STATE OF FLORIDA
DEPARTMENT OF HEALTH

RULE DEVELOPMENT WORKSHOP

RE: Rules 64J-2.006, .010. .012, .013, and .016

Trauma Registry and Trauma Quality Improvement Program

DATE:	June 21, 2016
TIME:	Commenced at 9:08 a.m. Concluded at 10:48 a.m.
LOCATION:	Room 301 4025 Bald Cypress Way Tallahassee, Florida
REPORTED BY:	MARY ALLEN NEEL, RPR, FPR

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LEAH COLSTON, Moderator
STEVE McCOY, Panel Member
KAREN CARD, Panel Member
JOSHUA STURMS, Counsel
MICHAEL LEFFLER, Clerk

I N D E X

P R O C E E D I N G S

MS. COLSTON: So I think we've gotten the bugs with the conference call line worked out, and I believe our court reporter is now set up.

This workshop will be documented by a court reporter, and as soon as the workshop is concluded and we're able to receive a draft, we will post that workshop -- the workshop transcript to the trauma website. We will send out notification once that is done. We want everyone to be able to have an opportunity to review that.

This is the first in a series of three workshops that will be held. The next one is scheduled for June 28th in West Palm Beach, and then the third one is scheduled in Orlando on July 11. So we will hold a series of three.

We will accept comments for two weeks, I believe, post the July 11th workshop. So those of you who are here are lucky. You will have the opportunity and a little bit more time to submit your comments up through -- I believe it's July 21st, but I'll clarify that date.

For those of you on the conference call line, if you could please send a email to Michael, M-i-c-h-a-e-l, dot Leffler, L-e-f-f-l-e-r, at

Florida FL Health -- I'm sorry, @FLhealth.gov, to kind of let us know that you're on the line, we would like to be able to add you to the records as being present for the workshop.

Good morning. My name is Leah Colston. I am the bureau chief for Emergency Medical Oversight here at the Florida Department of Health. Most of you probably know me. We're glad that you're here.

For the record, today is June 21, 2016. We are at the Capital Circle office complex in Building 4025.

Today we are going to conduct a rule workshop for 64J-2.006, .010, .012, .013, and .016. This is also being recorded on the conference call line, so again, we will give you an opportunity to speak. For those of you on the conference call line, if you will send an email with your request to speak and the rules that you would like to address, we will be monitoring that real-time, and that will be printed out. And so we will have an option at the end, as we've done with past workshops, to hear comments being received on the conference call line.

We have addressed the IT issue on the conference call line with being able to mute

everybody, so at this particular point, everyone is muted on the conference call line. When it's time to accept comments, we will unmute all of the lines, so just make sure that you are pressing the pound -- is it Star 6?

MR. McCOY: Star 6 to unmute.

MS. COLSTON: Star 6 to unmute when the opportunity comes for you to speak.

Let's see. I guess you guys know I'm serving as your moderator today. A couple of housekeeping rules. Please place your phones on mute. Again, we'll have a lot of folks speaking. We don't have a microphone in this room, so I would ask you to use your outside voices when you are providing comments to us. And also, if you could come here and speak, that could be great so that we can -- everyone can hear what you're saying.

We do have microphones that are interspersed throughout the room for people to be able to hear, and they are very sensitive. So if you're having private conversations and you're right underneath a microphone, please be very careful, because folks can probably hear that.

Joining me today is my panel. I have Steve McCoy, who is the EMS section administrator. Steve

was very involved several years ago, and up through today even, with working on the allocation rule and some of the data collection that is involved with that.

I also have Karen Card. She was instrumental in working through a lot of the methodology with the allocation rule.

And then I have Joshua Sturms, who is part of our data unit. He has taken Steve's place and joins us for the fun in working with all the data that's associated with the trauma registry and that sort of thing.

The restrooms are right out these doors. Men, you will go back to this door and go to your left. Ladies, you will go out this door, and you can go to your right. Vending machines are downstairs on the first floor, I believe it is, so if you get hungry, get thirsty.

I do apologize for the heat in here. I think it's starting to cool off a little bit, so hopefully we'll have a level of comfort here.

There are speaker request forms in the back of the room, so if you do intend to provide comment today, please make sure you fill out a speaker request form, and then Bernadette will bring them

up once we begin to open up the comments.

When you approach and want to speak, say your name and spell it for the court reporter, and also state your organization and the rule that you are addressing comment to. That way we will, for our purposes and also for everybody who will be looking at these transcripts once they are posted, they will understand what rule you're commenting on and the context of your comments.

Okay. So -- let me see here. So just a little bit. I know there was some question when we first began. We did not disseminate any rule language with this, and that's because there is none.

When the trauma system was first developed, there was a great need for trauma hospitals in the state of Florida, and we all know that was quite some time ago. We have not looked at revisions to that system since that particular point in time, and we know that the time in the environment is ripe for us to do that now.

We've been involved in a lot of litigation regarding the allocation rule and regarding the increased demand for trauma licensure, and a lot of this litigation has caused us to kind of step back

and look at how we're interpreting the rule and how we're looking at things. In my short tenure here, we understand that there are changes that are needed to the statute also. Things have changed significantly in the trauma environment, as you all well know.

And, you know, while in the past few years, we have been slow to move forward, we've seen lots of comments and we've gotten lots of feedback. And I can assure you from my perspective, that hasn't fallen on deaf ears. We know that there are things that need to change. It took 20-plus years for the trauma system to get old. It may take us a little bit to try to improve that trauma system.

In order to do that effectively, we need the input of our trauma system stakeholders. And I've said it before. I said it when I first began, that the input from the community is critical to us developing a good system and moving forward. I think we're well positioned to be able to do that, and I think we have a lot of things that are planned for the future to be able to accommodate us being able to evolve the trauma system and improve it and kind of bring it up to where we need it to be now.

Our legal counsel has actually looked at the statutes and the rules, and we know that there's a statutory limit of 44 trauma centers in the state of Florida based on what the Legislature has proposed, and that number -- it was several years ago when they developed that number. That number may have changed. We may need to look at that. We may need to evaluate. We have to look at what the needs of the trauma system are, and so that's part of what we want to do.

But since legal counsel has actually looked at statutes and rules, we're kind of revisiting how we determine whether or not that's a limit for the state, and should we impose additional limits at the local level within each TSA. And there are arguments for -- we've heard some of those -- and arguments against. But that's what we're here to do. We're here to collect the input from you as the stakeholders to kind of understand how we need to proceed.

So we're re-evaluating what we call need in the allocation methodology. We need to look at how we determine need. You know, we've heard comments that some of the elements are not necessarily indicative, true indicators of need, so we want to

revisit that.

We're also looking at -- and I think we've discussed -- we've had some discussions about the adoption of the ACS standards, and so we kind of want to look at the ACS standards and determine what role that plays, you know, in order for us to move to ACS verification.

Is that the thing for Florida to do? Because I've heard arguments on both sides that say trauma -- Florida's trauma standards are a little more stringent in some areas than the ACS standards; the ACS standards are merely guidelines, and so the Florida standards, when they were first developed, were intended to really kind of push some Florida-specific requirements and standards down. And, you know, they were in some instances much more stringent, the education requirements and that sort of thing.

If we were to adopt standards, then we really do need to look at the statute, and we really do need to look at how we need to make revisions in that statute that would align with adoption of the ACS standards. Is that the right thing to do? I don't know. I don't have the answers to those questions, but I think that as a group, you guys

do.

So again, what I mentioned before is, we have no predetermined rule language. The idea is, we want to go through these rule workshops. We want to get feedback from folks. We're going to go back to our legal office and have them kind of digest it and help us determine. We're going to get with folks in the community and kind of run through a process of trying to determine, you know, what's the best move forward? Can we do it through an advisory council? Because I heard at the last workshop that that's what we really need, and we are working on getting that together again.

In the State of Florida, we move very slowly, and we have to be very careful. We have to make sure that we're, you know, kind of trying to do things in a way that the community is going to accept. So, you know, I said before, I don't want to push stuff down and say, "Here. Take it." So we're developing a concept, and then we're going to vet it through the community, and we're going to kind of try to use that, in addition to these workshops, to actually develop a good approach moving forward.

So today, what I would encourage you to do is

give me your gripes, give me the issues, tell me what's wrong, because we know what's wrong. I've actually heard some things already. And I know that you guys are going to give it to us.

So give it to us, because it's going to be on record. We want to hear it. We have leadership that is concerned and wants to hear this. But while you're up doing that and while you're telling us what's wrong, tell us what you think we can do to make it right.

Is this a promise or a guarantee that everything that everyone says is going to get incorporated? No, because that's impossible. But what I can assure you is that all of your input is going to be used to formulate an approach. We will work with the community to be able to try to develop a system and an allocation methodology and everything else within that system that will work at least and is generally consensed upon by the community.

So bring your issues. Let's talk about it. I want to hear them. We're very open to hearing them. But I also want to know what you think the solution is for this. And if you don't have one, that's okay. You can just say that. We'll just

listen to what the issues are, because all of that is critical at this particular point for us to be able to move forward in what we're doing.

So we'll go ahead and begin. Thank you.

Sorry. Come on in.

Are there any questions for me before we get started?

Good. Smiles. This is a good thing. I think this is exciting. And I have thick skin, so if you get up and you yell, or you're mean, or you sound like you're upset and anxious and generally not happy, I understand that. I do. I get that, and I encourage it. Just give us your points. But also, follow that up with what you think we should do to fix it.

All right. Okay. So we'll to ahead and begin. Are there any speaker cards in the back? I'm not going to go in any specific order. I'm just going to -- I've been given these in a pile.

(Inaudible comment by unidentified speaker.)

MS. COLSTON: Okay. Are there any -- before I begin, let me go ahead and collect speaker cards.

Okay. So I will remind you again that when you come up to speak, please say your name, spell it, and then indicate the organization that you are

representing. I'm going to leave my secret squirrel notebook up here, so please don't look at this.

Okay. So we'll go ahead and begin.

Dr. Ciesla. Sorry.

DR. CIESLA: First one.

MS. COLSTON: You should have just stayed up.

DR. CIESLA: I put my name in last because I thought you were going in order.

MS. COLSTON: We can give you more time if you want.

DR. CIESLA: No, actually, I don't -- I mean, I don't really have a ton of things to say.

To start with -- so my name is Dave Ciesla, C-i-e-s-l-a. I'm a professor of surgery at the University of South Florida, I'm the trauma program director at Tampa General Hospital, and I'm a vice chair for the State's American College of Surgeons Committee on Trauma.

I'm not speaking for any one of them. I'm kind of representing myself and the membership. I think I share a lot of the ideas of people who are parts of those organizations, but I'm not officially saying anything on any of their behalf.

Okay. I had like -- in my mind, I had about

ten more minutes to get ready for this.

MS. COLSTON: We can give you additional time if you like.

DR. CIESLA: Okay. Well, first, what I want to say is, I think that -- I really appreciate everything you said. I think that this is a really great transition in the process. And the first thing I had on my notes to talk about was really the process. I mean, what we've been kind of working on under the methods of the last few years, where the Department would propose a rule, and then they would present it, and then the community could come up and take shots at it, it was almost as if it was an adversarial relationship from the get-go, which I think caused a lot of problems. It was really hard to get ideas in. It was hard for the Department to explain its rationale. And I think it kind of automatically put us at odds. I think that this is a welcome change to that.

I think that, you know, the process, it's tough. You know, we are in a complex area, there's no question about that. People make this the focus of their academic careers. Like, I'm one of them. You know, we have subject matter experts across the country who spend a lot of time on this. We have

people here that do the same thing professionally. And we should have an environment where they can collaborate and come up with rules and approaches together rather than, like you said, having it pushed down or pushed up from one way or the other.

And to that end, I think that my first comment would be to really create this kind of environment where you put together a committee of subject matter experts who can work on a draft rule together, then present that to the Department and to the Office of Trauma, and use that as a proposed rule for the rule development workshops. I think that that would shortcut a huge amount of time.

When you have -- when you have no committee and you open it up to the public, you, the office, has to sift through all that stuff and determine which comments are really based in fact and which are based on impressions or biases and which ones are practical and which ones meet the goal. So that would be my first comment, is on the process.

You know, in the past, when I first got to Florida in 2008, we had the Trauma System Implementation Committee that was run really through the Florida Committee on Trauma in collaboration with trauma nurse managers and state

officials. It was a really effective way, and that was the organization that helped put together the trauma systems plan up until about 2010.

It had representatives from all the different levels of trauma centers. It had representatives from community hospitals and EMS and nurses and the State. We had subcommittees, and we had charges for things like registries and research and performance improvement and standards, all the kinds of things that you would want to see in a rule. I think it was a great structure and should be brought back in some form.

Okay. So the rule specifically. So I'm going to go -- well, just some general comments about the rule. I think, you know, you are somewhat hamstrung by what the Legislature writes. But I would be willing to bet that if you came up with a rule that everybody liked and you didn't get sued over, that the Legislature would pass an amendment that would support that rule. So I think that that's -- I think that we should worry about the rule first and the legislation second.

With respect to the rules, I think it's critical that you state explicitly what the goals of each rule are, and not in general terms. Like a

general term where you want to provide high quality trauma care with universal access to every Floridian is not a useful goal. That's, you know, apple pie and mom and ice cream, and nobody is going to disagree with that, but it doesn't really help with you the details. Examples would be access; right? So one would be that you want to make sure that everybody who needs trauma care gets trauma care at the level at which they need it.

Okay. So I think as far as the goals of each rule, I think they need to be -- there needs to be a lot of goals, and they need to be very explicitly stated, and I have a couple of examples. I don't think, like -- I don't want to get too lost here. I don't think that -- this isn't really a working meeting. It's not like we're going to come up with a couple of elements that we're going to put into a rule and say, "Okay. That's something that we can all get behind." I think that you're looking for general ideas that you can take to a committee or, you know, even within the Department or something and say, "We can take this and operationalize it using specific methods."

All right. So I'm going to go a little bit out of order in terms of the rules, because -- I

can't believe you put me first.

All right. Okay. So the first thing I wanted to talk about was the apportionment rule, so .010. So the apportionment rule and the trauma center standards are really the backbone of your system. Everything else kind of depends on those two things. The apportionment rule, I think you have to specifically state what your goals of that apportionment rule are, so I wrote down a couple of things.

And one is, you want universal access; right? You want everybody who needs a trauma center to have access to that trauma center in a timely manner to the level at which they're in demand. Okay?

The second thing would be, you want it to be efficient. You don't want it to have duplication of resources. You don't want it to have -- there to be -- to have movement within the system if it's unnecessary. You want it to have high quality. In other words, you want all patients, regardless of what kind of environment they're in, to get the best care that they need. Sometimes the best care is in a community hospital. Sometimes it's a Level II, sometimes it's a Level I, and sometimes

it might even be, you know, out of state or something. Who knows? But you want there to be the minimal movement within the system as necessary.

You want it to be cost-effective; right? You don't want to be spending a lot of money -- it kind of goes to the same thing as efficiency. You know, if you want a high value system, you'll have high quality and low cost.

I think one of the things that should be explicitly stated in the apportionment rule is where the State and the Department feels the Level I's role is. If the Department and if the community feels that the Level I is really no different than a Level II, then state that explicitly in the rule so that we're not left kind of wondering why a rule would be in favor or not in favor of one or the other. And Level IIs are really important to the state, the community hospitals are really important to the state, and Level Is are. I think that in the rule it should state explicitly what the value the system puts on a Level I.

And then if there are political or economic goals that you want to rule to make -- you know,

one of those might be that you want to recognize the centers that are in existence, that you want to keep them functioning and that your intention is not to close them. State that in the rule. And if -- like, for example, you could say, you know, "We came up with this apportionment rule, and it says that your area is overdesignated, but we recognize that these centers have been functioning for a period of time, and we don't want to discourage that, so we'll leave them open. And if one of them closes, then we'll reassess the need to open another one," something like that. I mean, I think that in the rule, you should state those things.

And if there's an economic goal, like, say, you want the opportunity for free market or competition there, then write that down in the rule.

The second part of the apportionment rule would be regions. The first comment on that would be that the trauma service areas were based on a 30-year-old methodology and on population and transportation patterns that are just outdated. What we have in the state now is an infrastructure that can support rapid transfer of patients.

There's plenty of scientific literature on this that shows how long it takes patients to get from rural areas to trauma centers, and they all basically say the same thing: We have a great pre-hospital system in the state. We have tons of pre-hospital resources. We can get patients from almost anywhere to almost anywhere.

And that being said, it's probably not accurate to say that all the TSAs that are defined right now should have a trauma center in that TSA. Now, that's not to say they shouldn't have a trauma resource or they shouldn't be part of a larger regional system, but to put a trauma center in a rural county where most of its population happens to be in suburban -- in a suburban city that already has a trauma center doesn't make a lot of sense.

The example that comes to my mind is around Fort Myers. Most of the population in TSA 17 lives in suburban Fort Myers. It doesn't make sense to put another trauma center right next to one that's already serving that community. Something like that, to recognize those kind of things.

So the first comment would be that I think that the TSAs are outdated, based on old

infrastructure. I think they should be reevaluated. The TSAs themselves are small. The state is too big, and so you need something in between. I know that there has been a lot of talk about dividing the state into major regions, and the ones that make the most sense are the Domestic Security Task Force regions. I know that there's language like that in the statute.

I think that coming up with a rule to recognize those regions and then using those regions as a unit of measurement, not necessarily a measure of -- a unit of administration, but a unit of measurement that says, "Okay. Well, within west central Florida, where is the population, and what's the demand, what are our resources, what's our delivery capabilities?" and then that's how you figure out where the need is.

Okay. So now defining need. You know, if you want to come up with a system for apportionment that's needs based, then you have to define what the need is. I think that this is a really tough area, and this is kind of -- part of this is my kind of academic interest, but this is really tricky, because the need kind of depends on which point in time you're in. And trauma care and

triage and everything is a really dynamic process, and the mindset changes at every step. And so what might look like a trauma patient on one side of it might not look like a trauma patient on the other side. And I'll get to that in a second.

But specifically, what need is, it's really a reflection of what the demand is and what the capacity is. If there's no demand and lots of capacity, there's really no need. If there's lots of demand and no capacity, then there's lots of need. But you can't define need without looking at both.

So first, before you even get to that -- this is what makes it even trickier. Before you even get to that, you have to decide what a trauma patient is, and that is -- there is no standard for that. There are lots of ideas. There are lots of definitions, depending on what you're trying to study or what your goal is. But it's a really elusive, moving target. That doesn't mean it can't be operationalized into an objective system, but I think there are lots of considerations.

It's been done in a couple of different places. There's a method called the GEOS method that was done in Scotland. I think everybody is

familiar with that by this time. People are looking at that as a good model. That might not be the right formula, but at least that approaches a solid approach.

In that, you do a couple of things. One is that you look at, in terms of a trauma patient -- well, okay. I'm getting out of order. Defining a trauma patient is a really tricky thing, and that's where I think that it would be important to have clinical subject matter experts weighing in. There's this delusion that any patient with an injury has to be helicoptered to a trauma center; at least it sounds like that in some of the rhetoric.

The fact is that the vast majority of injured patients that go to hospitals have minor injuries that can be effectively cared for in community hospitals. The next biggest chunk have moderate injuries. They can be treated in any trauma center. There are a handful of patients -- and I don't mean a handful, but the minority of patients have serious and critical injuries, and those are the ones that really need emergent, on-time care. Those are the ones where all this infrastructure is built around.

We shouldn't sort of build the system to funnel all patients to trauma centers. We should send the patients who need trauma centers to trauma centers. We should send the patients who can get effective care in the community into the community. We should have a flexible system so that when we -- it gets it wrong, they be redistributed rapidly with a minimal amount of risk and morbidity.

Okay. So defining the trauma patient, there are examples of that. One of the ones that's in the statute is using the injury severity score. There's also the ICISS method. There are a number of other retrospective labels that are put on injured patients after all the information is acquired.

It's a convenient method, and sometimes it's really useful. It's really informative, but there's a lot of systematic errors in it. And what I mean by that is, once you have all of the information and you put a label on a patient saying, "Oh, this was a trauma patient," none of that information was available to the people who made the decisions at the time.

For example, you could have a patient who, you know, fell down some stairs, and to the EMS and to

the emergency physicians and to the physicians in the community hospital, that patient might have had injuries that could easily have been taken care of within their community. But then we go back, and we see the patient had comorbidities, they have a certain injury pattern, or they may have been at a certain level of risk of death, and we say, "Oh, no, no, no. This is a trauma patient. That patient should have been taken to a trauma center."

That is a systematic flaw that needs to be at least recognized and then mitigated in whatever apportionment we come up with.

Another method would be to say, "Okay. Well, we'll define a trauma patient as anybody who meets pre-hospital trauma triage criteria or interfacility transfer criteria," which is -- that's a good way; right? We have this pre-hospital triage tool. We give it to the paramedics. The paramedics use that to determine whether or not they should come to trauma centers. It's based on -- the problem with it is that, again, it provides a limited amount of information at a short period of time and is ripe for under- and over-triage.

The key to this is, in the actual delivery of

the care, is to be flexible enough that you can either go up or down and not consider it a failure. It's just a safety mechanism within the system. When you're -- when you're talking about quality and apportionment, I think you have to take both of those things into consideration.

So that would be measuring the demand. So for demand, you know, you would want your measure of demand to reflect a couple of things: The information available at the time the triage decision is made, in other words, trauma alert or not trauma alert. You would also want it to reflect the final disposition or the final state of the patient, so some kind of post hoc method like ISS or ICISS or something like that. I think that's the area where the clinical subject matter experts are critical in coming up with this.

The second part of need is capacity. You can't -- you know, you can't measure need without measuring the capacity. I think that there's been a lot of comments in the literature and over the last few years about what is the volume-outcome relationship in trauma centers. And I think there is a volume-outcome relationship in trauma centers. That's why you have trauma centers in the first

place. Otherwise, everybody would be a community hospital, and there would no need to concentrate patients in centers, period.

Where the State or the community wants to set that level, I think, should be sort of agreed upon. You know, we saw an event last week where the strengths of a Level I trauma center were really highlighted, and we have to decide whether or not those are things that we need to preserve.

The others missions of the Level I trauma center are research, system quality improvement, regional resources for scarce things, education and training of the people who go out to the community. We need to decide whether or not those things are important, and if they are, then put it in the rule in a way that allows the Level Is to flourish.

So capacity. There's all kinds of ways to measure capacity. We have a list of -- what now? Thirty-something trauma centers in the state? We all know how many beds there are. We all know how many trauma beds there are. We all know how many trauma surgeons are on the faculty at those places. We all know where they are in relationship to the population, and we all know what the EMS system is.

So that's how you would measure capacity.

It's not really that hard to get that information. It's as easy as creating a simple Survey Monkey, sending it out to all the hospitals in the state who are licensed by the State and saying, "Hey, fill this out if you want your certificate." You know, it's that simple.

Okay. Need. Okay. That's all I -- maybe it's good that I went first, because that's all I could write down for apportionment.

The next thing that I would talk about would be the registry. I think I'll go to the registry. So the registry is critical for -- it's just a tool; right? It's critical for measuring the performance of the centers in the system. It's really an integral part of the quality improvement process within each center. And then for a system, you have to have a system registry.

The downside to it is that it's really limited to only those hospitals that are participating in the system. And in this state, we say you're either a trauma center or you're not. That's by definition an exclusive system, which is okay, but you just have to recognize that it's an exclusive system, and there's huge amount of data that you're going to miss, so you need something else.

So sticking with the institutional registries for a minute, all of us right now are required to participate in the National Trauma Data Bank and the TQIP project, which really makes institutional registries at the state level kind of superfluous.

The NTDB is organized and administered by the American College of Surgeons through the Committee on Trauma. It's filled with panels of people who make this their academic interest. They are -- you know, they're professional systems scientists. They're objective. They don't really care what happens in Florida. They just want to know that their model works and that they can measure what they say they're measuring.

We've already kind of gone down that route. It really would be, I think, a great step forward to just essentially outsource our state trauma registry to the NTDB. All of us could submit our data directly to the NTDB. You would skip a step by going through the State. The NTDB would then provide a summary report and basically the whole State of Florida patient data back to the Department.

You could save a ton of resources doing that. You would get standardized, validated reports. You

could benchmark us amongst ourselves. You could benchmark the hospitals in Florida against the others in the country. You know, not being part of that level of the COT or the NTDB, I couldn't say this quite with authority, but I'm pretty sure they would be willing to work with you, you know.

The other part of the registry -- so that covers patients who are discharged from trauma centers. There's a whole ton of patients who come to emergency rooms and then are discharged, who go to community hospitals, get great care, and then discharged. Some even come to trauma centers and then are transferred to community hospitals for their reconstructive or their rehab beds. We need information on them.

And personally, I've been using the statewide discharge data set. I know Steve uses that a lot. There's a ton of information in there. And I think that that provides data on -- data on the level of resolution that's would give -- that's at least informative enough to say what's happening outside the trauma centers.

If you have identify an area that's kind of lacking from that data set, I think then you could target it. But to come up with a system that

requires all hospitals in the state to submit data on all injured patients to either the State or the NTDB I think is going to be a lot of waste of resources. So a combination of the NTDB and the state discharge data set I think would meet most of your needs.

The next thing about the NTDB and the TQIP is that it's -- like the models are constantly being refined, and they're constantly being studied, and the COT and the NTDB have the kind of resources that you just can't duplicate in the state. And they have numbers of patients that come in nationwide, so things, you know, where you would be limited to a sampling area -- I know we've got 19 million people, but with 350 million people, you would be able to sort out, you know, what are kind of sampling errors and what are not. It really does represent the state, or the science, at least, in terms of trauma systems and trauma outcome.

Okay. The next thing is -- you've got a check box. I'm going to go with the process for the approval of trauma centers, and I'm going to combine that with the site visits in the approval. And this is kind of getting back on the Committee on Trauma kind of soapbox.

So the key -- like the other part, aside from apportionment, the backbone of the trauma system is the standards for your trauma centers. In Florida, we have two standards. We have Level 1s and Level IIs and then nothing.

And the Committee on Trauma in the orange book has standards for all levels of hospitals, and it basically says that if you have these resources and these processes in place, then you fit this category of trauma center, and it's up to you as to whether or not you want to participate in that.

I think that it provides a really sort of operational structure where you can look at any hospital in the state using your Survey Monkey data and say this would be considered a Level V resource or a Level IV resource or a Level III resource.

It doesn't mean that they have to participate in the trauma system like -- you know, like you would imagine in Oklahoma or Texas or something. But as a state, you could say, "Well, of the 220 acute care facilities we have in the state, we've got 30 that we are considering kind of these core parts of the trauma system. We've got 190 hospitals out there that have injury care capability, and here's where they sit."

For the standards for the major trauma centers -- and by that I mean the Is and the IIs -- just like the NTDB and the TQIP project, those standards are constantly being revised according to the best evidence available. And many of the people on the Committee on Trauma are either in Florida or were part of Florida at some point or had a hand in developing the Florida system. Our standards are outdated compared to many of those. Some things that we thought were important 25 years ago turn out not to be that important, and some things that turn out to be pretty important weren't in the rule or weren't even existing 25 years ago.

So to have that document as a reference saying, okay, our standard will be, you know, the ACS Level I with some modifications -- right? Use it as a base, and then write explicitly which things you think are important and which are not. And then, you know, you don't have to rewrite the new rule every time a new version of the orange book comes out.

Sort of partnered with that is the approval and the site visits, so the Verification Review Committee and the Committee on Trauma. Originally the site visits that we had in Florida were almost

identical to the way the college worked. You would invite some outside trauma expert. They would come in with a review team, and they would go through all your charts. And they would say, "Well, here's where you're meeting standards," or "Here's what I think of your trauma system." It was -- there was lots of problems with it, because there would be a lot of reviewer bias. People would come in and say, "We think your trauma center should run like ours," you know, and they would determine that after, you know, a morning of reviewing paper.

The Committee on Trauma and the Verification Review Committee has, like, evolved orders of magnitude since then. They now have a formal education process where the reviewers are instructed on how to review centers. They're instructed on how to review centers according to the college standards and to their own state standards.

So when the VRC comes in, they will look at your center, and they'll say, "Here you're following your college standards, and here's where your deficiencies are." And if you have state standards, we're going to review you on those too. And so you might pass your state survey and not

necessarily your college survey, or vice versa. But either way, it's an objective review by a trained reviewer.

Their report goes to a committee, and so it's not really arbitrated by one person. The report goes to the committee, and the committee reads the findings of the review. They all sit together, and they send you back the report.

I just got ours yesterday, and we had no deficiencies, but you would be surprised at all the number of recommendations they would put in there. And they were larger than the reviewer who reviewed us.

So as a system, it works great. There's no -- I think the chance for reviewer-specific bias is minimized. I think that the process that they use to make sure that they're being -- that the reviewer is reviewing based on college standards alone is really good. And I think the system that they have of passing it through the committee and finally getting committee review is really good too.

And again, they have the kind of resource -- they've got this economy of scale where they can do this; right? It's not on the Department to

organize reviewers and to organize times and get hospitals to pay for all this. I mean, you're making the hospitals pay for this stuff anyway. It's easy to just say, "Hey, go get your certificate, and then we'll visit you." So that kind of combines the process for verification and sites visits.

I don't really have anything to say about extension of the application period, so I guess that's good enough for me.

But I would say this has been great. I'm really optimistic about this. I think that there has been a -- you know, the new year comes along, and it seems like the whole system is just charged and really -- people want to get involved in this. People want this to kind of get settled so we can get down to making this the best system we can.

But thanks for letting me talk.

MS. COLSTON: Thank you.

The next speaker, Chad Patrick.

MR. PATRICK: My handwriting is that bad?

MS. COLSTON: I don't have my glasses on. I get a pass.

MR. PATRICK: Good morning. Chad Patrick, C-h-a-d, P-a-t-r-i-c-k. I'm the CEO of Orange Park

Medical Center. And I just wanted to first thank the Department for accepting our application. That application was based on the proposed rules, and so we're obviously here to figure out this process and how that will play out.

We've expended, obviously, a tremendous amount of resources, millions of dollars in hiring people, surgeons, et cetera. Since May the 1st, we've been treating patients. We're saving lives. We're very excited about providing that service in the Jacksonville area in concert with UF Shands.

And that's about all we wanted to say at this time. So we're intrigued about the process, and we'll be very engaged. And thank you.

MS. COLSTON: The next speaker, Steve Ecenia.

MR. ECENIA: Thank you. I've Steve Ecenia. I'm here on behalf of Orange Park Medical Center and Kendall Regional Medical Center. Orange Park is a provisionally approved Level II trauma center, and Kendall Regional is a provisionally approved Level I trauma center. Both hospitals submitted applications in the current batching cycle and relied on the Department's rules in moving forward and submitting these applications.

You know, it's interesting. I'm reminded of

the famous phrase from Yogi Berra, "It's deja vu all over again." I've been working with the Department since 2008 on developing trauma rules and have been to I don't know how many workshops and rule development proceedings since then, but I think it's important to focus on where we are right now.

And certainly from an aspirational perspective, the trauma system, and I -- you know, Dr. Ciesla has been involved in I think as many workshops as I have. And really, the whole trauma community I think comes out and discusses its perspectives in these different workshops. And there's a wide array of opinions with respect to what the trauma system in Florida should look like.

And it was a tremendous effort, a tremendous, a Herculean effort to get the current rule in place. And that rule has provided the framework for the applications that the Department now has before it. And it's not only my clients' applications; there's an application by Jackson South.

So in the current batching cycle, you've got three applications for trauma centers that by virtue of the Department's current actions have

been somewhat left adrift. And I think it's incumbent on the Department to move forward with concluding the 2015 assessment, publishing a revised rule that adopts the 2015 assessment, and moves forward with that process.

To the extent that there needs to be a systematic reconsideration of the trauma statutory and rule framework, on behalf of all the HCA-affiliated trauma centers, I can tell you that we would actively welcome participating in that kind of an effort, being part of a larger collective panel to consider and recommend options to the Department.

But the difficulty of making these kinds of changes is so apparent that it's almost as though the Department is ignoring the elephant in the room. I think that you need to complete the process that you've begun with the applications that you have before you. To the extent that there needs to be changes made to the system to accommodate a fresh look at where we are in trauma, you know, I'm all for that.

I do think, honestly, given where we are -- here it is the end of June of 2016. We're not going to conclude workshops, or at least the first

series of workshops that we're here today to talk about, until July 21st. By the time the Department gets around to proposing a rule or has a rule that it can move forward with and gets consensus on, we're going to be in the middle of a legislative session.

And I would suggest that perhaps the best thing to do is to try to get all of the stakeholders together and try to propose changes to the statutory framework that govern the trauma system in Florida, and that that is maybe a more efficient and effective way of making changes to the system that the Department believes need to move forward.

I do think it's important to remember -- and I know that everybody that's here on behalf of the Department wasn't involved in the many rule development efforts, and I want to take a minute to go through the process that resulted in the current rule, the current allocation rule, Rule 64J-2.010, to give you some perspective on how difficult it was to get that rule into place. And I would urge the Department not to throw the baby out with the bathwater until it has a really firm understanding of where it needs to go next.

The effort to put this rule in place was unprecedented, and I can tell you that in my lengthy career of practicing administrative law, I've never been in a rule development effort that took as long, that involved as much input from stakeholders, and that resulted in a product that the Department I think can be proud of, as occurred with the development of this rule.

The Department conducted 13 different rule development workshops throughout Florida with the stated intention of building a consensus amongst the stakeholders. Over 1,100 individuals attended those workshops, which consisted of live testimony from almost 250 trauma system stakeholders. These stakeholders included trauma surgeons, trauma program directors, hospital chief medical officers, EMS representatives, police departments, county sheriffs, city commissions, state legislators, trauma patients, local business leaders, and other concerned citizens. Those that couldn't attend the workshops in person were able to attend by telephone, and video conferencing centers were set up in the Department's county health departments around the state.

All of the more than 1,100 interested persons

who attended the workshops had the opportunity to speak directly to department officials at these workshops and provide input regarding the development of the proposed rule. The Department also received 189 written comments from stakeholders. Nearly all of the hospitals currently involved in trauma litigation and involved in the various rule challenges along the way were active participants in the workshops.

In addition to the information submitted by stakeholders during the rule workshops, the Department also analyzed and considered over 20,000 pages of documents that included every medical article written about trauma care in Florida, trauma regulations from other states, and internal reports created by the Department's data team.

The first nine workshops were conducted from December of 2012 through the end of March of 2013 and were focused on gathering information and input from stakeholders. Over 700 people attended these initial workshops, and the Department heard from live testimony -- live testimony from over 180 speakers and over 170 written comments.

Testimony from these initial workshops included topics such as the low percentage of

pediatric patients as part of the total trauma patient volume, the effect of tourism on patient transports times, the enhanced access and improved outcomes at the newly established trauma centers around the state, the unreliability of helicopter transport, and the desire of EMS to obtain faster transport times.

In April of 2013, after these workshops, the Department began crafting an allocation rule based on stakeholder input received during the initial workshops. The Department's initial focus was on finding data to corroborate the information presented during these workshops. This data focus went hand in hand with the Department's statutory mandate under section 395.402 to conduct an annual assessment to determine whether the trauma centers are effective in providing care uniformly throughout the state. The Department determined that the assessment, which was created by the department experts, including statisticians and epidemiologists, would inform the allocation rule.

And then we've got the 2014 assessment. The Department's experts presented their first draft assessment to department leadership in August of 2013. A second draft was created in November of

2013, and a final version in January of 2014. The final version was later revised in light of the Department's negotiated rulemaking session, and an amended assessment was published on March 24th of 2014. The amended assessment was a streamlined, concise version of its predecessors, reflecting only the data that the Department found meaningful and measurable. In developing the amended assessment, the Department properly considered the elements of section 395.402.

The Department released its first draft of the proposed rule on November 1st of 2013. After that, there were three more rule workshops in Pensacola, Orlando, and Miami, and nearly 400 persons attended those workshops. Forty-two stakeholders gave live testimony, and 13 written comments were submitted.

After that, in an attempt to gain consensus on the rule, the Department decided to take the unusual step of conducting a negotiated rulemaking session. The negotiated rulemaking session was implemented with the goal of bringing together representatives of the various interested parties to hopefully obtain consensus on the factors that should be included in the proposed rule.

That negotiated rulemaking session was held on

January 23, 2014, and was moderated by former Supreme Court Justice Ken Bell. The negotiated rulemaking session resulted in the Department making several changes to the assessment in the draft rule, largely on the recommendations of the legacy trauma centers.

Finally, on January 13 of 2014, the changes the Department made to the assessment as a result of the input that it received at the negotiated rulemaking session were reflected in the final version that was published on January 31st of 2014. Then a final rulemaking workshop was held on February 25th of 2014, and comments at this workshop relating to community service and transport times led to additional changes that were reflected in the final version of the assessment in the allocation rule.

The Department's incredible efforts to craft the existing allocation rule were validated by an administrative law judge in 2014. Despite the inclusive efforts detailed above, that rule was challenged by legacy trauma centers, including Shands, Jackson, Tampa General, Bayfront, and St. Joseph's. After a thorough review of the rule, which included nine days of hearing and 14

witnesses compiling a transcript of nearly 2,000 pages, Judge McKibben determined that the allocation rule was well within the Department's legislative delegated authority.

Florida's trauma allocation rule is one of the most sophisticated trauma center allocation methodologies in the country. The American College of Surgeons has widely advocated for other states to adopt methodologies similar to the one created by the Department.

That brings us to our current conundrum. On April 23, 2015, the Department published its annual TSA assessment, and on May 23 -- on May 13, 2015, the Department published a notice of development of rulemaking regarding the allocation rule. On May 27th of 2015, the Department held a rule workshop regarding amendments to the allocation rule, including updating the TSA allocations. That workshop was attended by numerous stakeholders, and the Department collected input regarding the allocation rule.

On September 16th of 2015, it published notice of proposed Rule 64J-2.010, to include the 2015 assessments and allocations. And based on that proposed rule, as you heard from Mr. Patrick,

Orange Park submitted a letter of intent to establish a Level II trauma center in Clay County.

On October 26th of 2015, the Department held a rule workshop to discuss the proposed rule. That rule workshop was attended by numerous stakeholders, many of which submitted comments. The proposed rule was challenged by Jackson, and then the Department withdrew that proposed rule on December 7th of 2015, the day a final hearing on the rule was scheduled to begin.

Then in February of 2016, the Department published notice of an updated Rule 64J-2.010, which included new allocations and some other minor changes. These proposed amendments were challenged by Shands in Jacksonville. In the meantime, Orange Park Medical Center submitted an application in reliance on the Department's proposed rule, which included a slot in TSA 5 for its provisional trauma center. On April 13th of 2016, the Department withdrew that proposed rule just days before a final hearing was scheduled to begin.

As you can see from this lengthy discussion of the framework that resulted in the current allocation methodology, this was a long and tortured process to get a rule in place. I would

submit to you that despite everyone's best efforts, developing an alternative plan for allocating trauma centers will be no less difficult.

It is incumbent on the Department to carry through, in my view, its obligation to the applicants that have applications pending before the Department and to propose an update to the current allocation methodology that provides a clear path for them to conclude their applications and ultimately become verified trauma centers.

To the extent that the Department needs to consider significant updates and changes to the current rule, as I said, I believe that the legislative path is the best way to go. But we're certainly more than happy to work with the Department in developing changes to the proposed allocation methodology within the Department's existing statutory framework, but we believe those efforts need to be prospective and not retroactive and that the existing trauma applications need to be addressed by the Department as expeditiously as possible.

Thank you.

MS. COLSTON: Thank you. Do we need any biological breaks, or is everybody good right now?

Okay. I don't want to interrupt the flow, so that's good.

Okay. So the next speaker, Jeff Levine.

DR. LEVINE: Good morning. I'm Dr. Jeff Levine. That's J-e-f-f, L-e-v-i-n-e. I'm the trauma medical director at Orange Park Medical Center.

I would like to thank Ms. Colston and the Department of Health for hosting us. I would like to thank the Department of Health for granting us -- accepting our application and granting us provisional Level II status on May 1st of this year.

A lot of practical and good and positive things have happened just in that short period of time. We, since the implementation of provisional Level II status, have already seen in seven weeks 234 trauma patients, of which about half of those are trauma alert patients, which is obviously the highest, most severely injured trauma patients one can see.

In addition to that, Mr. Patrick mentioned the resources that have been put into it. There's a lot of human resources that I have helped put into this. I moved, myself, from Pennsylvania. I have

a new surgeon starting with me this week who has moved here from California. We have some orthopedic traumatologists that joined us from Alabama. And this points to the fact that all these people not only recognize the need for this, but recognize the emphasis and value that Orange Park has put on this and have come to help develop a trauma center.

In addition to the physician staff, we've hired additional allied health personnel who have come to join us. We have a large trauma management team, including our trauma program manager. All of this continues to grow as we continue to grow and expand. I'm hiring more surgeons. We're hiring another registrar. This all speaks to the fact that we are continuing to grow now that you've given us -- already granted us our provisional II status, and I expect this to continue on.

One of the other things that the sharp spike in volume speaks to is the fact that EMS has already recognized that we are a valuable resource to them, both because of our location and proximity, markedly reducing travel time, especially for EMS services in Clay County and points south like Putnam and/or St. Johns. Even

though we're only 22 miles from Shands, if you know Jacksonville at all, that can be a very long ride, depending on the time of day you happen to be trying to go downtown.

So EMS has clearly recognized not only that we're a valuable resource based on location, but that we are providing the highest quality of care, and have been willing to bring us the sickest patients.

And so we have already seen -- I just wanted to summarize by saying we've already seen a lot of positive, real impact by your implementation of our provisional Level II status. And like Attorney Ecenia has said, we would urge the Department to continue on and let us go through the process as originally proposed in the most recent version of the rule.

I think that's all I have. Thank you very much.

MS. COLSTON: Thank you.

The next speaker, Mr. Tom Panza.

MR. PANZA: Thank you very much, Ms. Colston. Thank you.

My comments today -- my name is Tom Panza, P-a-n-z-a, and I represent the Public Health Trust

in Dade County, which comprises the Jackson hospitals.

The position that we're taking is that -- or at least the arguments I'm going to make deal with sections 210 and 212, and they'll be less about the allocation rule itself.

The allocation rule, as Mr. Ecenia said, was challenged by Jackson, and I think others, but at least by Jackson. And in the challenge that was made by Jackson, the rule was -- on the first occasion, to have the actual rule hearing, it was withdrawn the night before or the day before the actual rule hearing took place to challenge it on the methodology that was being utilized for the allocation in the rule.

The second time the rule was published and it was challenged again by Jackson, in that instance, it was also withdrawn that time a couple of days, I believe, prior to the time when the rule was going to be litigated in front of the administrative law judge.

So there has been no decision by an administrative law judge over the challenges or over the issues that were going to be raised over the methodology and whether the Department itself

had a consistent methodology, whether it was arbitrary and capricious, whether it met the appropriate standards, whether the data that was used was consistent, and whether the data that was included was the same data that came out with those particular results. And we, of course, challenged that, and we, of course, took issue with the methodology and with the allocation rule itself.

That's currently -- I don't know if it's pending. I don't think it's pending. I mean, it's currently withdrawn, so I guess that's why we're here today to talk about a new allocation rule.

And the one thing that I would say, in the new allocation rules, there should be absolute transparency, number one; and number two, all of the stakeholders or all of the individuals affected by the allocation rule or by the opportunity to have a trauma center should understand clearly what that data is, how that data is derived, and that it's the same data used in each and every situation, so that everyone knows exactly what those standards are and whether they meet those standards or they fall below those standards.

And I think that it would be incumbent to have that information public and make it very clear that

this is the formula, this is what we're doing, this is how it's going to be done. And those are the areas that we think in the formulation of an allocation rule are critical.

The other issue that I want to talk about that I feel is equally critical is the process. And the process I have several comments about, because we did litigate this issue with Jackson South and the denial by the Department of a provisional trauma status of Jackson South.

I think there is an issue that has developed, and I'm not sure whether the Department has fully vetted this issue and fully understands this issue. But the issue is deciding whether this is a licensure procedure -- which a licensure procedure would be that if you meet health and safety standards, you get your license -- or is this a need-based program that's competitive. Which one is it?

Even though you have an allocation rule -- and I understand with an allocation rule, it says there's only so many. But you have a bastardized version of what the actual rules entail, because the actual rules act like each individual applicant is going out on their own to develop their own

program, their own response to their trauma application, and it's kind of in a silo by itself.

If there's more than one trauma center that's attempting to achieve provisional trauma status and there's only one slot available, then I guess by definition, it becomes some type of a competitive batch, because you only have one slot, and there's only going to be one entity that obtains that status.

So therefore, what happens is, under the current rules, which I think are erroneous, under the current rules, you have to go forward, develop your whole entire trauma center -- which I'm not telling anyone in this audience that doesn't know it. I'm sure you know it much better than I do, but it's maybe a $10 million or more process to do it. Between the helipad and between everything else that has to happen, the acquisition of the surgeons, the trauma teams, et cetera, it's probably well in excess of that. You have to go do all of that.

Then you have to take a risk, really. You're going to take that, and there's more than one slot. And so you go through this whole entire process, and it only becomes at the very end, if you have

two competing provisional trauma centers for one slot, that there's a tie-breaking procedure, and the tie-breaking procedure is at the very end.

And the tie-breaking procedure is a set of kind of, I don't know, criteria that are somewhat subjective, putting it nicely, and the Department would then have the opportunity to say in sequential order, not which one is the best, but in sequential order. So if you are the provisional center that goes first or gets number one, the first issue -- there's three issues in the tie-breaking procedure, but if you win the first one, you win. That's it. It's over.

And that just doesn't sound fair. It just doesn't have that depth of fundamental fairness that it ought to have. The parties ought to know up front if this is the case and if it's going to be a competitive review and what those competitive standards ought to be, not a tie-breaking procedure that happens at the very end of this whole process, which takes some 16 months or so.

The second thing that the Department, in my view, needs to correct is the vagueness of the standards. The standards are vague.

Now, I understand that in all -- I've been

doing administrative law a long time, and I understand that in all administrative law and all law, the regulations are vague and they're subject to interpretation, and it's always subject to an art form. It's not a scientific endeavor where somebody is going to punch it into a computer and come out with an answer. If that was the case, none of us would be sitting in the room.

So we do understand that it's an art form. However, that art form has to have parameters, and it has to have somewhat of an objective parameter so that everybody can understand what those parameters are.

And we think the standards themselves in the rule are inconsistent with that in the statute. There are words in the rule -- and "substantial compliance" is a primary example. And what does that actually mean? Where does it actually mean it? We have a position on what we thought that it clearly meant.

The third component of the rules are that it seems completely ridiculous to have a standard that says we're going to review a paper document, a piece of paper. Now, the piece of paper may have 353 different elements contained within that

checklist, but it's 353 of these things. The Department takes the position that every one is valued at the same amount.

That means if somebody has a blurry form that shows that they are board-certified and it's a little bit blurry and they don't get credit for that, that's the same amount as having, you know, the best surgeon at the world there. So that doesn't make any sense me.

The further part about the vagueness of the standards are, unless people treat these standards the same and evaluate them the same, you can't get any type of an objective review process. So there's no -- there's no underlying basis. There's no underlying procedure. There's no underlying data that supports what that standard ought to be. That standard is in the view -- you know, in the eye of the beholder, and it becomes an art form. So those rules, the standards are very vague as to what everybody is supposed to comply with.

The scoring system, what is the scoring system? What is it? We litigated this. I have no idea what the scoring system is. Is the scoring system -- I'm saying 353. I may be wrong. Maybe it's 348. I don't know. It's a lot of different

elements. But is the scoring system -- out of that number of 350, we'll say, is it that if you miss one, you don't get provisional? If you miss five, you don't get provisional? If you miss 22, you don't get provisional? If you miss a certain set of them that are less -- considered less important? Except the Department goes back and says they all have the same level of importance.

So you take a paper review, this paper review, this whole process lasts a month, one month. That's the entire process. You file the application April 1st, and the Department has to respond to you by April 15. You have till April 22nd or April 23rd, whatever the date is, to go back and write your reply. The Department then has from April 23rd to April 30th to go ahead and answer it. That's life or death over a trauma center. That was life or death over Jackson South, one month, a one-month review.

How long does the whole process take? Well, the whole process takes approximately -- if you start from October, it takes about 17, 18 months, because you file your letter of intent, or whatever you're going to -- whatever you call it, to initiate the process in October of the prior year.

So that's a 17-month process.

You have five months of in-depth review after this paper review. Then you have another -- whatever it is, eight or nine months for the site visit. And then the Department has another month after that to go ahead and make a determination based upon the site visit and the tie-breaker if that should apply.

So you've got this whole long process, and you have one month -- and actually, much less than one month. You've probably got about eight or ten days when the Department actually reviews this and gives you a life-or-death sentence over whether this is going to work or not going to work or you're going to be accepted or you're not going to be accepted.

And if you're not accepted, then you have to go through the administrative law process, which is going over to DOAH and having a hearing that's going to last five, six, seven, eight days, is going to cost millions of dollars for all the parties to be there. There's going to be numerous depositions. There's going to be all kinds of recriminations. Everything is going to get nasty. And that's what happens, and there is no reason for any of that.

And I'm not suggesting that this should be the same as a certificate of need, but at least in the certificate of need application process, everybody kind of knows what the rules are, and everybody knows the competitive batch, and everybody knows what -- you know, and the lawyers fight like crazy there. I'm not saying they don't fight, but it's a different kind of a fight.

The other issue is, what is a trauma patient? Is a trauma patient anybody? Because we heard plenty of testimony in trial. What is a trauma patient? Is it anybody who has a traumatic injury? A traumatic injury could be that you're in the butcher shop and cut your hand. That's a traumatic injury versus, you know, some life-threatening problem. So that needs to be defined so there's no question as to what this trauma center should be.

The main thing that I would really argue about is the determination of whether this is a competitive process, whether there's a limitation on the number of units that will be given out or the number of trauma centers that will be given out, whether the methodology that's used for the allocation is fair.

In the last allocation that was challenged, it

was two trauma centers in Dade County. Well, there's other counties that have half the population that have three or four. I mean, I don't know, but there seems to be something amiss.

So those are my basic comments from actually doing it. I don't have the experience that Mr. Ecenia had of going to all of the hearings in the past over the trauma rules. I'm telling you what the results were of the -- I don't know if was those trauma rules. I presume it was the trauma rules that went through this process, not so much on the allocation, but on the process itself.

And the process to me is a very, very difficult process to negotiate. And also, there needs to be -- if you're going to have the evaluators evaluate these things, there needs to be a standard that the evaluators are all looking at and not what they think that it should be, or what they think other people do, or whether they should have actual mock -- or they should have actual mock performances prior to the time that they get their trauma center or not.

Those are not the kind of issues that should be guessed about. There shouldn't be any guessing here. It should be pretty clear: Here's what you

have to do. Go ahead and do it.

And it shouldn't -- you know, it shouldn't be that much of an art form. But you shouldn't allow a paper process that takes maybe a week or ten days worth of evaluation to drive the entire system.

Thank very much.

MS. COLSTON: Thank you. So I think I'm going to give us a break for about five minutes.

UNIDENTIFIED SPEAKER: Thank you.

MS. COLSTON: Hey, I asked.

UNIDENTIFIED SPEAKER: I was just kidding.

MS. COLSTON: So again, I appreciate your comments. And so we're getting a lot of good feedback. You know, one of the things that I'll remind you guys to kind of mull over when you come back, because we're getting a lot of things where, you know, we're hearing what we need to do, and so I would encourage you, if you have some answers or some recommended suggestions to some things that other folks are proposing, it's not just about what DOH is trying to roll out here.

We also want to hear -- if someone is saying that you need to do this, maybe you support it and maybe you don't, but if it's a good idea, we want to hear about that, because you guys are the

professionals. You know, we're -- we need to hear from you. So keep in mind, that's why we're going to make these transcripts available as soon as we can, because hopefully folks will go through and comb through that stuff, and you'll start to look and say, "Hey" -- I'm going to call you out, Tom, because you just came up here.

But Tom made a recommendation about the process, you know, and the certificate of need, and maybe it should be like that. Maybe it should, and maybe it shouldn't. But if you guys have an idea about that or you have other ideas, you know, let's kind of use this to build on what folks are saying here, because again, I just want to encourage you to not only tell us about the issues, but tell us what you think the solutions might be so that we can have that information. Okay?

Break, ten minutes, back at 10:40.

(Recess from 10:29 a.m. to 10:40 a.m.)

MS. COLSTON: Okay. It is 9:40, so I want to go ahead and get started.

We have not received any requests to speak via the conference call line, so I just wanted to put out there, please ensure that if you have comments and you're attending by conference call, to please

send Michael.Leffler@FLhealth.gov an email with your name, your organization, and the rules you would like to comment on.

You know, I'm hoping that the amount of comments that we have or have not gotten thus far is kind of indicative of people just kind of digesting what the Department has kind of rolled out. And we're thankful for all the comments that we're getting so far, so hopefully that gives folks additional stuff to digest.

You know, we will have two additional workshops, so we're looking forward to additional comments then as well, then as well. But again, you can send an email and speak via conference call line, and then you also have the opportunity to submit your written comments, which will be due July 21.

Okay. So I have one more request to speak. Are there any other requests in the back?

Okay. So Ms. Kathy Holzer.

MS. HOLZER: Good morning. Kathy Holzer, Safety Net Hospital Alliance of Florida. We represent seven Level I trauma centers, six Level II, and then two free-standing pediatric trauma centers.

Most of our comments will be general in nature today, because we are looking at all of these rules, working with our trauma members, and coming up with some recommendations. But overall, what we would like to say is thank you for looking at this in a different light, going about the process in a more collaborative manner.

I promise not to give you a history lesson, but I was on some of those early technical advisory committees back in the '80s, and the foundation as far as trauma was a collaborative approach between hospitals, physicians, nurses, and the State of Florida. And we would like to see us go back to that foundational level. We think this is a good step forward.

We would like to see the Department reinstate the Trauma Advisory Committee so that that committee can lend you their expertise, whether it's around research, whether it's around defining what a trauma patient is, but let us be at the table with you and work collaboratively. We think this is a very good start.

There are a couple of points I would like to make just so that we can give you some insight today.

We strongly believe that for this process, you have to look at this holistically, what are you going to do with the staffing, what are you going to do with triage, so that we have a holistic look at the process.

The needs assessment, which is covered in 64J-2.010, is the foundation of this process. That process is broken. You need to look no further than 64J-2.016(7) and (11). If in a rule you have to make a provision for having too many trauma centers, verified and provisional, within one year of approving that provisional trauma center, you've got to have a hierarchy for, okay, we've just discovered we have more trauma centers operating and verified, so we've got a process for approving a provisional, that says your process is broken.

Florida's trauma system is a mature system. You should not see wide swings between Year 1 and Year 2. And yet we continue to see you'll have a cycle where you approve provisional trauma centers, and then the next cycle you say, "Oops, we've got too many trauma centers in that TSA." That is a clear indicator that your process is broken.

We again ask the Department to work collaboratively with experts. Let's develop a

transparent, objective, data-driven process that looks at demand and capacity, and not just the demand and capacity of trauma centers, but also include EMS, what changes do we need to make in EMS, and let's go about this in a manner so that we don't see a lot of wide swings, we move beyond the past years of litigation, and go back to having a cohesive Department of Health, recommending rules and legislation that we, the stakeholders, can approve.

As it relates to the trauma registry, I would just like to make one quick comment there. When the revisions were made earlier in January 2016, there was a perspective that this would bring us in alignment with the National Trauma Data Bank. In fact, it takes us way out of alignment, and so we are working on what our recommendations around that are.

But we do encourage you to continue to continue to work with this to reinstate that advisory committee and understand that to continue to do what we're doing is insanity. We must come up with an objective, data-driven methodology that's transparent, that looks at capacity and that looks at need so that we can move forward.

We look forward to providing you with additional comments as the next two rule workshops roll out and give you some written comments.

And just one housekeeping comment that Dr. Ciesla asked me to comment on. One of the speakers earlier said the ACS had adopted or was, you know, using the Florida methodology as its needs assessment tool. The ACS is not using that. They did look at it, but they have not adopted it, and they are not rolling it out. They are continuing to use a methodology that really does look at objective data.

Thank you. And we'll provide you more comments over the next two workshops, and we'll give you written comments, and we hope to be a partner with you in this.

MS. COLSTON: Thank you.

Are there any other comments at this time? Any received via the --

MR. STURMS: There are no comments online.

MS. COLSTON: So we are going to conclude this rule workshop. Again, as soon as the transcript is available -- we're going to try not to harass our person here, our court reporter, but we will ask that as soon as possible, simply due to the nature

of what we're trying to do here. We will have those posted and we'll send out the information.

We hope to see some repeat offenders at the next few work -- the next couple of workshops, at any rate, with additional comments after you've had some time to digest.

As always, if you have any questions, please feel free to call. I'll tell you what I know, and I'll tell you if I don't know. So I'm happy to assist in any way possible, and I look forward to seeing or hearing from everybody at some point in time.

Thanks. Safe travels. Have a great day.

(Proceedings concluded at 10:48 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, MARY ALLEN NEEL, Registered Professional Reporter, do hereby certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages numbered 1 through 72 are a true and correct record of the aforesaid proceedings.

I FURTHER CERTIFY that I am not a relative, employee, attorney or counsel of any of the parties, nor relative or employee of such attorney or counsel, or financially interested in the foregoing action.

DATED THIS 1st day of July, 2016.

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