FLORIDA HEALTH

TRAUMA CHAPTER 64J-2 RULE WORKSHOP
ORANGE COUNTY HEALTH DEPARTMENT
6101 LAKE ELLENOR DRIVE, ORLANDO, FLORIDA
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MS. COLSTON: Good morning. We're going to go ahead and get started. I want to thank the Orange County Health Department and Dr. Sharon and his staff for allowing us to have our Trauma Rule Workshop here today. His staff has been very accommodating, and so I just want to introduce Dr. Sharon for the purposes of, you know, greeting everybody for this trauma workshop.

DR. SHARON: Thank you, Leah. And I want to welcome everyone to the Trauma Rule Workshop today, and to the Florida Department of Health in Orange County.

Restrooms are out this door, and the ladies' room, this way and, gentlemen, down that hallway. And the cell phones on silence.

Obviously, this community has been through its own share of trauma in the last month. We are Orlando Strong. It is actually one month ago today that we went through the Pulse event. So on behalf of the Florida Department of Health, I welcome you to the Department of Rule Workshop. Thank you very much.

MS. COLSTON: Thank you for being here. We appreciate it.

DR. SHARON: Glad to be here.

MS. COLSTON: So I know that we have folks attending on the phone. As you are attending by phone,

please send an email so that we can know that you've attended the workshop to Joshua, J-o-s-h-u-a, dot Sturms, S-t-u-r-m-s, at flhealth.gov, g-o-v, and please just let him know.

In addition, if you're attending by phone and you would like to make any public comments, please send your request to speak to him as well. We would like your name, the organization that you represent, and the rule that you would like to make comment on. Joshua will be monitoring his email actively, so we will get those. We will allow the folks in the room to speak first and then we will call for comments on the phone.

I would also like to call your attention to the back of the room. Wayne North, our director for the Division of Emergency Preparedness and Community Support, is here today. And so we're happy to have him here to kind of see what's going on.

He is very aware -- pretty much I'm the thorn -- one of the thorns in his side. I wouldn't claim the only spot. But I'm a thorn in his side with my bureau and I stay in touch with him relatively regularly. So he's very aware. He's very interested in -- in moving forward as well with the direction of, you know, building our bridges in this -- in the trauma community and trying to get things moving forward again.

So we are glad to have him as the director. He's been here now for -- how long? Four months?

MR. NORTH: (Nods head).

MS. COLSTON: Four months. And he hasn't run away, screaming, and he has not had to be committed yet, so we are happy to have him here, still.

As you all know -- and thanks, Dr. Sharon. He kind of did the housekeeping. So there's also a break room that is right as you come in. They actually have healthy snacks. I don't know if you all know, but the Florida Department of Health endorses the healthiest weight initiative, and so there are healthy snacks in the vending machine.

The door is labeled "break room," so if you get thirsty or hungry -- it also accepts credit cards. So that's kind of exciting to me. I like technology.

But housekeeping is done. Request to speak and -- requests to speak and agendas are in the back, so if you are here in the room and you would like to make public comment, of course we welcome that, we encourage that. And I have two right now. I'm hoping for a few more. But they are in the back of the room, so please submit them or wave your hand and I'll be happy to come pick them up from you.

We're here today at the Orange County Health

Department on Lake Ellenor Drive to discuss the Rule 64J-2.006, .010, .012, .013, and .016. And we all know the history here.

This is the third rule workshop in a series of three, so we're three for three today. We were hoping for a little bit more attendance due to the fact that it kind of backed up to EMS advisory council meeting, but, you know, that's okay.

You will be able to submit public written comments until July 21st. And so, you know, I know that I've talked to a few people and there might be some hesitancy to speak or, you know, maybe even to submit public comments. But, you know, part of this is we are in rule promulgation. You've all heard me say this over and over again, but I want to say it just in case there are other people attending or either by phone or in the room that haven't had the opportunity to attend.

This is -- we are in rule promulgation and this is the way we're going to have to collect comments on how we move forward on these particular rules. We realize that the trauma system has been in existence for a while without significant evolution or update or anything of that nature.

And sometimes in the environment that we work in it's difficult to do that. But this is kind of our

starting point. We were asked to hold three workshops and we've done that. And, you know, we're -- we want to extend the -- we wanted to make sure that everyone had ample opportunity to submit comments, so that deadline to submit those comments is July 21st.

We hope to see some written comments. You know, we get a lot of -- in these situations with the rule workshops, we get a lot of "Here's what we think is wrong." And "Here's what's broken." "You all shouldn't do this." And "You should do that."

When you talk about what's wrong, what we're hoping for is that you will also tell us what you recommend to fix it. Because I've said over and over again, and I continue to say it. It's never changed.

You all are the ones that are the boots on the ground, and in the community working, you do the work. You know your areas, you know your -- your environment. You know the needs of the trauma system. If not locally, especially, you know, you may know your needs regionally.

And so that perspective, outside of us being able to set up an advisory council, we -- we've got to gain some comments this way.

Now, I will say since I mentioned the advisory council, I know that that's something that you guys

have asked for a very long time. I said it the last workshop. Unfortunately -- I mean, you know, we can have our two weeks. We haven't made a lot of progress with getting that forward, because it usually takes us a little while to get these things done.

But what I will say is that getting that trauma system advisory council up and running is -- has been one of the main priorities for me. Believe it or not. And so that's been something that, you know, we keep trying to get done little by little.

We've had change in leadership in the department and our new state surgeon general is very aware of the need for good community relationships and good partnerships.

And, you know, in public health -- I think I said this when I first started before I even, you know, got entrenched in this, that public health works best when it has good partnerships. It works best when we have the ability to lean on the community.

I worked in emergency preparedness and community support. Every emergency is local. And then when the local capacity is exceeded, then that's when you guys reach out. And that kind of translates to trauma capacity is local and the state is charged statutorily with doing certain things, but that capacity and the

ability to evolve our trauma system lies with you-all at the local level.

And so, you know, hopefully, these three workshops, we've gotten some good feedback. You know, I've encouraged folks with it when they've said, "We think you need to do X." I've said, you know, if you didn't say it while we were in the meeting, send me your comments, call me, tell me, talk to me. Let's find out what we're doing with this. Because right now, today, available to us is this trauma rule workshop where we will be able to get the feedback that we need.

What happens after the third workshop, is we wait until all the comments come on the 21st, and then what I will do is initiate a series of meetings with Wayne and with Dr. Philip, and with a number of different folks in our legal office so we can start to look at pulling together language based on the things that have been submitted to us.

And what happens is, we're not pushing rule language out and it just happens. So it goes out and then we kind of start this process over again, but what happens next is you would request a hearing on that proposed rule language.

So there's proposed rule language, but that's not written in stone. That language goes out and, again,

it's kind of like the step-by-step thing. You've got to pick the opportunity to look at it. We will disseminate it.

Much like we try to do with everything else, we'll use our DLs, we'll post a notice, we will send out emails, we'll put it on our website, and we'll do all these different things so folks will have the opportunity to look at all of this.

So that is the next step. Once we close this and -- on the 21st, once we close that out, I would say we probably need about two to three weeks to get everybody involved that we need to get involved at the department to look at all of the feedback that's come in and all of the -- the comments that we've received and look at the transcripts. We will meet with them. We'll keep you guys posted along the way as to what's happening.

I do want to say that the rule transcript is available from the 21st on our website. We did send out a message to let you guys know that, so hopefully you've been able to kind of take a look at that. Painful because you have to see all the "ums" and "wells" and all that stuff. But once you get past all that, there's a lot of information in there that will be valuable to you in crafting those comments that

we're looking for.

The rule workshop transcript from the 28th, unfortunately, is not available. It will be posted on the 13th, so you will be able to review that as well. And then once we get the transcript from here -- we'll kind of talk to our court reporter who is here today to make sure that we can get that available to you as quickly as we can.

I -- I want to introduce my panel today.

Steve McCoy is here. You all know him. He's the EMS section administrator.

And then also Joshua Sturms, who is our data section and is trying to adjust our technology here in the room so that folks in the room can hear me.

And then Karen Carter is also here, who is our epidemiologist.

Okay. So I want to go ahead and give some time for everybody to go ahead and give speaker requests, if you have any.

Do you have those?

Thank you. Okay. I've got this. I won't -- I won't do that to you this time.

Okay. So as mentioned before with these rules, the department has no proposed rule language. We didn't want to go down that road again. We've been there and

done that, right?

So what we've decided to do, is there have been a lot of different things that have happened, and we decided to look at the rule of the statute. We have a -- a cap already that's mandated by statute. It's 44 trauma centers in the state of Florida.

And so when our legal office started to look at this and look at all of the things, especially with some of the things that have happened over the last, I would guess, six to eight months, to try to step back and look at very carefully what is the department's role in this.

Now, it's good to have allocations. The American College of Surgeons said so. But if we have a statutory cap, are -- are we doing the right thing by having a TSA cap as well or are we not?

Now, one thing I want to make sure everybody understands, is we've got our current allocation of trauma centers. We have existing trauma centers already. There is no intent on the department's half to shut down any existing trauma centers.

I know that's, you know, something that may or may not be understood very well, but the trauma centers that exist are there. We don't intend to shut down just because the allocation table says, "Well, now you

only need" -- you know -- "three trauma centers in that area and you have four, so we need to shut one down." That's not the intent of the department.

Even if there have been existing trauma centers and the allocation tables come out and say, "Oh. Now you only need two." We have not shut down trauma centers nor do we intend to. So I just want to make sure everybody really understands that very clearly.

The allocation table is kind of interesting, because the way it's calculated, if we look at -- you know, if you're calculating in transport times and you add a trauma center in, naturally it improves your transport times. And so that, you know, may say you don't need anymore trauma centers so the allocation might decrease or other things may happen. But -- and so, that's one of the things we all know. We need to look at that allocation methodology.

We've heard that in developing that methodology we need to have transparency. Everybody needs to understand why we're allocating things the way that we are. They need to -- we need to understand need versus capacity. And so if someone is submitting a letter saying, "Hey, we really want a trauma center in this area, is that really indicative of the actual need for a trauma center in that particular area. And so we're

very aware of all of these things.

I will tell you that the department is being very cautious about how we proceed in the future. And that really comes directly from the top. Dr. Philip is -- is -- one of our directives -- I'll just kind of put that out there -- is to repair our relationships with the trauma community. And the way that we do that is we lean heavily on you guys to give us some expert advice on how to fix what we all perceive as being not necessarily broken, but in need of some tender, loving care.

So we want to talk about these rules today. As I mentioned in the last two workshops, we're happy to hear whatever it is you have to say. I don't care if it's -- you know, "You guys suck," and "You really need to figure you what it is you need to do," or whatever it is. You guys know what I'm talking about in that.

But if we are not doing well, if we are not doing something that makes sense, then also, when you're telling us that we're not doing something the way you think it might need to be done, also give us what you think may help us fix that situation. Recommend to us a solution to the issue or that the -- the thing that we're not doing the best we could. Because that is the most -- that is where the most value is in -- in fixing

and moving forward and evolving things as to get some solutions.

We've had a lot of great feedback and a lot of great comments, but then sometimes we've gotten some, you know, "You need to do X," and then that's kind of it. And so I'm really looking for, you know, do you have comments on things that other people have said. "Hey, Bill Campbell said you should do X, Y and Z -- he's not said anything, for the record -- but if Bill Campbell said, you know, "You need to fix allocation," and, you know, "This part of it is not good." And you're you reading that in the transcript, saying, "Yeah, you know, he has a good idea and I think you should do this." We're open to that.

So look at those transcripts carefully. That's why we're trying to get them out there, because we want comments just not on your thoughts, but on thoughts in general. What is it that we -- that we need to do to fix this. This is the environment that we're in now, so we have to get the comments this way.

And hopefully, soon we'll have an advisory council where we can open that up even more and we can start to talk about things. But for now, to move forward, we've got to get your comments in this particular arena. So I will encourage you to not only give your

recommendations, but to provide solutions as well.

Are there any questions right now before we move forward and any other requests to speak?

Okay. So I have two requests to speak. I'm sorry. Not two. One, two -- four. Four requests to speak from parties present in the room and one on the phone, so we will take requests to speak from the room first. And my first speaker will be Dr. Cynthia Gerdik. Please make sure you say your name and spell your name for the court reporter.

MS. GERDIK: Good morning. My name is Cynthia, C-y-n-t-h-i-a, Gerdik, G-e-r-d-i-k. I'm with U.S. Health Jacksonville. I want to thank you all for affording us the opportunity to speak with you all.

As you know, this past May, we had TSA-5 and a second trauma center approved in that district. And one of the rippling effects that I think the committee needs to look at is the less volume that now is coming to U.S. Health Jacksonville and how does it impact training nurses.

I've been an ICU nurse for over 40 years. Caring for level I trauma patients probably requires -- technically on paper -- maybe six weeks to twelve weeks of training if the nurse has got some ICU background. We're willing to care for a level I and we're confident

in caring for a level I, it's more likely that in six-months to twelve-months of training that they get that expertise in caring for a very, very difficult patient.

As you know, nationally we have a nursing shortage. Florida is number three in the country with a national nursing shortage. We -- we struggle in the TSA-5 in Jacksonville and particularly, there are eight other hospitals. We compete to get more nurses into our doors.

There again, caring for that level I trauma patient, really takes an expertise that is not just -- it's learned over time, so you've got to have the volume of the level I patients to care for to get that expertise needed to be able to care for that patient 24/7.

No offense to the physicians in the room here, but patients are -- at bedside is the nurse. They're the ones who are the physician's eyes and ears in making sure whatever little thing happens, we communicate to that trauma surgeon intensively so we can get a good outcome that we've had historically at U.S. Health Jacksonville. I thank you.

MS. COLSTON: Thank you very much. The next speaker is Kathy Holzer.

MS. HOLZER: Good morning. Kathy Holzer, H-o-l, "z" as in zebra, e-r. Safety Net Hospital Alliance of Florida.

THE COURT REPORTER: "K" or "C"?

MS. HOLZER: "K."

THE COURT REPORTER: Thank you.

MS. HOLZER: Safety Net represents the two freestanding pediatric trauma centers, eight level II trauma centers and seven level I trauma centers.

Our trauma centers include the oldest trauma centers in the state. Orlando Health and University of Florida Jacksonville were the first two trauma centers in this state to be verified under the new standards created in the early '80s. I had the opportunity to serve on a number of those original technical advisory panels and so have had a long experience with trauma.

Just as trauma within a local community is built on collaboration between the emergency services people and the trauma center, this state's foundation was that collaboration between the local private sector and the state, and we look forward to a day that we return to that, so that we can move forward with strengthening our trauma system.

We appreciate that the department held three regional workshops. I think that it is important to

get out into those communities. It is very difficult even when you're in their local community for everybody to attend, but it is truly appreciated.

Before I move to comments, I would just like to ask one clarifying comment. Did I understand correctly that the department's sort of process would be to move from these workshops, where you did not present draft language to presenting proposed language?

In other words skipping a phase of having draft language?

MS. COLSTON: No. Well, that's the next step, is the draft language that comes out.

MS. HOLZER: Okay. It will still be a draft and then you'll move to proposed.

MS. COLSTON: Yes. So the draft language will come out. I don't know if that gets disseminated, because we have to follow the specifics of the rule promulgation process.

MS. HOLZER: And the rule promulgation process would be draft language --

MS. COLSTON: Okay.

MS. HOLZER: -- and then the proposed language.

MS. COLSTON: I'm sorry. So that's -- I'm -- I'm thinking -- I'm -- I'm ahead of that. So -- but yes. So the draft language will come out and we'll follow

through with the rule promulgation process as it unfolds. That's correct.

MS. DAVIES: Wonderful.

MS. COLSTON: Thank you for that question.

MS. HOLZER: So moving to our comments. We appreciate that the department is looking at how to complete the technical -- I mean, the advisory committee. And we look forward to that.

We would like to put -- sort of make sure that we're clear and we will be providing written comments -- as I think Dr. Ciesla said at the first workshop, the -- you know, the standards in the allocation methodology are the backbone of our trauma system.

And while you will be preparing draft rule language, we really encourage you to make sure you get that advisory committee established so that the assessment tool that is a part of 64J-2.010, apportionment of trauma centers among the TSAs, can be developed collaboratively using the expertise of people like Dr. Ciesla and other trauma surgeons and other trauma program managers in this state.

And the department staff, you-all have been great to work with, but absent having that collaborative effort, we'll continue down the path we're going, and

if you look at sound health planning, you're using sound health planning, you know, barring some disaster where there's mass population migration, you don't see large year-to-year swings.

When you look at the assessment methodology that's currently being used, you see those swings. In fact, your rules address a work-around of -- in the approval process and a site visit wherein if while you're doing the final provisional checks to verify a trauma center you discover that there are more trauma centers than are allocated, you've got a whole process to work around that.

So if from year to year you're seeing -- you're having to worry about, "Oh. Before I verify this trauma center, ooh, we don't have those in the allocated?" You -- you have to recognize the process is flawed.

The department has been very clear of talking about a willingness to grandfather or not wishing to close any trauma center when the allocation number is less than -- or it's greater -- less than the operating trauma centers. We would ask you to put that in a rule.

You know, all of us tomorrow may have different jobs and there may be a new set of people sitting in

these chairs, and so it's always helpful if the department has a position, if they put it in the rule so that everybody is comfortable that my trauma center is going to be able to remain and operate.

The other thing we would like to address is, in some of our comments -- and I -- I'm speaking specifically around the trauma registry and trauma quality rule 64J-2.006. We will make specific recommendations. We will try to address the issues that we know you may be trying to accomplish.

We would ask that once we send you that comment letter, if you don't understand or you think we haven't addressed something, give us a call. Let us know. Because of the intent our effort is to make sure that we communicate clearly and that we provide recommendations that both address what you see as your needs and what our people out in the field actually in our trauma centers see as the problem to be addressed. We can always gather a group of people together and clarify comments for you.

Again, we appreciate your efforts. We -- I want to reiterate Cynthia's comments. When you're looking at the allocation of trauma centers, you have to consider what is one of the basics in the American College's comments is that it is volume. You need volume to have

quality outcomes, you need volume to train trauma surgeons, you need volume to train nurses. And it's not just looking at today. It's looking at our future and making sure that we have the resources going forward. Thank you.

MS. COLSTON: Thank you. The next speaker will be Clint Shouppe.

MR. SHOUPPE: Thanks, Leah. I appreciate the chance to speak. Do you want me to use that (indicating microphone)?

MS. COLSTON: You can.

MR. SHOUPPE: Clint Shouppe, C-l-i-n-t. Shouppe is S-h-o-u-p-p-e. And I'm with Bay Care, B, as in boy, a-y C-a r-e over in the Tampa Bay area. St. Joseph's Hospital is part of the Bay Care system, which is a level II pediatric center in the Bay area. So I want to make a few comments. And first some things I appreciate -- we appreciate.

The first is, you mentioned that -- the issue of grandfathering trauma centers and the -- is not the intention of the department when there is a trauma -- more than 15 trauma centers in your trauma slots, that that wouldn't have any impact on re-verification.

As Kathy said, that's really -- that's really not what we hear, especially in a place like Hillsborough

County, for example, where there is a TSA that I think currently has an allocation of either zero or one, but has two existing trauma centers and there are other around the state that are in the same boat. But Stephanie mentioned in -- what we would recommend, is keep looking for ways to continue reinforcing that.

So for example, if, in a re-verification, a trauma center were to not meet every point and then there -- and then there was an allocation of one where there were two trauma centers, would that trauma center have no chance to just reverify it at some point if there were issues that that trauma center had.

Or for example, in -- where trauma centers are shut down for a period of time. If that allocation accounted for them initially and then they were removed from it, but the data really reinforced that they should have been there or data to them being, how would they ever go about it.

So I guess I think it's -- on one hand it's simple to just make clear that existing trauma centers will be able to exist. And on the other hand, I think it's useful and important to think through what would happen in the event that -- what -- what could cause that to actually occur and how would that be handled. Because I don't think it's clear to me or those of us in the

hospital industry what would actually happen in the event if an existing trauma center is closed or put on probation, and how that would impact the allocation averages.

The second thing and probably the most important thing, is to thank you for what y'all are doing to re-institute the trauma advisory council. That was before my time, but from those in our hospital and around the state that I've spoken to, it almost seems like the dissolution of the advisory council coincided with the challenges that we've had in the last six to eight years in this area.

Because bringing the advisory council together, it will be tremendous for helping us move forward. So the trauma advisory council really has two roles. One is to help work with the department to set a vision and a goal for where trauma system will be over the next five to ten years, and there's also a technical side of it.

I know that y'all kind of work on an active basis with trauma program managers in finding ways to incorporate trauma program managers, either a subcommittee or sub-council, of the trauma advisory council will be helpful, because a lot of day-to-day trauma injury challenges with the given rule or how the trauma injury data is collected are really the purview

of the trauma -- the trauma program managers and relying on them to provide the guidance will help make it a smoother process if you pool the data to make the changes that the department is seeking to accomplish.

The second thing I would mention about the -- or the next thing I would mention about the trauma advisory council is that I understand that it takes some time, but I think providing some clarity to the audience. We may not know today, but what about what that group is going to look like, when it would start.

In theory, I would presume that a trauma advisory council would be providing guidance to the department on exactly what we're doing today, which is the development of rules.

So if the -- if the rule promulgation and the rules are written in two weeks and the trauma advisory council doesn't get started for a month, then it kind of seems that's putting a cart before the horse, at least with the intent of the trauma advisory council.

So the intent -- what we recommend, is focus on using the trauma advisory council together, which would not only have the benefit of making the rules more effective, it's also going to have the benefit of having broader bodies around the trauma community around the state to make the process of implementing

those rules smoother.

The next point I would like to mention is the importance of improving the processes by which provisional -- or applications for provisional trauma centers are evaluated. It's my understanding the rules in the statute are both relatively unclear about how completing provisional applications would be evaluated when there are more than one -- when there are more applications than that are slotted. And so putting some flesh around that and especially thought about how it would be an effective -- would be a great opportunity for the rule.

One potential area is community support, for example. We have -- we have often talked over the last several years that community support is not an effective tool for measuring where there is a need for trauma centers.

Community support is a very effective tool for measuring the -- kind of the application of it of a trauma center. So if a trauma center has community support, maybe that's a good way to evaluate whether they should be chosen or not or at least one of a multiple -- multiple range of rules. But it's important determining community support is and where community support is not. So where it is important and

it does make sense in sort of determining where in the state a trauma center should exist, maybe it will make a lot more sense for determining which of the -- or helping determine which competing trauma center application should be chosen.

I would also mention the geographic distribution of trauma centers. So in a trauma center IV, for example, which includes -- let's see -- it looks like eleven counties and one TSA. And -- and I say this fully supportive as I have been fully supportive in the past, but why even a TSA would reflect the regional and certain tests from regions.

But these current rules don't really provide any consideration for whether a new trauma center is -- is five miles from the existing trauma center or 150 miles from -- from an existing trauma center.

So as long as it's within the region, whatever that region is, then it's evaluated the same. But it's -- it's self evident and obvious to all us that two trauma centers across the street from each other provide a different level of value to the community than trauma centers that are maybe 100 miles from each other, depending on region.

And again, this -- it varies. In Hillsborough County, which is a single county TSE -- TSA, than it is

in trauma service for trauma service area four.

And so we would encourage you to think through ways that we can consider not only where the allocation should be for trauma in a given TS- -- where the allocation should flow on the various TSAs, whatever region they may be structured around, but also thinking through with any given TSA, where is the need for a trauma center, especially for a geographically diverse trauma center, which may have a wide range of areas.

Next is when you are evaluating the data and in the -- the calculations for determining allocations are very quantitative cal- -- very quantitative calculation system but, at least in my understanding, they don't take into account any data that would derive from pediatric trauma centers -- from the freestanding pediatric trauma centers as well from provisional trauma centers.

So for example, one of the calculations that's used in the -- so one of the calculations used in the rule now is -- is the existence of -- of verified level I trauma centers -- or it uses two verified level I trauma centers the points that it accumulates.

Well, in a region like Miami Dade, for example, which now has a provisional -- has an active provisional level I trauma center, that wouldn't count

for the purposes of allocation for the coming year. Yet they are operating at that level I trauma center today.

And so that is just one example in our opinion, TSA I think it's -- I forgot which one it is. I think it's the one in Quizno or Pasco, where All Children's Hospital is located that operates out of a pediatric stand-alone trauma center. Or in Miami Dade, again, where Nicholas operates a pediatric stand-alone trauma center, that -- that data is not allocated for the purposes of the trauma allocation rule and not incorporated, but those trauma centers are treating patients and they should be incorporated. And they extend also to the provisional trauma centers that are mentioned. Where a provisional trauma center exists, they are providing services and providing trauma care for those patients in those communities.

And so for the purposes of calculating allocation, it's important to incorporate those trauma centers whether it's verified or provisional in the data. And the reason it's important is because if you don't, then essentially you'll be listing that data as if that provisional trauma center doesn't exist.

And so it's better -- it's better to look for it over the next year or two years hence, as that data

catches up with time to account for the fact that the trauma centers do exist even if they're not -- even if they're only pediatric or if they're not fully verified yet.

And finally, I just want to re-endorse the thing that Dr. Ciesla said at the first trauma workshop that we did a week ago, which is this -- is an important job evaluating demand and capacity in the trauma center and the trauma system. And it probably should be the number one goal of the department when you're coming up with the rules for how we operate our system. Demand and capacity are the core -- are the core elements of how we know when there's additional need or whether there is not additional need.

For example, the existing allocation rule reutilizes the population, but I think it's important to consider that population truly is reflective of trauma demand. And then also what the capacity of the given trauma center in that area is to serve its patients.

So again, that -- I apologize for the haphazard way I preached that, but that just raises a couple of the items we want in the rules that we wanted to mention. And I will be writing those out in a format in the coming weeks.

MS. COLSTON: Wonderful. Thank you so much.

Dr. Ciesla?

MR. CIESLA: Who -- who's on the phone? Who wants to speak on the phone?

MS. COLSTON: Michael Marcus.

MR. CIESLA: Why don't you let him go.

MS. COLSTON: You want to go last?

MR. CIESLA: Yeah. I'm up here all the time.

MS. COLSTON: So Michael Marcus, can you star 6 to unmute your line?

MR. MARCUS: Good morning, Leah. Can you hear me?

MS. COLSTON: We can hear you. Good morning. How are you?

MR. MARCUS: Oh, I'm well here. It's a beautiful, humid day.

MS. COLSTON: Yes, it is.

MR. MARCUS: That being said, am I up?

MS. COLSTON: Yes, you are up. You may begin.

MR. MARCUS: Okay. Thank you, and thanks for the opportunity.

Good morning. I'm Michael Marcus. I want to comment a little bit on the registry rule here specifically, and to give a little bit of history too, that kind of landed us to where we're at, because we're having some issues with this latest data upload and

it's kind of brought a lot of it itself with the server.

I want to clarify maybe just a few terms at the outset. NGTR is Florida's next generation trauma registry. NTDB is the national trauma data bank. And TQIP is the trauma quality improvement program offer through the American College of Surgeons.

I want to just do a little bit of retrospect here, but in -- in order to understand the importance of this registry, you have to first understand, really, the sequence of events surrounding injury, the causes of injury, and the subsequent continuum of care for the injured patients that have to be established.

But we have to have a clear understanding of is the relevance of timing, where the golden hour, when it comes specifically to critically injured patients, and accordingly be able to measure, evaluate, and study each one of these events.

So the trauma registry, really, is designed to be the foundation of a trauma program and subsequently trauma performance improvement and trauma quality management.

And -- and so a little bit more background here. You know, the -- really, the purpose and intent of this is to support the performance and improvement of the

patient safety process by serving as a conduit so that we can monitor system trends, we can get some benchmarking data, we can identify injury trends, we can look at age, geography, causes of injuries.

We also generate a fair amount of data for the evaluation of outcomes for specific trauma entities, get some information as well that can be used to evaluate timeliness, appropriateness, quality of patient care and, again, retrospectively.

And this registry is maintained by a trauma data expert known as a trauma registrar. And a trauma registrar is a highly specialized field of data acquisition and subsequent registry maintenance. The work of the registrar and trauma registry is of special importance, because they support the feeding of the statistical model for the evaluations of trauma activity as facilitates trauma research endeavors.

Despite all the positive attributes, though, it's very notable and very important that the trauma registry was never designed, intended, or certified to function as a tool of finance compliance or reimbursement. It was meant to be a scientific tool.

Our Florida trauma center here locally has a history of participation -- long history of participation -- in development and the evolution of

this state registry, including direct representation on the former DOH registry committee by both the medical director, trauma program manager, as well as our registrar. We have devolved some of the original stuff for the state. The FTC server that unfortunately went away, but then we started to evolve a little bit.

Prior to the existing struggle we actually enjoyed a very nice interactive working relationship with the department, and this program here is maintained NTC participation since 2008.

We're also the first site in Florida to participate in the trauma quality and improvement program as part of the TQIP pilot. We've also served on the surgeon general's ad hoc registry committee. We've also authored a couple of papers nationally on trauma registry data analysis.

We do enjoy an ongoing working relationship with Joshua and Karma (ph), and we actually do consider them part of our team. They do great work with our registrars and with our program.

Our feedback, however, along with our partner program, is going to be intended to refocus the registry components to work for us, the trauma programs, and maintain our focus on the intended registry function.

It appears that much of the feedback during the rule development previously was significantly mutated from its original purpose, and/or gone largely ignored. And, really, it's resulted in the need to provide this feedback and this open forum is a real good opportunity to do it.

I had mentioned at the very beginning of this, we -- we have a real fiasco with the way the data uploads and I want to -- I want to highlight a little bit of that with the current status as far as point a few ongoing counts revolving around this NGTR of the Florida registry.

I -- I think one of the most important parts of this, first and foremost, how everybody in the room, everybody on the phone, and anybody who will read this in the future to understand that if you are a trauma patient in the state of Florida, your injury, your diagnoses, your medical history, your comorbidity will be sent to the Florida Department of Health, along with your mechanism of injury, motor vehicle or fall, for example, and the results of your drug screen and of your alcohol testing.

And mind you, these will be sent to the Department of Health through an identified data stream by your name, your date of birth, and your social security

number. To clarify, we are currently collecting identified patient-level data within the Department of Health.

This is all without the knowledge or informed consent, period, of any patient simply in the name of compliance with the registry rule.

The situation exists despite the protests of the trauma program managers, the trauma medical director, the counter to best practices by national programs. We consider this unsound, unsafe, and should immediately be halted to protect the confidentiality, safety, and civil liberties of our patients.

Additionally, we do not maintain any identified data within the eclipse of our NTDB. They only collect the identifying data, period.

So to be clear, the state is collecting identified patient-level data. The national program only utilizes the identified data. So that's the overview.

Anybody need a break yet?

MS. COLSTON: No. I think we're good. Everybody is ready to --

MR. MARCUS: Okay.

MS. COLSTON: -- ready to go. Keep going.

MR. MARCUS: All right. So along with the current issue, we've identified a -- a problem with the data

stream as well within our triangulated data conversation. And going to the upcoming -- this last registry deposit that we made prior to July 1st, a little bit of overview.

We experienced a large diversion of productive time, which appeared to be the sum of two issues. One of the NTDB sequence national database is missing criteria and the other is DOA State of Florida data dictionary, which is significantly different from the NTDB, yet using the same data validator driven by the national dictionary, and it actually conflicts with the DOH submissions.

And to detail this a little bit, the NTDB in frequent national reporting is driven on admission. The DOH Florida is driven on discharge date. With the adoption of the NTDB data dictionary by the DOA, they failed to do the legwork to modify the DOH validation software to conform with our statutory DOH submission routines outlined in the 2016 NGTR based upon discharge dates.

This discrepancy within the Florida validator will not accept patients that were admitted from '15, but stayed until January 1st of '16. 2015 patients have one data dictionary. Subsequent to national updates, 2016 has another set of data dictionary. There's no

rules in coding.

This subsequently causes a conflict with the DOH validator, which becomes a high level error and our entire file winds up rejected. It will not allow us to submit our trauma data at all.

Unfortunately, the work-around, which winds up having to be supplied by our vendor, is that we had to divide the submission into two separate uploads, one for 2015 patient, one for 2016 patients, and both now based upon admission dates, not discharge date as prescribed in the Florida data dictionary rule.

This work-around has cost most of the trauma program loss of time, lots of aggravation, and loss of vender work time, along with lost productivity due to the failure to prepare for the heads-up that this problem even exists.

The DOH registry has been, really -- we just had a headache for the last month. And we tried over and over to submit the data while attempting multiple fixes on our end -- we thought they were mapping -- to no avail until we got the vendor involved.

We understood from our vendor that at some point a software fix was supposed to be coming either from, through, or subsequent to the DOH in one way, shape, or form. It has to be their vendor. And that was

supposed to be done by June 29th. Mind you, two days before the submission deadline of July 1st. And ultimately, it never transpired.

It resulted in what wound up being twelve months of work-around, and near as we can tell, this is set up to happen annually with each change in update of the national dictionary.

And from where we sit, I -- I guess I suppose the law of unintended consequences prevails here.

Interestingly, our submission to the national TQIP NTDB was relatively smooth. We -- this program here submits our own data unilaterally to the NTDB. We do not allow the DOH to have their data through due to security issues that issued from the past with data integrity.

So we spent a -- really, the DOH has spent a tremendous aspect of time and money on this next-generation trauma registry to duplicate the existing NTDB sequence program registry, yet haven't really done a very good job recreating it, and nor have we received any substantial facet above that of the NTDB sequence programs that we already participated in. A beautiful set of reporting tools, by the way.

To us, the program, this NGTR, is broken. It is resulting in unnecessarily increased burdens on our

trauma registrars and our software vendors. It's important to note that the DOH was forewarned of these potential issues back in 2013, during a registry task force meeting. Despite the well-documented protests by the trauma programs, the program managers, the Florida committee on trauma, the DOH persisted with collection of identified data, adopting this national reference by records, attempting to recreate the existing national validator, and they did not make the appropriate modifications to meet the Florida data submission rules.

Additionally, it is very important to note that the standards describing the ratio of registrars for registry entries, which is currently in our book -- I believe it's 750 to 1,000 pro registrars per year -- again, something we discussed in the 2013 ad hoc committee -- we are -- we are setting ourselves up understaffed.

Given the recommended FTE structure describing current standards, it is nearly impossible to maintain concurrency or effective validation, especially in the TQIP participating program. This part of the standard needs to be brought immediately in line with the current recommendation provided by the orange book so that the program can have adequate support in the

registry and documentation for increasing the needed registry FDE.

This triangulated data conversation as well has no scientific value or support. It's been discussed in the past too, that the DOH is holding a tighter error level and we have -- you know, our -- our data is tighter. Again, it -- it's really irrelevant. There's no scientific foundation in any of those claims.

We do offer a potential solution and -- and, hopefully, this will be helpful. Today the Florida trauma centers are required by statute to participate and contract with and submit to the national trauma data bank and the trauma quality improvement program through the American College of Surgeons.

At approximately $9,000 per year per hospital -- and you can do the math there. It's about 300,000 per year recurrent for trauma centers -- all trauma centers in the state are participating in the national program. The DOH could effectively consider with the NTDB and with TQIP to receive aggregate reports -- remember the identified -- aggregate reports with adjustments reflecting the entire state of Florida performance improvement and trends, eliminating a dual submission routine, streamline the data stream, and overall improve the data integrity and patient safety while

foregoing this triangulated, burdensome, conflicted NGTR.

Oh, wait. Oh, wait. There's more. All of this and at a much lower cost to the program, not to mention the paid registrar productivity time and the taxpayers of Florida who are paying to try and duplicate what already exists nationally. So that's enough on that one.

A couple of other things that need attention with some immediacy. Somehow without the knowledge of the trauma program managers or the trauma registrars and, really, without discussions prior to implementation, the 2016 NGTR registry inclusion criteria was arbitrarily changed to mirror the CMS two-midnight rule. That CMS two-midnight rule was created for reimbursement for payment purposes. Again, something the registry was never designed for.

So it's a complete surprise to the community and was discussed months ago, I believe, in forum with -- I think, Leah, you were -- you were there as well. And we were supposed to immediately repost this rule and restore our historical inclusion criteria of 24-hour length of stay.

Of note, the CMS two-midnight rule doesn't especially disenfranchise our pediatric programs, as

well as have the potential -- if you think about it, you're changing all inclusion criteria. You have the potential to adjust or alter the aggregate risk-adjusted benchmarking, as well as volume training, put forth by the trauma centers because we're skewing admission criteria from our historical reference.

As stated earlier, the registry was never designed, never intended or certified to function as a tool of finance, accounting, compliance or reimbursement. This needs to be corrected to reflect our historical inclusion criteria, which is that of 24 hours with an injury diagnosis. If any changes are to be made, it should be with raw feedback from the working experts in the state.

Let's see.

Additionally, it appears, at least from the latest mapping in the NGTR, we're no longer collecting Florida trauma alert criteria and based upon -- I think these are all maps of something called local criteria at this point. And just so you're aware going forward, it's going to hobble your ability to benchmark the current triage criteria and performance, and, two, note any changes or variations if we do modify it because you've now got no baseline to try to compare it to.

So I recommend that you restore that. But it seems

that, well, the horse is out of the barn already, so I'm really not sure what to do with that one.

We are also still submitting compliance reports based upon standard 18, which has to do with quality and performance improvement. Yes, I know it's in the statute, but I do believe that the trauma quality improvement program and the NTDB more than satisfy standard 18. We should probably put that by the wayside as a compliance report an utter waste of time.

Thanks for listening, and I'm -- I'm hoping that we're not back with something -- these same issues three years from now. Have a great day.

MS. COLSTON: Thanks, Marcus. That makes probably about 30 of us.

I've got another speaker in the room. Doctor, if you want to come forward.

MR. COCKBURN: Good morning. My name is Mark Cockburn. It's M-a-r-k C-o-c-k-b-u-r-n. I'm the medical director for Adeventura Hospital and trauma services in Adventura/Miami.

I first want to commend all the DOH staff represented here today for their persistence and patience in going through this process. I think everybody is concerned and all of the comments that have been -- been made in the past few meetings have

for the benefit of the patients, and I think it's important for us to keep that in focus.

It's a complex formula that everyone is aware how many patients are seen in a trauma center in terms of volume. One of the prior speakers mentioned specifically the fact that keeping -- having an adequate number of trauma patients in the center will impact our quality of care, certainly because you -- you're doing it enough and frequently enough that you're able to perfect what you're doing a little.

At the same time it's important to keep in mind that overwhelming a trauma center also will have an impact on the care and it's important that patients in any particular center and TSA has -- has access to a trauma center.

We also are aware that Florida -- particularly last year -- had the second largest growth in any state in time in the United States, being beaten by Texas and followed by California. And I can probably predict that as time persists, we'll see even more growth in the state of Florida. Hence, as the population grows there will be a need for more access.

This significance of having a trauma center, as you all know, would increase in volume, will provide timely care to patients. And I just wanted to also commend

the fact that the recognition that we -- as we do trauma here in the state as a team, it's important to make very good decisions.

We should have an advisory council with the persons who are all interested in making this a better -- provide better access care here in the state, that we all get involved in making these decisions and working this through.

I think it's going to have to be fluid. One decision today is not going to be probably effective in five years. We -- we have to keep in mind and keep working on it. And all the -- the programs in the center probably will have people willing and volunteering to be a part of this decision-making, and I commend you guys. Thank you.

MS. COLSTON: Thank you.

One more -- or actually two more. Dr. Susan -- or not doctor. Susan Ono.

MS. ONO: My name is Susan Ono. S-u-s-a-n O-n-o. I'm the trauma program manager for Orlando Health. So I'm just going to be brief in echoing some other comments made earlier from Michael Marcus. 65J-2.006, trauma registry and trauma quality improvement program. One of the -- I -- I know that you guys -- and I appreciate you-all taking up feedback regarding some of

the changes in the day-to-day chair for 2015 in regards to the two-midnight rule. I know that you guys asked for our feedback on the call regarding what we wanted to see and I really appreciate that and I feel like that's the only reason why you're asking for feedback on this rule now.

However, it has brought to the table some of the other changes that we would like to see and I appreciate you-all for also taking that feedback.

So one of the things that did come up in previous submission and submissions before that, really, the data submission is -- is cumbersome. And that's not just for the state, but in general. We have to fix a lot of mapping issues errors and that takes a lot of time from our team. So having to do that right after we go through an NGB and submission, it does take a lot of resources and time. It is, as many systems are with the date of submission date for which you submit, so admission date versus discharge date is how we're submitting, which does cause a lot of errors.

So when -- when you think you're clear and you submit it to the national trauma database and then you think you're ready to go and you go submit again to our state registry and you get back a slew of errors and then have to turn to your team again and start working

on more error corrections and issues that make the errors that are accepted by the national trauma databank aren't expected by the state, some of which can be corrected and -- and is our responsibility of the trauma center. Some which can and should not be corrected such as something also that is different, that takes some time as well.

Because once you have an error come up, you -- you like for your whole team to go through and make sure that those errors are corrected, so that's a duplication again to make sure, indeed, that was what's happened and you're not missing something or an error on that side.

In addition to that -- so some of our -- some of the recommendations that we have are -- are really -- I guess just really focusing back on concurrency of the registry, focusing on QA. The reason why we want a robust, concurrent registry, so that we can have time to follow-up on the quality concerns and the identification issues.

So really getting back to that, making sure that our registry is concurrent and that we keep it concurrent by reducing the amount of time spent on that back end, on doing another submission to the state.

So really, just going through the NGB NT program

and using that Florida aggregate and some quality around the state is also a recommendation such as Michael Marcus said.

And then in addition to that, again, the QI -- the QI report that we sent in, that also doesn't take a lot of time and that's something that we can get through the HIPS program within our organization and then also the data there. So that's all I wanted to say. Thank you.

MS. COLSTON: Okay. Great. Thank you.

I'm going to go ahead and take a caller on the phone. Dr. Smith, hit star 6 to un-mute your line, sir.

Dr. Smith, are you there? Star 6 to un-mute, please.

Okay. Maggie Crawford.

Last call, Dr. Smith, on the phone. Star 6 to un-mute.

MS. CRAWFORD: Good morning. My name is Maggie, M-a-g-g-i-e, Crawford, C-r-a-w-f-o-r-d. I'm the nursing director of trauma service of Delray Medical Center, and I also represent Tenet Health South Florida.

THE COURT REPORTER: I'm sorry. I also represent . . .

MS. CRAWFORD: Tenet Health South Florida.

THE COURT REPORTER: Thank you.

MS. CRAWFORD: So just to add on several things that had been said today and in prior workshops as well, you know, the goal here, as Dr. Ciesla said very well in the first workshop several weeks ago, is to improve access to care but, really, specifically trauma care is our focus.

Many of the things that were said to you about the registry are things that I think are valid. You know we -- we do a lot of duplicate efforts and really, we need to look at what the standard is for the future and make sure the language reflects the acceptance of the national trauma bank dictionary, which when you look at the rule this year, it does say that it's reflecting that, and look at how we reduce incidents of hearings just because there's a data in here.

With reporting, as Mr. Marcus said as well, direct reporting to ACFs with components, because it is a lot of work that occurs to make sure that we have accurate information going to both places.

Regarding allocation, Leah, despite your assurance that there is no intent to pull trauma centers back, I think that language needs to be included because it's one of the things that comes up in every time, and that

language is not there. So I think for assurance, because as has been said, many of us can change our job tomorrow and not be the person standing here to have the same thing.

My other question would be does this really need to be a yearly assessment -- reassessment that's done for the allocation versus something that's a three-year or five-year plan, because a lot of time and effort is spent every time the allocation comes out to determine, you know, is this accurate, is this not accurate. We have other centers that are going through the application process that may not be reflective when the current allocation comes out.

From the standpoint of how do we look at those areas that even though they're included within the TSA as being more rural areas than they are urban areas or suburban areas. How does that really get reflected, because a lot of times those areas do not have the level of commitment within the community from the surgical and nonsurgical specialties to really support them moving in with a trauma center.

When I look at some of the areas that I travel through in the state -- I'll use Sebring as an example -- great hospital there. I see a lot of different medical practices there. But if you went to

that community and say, "Do you want to be a level II trauma center," there probably wouldn't be that level of support. But yet, those people need trauma care. And they need to have access to care that is appropriate for -- for what happens in that very visible and highly traveled area.

If you go back to some of the other intentions that occurred and how the allocation is defined, I would also ask how the acute-care trauma registry has impacted that. A lot of the information is coming from those hospitals that are now allowed to be trauma centers, but when we look at that impact -- because it was really trying to see, if I recall the original intent, that we would get information to look at what numbers were and what kind of patients were being kept in non trauma centers that probably need to be in trauma care.

Under rule 2.012, the processes for approval, it's still a very cumbersome application process. A lot of things are based upon standards that I remember going through rule hearing in the late 2000s, 2007, 2008, that looked at the last version of the optimal resources done at the American College of Surgeons committee on trauma that led to the standards today.

So those standards are from 2010. We're six years

into this. We have a new optimal resources document that came out last year. Why do we continue to change the standards? Because that's going to be another change that we would have through workshops and hearings again if we do accept the American College of Surgeons standards. And then how we foreignized (ph) it to what we have historically done in the state. It's not a bad process, but it's time, cumbersome, and we really need to look at how we can take one standard that really is a national standard to determine what trauma care standards are and trauma centers and the different levels that are there.

If we use -- only do level I, level II, or pediatric centers, that's fine, but I think we just need to -- to move forward with the acceptance of the optimal resources document and use that. And the same for the application process and the standards that we have are very heavily focused on paper. Even though there is an electronic component, that is one thing that has changed.

And I have -- in my prior life with trauma -- have been an ACS surveyor. I was there at the point in time when we went to paper to electronic and how that really smoothed things down. And a lot of the paper was at the centers when they came in to do the site survey

with that. So that would be just, again, another recommendation with that as well.

On rule 2.016, the site visits. Again, a lot of references still for standards. We need to determine what we're going to use as our standards, whether it's the optimal resources document standards and whatever the current version instead of having to update rule language every time. But whatever is the new version that comes out will be what is accepted if that is where the border keeps it to go.

And in the same accord, will we -- should we move to the optimal resources utilization of ACOs, will we have different processes for selection of the survey team or will we rely completely on the American College of Surgeons on that as well.

Lastly, I want to go back and it's been said many times today about references to the new forum on the trauma advisory council ACS state survey from a few years ago. It needs to be multifaceted. In other areas within some of the councils and committees that had been in place to say and of course this week is -- is ClinCon an the EMS council, advisory council.

There has been some trauma representation on that in the past, but we really need to pull those people back to the table and really make trauma super common.

It has to be multifaceted, we have to look at all components, we need to look at those areas that are -- again, are not really representative as trauma centers such as the rural areas that are there, and develop people that will be the subject matter experts as those individuals are selected to participate on this committee, and will act in a collaborative dialogue to assist in moving forward, to say moving forward with the trauma center processes. Thank you.

MS. COLSTON: Thank you.

Okay. Mr. Smith, I understand you're having some problems with un-muting, maybe? Can you press star 6 again for me or is your personal line muted.

MR. SMITH: This is Dr. Smith. Can you hear me now?

MS. COLSTON: Yes, I can hear you now.

MR. SMITH: Oh. That's delightful. Thank you for letting me make some comments.

MS. COLSTON: Sure.

MR. SMITH: First of all, I'd like to echo the comments from some of the previous speakers and that the process, as we move forward, really should be as transparent and as open as possible as -- as it possibly can be.

Just a bit of background. I have worked in other

trauma systems throughout my career including in states where trauma center verification or designation was totally unregulated. And it was -- if a hospital wanted to become a center, they simply had to meet the -- the ACS standard and they could proceed.

And I also worked at very highly regulated state systems where the number of trauma centers was very closely controlled for good reason, I think. And the best example is Pennsylvania. And I must say that based on my experience, an unregulated system is not desirable for a number of reasons.

Just first of all, I think it -- it not only impacts patient care usually in a negative sense, but it also increases the cost of overall care. There's a great deal of duplication of services and unnecessary duplication, I would say, that doesn't really improve care.

And this, quite honestly, has led to some locals to have trauma centers literally across the street from each other, which is a very undesirable circumstance for -- for, I think, everyone, including the patients.

I don't want to drone on forever, but I do want to read into the record some direct quotes from the Orange Book of Resources for Optimal Care of the Injured Patient published by the American College of Surgeons

on major trauma, which is currently used for trauma verifications, and I will forward these documents with my -- with the areas that I'm going to read into the record highlighted at a subsequent time.

The first comment -- or quote, I should say -- is from Chapter 2 of the Orange Book. I'm going to read it verbatim. "To ensure adequate experience and expertise, the level I trauma center requires a certain volume of injured patients to be admitted each year, including the most severely injured patients from the system. In addition, certain injuries that occur infrequently should be concentrated in the special center to ensure that these patients are properly treated and studied. A minimum volume of patients is required to ensure that an adequate number of injured patients are cared for at the institution to support the required educational programs in training future trauma care providers. Research activities are necessary to enhance our knowledge of the care of injured patients."

That's the -- the first quote. And my comments are that by spitting up additional trauma centers, you traditionally place level I trauma centers who fulfill all of these roles at risk.

The next quote -- let me scan down the document, so

give me just a second.

Okay. This is another direct quote from the Orange Book, Chapter 2. "The ACS committee on trauma supports trauma center and trauma system development and related public health policies including needs assessment, policy development, and assurance. Each community should assess its true needs for trauma care emphasizing systems approach. While there are roles for all acute care hospitals treating injured patients, the ACS committee on trauma center classification's team is intended to assist in communities in their trauma system development. This approach implies that there should be limitations on the number and level of verified trauma centers within a given area."

And if you'll get to the end of that quotation, if you'll give me a second to scroll down the document for just a minute. And I apologize for the delay.

Referring to Chapter 1 of the Orange Book, and then the direct quote from the Orange Book. And here it is. "The designated authority in partnership with the broader regional trauma system should ensure that the optimum number and type of trauma centers exist in the given geographic region. The development of level II trauma centers should not compromise the flow of patients to existing high volume level I trauma

centers." End of quotation.

And that's for the purposes that I mentioned earlier. The trauma -- level I trauma centers are really the life blood of future trauma care. These are the areas where trauma surgeons are trained, where research is carried out, and where expertise is developed.

So the spin on this, if you will, additional trauma centers must take into the account the effect of those new trauma centers and the state level I trauma centers.

So I would simply close with the statement that if the new rule-making progresses, I think it's very appropriate and advantageous to specifically state that a proposed, new trauma center, particularly a level II trauma center, should be required to demonstrate that its existence would not only improve patient care or improve our directed deficit in ongoing patient care, but also is that new trauma center would not endanger the function of the -- that a nearby level I trauma center already carries out.

Again, we need our level I trauma centers to propagate trauma care for the next generation and endangering level I trauma centers really serves no purpose.

Thanks very much for allowing me to comment on those and those are the only comments I have today. I will submit these documents that I've comment by the deadline.

MS. COLSTON: Great. Thank you, Dr. Smith, and we look forward to your comments.

MR. SMITH: Thank you.

MS. COLSTON: Okay. Any other speaker requests right now?

Okay. Dr. Ciesla.

MR. CIESLA: All right. It's like a bookend.

Okay. Well, my name is Dave Ciesla, C-i-e-s-l-a. I'm a professor of surgery at the University of South Florida. I am the trauma medical director at Tampa General Hospital for the regional level of trauma program, and I am a vice chair of the Florida committee on trauma.

I'm not representing anybody, which I guess makes me at large, but I do feel comfortable speaking for a lot of the other academic trauma center medical directors. I think a lot of what I have to say aren't really my ideas. It's really a summary of discussions that we've had over many years.

And what I wanted to do is just run down a couple of things. The last time -- or last time I was in a

rules government workshop, it was great. You know, we -- we saw a nice, refreshing approach to this where, you know, we recognized where the problem is, we recognized that there's a damaged relationship and we want to look forward to creating something new. And so I think that this is a great time for this.

Our old -- you know, our existing trauma system is based on ideas and information and infrastructure that is almost three decades old. I think that -- I think that everybody sees that, you know, things are a lot different now. Our patients are different, our capabilities are different, population is different.

You mentioned the allocation table and the allocation is based on the rule, and so my interpretation of that is that the allocation table will sort of fade out as a new rule is developed. I think that -- you know, what you mentioned also in statute was that we're limited to 44 trauma centers in the state right now.

I think most people would claim -- well, I think many people would claim that we're currently over designated at whatever number we have right now. It was the 30th, if I understand it.

So just a couple of comments. I'm not -- I'm not going say anything that really hasn't been said in one

form or another. First, with respect to the process, there's a big demand for this advisory committee. I would urge that that get done with all deliberate speed before a new rule is published.

You know, we have close to 30 trauma centers in the state right now. I don't see that there's a giant rush to hope for more. I don't think that anymore should be opened until we really assess what the needs are.

I think Dr. Smith did a really great job of outlining kind of the current position that the American College of Surgeons has on it. And that position is based on all of the best available scientific evidence from decades of purity and study.

We want a rule that's based on objective and measurable factors just like the college points out, using the best available scientific information. And we -- you know, we don't need to rush a rule together based on speculation or ignorance or anecdote. I think those are kind of dark-ages style reasoning. That's really kind of irresponsible in this age given how much information we have at our fingertips.

So I want to kind of go into talking about a couple of things. First, between the registry process, the application period, and the site visits, those, I think, have been covered. And now really, we're

spending a lot of time focusing on the apportionment. Nobody here today stood up and talked about anything other than the registry or apportionment, so I'm going to kind of just stick with apportionment.

So having a needs-based system is what we're talking about. And how you define need is really at the core of this issue. We've been talking a lot about defining need in terms of demand and capacity. People's views on this are all grounded in -- in a couple of ideas. And so there's -- there's one perception that, number one, all injured patients need trauma centers. These are actually -- I -- I kind of consider these more like delusions than perceptions even.

The first one would be that all injured patients need care at a trauma center. The second one would be trauma centers improve the outcome of all injured patients and that -- that care for any injured patient is always better, cheaper in a trauma center. None of those statements are true.

It is true that trauma centers help injured patients. The -- and what they're designed for is taking care of the sickest of the sick. They don't have the capacity and it's not in their mission to take care of all injured patients across the state.

So here I crunched some numbers out this morning on my laptop, and Steve could check them if he wanted to, because he's got them on his laptop. So I looked at the 2014 date set, and based on my best estimates, there are about 153,000 patients discharged from Florida hospitals with injury-related diagnoses. And 21,000 of those had isolated hip fractures. Six and almost 7,000 had isolated sprain. About 50,000 of those had no principal injury diagnoses.

In other words, they -- they came in with a principal diagnosis that was not an injury, but had an injury in their list of 30 diagnoses the data set collects.

So of the 153,000, just about half of them had a principal diagnosis injury. Of that half, about 25 percent or around 20,000 were associated with a trauma alert charge. About 15 percent, or right around 12,000, had an injury -- or an ICISS less than 25. And those are the -- that's the threshold of these kind of conventionally considered as -- we're -- we're terming that a high-risk injury patient. And about 50,000 of those patients have ICU admissions.

Now -- so you can see -- like, right off the bat you could consider that almost half of the patients don't even really rise to the level of a moderate

injury. They don't have a principal diagnosis of injury.

We also have to recognize the critical role of community hospitals or non-designated trauma hospitals for this type of care. There's something like 220 acute-care hospitals in the state. They take care of -- I don't know -- something like a million hospital visits or 2 million hospitals visits a year.

There's 20 -- 20 million patients in the -- or 20 million people in the -- in the state and about, you know, one in a 100 gets an injury-related diagnosis. So if you run those numbers out, the number of patients that you're really talking about that need trauma center care and who would benefit from trauma center care is actually a lot smaller.

So my best guess, probably somewhere around 76,000 as a baseline and somewhere around 25,000 are really the ones that need trauma center alert criteria and would benefit from the trauma center. So that's 25,000 patients divided among 25 trauma centers, so that's 1,000 patients per trauma center.

Now, bear in mind the trauma centers are also big community hospitals, so they take care of lots of minor injuries. They take care of, you know, the community as they're supposed to. They're big hospitals in

population-dense areas, and so they have this additional role of providing regular injury care.

And then the other thing is to consider -- like Dr. Smith, I think, put it way better than I could have -- what's the role of each type of trauma center in the system. Quoting from the Orange Book, I think, is more effective than what I would do. I would simply say that the role of a level I trauma center, it is the focal point in any regional organized trauma care.

It has a role beyond just providing complex care to multiply-injured patients who have, you know, the wide range of injury severity. It's got an academic mission of research, education, injury prevention and -- and system performance.

The level II has many of the same capabilities. It has many of the same missions. It participates in the system similar to the level I, but the idea that the level I as a measure or equivalent is not in line with the current best thinking for trauma system design. Each has a role just like the community hospital does and you can't replace one kind of center with another.

I want to back up one second and talk a little bit about the -- you know, this has been going for a long time. We all recognize that. The existing rule, we very happily saw that go away. Every element in your

apportionment rule can be checked to see if it's appropriate by scientific study.

Like, for example, if you want to know if transport times are relevant to apportionment of transport centers, go look it up. There's literature on that. There's a paper published just this time that was presented at the WAT, that showed transport times really don't make a big difference when you're talking about regional trauma center design. If it doesn't make a difference, maybe we should at least ask the question scientifically and not rely on perception or kind of ignorance.

Okay. So I wanted to -- so last time I was here, I said, okay, well, you know, here's some ideas. So I wrote some more down. So, you know, one of my -- for your apportionment rule, I think that your apportionment rule in the context of designing a -- designing a trauma system, I said explicitly state what your goals of the trauma system are. So I wrote down some. And some you might like and some you might not, but I figured you wanted some suggestions, so I'm giving them to you.

Okay. So like, one, you wanted statewide coverage. You want everybody in the state to have the ability to make it timely to trauma care. Two, you want patients

to be able to access care at the level where they need it, all right? If you need a level I trauma center, you should be able to get to a level I trauma center. If you can get your care at a community hospital, then you should get your care at a community hospital. If you happen to be a level I trauma center, then you should get care for minor injuries too. Wherever you are, you should get the care that you need or have the ability to get to the care you need.

Another goal might be to meet all of the West criteria for inclusive trauma systems. And so everybody, I'm sure by this point, is familiar with the paper that West wrote and defined essentially how we think of regional trauma systems.

One of those criteria is have a -- I can't rip them all off the top of my head, but the ones that stand out are designating authority, a process for designation, triage criteria that allow you to bypass non-trauma centers in favor of trauma centers for patients who meet the criteria.

You want to have a limited number of trauma centers based on need. You need to have a system to evaluate trauma system performance. That's one of the key ones. And that -- in the trauma system assessment about 15 years ago or so, that was one of the West criteria that

this state didn't meet. We need to have that.

You want your trauma -- so another idea would be you want your trauma system to deliver high quality but low-cost care in an environment, so the next point would be, that fosters education, training, and research in injury prevention. You would want -- you know, if you think it's important to protect the existing trauma centers, well, then, write that down.

I think a good goal at this point would probably be to write a rule that keeps the DOH out of administrative law courts. I think we're all after that one. If you think it's important that it -- that it be convenient for EMS to deliver patients, write that down.

You know, when you're thinking about the system of care, it's not just, you know, the patient at the hospital. EMS is really the glue that -- that knits this whole system together.

If you think it's important that you make room for new hospitals to become trauma centers, if it happens to be a good business plan, then write that down too. If you think it's important to help keep some of our legislators in office, write that one down. You know, if you don't like those, cross them off.

We talked about a regionalization last time. I

think we -- we -- you know, in the past -- let me back up. We're going on a little bit of a tangent.

In the past, the rule sort of became formed with the legislation. All the work that was done in the systems committee was taken to the legislators and they wrote laws that would support the ideas that the system planners came up with.

And now it seems like we've got that backwards. It seems like we have the statute that nobody is willing to tackle or go against, and that everything that we're doing now is inside the statute. It was meant to be a temporary statute. If you read that statute, it can't say or explicitly define. And the end of that paragraph says you're going to deal with these TSAs until the next trauma system evaluation is done, at which time it will be re-evaluated.

That trauma system evaluation was done. Nothing was done with the TOA and we're stuck with this law that doesn't do anything for us, so we shouldn't be hamstrung by the idea we're stuck within the TSA and we can't redraw the map.

The existing TSAs are based on 26-year-old methodologies. They make assumptions based on 1980s population distributions and transportation infrastructure, again, medical practices.

They're also too small of an area of measurement. There -- there's too much traffic across these TSAs. Like my own Hillsborough County, the county borders are really irrelevant when it comes to distribution of patients. So our -- the region that we serve is much bigger than that. We even wrote a paper on it about four years ago describing what the national attachment areas of the 20 trauma centers were existing at that time. So we should look at something like that.

And all this information is readily available. I did it on my -- Steve did it on his computer probably as I'm talking. We have geographic information system software, we have collected data from the occudata set to kid's level to -- resolution through a level of ZIP codes. All of that can be geomapped.

We mentioned the DSTFRs, I would just plug them by saying they -- you know, they provide a familiar regional map that's familiar to the public safety organization. They're large enough to cover the major population centers of the state with very little traffic across those boarders. They are an excellent candidate for regionalization of system performance measurement.

So now we get to the idea of -- of looking at needs-based apportionment within these regions. The --

the hardest thing I think to start with -- we mentioned this last time -- is to define what is a trauma patient. We said this last time too, is that a trauma patient, that definition changes temporally and it also changes based on how you're looking at it.

So the example I used last time was field triage criteria. If EMS rolls up on a patient and they need field triage criteria, that is a trauma patient. They take them to the nearest trauma center according to their medical direction. It may be that patient doesn't have any injuries, so that's still a trauma patient once all the information has been gathered, you know.

And if you make -- if you do your system planning using only one of those two things, it will be inadequate. I think that defining and I -- like defining a trauma patient from the perspective of estimating what your demand for services is, is a little bit more complicated than just assigning an IC9 based -- and ICD9 based risk adjusted mortality.

So just some ideas. So one would be, first of all recognize that trauma as a spectrum of injury. The great majority of patients with injuries have minor injuries or moderate injuries. Almost all of them can be taken care of outside of trauma centers effectively.

And we want that, right? We want people to get the best care to the -- the most proximal care to them as long as it's good to high quality care.

Let's see. I had a number for that, which is -- here. So I think I already said it, 85 percent of the patients -- and these are the ones who have principal diagnoses of injuries. About 85 percent of those would be retrospectively considered to be low-risk injury patients.

Now, that doesn't mean that patient -- or that a local community hospital has the capability of taking care of that patient. It means that if that hospital did that capability, they would probably get good, effective care there.

There have been a number of studies in the northwest that show that patients who do not meet hospital triage criteria, especially for the elderly and especially for falls, get more effective care at lower costs when they're not transported to trauma centers. Okay? Just keep that in mind. The community hospital has a critical role in taking care of injured patients just like the TD1s do.

So the first would be estimate the overall burden of injury within a region using the occudata set. The second one would be catalog the demand on EMS. Each

EMS provider knows how many trauma alerts they're running every year and they provide that information to you all. That's critical information to know what kind of things EMS is seeing. And that puts some of the information that the earliest providers have in their hands into your hands when you're looking at system design.

And then the second is, to use something like the retrospective definition, ICISS is convenient. It's by no means authoritative. It should not be used to develop thresholds. It's simply as a measuring stick. It's more or less a barometer to see how well you're doing.

Those are -- those are the three things that you could use to measure the overall demand. Measure the demand of a minor and moderate injuries or the minor trauma patients, the major trauma patients, and just sort of the minor injury patients.

The next, we were talking about demand and capacity. Measure the capacity within a region. We mentioned last time that's a pretty simple thing to do given today's technology and I -- I suggest, yes, surveying would be something to really consider. Easy to do. You want your -- you want your -- I'm not talking about just trauma centers. I'm talking about

all licensed hospitals in the state. Fill out a survey that says, "Yeah. We have a certain number of ORs, we have a certain number of hospital beds, we have these clinical capabilities." You know, maybe your general surgeons don't take calls at all. In that case, you don't have really any general surgery trauma capability at that hospital. You don't have to make them do it. Just know whether they're doing it or not, you know, where these things can be.

You also want to measure -- so I split that up into two things. Measure the resources at the existing centers, measure the resources at -- of the non-designated places and kind of get an idea of within each region, what is your total injury care capability. That should be pretty easy to do.

The next thing you could -- it's a little bit more complicated than just demand and capacity. The next thing you would want to look at would be the utilization of the trauma centers within a region.

So of all the -- of all the major trauma patients, however you define it, what proportion of them are being treated at their designated trauma centers and what proportion are being treated outside.

So I can tell you that statewide -- this is -- this is just an example. I'm not trying to promote this as

a -- as a done method. But last in -- I did 2014. So we would -- we said that there were about 1700 -- or 11,700 patients with an ICISS of 85. Only 1726 of those were treated outside of trauma centers. That's a really high utilization rate.

So I -- I mean, I can't do the math off the top of my head, but 1700 divided by 11,000. So that -- greater than 80 percent.

I do know that those 1700 patients, almost all of them were elderly, almost all of them were falls, all of them required either extremity orthopedic care or had non-operable -- or non-operative traumatic brain injuries.

I'm not saying those patients aren't sick. Those patients are sick. They need care. They might not necessarily need a trauma center. They're also in a system where 85 percent of the people do get it right, you know.

So it's important to look at utilization not just of your major trauma patients, but also your minor trauma patients. And if it turns out that all of your minor trauma patients are going to your trauma centers, then you need to know that and you need to make allowances for it.

You also need to recognize the differences in the

state. If you lived at the DSGFR2 up in the panhandle, there are very few hospitals there. So artificially it looks like utilization is really high. I mean, they all happen to be going to hospitals that are trauma centers because there's no place else to go.

So they -- they look really great from a -- from a -- they look great from an under-triage point of view. They don't look so great from an over-triage point of view. But that's just the definitions. It's not a system issue.

And you have to recognize that the -- the failures of utilization are not necessarily because you don't have enough trauma centers. It may be a disconnect between delivery.

So in other words, you would want to know is your utilization problem a result of misapplication of your triage criteria or is it just simply that EMS can't deliver a group of patients to a trauma center in a timely fashion? Like maybe there's a population density that's just too remote from your major trauma centers and they just can't get them there first? They have to go to some place else. You would want to know those kinds of things.

You would want to know what the rate of secondary triage is. So of the people who go to community

hospitals first, how many of them wind up being transferred to the trauma centers. All of these things are -- you need know these things if you want to create a rational, objective needs-based trauma system.

The next thing would be -- was mentioned earlier too, I think, was that you don't just say, "Oh. Well, there's a need here and we'll just make room for another trauma center and it just so happens this one is across the street." This really does not address any of the access issues or the utilization issues or the timing issues. All it does is increase your capacity .

It's very simple. And we mentioned this paper from Scotland earlier about how to geocode these things. This stuff is really easy to do by people who are tactile with this kind of software.

So the step would be, okay, first determine your demand, then determine your capacity, then look at your utilization and find out why utilization is really low. If it turns out that there's an area within a region that could benefit from a local resource, then look at the hospitals that would be good candidates to serve that area, and then pick among those the best one which would suit those needs.

You wouldn't want to pick the smallest hospital

with the least number of operating rooms and the least number of in-hospital beds and the smallest emergency staff. That would sort of be a misuse there.

And then finally, I -- I think one of the things that gets to the West criteria is limiting the number of trauma centers based on need. I think that that term gets tossed around a lot by saying that, "Well, what is the need?"

There's an idea that if you -- if one trauma center suddenly reaches a -- a threshold of the number of severely injured patients, well, that's all that -- that trauma center really needs and there's room for somebody else. You need to differentiate between what the patient needed or what the community needed or are you addressing a need or are you trying to create an area for expansion. Okay?

So if your -- if your demand is lower than capacity, but it's above a threshold where you think that, "Well, you know, this trauma center has 800 patients and so there's room for somebody else." That's not addressing a need. That's allowing for expansion and you have to recognize that's what you're doing.

If you think that that's important -- that's one of the things I said earlier. If you think that one of

your system goals is to make room for new hospitals to become trauma centers if it's in their interests, then recognize that that's what you're doing. You're not addressing a need, you're allowing expansion. But also recognize all the -- the down sides of that.

So in terms of apportionment, I think that's the right process to do it, you know. Other things that don't add or are not informative to that, I don't think belong in a points-based assessment for your apportionment.

I think it's really important to have community support. I don't think you can be a trauma center without having community support, but by itself community support does not demonstrate any need. I think it needs to be in there somewhere, but it doesn't counsel the same as, you know, 500 patients who are trauma. All right? That's different.

Okay. Now, I wanted to say two things. I'm going to close that. So at the beginning, you know, you mentioned that -- it's been kind of a tough half a decade, I guess. I think that we're all ready to get moving. Everybody wants to work on this.

We do need a better relationship between the people who are -- are in this business, you know. I mean, Kathy mentioned nobody knows where they're going to be

in five years. I'm going to be here in five years. This is what I do for a living. This is what I picked as my career and this is what I picked as my academic mission, I would say.

We want better relationships too. We want to be involved in this. If you want to repair the relationship, then listen to what I -- what we're saying.

You might look at this and say, "Well, a lot of people are saying the same thing." And that's because you guys all got together. I kind of think of it differently. I think many people are saying the same things over and over again because that's what decades of scientific study would point to.

Like converse evolution. You know, sharks look like dolphins because they have a pointed fishy shape.

That's what I hope to see. I'm glad that -- I'm glad that we're doing this. I hope that the next step would be convening a systems advisory panel. And these are just ideas I came up with in my office by myself. I'm sure that if you fill a room full of smarter people than me, like Steve Smith, you could come up with way better ideas and they would sound much smarter than when they came out of my mouth.

So I really appreciate the opportunity. Hopefully

we'll move on. Any questions for me?

I did -- oh. I knew it. I'll add one other thing. Here's some more numbers for you. The 11,000 patients -- so we'll call them 12,000 patients. We have an ITISS of less than 85 in 2014. At the time, there were 25 trauma centers in 2014. That's about 470 patiens per trauma center.

The actual number of patients treated in those trauma centers ranged from 142 up to 869. There were a handful of places that had more ISS -- or ICISS less than 25. There's the obvious ones. ORMC, Jackson, Shands, Jacksonville.

The level I's by and large -- there are a lot of level II's that treated a lot of sick patients. By and large, the level I's had higher volumes, but there were many level I's that had lower volumes than some of the level II's. If you want a system that flattens everything out so then everybody looks level II, then that's -- that's what you get from the system.

Steve made a big point about the value of level I's. I could emphasize that more. I think, you know, not long ago what a level I was capable of right here in Orlando. Most -- I don't know if this is right or not. But my feeling is most of the people who practice trauma surgery as a profession came out of one of the

level I's in the state. They got all of their training and all of their experience from the level I and they were able to do that because of the concentrated experience that the level I's have.

And the level I's are huge hospitals. All right? They're capable of doing all these and we shouldn't hamstring them by limiting what their volume is. We need to be conscience about that. Take into account what the effect of your crown jewels in trauma system will have when you allow this expansion of level II's.

That's pretty much all I have to say. Again, thank you.

MS. COLSTON: Okay. Great. Thank you.

Any other comments on the phone?

Josh?

No?

Any other comments in the room?

No?

Okay. So I think we've gotten some really great feedback again. I know there's a lot of excitement about the advisory council. I am excited too. You just can't tell because it doesn't seem like it's going anywhere, but excitement sometimes translates to something a little different for me, like throwing things at the walls because you can't have what you

want when you want it. So bear with us. We're working on that.

Again, all comments from any of the workshops that were attended between the June 21st one to today's workshop will be accepted through July 21st. If you have documentation -- Dr. Ciesla, you cited some numbers for us -- you can, you know, quickly jot those down so we can look at those and use those in part of your consideration. And we appreciate all of that.

So we want to thank you for your time and -- Kathy?

MS. HOLZER: To whom do we send the comment letters to?

MS. COLSTON: You can send them to -- I think everybody knows my email, but it's Leah, l-e-a-h. Colston, C-o-l-s-t-o-n@.flhealth.net.

Thank you very much for your time and we hope to get some things moving forward here very shortly.

(The proceedings were concluded at 11:00 a.m.)