STATE OF FLORIDA
DEPARTMENT OF HEALTH

RULE DEVELOPMENT WORKSHOP

RE: Rules 64J-2.010., .012, .013, and .016

Trauma Registry and Trauma Quality Improvement Program

DATE:	September 26, 2016
TIME:	Commenced at 9:01 a.m. Concluded at 10:24 a.m.
LOCATION:	Room 301 4025 Bald Cypress Way Tallahassee, Florida
REPORTED BY:	MARY ALLEN NEEL, RPR, FPR

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LEAH COLSTON, Moderator

I N D E X

P R O C E E D I N G S

MS. COLSTON: Okay. There is a slight change. If you have comments to provide and would like to speak and you're attending by conference call line, please email Bethany, B-E-T-H-N-Y, dot Lowe, L-O-W-E, at --

MS. LOWE: B-E-T-H-A-N-Y.

MS. COLSTON: Oh. What did I say?

MS. LOWE: N-Y.

MS. COLSTON: Oh, gee. B-E-T-H-A-N-Y dot L-O-W-E at flhealth.gov. My apologies.

Again, if you are attending by phone and you wish to provide comments or wish to speak, please email bethany.lowe@flhealth.gov.

My name is Leah Colston. We are here at the Florida Department of Health. The address is 4025 Esplanade Way, and we are on the third floor in Room 301, the conference room.

Just a few housekeeping rules. The bathrooms are out these doors. Ladies, you will go to your right. Gentlemen, you will go to your left. There are vending machines down on the first floor if you get thirsty, want water, depending on how long we go. We will try to take a break at a reasonable time if we go long. We'll try to take a break, and

that will allow everybody to kind of stand up and stretch a little bit.

We are here to hold a rule hearing for Rule 64J-2.010, 2.012, 2.013, and 2.016.

For the folks who are attending here in person, please make sure that you have signed in to register your attendance here at the workshop. In addition, if you would like to make public comment, there are speaker cards in the back that you will fill out, and we will make sure that we have them. I've gotten a few so far. Bernadette in the back will be happy to take your speaker card, and at the end of -- at an appropriate time, we will allow for comments and questions as part of the rule hearing process, so please make sure you fill out a speaker card if you wish to speak.

I just wanted to go ahead. We all know the allocation rule. We're all pretty familiar with that. I just to kind of give some background to this before we get started with hearing comments. It looks like we have a great turnout today, so I'm glad to see that.

Our -- yes, ma'am.

UNIDENTIFIED SPEAKER: Is there a Wi-Fi password that we can use?

MR. LEFFLER: We can get you the Wi-Fi information.

MS. COLSTON: And there is a Wi-Fi password if we need to have that for those who are in attendance.

UNIDENTIFIED SPEAKER: I can provide you with the address.

MS. COLSTON: Okay. Today's date is Monday, September 26th. It is 9:05 now. My name is spelled L-E-A-H, C-O-L-S-T-O-N. I am the chief for the Bureau of Emergency Medical Oversight and also the interim trauma section administrator.

The Legislature first adopted a statute regulating trauma centers in 1982. Many of you are already probably familiar with the history, but I feel like it's very important that we kind of set the background for where we are today.

During the first five or six years after the passage of this law, there were numerous trauma centers that were established through a process which combined self-designation and an application approval process by the State. A showing of need for a proposed trauma center was not required at that particular time.

By the mid '80s, there were 33 trauma centers

recognized in Florida. However, that number of trauma centers dropped to 12 by 1988, which is a drop that we can attribute to the cost of providing trauma care and competition for scarce resources.

In 1989, the Florida Legislature directed HRS, which was our predecessor, the Health and Rehabilitative Services, to submit a report, which is the 1990 report, with a proposal for funding trauma centers to ensure adequate trauma care throughout the state.

The 1990 report recommended the creation of 19 trauma service areas, which we're all very familiar with, and to recognize total trauma center need as between 44 and 60 trauma centers. At that particular time, there were only 12 trauma centers in existence at the time of that report.

In 1990, the Legislature amended the trauma statutes to ensure reasonable access to trauma care services through the establishment of a state-sponsored trauma center system and the partial funding of the cost for providing trauma care.

The Legislature had the 19 trauma service areas as recommended by the 1990 report and established a minimum of 19 trauma centers in the

state by requiring at least one Level I or Level II trauma center in each trauma service area. The amended statute also provided for no more than a total of 44 state-sponsored trauma centers in the state. The Department was directed to establish the approximate number of state-sponsored trauma centers needed to ensure reasonable access to high quality trauma services.

In 1992, a rule was developed to allocate trauma centers to the TSA. This rule allocated the total number of state-sponsored trauma centers allowed by the statute. So for the next decade, Florida's trauma system kind of had some slow growth, and by 1999, there were 19 trauma centers operating in 11 TSAs. However, 8 of the 19 TSAs had no trauma center, so in February 1999, the Department submitted its trauma system report on timely access to trauma care in response to the 1990 report that was generated by the Legislature.

The 1999 report found there was an inadequate number of trauma centers to meet the needs of trauma victims in the state, because the locations of existing trauma centers were enacted to meet the needs of trauma patients in the state, and time and distance between these existing centers was too

great to allow timely access for all trauma victims.

Now, historically, many of you who have been with this system for the length of time that it has been in existence remember that way back when, basically, we were begging folks to become trauma centers. However, in 2002, that kind of changed, because the National Uniform Billing Committee created a trauma response fee. This allowed trauma centers nationwide to offset the cost of maintaining specialized equipment and a team of surgeons and specialists at the ready by charging a trauma fee.

We've seen some negative reporting, negative news articles and that sort of thing that have come out regarding the amount that's charged by some hospitals -- and that has kind of shed a negative light on some things -- for this trauma activation fee that's in existence. But the positive net result of that availability of that fee was that there was an increase in the number of trauma centers throughout the State of Florida, including in TSAs that previously were unserved or underserved by trauma centers.

A rule challenge in 2011 resulted in the

invalidation of the Department's rule regarding the allocation of trauma centers among TSAs. Now, remember, this rule had been developed by HRS in 1992, and it had been in effect for nearly 20 years. But beginning in 2011, we find ourselves to be in constant litigation, and everything that we are doing is being challenged and litigated. And that's not necessarily a bad thing or a good thing. It's just, we are unable to move forward with evolving a trauma system if we are constantly litigating and we're constantly kind of at odds.

In February of 2013, a working group of the Trauma Systems Evaluation and Planning Committee of the ACS came to Florida for a consultation visit. The resulting trauma system consultation report, which is the 2013 report that we're all very familiar with, noted that over the past two years, the Department of State, the Department of Health, and the trauma systems stakeholders had been embroiled in a contentious legal battle regarding the rules that govern the designation of the trauma centers.

While acknowledging clear and undisputed need for these trauma centers, the 2013 report noted that established trauma centers had some issues

with the addition of new ones and issues with the allocation methodology. And so everyone ultimately agrees that trauma centers should be designated primarily to serve the need of the population; however, need and how that's interpreted is kind of interpreted in different ways by different groups.

So the metrics that we should use to determine need, ultimately, to find that optimal balance between the choices and tradeoffs, while we may not have a single, universal solution, it will largely depend on a variety of different factors. I mean, we've talked about before that there are different demographics throughout Florida. You know, population density is much higher than it is up here, but access to resources up here in the Panhandle area may be a little different than access is to southern Florida, as an example.

In 2014, the Department issued a new proposed allocation rule after a yearlong rule development process. That rule was challenged, even though we had a lot of input from impacted stakeholders and modifications to the proposed rule based on that input. Ultimately, the new allocation rule was upheld, but there continues to be constant litigation concerning both the rule and approval of

new provisional trauma centers, and this litigation kind of drains resources that are needed to make improvements to the trauma system as a whole.

In addition to that, last year we had two acute care hospitals that applied to become provisional trauma centers in a TSA where the rule allocation only called for a single additional trauma center. The Department has never faced this scenario before. In the past, as I mentioned before, we've kind of had to try to beg folks to become trauma centers, and the environment has changed and is very different now.

And these two hospitals, they applied, despite the uncertainty concerning the availability of a slot, and despite the expense of putting together facilities, equipment, specialities, staffing, and all those things that are necessary to qualify as a provisional trauma center.

During some litigation that we recently experienced, the administrative law judge reviewed our trauma statutes and rules and determined that the provisional review stage of the application does not under any circumstances involve any competition of any sort. By statute, we are required to review every trauma application that

comes in.

The trauma statute lays out a process and lays out requirements by which we must conduct ourselves and conduct the review of applications that come in, and there are timelines that we must meet. So at the front of this, what the ALJ said is, by statute, you will review a trauma application within a specified time period and respond based on the completeness and the ability that was demonstrated by that application to fulfill the critical elements that are outlined in statute.

This decision by the ALJ, which was different than how we had looked at it before, prompted us to kind of conduct a review of our own trauma statutes and the rules and our processes for allocating trauma centers throughout the state.

The 2013 report noted a long-standing tenet of trauma system design that is the system's -- that the system's lead agency must have the ability to limit the number and level of trauma centers. Florida's trauma system is limited by statute statewide to 44 trauma centers and the requirement that each TSA have at least one.

The Department's proposed rule re-evaluates need by establishing a minimum rather than a

maximum number of trauma centers needed in each TSA, of course, subject to that statutory cap of 44 trauma centers statewide. All of the hospitals have demonstrated commitment, resources, and a willingness to seek new trauma center designation, and these hospitals have the resources and the ability to evaluate the marketplace and make sound financial decisions regarding the sustainability of a new trauma center in a particular TSA. Therefore, it's our position that the Department should not limit the number of trauma centers in a particular TSA, subject to the statutory cap.

In summary, our experience in regulating trauma centers has been focused on addressing a shortage in trauma centers needed for reasonable access to care. DOH continues to address gaps in coverage of the trauma system because, as noted in the 2013 report, Florida has strong academic trauma centers and is now fortunate to have a significant number of well-organized health care facilities with the commitment, resources, and willingness to seek new trauma center designation.

The willingness of these new trauma centers to join the ranks of existing trauma centers to create a more comprehensive regional trauma system is an

important asset that can ultimately result in a stronger system of injury care for the state's population and visitors.

So I think that kind of just sets the stage for what the position of the Department is. You all have seen the proposed language. We've kind of just looked at how we've been doing business based on the litigation that we've been through, and we're re-evaluating our position. We're still establishing need in the state. We're just doing it in a slightly different way.

So I would love to go ahead and start opening the floor to take comments at this particular point in time. Do we have any more speaker cards available from the floor?

Okay. Please remember when I call your name, when you come up to speak, please state your name, spell your name, and indicate the organization that you represent.

Okay. Mr. Tom Panza.

MR. PANZA: Thank you very much. I just have some brief comments.

My name is Tom Panza, P-A-N-Z-A. I represent the Public Health Trust, which is Jackson Memorial Health System, Dade County.

And we support the new rule, and we support the minimum allocation. We went through all the litigation before, and we were, I guess, parties to the ones you're referring to. And we think that this would solve a lot of the problems. There is a statutory cap for the whole state, but I think that this would recognize the needs within the particular counties and allow for a reasonable process to go forward to select a trauma center.

I do not believe that this will in any way develop a situation where you'll have a trauma center on every corner. It costs basically $15 million or so, thereabouts, to develop a trauma center. So whoever is going to develop a trauma center is going to have to think about it quite hard and understand whether they've got the internal mechanisms to do it, the internal wherewithal to do it, and the needs to do it within that particular community. Otherwise, it's going to be a very costly event.

And we think by spending that kind of money, that as long as there are slots that are open within the state statute, that you should be able to go ahead and invest that money with some degree of certainty.

The way the statute reads now, you're investing all this money because you have to demonstrate to the State that you're fully capable of doing this, and you have to start the day after you complete your provisional review and you get approval after your provisional review. And that means it's a $15 million or so process, and everything else in the recruitment of physicians and nurses and everything else that goes with it.

And then you're going to -- if there's more than one in a particular trauma district and you have to go through the tiebreaking procedure, there's a great amount of jeopardy as to what you're going to be able to do over a long period of time, over at least a year to 15 months.

And it just seems to be quite unfair to be able to require -- or to require someone to pay that kind of money, to develop that kind of program, to disrupt all of the surgeons and everyone else's lives as far as the staff and everybody else goes, to go put them into a trauma center and then go through a tiebreaking procedure some 15 months later, after they have clearly met all of the requirements. And we just don't think that this is a fair or appropriate way to do it.

We think by having a minimum number would be sufficient for the State to make a determination up front, and if you meet those qualifications, you should be able to receive it. And it should be remembered that the hospital that's proposing the trauma center is going at risk for all of that money and all of the other prestige and everything else that goes along with it.

So with that being said, we're in support of the rule. We think it makes a lot of sense. We've been through the rule the other way, and I really believe -- and the last time I was here, I gave many comments about why I thought that didn't particularly serve the best interests of the public. I think this does serve the best interests of the public, and we would support the rule.

MS. COLSTON: Thank you, Mr. Panza.

MR. PANZA: Thank you.

MS. COLSTON: Dr. Gerdik.

DR. GERDIK: Good morning.

MS. COLSTON: Good morning.

DR. GERDIK: My name is Cynthia Gerdik. I'm from UF Health Jacksonville. Thank you for affording me the opportunity to speak again, and I have spoken about this before.

I've heard this morning talk about capacity and demand. I've not heard a word about evidence-based medicine, and that is something, as a Doctor of Science in nursing, we strive to do and help lead our organization to do that. So I am asking the committee to please look at that allocation rule, only because if you look at our evidence-based practice and what we now know in the trauma world as the orange book, or the Resources for Optimal Care of Trauma Patients, that there really is on Chapter 1, page 4, evidence-based research demonstrating that if you have too many trauma centers in a district, you're going to dilute the expertise and the research capabilities of your Level Is.

Orange Park Medical Center opened up in May. In our first three months at UF Health Jacksonville, we have seen a decrease in our complex trauma patients by 16 percent. That's diluting my expertise of not only my trauma surgeons, but also the trauma nurses that I have to train. Trauma nurses usually take three to five years to be able to take care of that complex trauma patient. I compete with eight other hospitals, and now I've got less volume.

That is going to hurt patient outcomes, which is something else I've really not heard this morning, and that is making sure we have the expertise to provide care, quality care with great patient outcomes to those complex trauma patients, or what I like to refer to as low volume, but very high risk trauma patients that come to Level Is. And now that we have a Level II in our system, we've had a 16 percent decrease in them.

Thank you.

MS. COLSTON: Thank you.

Jeff Levine.

DR. LEVINE: Good morning.

MS. COLSTON: Good morning.

DR. LEVINE: I'm Dr. Jeff Levine, L-e-v-i-n-e. I'm the trauma medical director at Orange Park Medical Center. Thank you for having us here. Thank you for giving me the opportunity to speak.

At Orange Park, I want the committee to know that (a) we support what the Department of Health is doing; (b) we are providing a huge improvement in access to patients in Clay County, Putnam, and St. Johns County.

I testified previously that while we're only 22 miles from Shands, as traffic patterns are in

Jacksonville, that ride for anybody south of us is oftentimes more than an hour, putting them well beyond the golden hour prior to them even arriving at Shands.

We are currently averaging 130 to 135 traumas per month. However, listening to Ms. Berdik [sic], in her sworn deposition of September 14, 2016, it could not be clearly demonstrated that there was a correlation between Orange Park's prior trauma center, or attempt at a trauma center, and any changes in volume. In 2014, when Orange Park was not even a trauma center, there was a substantial drop in volume at Shands that could clearly not be attributed to any trauma center at Orange Park.

Currently, our mortality is better than national benchmarks, and 12 to 15 percent of our traumas are ISS greater than or equal to 16. So we are seeing severe traumas and doing a fine job caring for them.

In sworn testimony, it was clear that while Orange Park had made a previous attempt to be a trauma center, the mortality and complication rates at Shands went down, not up, so there was no negative effect other than possibly some volume change that's not clear to being attributable to

Orange Park. There was no effect on mortality or complication rate.

Our trauma surgeons stay in-house 24/7 and respond to trauma alerts within 15 minutes, just like any Level I trauma center would do. I don't think -- with an MSA of 1.2 to 1.3 million people in the northeast Florida region, I certainly think that the region is more than capable of supporting two trauma centers. And to date, there's no evidence that we are providing anything less than the standard of care, and there's no evidence that we've actually truly impacted the ability of Shands to provide the care that they are also providing to our region.

That's all I have. Thank you very much.

MS. COLSTON: Thank you, sir.

Kathy Holzer.

MS. HOLZER: Good morning. Kathy, with a K, Holzer, H-O-L-Z, as in zebra, E-R, representing the Safety Net Hospital Alliance of Florida. Safety net represents two -- the two free-standing pediatric trauma centers, six Level II, and seven Level I trauma centers.

I appreciate that you sort of set the stage by giving the history. I think there were additional

reasons that you may find that you've been in a constant state of litigation since 2011.

This state's trauma system in the early '80s, and up until approximately the time that the litigation started, worked on a collaborative basis. Trauma centers, acute care hospitals, EMS, and the Department of Health worked hand in hand to develop the initial standards to make all the revisions along the years. That collaborative working relationship is what made Florida's system the envy of every other state, the model of every other state.

And, yes, we all would like to get out of this vicious cycle. We ask again that the Department return to a collaborative working relationship with all stakeholders, that we return to a transparent process.

Working collaboratively and having a transparent process will remove some of the stress that exists. It will put us in conformity with the recommendations of the American College of Surgeons' orange book, which specifically includes language that the trauma leadership needs to be engaged with the regulatory body.

And so again, we ask you to work with us. We

ask that we go back to a transparent, collaborative approach.

As it relates to the allocation rule, we oppose the rule for the following reasons: This proposed rule perpetuates the lack of transparency, ignores Florida Statute, and the input year after year of the majority of Florida's trauma experts. It's also contrary to the ACS orange book guidelines and numerous peer-reviewed research papers that the Safety Net membership has provided to the Department of Health.

Specifics: If you look at the current statute, you are required -- the State Legislature set a minimum of 19 and a maximum of 44.

I will, for the essence of time, not give you verbally the numerous numbers of references in 395.402 and in 395.4025, where the Legislature made clear that it was the role of the Department of Health working with stakeholders to define need. They set the minimum, and they set the max. The Department in this rule appears to be attempting to override state statute and to ignore its role of reviewing the number and level of trauma centers needed for each TSA.

And it does have to be on a TSA basis. I

appreciate the comments about the diversity in Florida. I've lived in both ends of this state. The solution to need in Miami-Dade County is very different than the solution to trauma need in TSA 3, which includes counties like Liberty and Franklin that do not have the resources available that you can find.

We also find -- I want to restate our opposition to the assessment methodology, in that it does not accurately measure need as a factor of demand and capacity. We specifically object to the inclusion of the 2015 Amended Trauma Service Area Assessment dated January 6, 2016. This assessment fails to comply with the adopted version of 64J-2.010, in that it allocates two trauma centers to TSA No. 5, which is not supported by the data and the assessment. If you look at the data in the assessment, TSA 5 would be awarded five points, which equals an allocation of one, not two, trauma centers.

Out of respect for time, I will -- we will resubmit the Safety Net comments defining the additional issues and problems that we have with that particular assessment. We ask again that you step back from this proposed rule and find a way to

work collaboratively with all trauma stakeholders and move the process into the sunshine.

The Department held three rule development Workshops this summer around the state. They provided no draft language then. They did accept comments. If you review those comments, the majority of those comments asked you to go back to that collaborative method and did not support the existing methodology. Without the opportunity to even look at a draft of this language, the Department moved to proposed language. We really are concerned that our voices were not heard. We ask you again to move back to a transparent process.

We do appreciate the inclusion of the grandfathering language in this rule, the language to grandfather existing verified trauma centers in the event that the Department determines that there are more trauma centers operating than allocated. However, we object to the linkage of the grandfathering language in 64J-2.010(4) to defining the number of trauma centers in the table in the rule as the minimum number of trauma centers required for a TSA.

We also would recommend a technical change,

that the Department look at 64J-2.010(3)(b), deleting the word "or" between "city" and "county" and inserting the word "and" to make (3)(b) consistent with (3)(a).

We will provide you with additional details, as I stated, as to our objection to the inclusion of the 2015 amended TSA assessment and the specific sections of statute that we believe require you to do -- that use that table as a max for -- based on need and not as a minimum.

MS. COLSTON: Okay. Thank you.

Ellen Anderson.

MS. ANDERSON: Hi. Good morning.

MS. COLSTON: Good morning.

MS. ANDERSON: I'm Ellen Anderson. I'm here on behalf of Community Health Systems. We own and operate 24 hospitals in Florida and one -- a trauma center in St. Pete.

One of our -- it's more of a question and something that we look forward to working with the Department on, on the allocation of pediatric trauma centers.

We are a partner with All Children's in St. Pete, so one of the considerations that we would ask is that you all work with us, as we are

partners in our venture there. And especially dealing with trauma and our medical staff, we look forward to working with you on that and clarifying exactly how that allocation -- would it go into consideration with the Pinellas area as well as other parts of the state when you're looking at -- are you going to differentiate Level IIs with pediatric trama centers, or are they going to be held on their own and, you know, be separate?

So that is it. Thank you very much.

MS. COLSTON: Thank you.

Are there any other speaker cards from in the room at this time?

For those on the phone, just a quick update. We've got two additional speaker requests, so we will get to your requests shortly.

MR. ECENIA: Good morning. I'm Steve Ecenia. I'm here on behalf HCA's 46 affiliated hospitals in Florida and to speak in support of the Department's proposed rule, particularly as it relates to the allocation of trauma centers.

We have been involved in the trauma rule development process throughout the time the Department has attempted to craft additional rules and new rules that fairly allocate trauma centers

around the state, and have been privileged to initiate trauma services at a number of new hospitals where the outcomes have been outstanding, access has been significantly improved, yet we continue to find challenges to try to move forward and enhance access and create new access points, because there's constant litigation over the Department's rules and over the approval of new trauma centers.

We believe that the efforts that the Department has undertaken here to try to put all of that behind us and move into a new world where we start looking at outcomes and putting resources into developing the kind of collaborative process that Ms. Holzer talked about, which we're never going to get when we're fighting over which need methodology is the most appropriate to determine how many trauma centers are needed.

I believe the proposed rule is consistent with the statutes and is certainly supported by the Legislature and its effort to establish an ultimate cap of 44 trauma centers statewide. We think that the effort that the Department has undertaken here will move the trauma system in Florida into a new phase where there is true collaboration and data

sharing and a focus entirely on assuring that the citizens of Florida have access to timely, appropriate, and quality trauma services in the right locations.

And I think that if we can get past this notion that the trauma system should be treated like certificates of need for new hospitals, we'll all be in a much better place. I don't believe that the Legislature ever intended for this process to have been manipulated the way it has over the last years to require that the Department's entire resource in developing trauma go to defending rules and supporting approvals for needed new programs. If we can move past that paradigm that we've been stuck in, I think we're all going to be better off, and we will be able to find a collaborative balance that hasn't existed in Florida for as long as I've been working on these kins of issues.

So we applaud your efforts and look forward to working with you as we work through the process.

Thank you.

MS. COLSTON: Thank you.

Dr. Ciesla.

DR. CIESLA: Okay. This seems to be a lot more formal than the last three, so I'm going to do

something a little different.

Like Kathy said, I really appreciate running through the history that you did. It's not easy to find all of that information in one place, and I'm sure it took a lot of effort for someone to pull all that together.

MS. COLSTON: Dr. Ciesla, can you say and spell your name and state your organization? Sorry.

DR. CIESLA: I'm sorry. I'm getting too familiar around there.

My name is Dave Ciesla, last name C-I-E-S-L-A. I am a professor of surgery at the University of South Florida in the College of Medicine. I'm the trauma medical director at Tampa General Hospital, and I'm vice chair for the Florida Committee on Trauma. I'm here on my own time and not representing any of those institutions today.

But I can say that I'm speaking on behalf of Nick Namias, the professor of surgery at the University of Miami and the medical director of the Ryder Trauma Center and our current Epcot chair. I'm also speaking on behalf of Andy Kerwin, who is the trauma medical director at Shands Jacksonville and a professor of surgery at the University of

South Florida; J.J. Tepas, same academic rank and institution; and also Fred Moore, who's the trauma director at Shands Gainesville and a professor of surgery at the University of South Florida.

And by speaking for them, what I mean by that is, I asked them if I can represent their ideas and opinions fairly as individuals and not representing their institutions. So let's just say we're kind of speaking in that way.

I would share the thoughts that Kathy said about moving more to a more transparent process. Earlier this year, it looked like the Department was going to move forward with developing a more collaborative approach to this. I'm kind of disappointed that that doesn't seem to have taken place.

We seem to be in the same place now where we were three or four years ago, where we're not working together and coming up with a product as a collaboration, but we're in this room with a rule where people are giving one-way comments. There's very little two-way interaction here.

And I think that when you look at your timeline and the litigation, most of that is, kind of coincidentally, initiated when the Department

moved away from collaborating with the subject matter experts and the Florida Committee on Trauma and the Systems Design and Implementation Committees.

You know, before 2010, when the -- actually, you actually said it. In 1996, the TSAs were developed and the need estimated using opinions of subject matter experts and social scientists and professional trauma care providers in the state. That's where we started from.

But by the time we got to 2012, all of those experts had been excluded from this process other than to participate in a format like this. I think it has been counterproductive. I think that's what has led to this perception that the Department is doing this in a non-transparent manner, and I think that that's what's causing these negative reactions from the community. When we see a rule, we give opinions, and we see that there has been no response from the Department.

I've been coming up here now for probably four years. I have not seen any changes in the rule that would reflect the voices that have been voiced here, essentially.

So let me just read something. I wrote a

bunch of stuff last night. I have -- what I've prepared on behalf of the people that I spoke about is kind of a lengthy document that looks at principles and also looks at the specifics of the rule. I'm not going to go through the whole thing here, but I'll submit it for comments, but I do want to read a couple of things. And I might paraphrase it a little bit just because it's long.

So since 1982, Florida has been the national leader in statewide trauma system design and implementation. Major challenges to its continued evolution have included ensuring a stable funding source, regional variations in triage accuracy, and ensuring rural major trauma victims' timely access to trauma center resources.

One unexpected challenge has been the recent proliferation of trauma centers in areas that are already served by existing trauma centers. Disagreement over the design of the new trauma centers and the processes by which to implement change has divided the Florida trauma community and incited near civil war between hospitals, health care systems, and the Department of Health.

The 2016 revised rule that we're talking about this morning, 64J-2.010, is the latest effort by

the DOH to bring stakeholders to an agreement on these issues. And while the intent of this rule and its amendments are to provide an objective method to assess the need for additional trauma centers and the distributing centers according to the need of the population, the rule and the amendment does neither of these.

So I would say that Florida established one of the nation's first organized statewide trauma systems in 1982 through the efforts of the health care providers, the DOH, and the Legislature, and since then, Florida has led the country in trauma system development and is recognized as having one of the most organized and comprehensive care delivery systems in existence.

As of 2010, pre-hospital emergency medical services statewide injury triage guidelines and broad geographic distribution of the state's designated trauma centers ensured that 96 percent of the population could reach a trauma center within 85 minutes of injury, and by 2010, 96 Floridians lived in an area already routinely served by at least one established trauma center, and nearly all severely injured patients -- nearly all severely injured children and severely injured

adults were actually treated in those centers.

Moreover, care developed in these centers up to 2010 conferred an 18 percent survival advantage and a substantial cost savings. It was estimated that care in those -- and this is a 2006 report commissioned by the Governor. It showed that it was approximately a $35,000-a-year-per-life-saved savings comparing treatment in trauma centers compared to non-trauma centers for patients with major injuries.

This is an extraordinary public health services success story that was brought about by public policy guided by scientific study and a collaborative relationship between trauma subject matter experts and the DOH. This apportionment rule threatens to undo three decades of effort by effectively deregulating the designation of trauma centers in Florida. In our state, where nearly all at-risk patients are already afforded timely access to proven effective care, the uncontrolled addition of new trauma centers will not increase access or improve trauma center utilization. It will redistribute trauma patients away from established centers, decrease trauma center experience and quality, and add substantial cost of care and of

readiness to the community and to the health care payors.

Now, there are certainly improvements that can be made in the Florida trauma system, such as adopting national trauma center standards, improving pre-hospital communication, triage tools, and matching the distribution of resources with the population's needs.

Up to 2010, the Department worked collaboratively with the ACS Committee on Trauma and other subject matter experts to establish the Florida trauma system's Planning and Implementation Committee. We are urging that the Department withdraw this proposed rule and suspend the designation of additional trauma centers and establish an advisory committee of subject matter experts to collaboratively develop a rational and objective apportionment rule accurately measuring in terms of the demands of the population and the capacity of existing trauma centers.

I'm not going to go through the point-by-point criticism and recommendations for the elements in the allocation rule itself. I'll submit those as written comments. I will say a couple of things, though.

One, the application of this rule to the Florida trauma system, it appears that the DOH has been designating trauma centers regardless of what rule is in effect. Like you said, the State intended each TSA to have one trauma center, so starting with 19 and then setting a maximum of 44, there's no other method that determines how to distribute the difference between those two within the state. And by removing a maximum in each TSA, in principle, you could stack all of those other trauma centers in a single TSA if there were enough hospitals in that TSA to become trauma centers. So lacking a method to regulate the geographic distribution of these trauma centers is potentially destructive to any one TSA and to entire regions.

Application of this rule to the -- or application of this rule in the 2016 needs assessment showed that this rule would suggest that eleven of the TSAs have the appropriate number of centers currently, four have too many, and four have too few. The ones that are suggested to have too few are primarily lower density population and rural areas. The ones that are suggested to have too many are primarily urban, dense population areas.

This is pretty consistent with application of a version of this rule to the state of California. So last week at the AAST meeting in Hawaii -- so the AAST is the American Association for the Surgery of Trauma. It's the premier academic professional society meeting where trauma surgeons present their research. This tool was -- so a version of the Florida rule was evaluated by the American College of Surgeons' Committee on Trauma. It was being considered as a method to assess need in geographic regions.

A number of investigators took this rule and applied it to the State of California and measured its -- or tried to benchmark it with the opinions of the administrators for their trauma regions, sort of like if we had a governmental official in each of our TSAs, we would apply this rule based on the methodology, and then we would go ask the administrators, "Hey, does this sound right to you?"

So essentially, the application of the rule in California found the same thing. It suggested there should be fewer trauma centers in urban areas and more trauma centers in rural areas, and this was not supported by the administrators in

California.

This caused the -- this is essentially causing the American College of Surgeons to reconsider using this tool as its standard. It has not been adopted as a standard. It has not really been promoted has a standard. It has been sort of promoted as an idea. And the conclusion of the presentation was that this is something in evolution. It's certainly not something to implement at this point, but it does seem to be a good starting point.

If you look at what has happened in Florida over the last five or six years, we did that this year. We presented our paper at the AAST last week. I'll provide it. I've been given permission to provide a manuscript to the Department prior to publication.

We studied the effects of adding the five trauma centers between 2010 and 2014. Essentially, we took the 2010 data compared to 2014 data, and in the interim, five centers had been opened, one in the Panhandle and then four others in proximity to Level I trauma centers.

What we found is that essentially -- what we found was that the state's population increased

8 percent, that the injured patient population increased 17 percent, and that the severe or high-risk patient population increased 50 percent -- 15 percent, one by; that the addition of the new centers did not improve the triage of high-risk patients to trauma centers.

Our undertriaged rate remained at 2 percent, our overtriaged rate increased, and our overall triage accuracy decreased. We found that the patients were not -- we found that the patients were essentially being redistributed from existing centers to new centers, and the effect it had on the Level I trauma centers was an older, less injured, and less high-risk patient population with lower acuity.

We found that over time, the difference between Level I trauma center patients and Level II trauma center patients was less. In other words, there was less differentiation between Level I and Level II trauma center patients.

We found that the charges statewide increased 47 percent -- so on a patient population that increased only 17 percent, the charges increased 47 percent to almost $10 billion -- and that the median charges at newer centers were almost twice

that of the median charges at established centers. And we estimated that if the charges at new centers were on the level of existing Level II trauma centers, that would result in approximately 4 1/2 -- or $450 million less. It's in the -- it's worded much better in the manuscript.

So with that, our conclusion was that -- our conclusions were that by proceeding in this manner, we are not putting trauma centers in geographic regions in a thoughtful manner and that we run the risk of limiting the ability of the Level I trauma centers to complete the academic missions, and we are threatening the economic viability of the existing centers.

Now, we quote the statute a lot. Also in the statute is it a provision that the annual needs assessment consider the current referral and transfer patterns of trauma patients in regions. Also in the rule, it states that the composition of the TSAs should be reconsidered annually and that there should be consideration of moving towards adopting the regional domestic -- the Domestic Security Regional Task Force Areas. There has been a lot of talk about that. And we are recommending that we look closer at what is in the statute and

try and get this rule to come closer to what the legislative intent was.

So with that, I have a couple of last things to say. One was that by changing the rule to reflect a minimum number of centers in a TSA, that's effectively deregulating that region, and that does not jibe with the idea that it's needs-based or that the number of trauma centers is limited based on need.

The other thing is that this rule has been -- it's kind of continually revised, and the rationale behind the revisions is not published, and it makes it look like the Department will revise the rule to reach whatever kind of predetermined decision it has made. In other words, you know, if someone wants the state to have a certain number of trauma centers and they want them to be in certain areas, then the Department can just rewrite the rule to justify those placements. I'm not saying that's what happened, but without the kind of transparency and the scientific rationale behind the rule, it's easy for someone to interpret it that way.

And I would tell you that with a rule that eliminates a maximum and supports a minimum, it makes it look like this rule is designed to create

opportunity for hospitals to become trauma centers more than it is to respond to an increase in demand by the population or a shortfall in the capacity of the existing trauma system to meet those demands.

That's all I have to say. I will make the manuscripts available, as well as the comments from the reviewers at the meeting, as well as this document that we put together.

MS. COLSTON: Okay. Thank you.

Do we have any other speakers that are present here in the room, speaker requests?

Okay. We would like to move to speakers on the phone. When I call your name, please press Star 6 to unmute your mike. Please remember to state your name and spell it, along with stating the organization that you represent.

Dr. Kerwin, Star 6 to unmute your line, sir.

DR. KERWIN: Can you hear me?

MS. COLSTON: We can hear you.

DR. KERWIN: This is Andy Kerwin, K-E-R-W-I-N. I'm the trauma medical director at UF Health in Jacksonville.

The only thing I want to -- comment I want to -- a correction. Dr. Levine had stated that at UF Health, our trauma volume was decreasing in 2014

and that the opening of Orange Park Medical Center had no impact on decreasing our volume.

That's not accurate. Our trauma volume was actually increasing during that time period. So I just want to make that correction for the record.

That's all.

MS. COLSTON: Thank you, sir.

DR. KERWIN: Thank you.

MS. COLSTON: Cheryl Rashkin, Star 6 to unmute your line, please.

MS. RASHKIN: Good morning, all. This is Cheryl Rashkin. I am the Broward -- excuse me. It has been a long morning already. I'm the manager of the Broward County Trauma Management Agency with the Office of Medical Examiner and Trauma Services. Can you hear me?

MS. COLSTON: We can hear you.

MS. RASHKIN: The spelling of my name is Cheryl, C-H-E-R-Y-L, Rashkin, R-A-S-H-K-I-N.

I would like to say I want to thank all the commenters that have gone forward so far this morning, because I concur with most of them. Kathy, thank you again. I wish I could have been up there to see you.

In reference -- let me start out with -- when

we go through the documents for the proposed rule change, our legislative staff and I felt that when you go through the summary as to what the allocation talks about with the minimum centers, it's just a little too vague, so maybe you want to think about strengthening that part.

Second, I wish to address 64J-2.010 again. And this has to do with the allocation of centers. When it talks about the need for the different levels of center, it does leave out my pediatric centers in my counties, and I know it probably leaves out a few others throughout the state. You may want to take that into consideration when you're addressing the number or the minimum number of TSAs in my county, or in Miami-Dade or Palm Beach, because they also have pediatric trauma centers, as well as several others throughout the state.

So you want to take a look at that, because right now, if I take a look at what you have listed as the minimum, I show like 25, when in actuality, we have 32 across the state at this point that I know of off the top of my little brain. So we may want to look at that.

The last speaker addressed the issue of

minimum within the standards, and I concur. When you list just the minimum, does that give an open lane to anyone else throughout the community to come aboard and say, "I want to be a trauma center," and they start going through the process? It's extremely expensive. It's extremely time consuming. And it's -- this doesn't really give them any definitive guidelines as to does this community actually need it.

Luckily, in at least five of the areas of the state, we have trauma agencies that help facilitate the need for that within their community, so that's a good starting point.

So if I move on to the next section, and that is 64J-2.010, and I'm looking at the time frame -- I know I brought this up before, but as a trauma agency, I'm good, but I'm not that good, and neither is my Trauma Advisory Panel, that they can take and go through an application -- lots of them are thousands of pages -- and review it in less than seven days from the time it's submitted to the time you need our response. It's just not feasible.

The last time such was done in this community, it was not feasible, and we asked for an extension

to review an application. It wasn't granted. And this is going back quite a while. And it's -- it's just -- you can't do it.

If you go down and you look at another part where -- let's see. If I go in that same section and I look at (k), it doesn't really follow suit with the chart. If you want to allow a trauma agency to help look at these applications, they need to have a similar type of time frame that you, the Department of Health, have to look at it so we can give you back some guidelines or some suggestions from our community as to (1) yes, we do need the center, or (2) we really don't need the center, and this is why, and give you all that background information. So that's a help.

But I see, if you go on, you still have the extensive listing for your site visits, but it doesn't follow suit with what you put in for your change in language in 2.(k). You may want to take a look at that and make it coincide with whatever your chart is saying, because it really doesn't. It says it's going to start on or before October 1st, but it doesn't identify, you know, when your deadlines are going to be.

Continuing on from there -- you can tell I

didn't have any time with this, can't you? And that is having to do with the very last section, if I can find where I'm at. No. .016, and that is (e). I'm sorry. It is 3.(e), and that is that a hospital recommended to be a trauma center in the department-approved trauma agency plan shall be given approval preference over any hospital which is not recommended.

Well, if you're addressing provisional Level II, in our trauma plan, you wouldn't have that in my area unless we had the opportunity to review the fact that (1) we needed an additional center, and (2) we had information from facilities within our community that wished to become trauma centers that we could actually give you this recommendation.

So you have to -- I think you need to clarify your language here to say that if it's going to be in a plan, that would be at that five-year time frame where we would all have to do our reviews, to let you know that this is what we're planning on doing in a five-year time frame. But I can safely tell you at this point, getting ready to go forward with our next five-year plan, that's not in there. So as added language, it needs to become a little

bit stronger.

But I wish to thank everyone for listening to me today. We will have our written comments for you. Unfortunately, our legislative affairs staff got involved in another major issue on the other side of the house today. So I wish to thank you again. I appreciate it. Do you wish me to mute now?

MS. COLSTON: Yes, please, if you're finished with your comments.

MS. RASHKIN: I am. Thank you very much, Ms. Colston.

MS. COLSTON: Thank you.

Donna York, Star 6 to unmute your line, please.

MS. YORK: Hi. This is Donna York. Donna is D-O-N-N-A. The last name is York, Y-O-R-K. I'm with UF Health in Gainesville, the trauma program manager.

I wanted to say thank you again for the wonderful job that you did in summarizing what has happened with trauma centers within the State of Florida. I knew bits and pieces. Most of it happened before I arrived in Florida, but it was helpful to have it all put together for us very

well.

The reason I wanted to talk today was really to look at this minimum versus maximum number. I have concerns about that, and I'm going to reiterate what previous speakers have said. But my biggest concern is that looking at it as minimum means that, again, as the previous speakers have said, any number of trauma centers could open in any trauma area. And I'm not sure that that will actually meet the needs of what the State of Florida is looking for.

It's great to want to have a trauma center where there isn't one and people do not have access to care. But again, I believe it was Dr. Ciesla that said that in a study from, I believe, earlier on that the majority or our population can get to a trauma center within a reasonable amount of time. And that was 2010, if I have my notes correct. So again, it's open season by opening that up.

And so I think by changing that -- and not knowing what your intent was, it appears -- or at least one of my thoughts was, it gets rid of all the litigation, and then maybe we can move forward. But I also think that if we all were sitting in a room and negotiating at a table, we could help get

rid of some of this litigation. I feel like we don't talk unless we're in rule hearings or we're in litigation, and I think that that's a real downside to moving forward within the State of Florida.

For a minute I would like to take a look at our metrics for determining need. I would like to applaud the State of Florida for coming up with some metrics. Many people don't have any. There's nothing in the literature that I've been able to find that says this is what you should do to determine whether or not you need a trauma center.

I think the State of Florida was really forward-thinking in going forward and finding a list of metrics and trying to apply them and trying to use them. It has come to the attention of other people in the nation, particularly the American College of Surgeons, who are looking at their NTDB.

And again, I also had read the article that was referenced by Dr. Ciesla from AAST showing California taking a look at applying these data. We don't have validation that they're accurate. But when we don't have something that is validated and aggressive, then you come up with something, and then you test it.

So I would like to applaud the State for coming up with those. I don't agree with them all, and that's okay.

I think that there's times where getting people to write letters isn't really in the best interest. If you're in a county where there is a tax base, then I think those letters are extremely important. But in most of our counties in the State of Florida, we don't get tax money routinely for trauma centers, and so having anybody write a letter is just having them write a letter. It's like standing outside the grocery store and getting people to sign your petition for whatever it is.

When you look at length of time that it takes EMS to get to a trauma center, you've got to take into consideration where you're at. We're a very rural trauma area. We get people from EMS that have maybe one ambulance to cover their entire county at night. They can't really take that out of service to do an hour's trip to a trauma center, so they have to come up with other things.

So the metric would appear, if you have a lot of those, "Hey, we need another trauma center." Maybe what we don't need is another trauma center. Maybe what we need is more EMS support during night

shift, which would be much cheaper than the cost of setting up a trauma center.

I think the population base is a good thing, but again, all of those are not as yet evidence-based. I think it's good to have a minimum number of trauma centers required for the State of Florida. Having one in every trauma service area does make some sense.

And I know that I was told from the State that when our place opened as a Level I back in 2004, I believe, the actual mortality rate dropped, and it had a huge impact just having us here. But the closest place around before us was way far away, so it makes sense. At this point in time, when you look at having 32, 33 trauma centers within the state, is anybody that far away? I don't know.

I really do appreciate the grandfathering language that I think is very important in this rule that you have added, and I appreciate you putting that in.

One of the things that I have problems with is the long-term impact of opening an additional trauma center anywhere that somebody wants to put one as far as research and training. Now, I don't do high level research, but I do get requests from

many physicians who do research in our area, and what they ask me for consistently is, "Donna, tell me, how many patients did we have that had a high ISS in the last year or the last two years?"

And those numbers have fallen with the addition of other trauma centers, making it less likely that we may be able to do a study on our own, meaning that the length of time for that study will be increased to get the numbers that you need. Or if you have to -- if you're contributing to multicenter studies, it adds some variances. So multicenter centers can be really, really gross, and then if there's variances in how something rolls out with a study, it could make the study invalid. So I think there's some things that you would have to look at with that.

The other thing that I want to talk about for just a moment is the training. We do train surgical residents at our Level I trauma center. And what I've seen over the last couple of years is, with the decrease in the really sick trauma patients, a lot of our graduating surgeons have not had the opportunity to see some really sick trauma patients. They still graduate. They have their minimum number of surgeries. But when they go out

and they're hired at a trauma center, are they really ready to practice and be on their own in the middle of the night? And not all of them are.

And so that's creating problems for those people who hire brand new people out of a fellowship or brand new surgeons right out of their time and they're not ready to go. They don't have the experience that they need. And that impacts all of us, because they can't go out. You can't say, "Hey, welcome. You've got your credentialing. You're good to go."

You're going to have to have a backup for them. You're going to have to stretch yourself thinner until they get up to par. Essentially, they have to have a preceptorship before you can let them go on their own. And this impacts the cost of our health care. It impacts the care that patients are being given, and I think that we have to look about that.

I would really like to see work on -- some collaborative work to look at outcomes. The things that we talk about here are not about outcomes. It's not about making our patient care better. And that, at the end of the day, is what almost everybody in this state got into trauma for. We

don't want to argue. We don't really want to fight. But we do want to make care better for our patients, and I don't think we've done that.

We've all been required to submit the TQIP. We've been submitting that for a while. But what have we used that data that we submitted for? Have we gotten together and talked about, "Hey, look. Somebody down in Miami has a great record for their patients that are in hemorrhagic shock. What are they doing right? Let's investigate it. Maybe we need to implement their plan in other institutions across the state and we would have better outcomes for everybody."

No. What do I hear? I hear people standing up saying, "We have a great mortality rate at our institution. We have great outcomes. We have great care." But obviously, we have people dying in the State of Florida, and I think that we all could do better. But we're not sitting down at the table and talking and using information that we're mandated to collect to do better for our patients and participants and people that live and travel in the State of Florida.

Okay. I'll get off my soapbox on that one.

I also would like to agree with Cheryl, who

talked about giving trauma agencies greater than seven days to review an application. I know that we were offered an opportunity at North Central Florida Trauma Agency to review an application in our agency. And with a week, people deferred reviewing it because there just wasn't time to sit down and do it well, and people didn't want to do it poorly. They didn't want to do it and have it perceived incorrectly from people in the midst of all the legalities going on, and so people did not even have an opportunity to sit down and review it.

Could we have gotten a subgroup together from that agency and without bias reviewed that? Yeah. But it wasn't going to happen in seven days, I've got to tell you. So I would agree that having a little bit longer time to make recommendations would be very helpful.

I think that that's really all I have to say. I appreciate the opportunity of saying this, and I appreciate the work and effort that has gone into the multiple revisions, so thank you very much.

MS. COLSTON: Thank you, Donna.

The last speaker from the phone line, Clint Shouppe. Star 6 to unmute your line.

MR. SHOUPPE: Leah, can you hear me?

MS. COLSTON: I can hear you now.

MR. SHOUPPE: Thanks. This is Clint Shouppe with St. Joseph's Hospital in Tampa. I just want to mention a couple of things that hopefully won't be too duplicative.

I'll start off and just say that the effort to grandfather in existing trauma centers in space-limited TSAs is laudible, but the approach taken by DOH has the effect of simply negating the TSAs and the need-based methodology that had been in effect to this point. DOH is proposing that provisional trauma center applications can be accepted as long as we aren't over the state max of 44 trauma centers, rather than looking at each TSA individually. By focusing on the 44 trauma center statewide cap, DOH is putting at risk the existing legislatively created trauma system.

Leah, you went through a great review of the trauma center history in the state and talked about what has happened when the trauma system in Florida has grown too rapidly, yet here we are today, and our system added 10 new trauma centers over the last five years, and this rule will allow for an additional 11. Has the unserved volume of trauma patients in the state doubled in that period? No,

yet here we are.

This rule would also have several adverse results. One, the new trauma centers will largely open in urban areas. That is what has been shown. That is what has been shown to be the case. Rural areas will continue to struggle with access, while urban areas will see quality issues while supply grows, but demand stays flat.

And published research out of Pittsburgh has shown that the increased number of trauma centers decreases the proficiency of all centers and contributes to poorer outcomes for patients, which is exactly what we're trying to avoid.

The new minimum volume requirement could even create a scenario wherein trauma centers in a newly overserved area end up closing for not meeting the new minimum thresholds.

And finally, where is the Trauma Advisory Council? This was proposed by DOH and hasn't happened. Had it been restarted, DOH could get the kind of advice necessary to avoid exactly these kinds of messy rulemaking processes that are happening today. And this is -- to be clear, this is much bigger than the review of a few provisional trauma centers in a few isolated areas.

We implore the Department to reconsider its approach. The Department this summer talked about a reset in the approach to trauma and taking a more collaborative approach going forward. This proposed rule is not consistent with that goal.

And I believe there are two options to move forward. The first is the current path, which is more division, litigation, and uncertainty, which will happen if DOH moves forward in the top-down proposed rule.

Or do what DOH committed to do this summer: Restart the Trauma Advisory Council. Go through the process of putting a rule together that will get wide support from all stakeholders, and then come back to the rulemaking process at this point. Taking two steps back right now is the only way you can acceptably and speedily move forward to keep the high quality trauma system Floridians have come to expect.

Thank you.

MS. COLSTON: Thank you.

Do we have any other speakers from within the room? Any other speakers on the phone? Do we have any other requests to speak?

Okay. We will open a comment period for a

week, so please submit all written comments and materials. I know there were several folks today that I've noted will be sending in written comments or research materials. Please submit those no later than close of business on Monday. We will send a message to all stakeholders, indicating the deadline for the written comments.

Thank you. We appreciate your attendance.

(Proceedings concluded at 10:24 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA:

COUNTY OF LEON:

I, MARY ALLEN NEEL, Registered Professional Reporter, do hereby certify that the foregoing proceedings were taken before me at the time and place therein designated; that my shorthand notes were thereafter translated under my supervision; and the foregoing pages numbered 1 through 61 are a true and correct record of the aforesaid proceedings.

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

DATED THIS 29th day of September, 2016.

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