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ALABAMA STATE BOARD OF PHARMACY

WORK SESSION

Wednesday, July 16, 2014

8:13 a.m.

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

REPORTER: Sheri G. Connelly, RPR

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 Henry Burks, Chief Inspector

12 Susan Alverson, Director of Professional
13 Affairs and Secretary

14 Cara Léos

15 David Clark

16 Jim Easter

17 Julie Hunter

18 Karen Nishi

19 Rick Stephens

20 Louise Jones

21 Tracy Davis

22 Richard Lambruschi

23

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

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

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

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

21 DR. MARTIN: Proposed or is it that
22 far?

23 MR. CONRADI: No, it wasn't that

1 far.

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

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

23 The question came, well, what about

1 those who are in the middle that are making it
2 in anticipation of in large quantities that's
3 obviously not patient specific and so they're
4 going to be calling those outsource compounders
5 and they'll fall under this category called
6 503B, and as I understand it, they'll be
7 required to comply with something that's kind of
8 like GMP but it's not full GMP. Is that what
9 y'all understand Mark, Susan?

10 DR. ALVERSON: Yes.

11 DR. MARTIN: Rick?

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

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

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

23 DR. MARTIN: Yeah.

1 MR. STEPHENS: They want to be
2 serious.

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

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

18 DR. MARTIN: Yeah, please do.

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

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

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

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

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

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

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

10 MR. EASTER: Yeah.

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

13 MS. LÉOS: Sure.

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

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

18 DR. ALVERSON: Pardon?

19 DR. MARTIN: Were you finished?

20 DR. ALVERSON: I am.

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

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

3 So that's 503B and you know, stay
4 tuned and you can go out and Google it and
5 you'll read a bunch of stuff and you know, most
6 of it is spin and chatter and until -- until we
7 get the real thing, we don't know what it is.
8 503A, on the other hand, gets more to the heart
9 of what the act was that generated all of this
10 and that's the Drug Quality and Security Act.
11 You'll hear it referred to as DQSA and it will
12 more or less establish a pedigree from the
13 manufacturer to the pharmacy but it won't go
14 beyond the pharmacy to the patient.

15 MR. CONRADI: Yet.

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

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

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

8 What other things are on your mind
9 this morning?

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

13 DR. MARTIN: Yeah.

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

16 DR. MARTIN: The checklist for?

17 MR. EASTER: Compounding.

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

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

1 MR. EASTER: Okay.

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

6 MR. EASTER: Okay.

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

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

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

21 MR. LAMBRUSCHI: Pretty good shape.

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

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

7 MS. LÉOS: Cara Léos with ALSHP.

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

10 MR. EASTER: Jim Easter, Baptist
11 Health System.

12 MS. HUNTER: Julie Hunter, Omnicare.

13 MS. NISHI: Karen Nishi, Cubex.

14 MR. STEPHENS: Rick Stephens, Senior
15 Care.

16 MS. JONES: Louise Jones, Alabama
17 Pharmacy Association.

18 MS. DAVIS: Tracy Davis, Alabama
19 Pharmacy Association.

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

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

1 like to discuss this morning? Louise?

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

19 DR. MARTIN: Uh-huh.

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

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

4 MS. JONES: She did not.

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

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

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

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

1 MR. CONRADI: You can't replace me.

2 MS. JONES: Well, you're right -- to
3 fill the position that Mark will leave a huge
4 hole in --

5 MR. STEPHENS: A huge hole.

6 MR. CONRADI: Huge hole.

7 MS. JONES: -- are Tammie Koelz and
8 then -- let me think, gosh, my mind is blank --
9 Donna Yeatman and Joe Street, Junior. So those
10 are the three names that went to the Governor
11 and --

12 DR. MARTIN: Now the waiting begins.

13 MS. JONES: Yes, may the lobbying
14 begin. It seemed like there was one other thing
15 but I can't remember.

16 DR. MARTIN: Let's go back to your
17 first topic for just a minute.

18 MS. JONES: Okay.

19 DR. MARTIN: And I know that
20 occasionally I've had a conversation with a
21 board member about how they think we should
22 handle that and it tends to go back around to
23 the issue of you can't regulate everything. You

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

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

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

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

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

23 DR. MARTIN: It touches a lot of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 Yes, sir, Rick.

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

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

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

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

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

23 MR. CONRADI: Yeah.

1 MR. DARBY: That's good.

2 DR. MARTIN: Okay.

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

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

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

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

1 things.

2 DR. ALVERSON: Right.

3 MR. STEPHENS: That's been --

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

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

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

16 MR. STEPHENS: Dot 18.

17 DR. MARTIN: It's not 18?

18 MR. STEPHENS: No, I think it is.

19 DR. MARTIN: It is 18.

20 MR. CONRADI: 518, yeah.

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

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

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

8 MR. STEPHENS: Uh-huh.

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

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

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

22 MR. STEPHENS: I vote for that.

23 MS. HUNTER: Me too.

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

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

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

14 MR. MCCONAGHY: Yeah, that's it.

15 DR. ALVERSON: That's it.

16 MR. DARBY: What is the federal
17 guideline?

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

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

9 MR. DARBY: Reviewed by those same
10 three people?

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

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

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

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

5 MR. STEPHENS: Right.

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

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

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

1 MR. STEPHENS: Our law uses a
2 cabinet.

3 DR. ALVERSON: Pardon?

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

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

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

23 MR. LAMBRUSCHI: It would all still be

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

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

5 MR. LAMBRUSCHI: Those that have
6 pharmacies.

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

11 MR. LAMBRUSCHI: No, sir.

12 MR. BURKS: No.

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

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

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

1 it, epinephrine, two or three things.

2 DR. MARTIN: Some of them do morphine.

3 MR. LAMBRUSCHI: Morphine.

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

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

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

14 MR. STEPHENS: Okay.

15 DR. MARTIN: -- on Wednesday
16 afternoon.

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

20 DR. MARTIN: Yes.

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

1 DR. MARTIN: Yeah, yeah.

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

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

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

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

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

10 MR. CONRADI: At least we're
11 consistent.

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

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

16 MR. STEPHENS: Right.

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

22 DR. MARTIN: And were the regulations
23 adopted?

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

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

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

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

22 DR. ALVERSON: Yes.

23 MR. MCCONAGHY: -- or whatever if he

1 felt the need to.

2 DR. MARTIN: Yeah.

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

7 DR. ALVERSON: Right.

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

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

19 Thank you so much for being here.

20

21 (Whereupon, the hearing was adjourned
22 at 8:52 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 9/30/2014

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