suspect.

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

14 MS. JAMES: The licensed personnel.

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

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

1 conscience allow that to happen and let that go
2 as the final check and we didn't have any
3 pharmacists that weren't like I couldn't let
4 that happen. While it's very good and probably
5 99.9 percent accurate, that .1 percent when
6 you're filling as many prescriptions as we do,
7 it's unacceptable and that's where we just don't
8 have the comfort level today to let that go
9 without that final check. Bottom line, that's
10 where we came to our genesis on what we have.

11 MR. FREEZE: That's right.

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

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

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

1 emergency meds too as opposed to --

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

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

15 MR. BUNCH: Start out slow.

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

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

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

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

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

13 MR. YARBROUGH: Yes.

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

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

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

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

8 MR. YARBROUGH: Correct.

9 DR. MARTIN: Okay.

10 MR. FREEZE: For every medication.

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

14 MR. FREEZE: That's right.

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

21 MR. YARBROUGH: I would say so.

22 MR. STEPHENS: I think basically,
23 yeah.

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

3 MR. EASTER: Jim Easter, Baptist
4 Health System, and because some of this crosses
5 into the institutional side where we've used
6 unit based cabinets for a long time.
7 Dr. Conradi asked about how this material gets
8 into the cabinet. The ATC 212 that Tim and I
9 came up through the system with would require
10 about an hour's worth of downtime every day to
11 clean the chutes and everything else and in the
12 technology that most of us have moved to --
13 Pyxis, Omnicell and so forth -- we all use
14 barcode scanning as a safety device. So if you
15 want to open up any one of the CUBIEs that we
16 use, you have to scan the CUBIE or go on the
17 screen and then scan the product that you're
18 going to put in there, which significantly
19 increases the safety for our patients, so thank
20 you.

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

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

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

11 FEMALE ATTENDEE: Yes, it is.

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

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

1 DR. MARTIN: Right, so -- go ahead.

2 MR. STEPHENS: And that patient
3 information would be input that we need a dose
4 of this medication --

5 DR. MARTIN: Yeah.

6 MR. STEPHENS: -- for that patient.

7 DR. MARTIN: Yeah.

8 MR. STEPHENS: It doesn't come out
9 packaged with anything that has that patient's
10 name on it.

11 DR. MARTIN: Right, right. And so it
12 comes out like perhaps as a unit dose of --

13 MR. YARBROUGH: That's correct.

14 DR. MARTIN: But not patient specific.

15 MR. FREEZE: That's correct.

16 DR. MARTIN: Not with an overwrap and
17 I guess two comments there and maybe I shouldn't
18 even be commenting because I wasn't part of the
19 group but in other environments that there are a
20 couple of concerns when that happens and one
21 concern is that at least in the hospital
22 setting, if the -- if the person, usually a
23 nurse I guess, goes to the machine and all of

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

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

17 MR. YARBROUGH: That's right.

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

23 MR. YARBROUGH: And that kind of fits

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

4 DR. MARTIN: Yeah.

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

12 DR. MARTIN: Yeah.

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

15 MR. YARBROUGH: That's right.

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

20 MR. STEPHENS: More accountability
21 there.

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

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

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

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

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

15 MR. YARBROUGH: Yes, yes.

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

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

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

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

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

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

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

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

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

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

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

1 DR. MARTIN: Right.

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

4 DR. MARTIN: Right.

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

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

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

1 MR. YARBROUGH: That's right.

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

6 MR. CONRADI: How deep their pockets
7 are.

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

14 MR. YARBROUGH: Yes.

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

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

19 MR. YARBROUGH: We would want a
20 formulary.

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

23 MR. YARBROUGH: Correct.

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

3 MR. DARBY: Yeah.

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

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

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

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

1 or modify the provisions of Alabama Code Section
2 34 Chapter 23 or supporting regulations,"
3 meaning the rules and there may be better
4 wording for that but our intent is not supercede
5 obviously anything else. I'm not aware of
6 anything that this conflicts with but it doesn't
7 mean that Jim Ward's eyes certainly don't need
8 to be on it. I don't know.

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

11 MS. JONES: No.

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

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

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

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

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

1 process than the other so.

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

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

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

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

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

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

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

10 MR. CONRADI: What's new?

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

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

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

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

17 MR. CONRADI: About three minutes
18 left.

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

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

3 MR. YARBROUGH: It does not.

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

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

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

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

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

19 MS. JONES: Okay.

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

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

1 going to do it has not been decided.

2 MR. MCCONAGHY: Yes.

3 DR. MARTIN: We're in agreement --

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

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

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

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

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

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

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

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

22 MR. FREEZE: Right.

23 MR. MCCONAGHY: I understand if

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

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

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

8 DR. MARTIN: I need to say --

9 MR. CONRADI: One minute.

10 DR. MARTIN: One minute, okay.

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

13 DR. MARTIN: Did y'all discuss
14 downtime?

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

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

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

23 DR. MARTIN: Yes, how does a nurse get

1 access to the medications they need for a
2 patient.

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

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

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

14 MR. FREEZE: I just don't --

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

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

22 DR. MARTIN: Yeah.

23 MR. YARBROUGH: We felt that a lot of

1 that would be hashed out on policies and
2 procedures.

3 DR. MARTIN: Yeah, yeah, yeah.

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

6 DR. MARTIN: The last thing I just
7 wanted to say for the record in case we ever go
8 back and pull these minutes and try to decide
9 what we talked about is we're talking about
10 rules that are to be promulgated pursuant to
11 34-23-74 section B, so if somebody is trying to
12 find out where all this came from, that's where
13 it is. Thank you.

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

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

21 MS. BOOTHE: Jeanna Boothe with
22 Decatur Morgan Hospital.

23 MR. BURGESS: Chris Burgess, Heritage

1 Pharmacy.

2 MS. SMITH: Melanie Smith, BuzzeoPDMA.

3 MR. ARMSTEAD: Scotty Armstead,

4 Turenne PharMedCo.

5 MS. SPRAYBERRY: Wendy Sprayberry,

6 Calhoun Treatment Center.

7 MS. PAYNE: Leslie Payne, Calhoun

8 Treatment Center.

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

12

13 (Whereupon, the work session was
14 adjourned at 8:57 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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