EXCERPT:
ELIMINATE THE USE OF DSAs AND REGIONS IN LIVER DISTRIBUTION

Four Seasons Resort and Club
Dallas at Las Colinas
4150 North MacArthur Boulevard
Irving, Texas 75038

Monday, December 3, 2018
3:48 p.m.
Eliminate the use of DSAs and Regions in Liver Distribution
   Dr. Heimbach

Motions: 110, 133, 162, 199
(3:48 p.m.)

MS. DUNN: All right, everyone. I think -- do we have most of the board members back? All right. Brian Shepard is not here but we will start without him. Oh, there he is. There he is. All right.

(Laughter.)

MS. DUNN: Okay. If I could have the slide that starts -- it looks like it's number -- oh, I don't have a number on it. Process for Policy Action Items.

(Slide.)

MS. DUNN: There it is. Okay, thank you. All right. So I have quite a bit to read here, to talk us through the process that we're going to go into. It's not on a slide but I would really ask that you pay attention. This is kind of unprecedented in terms of how we are going to handle the amendments here. There were a lot of amendments last year. This is a little different because we have some different scenarios that might take place.

We have time scheduled for this to go as long as we need it to go long. And you will -- I will
remark a little bit more about that in my comments. But before I go into how our process is going to go, I would like to turn this over to Deanna Santana, who is our Vice President of Patient and Donor Affairs, who would like to frame her thoughts as a donor mother here for our discussion.

MS. SANTANA: Thank you, Sue.

I just am usually one to listen and speak and the speak at the end. But I thought today it might be appropriate for me to speak at the beginning, to keep in mind that none of us would be here in this room today if it weren't for people like my son, people like my family. There're other donor families that are in the room. We say yes to donation at the worst moment of our lives because we want to help another family not walk through the same heartache that we're walking through.

When you bicker and fight over organs, and I know that to transplant centers and to OPOs, they seem like very important changes. But when you bicker over some of the small details and you're not kind to one another, that really kind of actually makes me question
my decision to be involved in this community. So I hope you do your discussions respectfully and I hope you always keep in mind that all of this is only available because of the generosity of a family who wishes to help as many people as possible. Thank you.

MS. DUNN: Thank you, Deanna.

So on the heels of that, to go into all of this detail feels a little hard. But I think it's really important.

So the chair of the sponsoring committee will be presenting the final proposal, and that is Dr. Julie Heimbach, who is teed up here in the back of the room. After she has presented the proposal, I will call on the leader of the board policy group that was responsible for reviewing the proposal to report out on the group's discussion, recommendations. And that representative is Dr. Yolanda Becker.

Our only policy action for today's open session is the Liver Committee proposal. So first, Dr. Heimbach will present the proposal from the Liver Committee.

Following Julie's presentation -- oh, I'm
reading this, so I just said this -- we'll hear from Yolanda, the group leader for the board policy group. Once Dr. Becker has reported out the recommendations, we will then discuss a number of amendments that have been offered on the proposal. So I want to thank everybody for sending your amendments in advance. It was very helpful to see all of the amendments and to take them in a logical order.

So there is an amendment book that all of you should have, as well as some updates to some amendments that were placed at your spot here this afternoon. So I would say, make sure that you have all of those nearby and in hand. And I'm guessing -- I'm hoping and I would be expecting that you've already looked at all of those.

Staff have prepared a table that is also a chart. They made it big enough so that you could read it without too much of a magnifying glass. I would ask that you pull that out and you should make sure that it actually has the updated Monday, December 3 date in the upper right corner. So that we're looking -- we've had some changes to this with some of the updated policy
amendments. So make sure you have that as a tool at your fingertips.

And hard copies of the amendments, again, are in a booklet form. So have those.

After Julie's presentation, we will open the floor for general discussion and questions before we take up any amendments. And I will ask everyone to try and save their specific feedback or questions on an amendment for the presentation that's on that amendment, so we can try to keep this streamlined and keep it clear about what we're talking about. Sponsors will present their amendments in the order designated.

Again, please press the button on your mic in a request to speak and I will call on you in order. I would ask that you try to keep your remarks concise. And that even simply saying, I'd like to associate myself with so-and-so's comments rather than repeating what another board member had said certainly makes its mark in the same way. If you have something new to add to the discussion, we want to hear that. But if it's a reiteration of what someone else has said, I think saying that you agree with that person is a beneficial
There are so many people that deserve thanks for the countless hours that they put into this project. They're not all people in this room. But specifically, I would like to thank Dr. Julie Heimbach, who has taken on the task of really molding public comment into the proposal that we have before us today. We will discuss the proposal in a way that I hope adds clarity, transparency and focus. And I would like to recognize that in discussion we want to hear from all of the viewpoints around the room and I know that we can accomplish this today if we carefully listen to one another.

My role today is to facilitate professional discussion and debate among the board. We are accountable for our decisions and our actions when we walk out of this room today. And this board, like many boards before it, is asked to act with transparency as well as courage. And I hope we can fulfill the expectations of our community at large.

I want to ground us also in that our strategic number two is to provide equity in access to
transplants. And we're officially now opening the liver/intestine distribution using distance from donor hospital discussion. But before the committee starts to kind of give their viewpoint or to report on the policy, I would like to begin the discussion today by refocusing our charge as a community.

As everyone well remembers, we're acting today following a directive from the Secretary of Health and Human Services. Our partners at HRSA have continued to serve as guides in this process and I am going to call on Cheryl Dammons, who is the Associate Administrator of Health Care Systems Bureau in the Division of HRSA, to reiterate the Secretary's instruction as we begin our deliberations today.

So Cheryl, thanks for being here and I will turn the mic over to you.

MS. DAMMONS: And Sue and the board, thank you very much for this opportunity. I am joined by my very capable colleagues. Frank Holloman to my right. He is the Acting Director for the Division of Transplantation. And to my left, Chris McLaughlin. Many of you know Chris, who is the Chief of the Branch
of Organ Transplantation.

And so I just really want to thank you for this opportunity today. And we at HRSA want to be clear that we believe that organ allocation policies are best developed by the experts within the transplant community, which is each and every one of you around the table.

As members of the OPTN Board of Directors, you have a responsibility for determining how the national resource of donated organs will be distributed, consistent with the requirements of the OPTN final rule. We wish to express our deepest appreciation for the substantial time that the OPTN board, the Liver Committee and others have expended studying and discussing the liver allocation policy.

MR. HOLLOMAN: As most of you probably already know by now, in a July 31, 2018, letter to the OPTN, HRSA informed the OPTN of its determination that the OPTN had not justified and could not justify the use of donation service areas, DSAs, nor OPTN regions as currently constituted in the current liver allocation policy and in the revised liver allocation policy that
was approved by the OPTN Board of Directors in December 2017 under the requirements of the final rule. HRSA explained that neither the DSAs nor the OPTN regions were created to allocate organs equitably or to optimally distribute donated organs.

HRSA further explained that the 58 DSAs and the 11 OPTN regions in the U.S. vary widely in geographic size and population. HRSA's letter and guidance resulted in from the agency's consideration of critical comments that were received by the HHS Secretary in May of 2018.

The letter also provided direction to the OPTN board to approve a liver allocation policy consistent with the terms described in the letter and the OPTN final rule by December 2018, so by this meeting.

HRSA did not and is not directing any particular policy outcome nor allocation scheme. However, HRSA has made it clear that the OPTN board must consider and explain how any liver allocation policy approved by the board satisfies the requirements of the OPTN final rule.

In addition to the eliminating the use of DSAs
and regions, the OPTN board was directed to provide its written rationale together with supporting evidence explaining how any geographic limitation is justified and required by 42 CFR 121-8.

(Slide.)

MR. HOLLOMAN: As you see up there behind you, we thought it was important to pop that up on the screen, as well, the allocation of organs. Such allocation policies shall be based on sound medical judgment, shall seek to achieve the best use of donated organs, shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation and to promote the efficient management of organ placement. And under 8, shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs A1 through 5 of this section.

And the board was instructed to provide its rationale as to how any specific geographic units of distribution is justified by one of those regulatory factors.

It is imperative for the operation of the
national organ transplant network to maintain public trust that the system is fair, equitable and consistent with the statutory and regulatory requirements. We appreciate the OPTN's diligence in developing a proposal through an expedited yet thorough process in accordance with the Department's requested time line.

MR. McLAUGHLIN: And much of the deliberations during the last few months have rightly focused on the need to balance competing factors that need to be weighed in development of a fair, equitable and successful liver allocation policy. HRSA reiterates that, no matter which of the relevant factors listed in the final rule are used by the board to set geographic limits on distribution, the board needs to provide sufficient evidence to justify its decision.

So as an example, efficiency has been regularly discussed. The final rule provides that organ allocation policies shall be designed to promote the efficient management of organ placement. There has also been considerable discussion regarding the requirement that organ allocation policies shall be designed to promote patient access to transplantation.
If the OPTN board determines that a particular geographic limitation is justified based on such factors, the board needs to explain why those adopted geographic limitations are necessary for the sake of such efficiency or access.

HRSA is aware that there were discussions amongst the Liver and Intestinal Committee and within the community regarding the lack of modeling for the B2C model at MELD 29. You know, in short, government contractors have finite time, finite money and manpower allotted to provide services. HRSA was able to provide the committee with its initial modeling request but was unable to provide additional resources for additional modeling.

Absent the additional modeling, the modeling for MELD 35 and MELD 32 provided the committee with data to assess probable MELD 29 results. Additionally, there are other OPTN modeling requests in the pipeline, including what HRSA projects will be an extensive effort for kidneys. And unfortunately, HRSA was unable to fulfill additional modeling requests.

Further, as my may be aware, the final rule
provides that allocation policies shall be reviewed periodically and revised as appropriate.

Finally, HRSA asks that the OPTN board produce a written summary reflecting the considerations examined during its deliberations. So that would include the amendments considered and the votes taken, and the process followed to consider the range of options that are available to you as you make this decision, the underlying data, the public comments that have been received during this process to develop a new OPTN liver allocation policy.

This written summary, along with the existing documentation that's been included in the OPTN Liver Committee's report to the board will be invaluable for HHS as it evaluates the policy that's adopted. As always, HHS's evaluation of any allocation policy's compliance with the OPTN final rule will turn in large part upon the process the board used, the data and comments it has considered and the board's rationale underlying and justification for concluding that a particular allocation policy best meets the requirements of the final rule.
MS. DUNN: All right, thank you, Cheryl, Frank and Chris.

And with that, I will turn it over to Dr. Julie Heimbach.

DR. HEIMBACH: Great, thank you very much.

First, I would like to thank the board, not only for your service. This is really a truly exceptional group of people. But I also would like to thank you for your careful consideration for this really complicated proposal. It was actually a complicated proposal even before we had 14 amendments. So I really do appreciate your efforts today. Thank you very much.

And especially thank you to Chelsea, Brian, Sue, and the rest of the leadership for, you know, carefully organizing all the amendments in a way that they can be understood and processed.

I would also like to thank my Vice Chair of my committee with me, Dr. Trotter, as well as Rio Hiroshi who was the chair before me. And, most especially, my committee. We actually have met almost every week as a full committee since June, which is a remarkable thing,
considering almost 90 percent participation for almost every meeting. So it has really been a team effort to what we have to bring to you today. And I just really appreciate that.

And I would especially like to thank Elizabeth Miller, who is our committee liaison, who -- I didn't actually realize this until five minutes ago, agreed she stepped in, you know, talking about changing horses in midstream -- she stepped into this role in June, thinking we were going to be implementing a policy. Little did she know that we were not going to be implementing a policy, we were going to be doing something very different. So Elizabeth last night was furiously crafting the language for all of the amendments and we were texting and working together through the night and that represents the dedication that she has put to this process the whole summer and fall. So I really need to put a special thanks, she's exceptional and we definitely wouldn't be here without her work.

So with that, we will just launch into this. And what you have already heard nicely
presented by the leadership of HRSA, just to walk you again through that history that was described to you that many of you were here last December when I was talking to you and we actually worked our way through 11 amendments and passed a policy that was sharing for the region plus a 150-mile circle around the donor hospital with a threshold of 32.

Following that, we received a critical comment that came to HRSA in May with a subsequent lawsuit that actually came in July, and we received a direction from the Executive Committee to the Liver Committee June 25 that asked us to remove the DSA and the region from the policy, thus basically asking us to create a new policy that could be developed and delivered to you by December of 2018, which was a remarkable idea but that was the idea. And we also needed to make sure that the policy that we brought forward would be compliant with the final rule.

We got that on June 25 and we needed to have our modeling request by July 13, which is like not very many days. So in order to do that, we had to think about a different way to do policy. If we're not going
to use the region and the DSA, how may we best do it?

And, of course, we started by thinking about the United States. And the first thing that would be obvious to everybody is that it's not homogenous. There's quite a difference around the country. So the first thing that we wanted to do was to think about that.

And we agreed that right away we had to have a circle-based framework. And it seemed to make the most sense for us to have a population-based circle so that we could address this fact that the United States is not the same all around the country. We strove to do that and right away it was clear that we were not going to be able to make our July time line. SRTR provided guidance to say that this is just not possible to create something that we could model in this time frame.

So we had to let go of that idea, which was our goal, and come to the second idea, which we came up with two different circle-based frameworks that we considered. And we were luckily allowed to model both of them. And the SRTR did a tremendous job in
delivering that modeling to us in a timely way. So the first one I am going to explain to you is called B2C. and both of these policies have an initial, large circle. It's a 500-nautical-mile circle for what is called a status one, which is the most critically ill patient with an expected survival of less than one week. In this policy of B2C then there is a second allocation, which is to a medium-size circle, a 250-mile circle for what we would consider an urgent patient. This is a MELD 40 candidate down to different thresholds. We looked at several different thresholds, 35 and 32 were modeled but we actually also asked for comment during public comment on the concept of 29 at a different threshold. And then there's a smaller circle, a 150-nautical-mile circle, down from wherever we put that MELD threshold, 34, 31, 28, down to that 15. And then it would go back up, sort of like a ladder goes down and back up again, and then it would finally go nationally. So that's the B2C. The second circle-based model is what is called Acuity Circles or AC model. And this attempted to actually be a surrogate for a population-based
circle. It was not perfectly that but that was the idea when we had the concept. And it was again a large circle for that most sick patient, that status one candidate. But then contrary to what we did before, it actually went to a small circle for a really sick group of patients, the 37 to 41, 50-mile circle. And then only if there was nobody in that small circle would it go to the bigger circle. So we thought maybe this would function well in a densely populated area, because there would probably be a candidate in that one 50-mile circle. But in the more sparsely populated areas, that there wouldn't be and so then it would just go to that next size circle, a medium circle, 37 to 40, and then a large circle, 37 to 40. Then again, it would go down to a second band, 33 to 36, small circle. Then a medium circle, 33 to 36, and then a large circle, 33 to 36. We hoped that this would result in sort of the good things about population-based models where you wouldn't travel unless you had to travel and those kinds of things. That was our goal with this model.

(Slide.)
DR. HEIMBACH: And so this just gives you a graphic representation. That's obviously the United States and those circles, the darker of the two is a 150-mile circle and the lighter, larger circle is a 250-mile, nautical mile circle. So you can just kind of orient yourself on what that would mean depending on where you are. Those dots actually represent transplant centers and the colors are the different regions.

And then we have this map, which gives you the 500-mile circle. And I think it's important to just actually look at that for a minute. Because a 500-mile circle does different things on the west side of the United States compared to the east side. You can see on the west, there's not as much overlap of those circles and they kind of stay almost within individual regions. But that circle of 500 up in the Northeast actually has got five regions in it. So it's interesting to see the impact of those different size circles around the country. I think that's an important concept that we got, we heard loud and clear in the public comment.
DR. HEIMBACH: So this is the modeling that is provided to us by the SRTR. And what you can see there is current, meaning this is what we're doing today. We're also allowed the comparative data for what we would have approved if we had gone forward with the policy from December of 2017. And then we have the two different versions of the AC model or Acuity, which we used the different-sized circles of 150, 250, 500 or 150, 300, 600. And then the B2C at two different thresholds of 35 and 32.

And what you see in the first column there is called the variance. And we would like that to be as close to 1 as possible. And what that is reflecting is the difference in the score around the country that is required to access transplants. So we would like it to be the same. That's actually the goal of this policy, is to reduce the difference. And, you know, where you are living in the country, how you can access transplant.

And you can see, currently, it's 10. With what we would have approved in December, it would have
gone down, which is a good thing, down to 7.4. And I think the best part of this is to see that with both of our models, we are going to move this in the proper direction. Both Acuity and B2C do what we were wanting to do, which is to improve this difference in access so that patients around the country can feel that they have a similar chance of accessing transplant. Because that's what we're trying to do.

We also looked at different things that would happen. Obviously, when we share more broadly, we have to consider what is that going to mean for the community. So the next column is the median transport time in hours. So that, you can see, currently was 1.7. We had spent a lot of time on the model we approved last December to try to minimize these logistical impacts. And you can see we had the exact same estimate in the travel time. With both AC and B2C, we're going to go up but it's only very slightly in time. And distance will also go up but, again, it's not a dramatic change in distance.

But one of the big changes you can see in the next column is the percent of organs flown. Where in
the current model, we're flying about 50 percent of the time. But that will be projected to go up. We would have gone up just a little bit with the model we approved last December. It will go up more significantly.

So even though we were expecting the Acuity model to hopefully not impact this as much as it did, it does show us to be flying in the neighborhood of 70-ish percent of the time, depending on those sizes of circles. And we know that these numbers are not going to be exact because this is a model. But we can say from the modeling that the trends will be in this direction. We don't think it actually would be 71.4 percent but that would be the trend that we would project that we would be flying more with AC than B2C, according to the modeling. Which was not what we were hoping to see but that is what the modeling showed us.

We also were able to get information on wait list mortality with the count and the rate. And you can see this is the number of patients that would be impacted with the current wait list deaths at 1455. And then with all of our policies, moving it in the
right direction though with different degrees, the AC model making a bigger difference on this important end point and the B2C still moving it in the right direction but not as much.

It's important to recognize that we're not doing a lot more transplants with this because this doesn't make more donors available to us. This is not the goal of a project that makes more donors. What we are doing here is trying to provide equal access around the country. So again, a waitlisted patient in one area of the country can feel that they have a similar access to a patient who is equally sick in another area. That's what this policy does.

(Slide.)

DR. HEIMBACH: So, once we were able to obtain this data, we could not get this modeling done in time for the normal public comment cycle. So what that meant was we had to be ready for a special public comment cycle and that was done from October 8 to November 1. And what we did was we looked at that modeling and the committee recommended, after a lot of discussion which we had to do in a very short time
again, over about two weeks, we had to analyze the extensive output from the SRTR and come up with a recommendation.

What we sent out for public comment was that the committee felt that B2C at a 32 would be the policy that we would recommend. However, when we sent that out for public comment, what we wanted to know was feedback on that B2C model. And we also wanted to know for feedback on the Acuity Circles. We wanted to know people's thoughts on the threshold, whether they thought 35, 32 or potentially even 29 would be the most suitable threshold if we did adopt the B2C model.

We also asked for feedback on the size of the circles and whether people thought they were the right size as we had proposed them or if they should be larger or smaller.

Then once -- actually one day after that public comment cycle closed, we met in Chicago to consider all of the public comments and to make our recommendation to the board. So I will just walk you through a little bit of that public comment that we were allowed to see.
And what you can see here is that we received 1,242 comments. This is actually the second highest number of comments. And it's actually, I thought, well, maybe the first would have been what we did last fall. But that was not true, we only had 647 last fall, so this is nothing compared to that.

And then when we had to do this, we had to do webinars. We did two national webinars about this topic. I have become the queen of the webinar. I just want to let you know, this is my new career. I'll just do webinars.

We did 11 regional webinars. Because we did not have the ability to go to the regional meetings and present this, although of course we presented an update of what was happening to every regional meeting, we then had to present the proposal to each region and then gather that feedback, which we did with each individual region a webinar. And we also had to present to all the UNOS committees that wanted us to present. So that was a lot of feedback that we were able to gather.
DR. HEIMBACH: And you can see there in those different slides, that just gives you the different types of people that responded with the most significant responses being on the bottom, which is transplant hospital. But really, we got feedback from OPOs, from individual patients, from general public. We got really robust comment as you can see. (Slide.)

DR. HEIMBACH: This map is, I think, great because Guam submitted a comment. That's why it has to be so large. But we got comments from all around the country.

Importantly, relative to the population size, we do have a disproportionate number of responses from four states. So you can't say, well, we just add up the number of comments and that should be the decision. Because, of course, you know, you can read the comments. You can see that about, you know, 40 times the same comment would be submitted. So it's not necessarily as meaningful to have that kind of comment repeated by, you know, whoever is able to send that out on their Facebook. That is not so helpful to guide the
committee's deliberations. So we know that the numbers mean something but the actual substantive information that is contained in the comment is also very important to the committee, as we looked at each and every comment. But you can see where everything came from. (Slide.)

DR. HEIMBACH: And then you can see these are some interesting charts that James and his team were able to create for us that would show us how these comments could be considered. And I don't think you'll be able to tell but those different colors are actually little squares that have a state written on them. And what that is supposed to represent is, according to the population of the state and how many people are listed in that state and then what the response was. You know, what did those different states prefer.

And what we have on the top is neutral and then I think the red is people that didn't like anything and the blue is Acuity and then the green is B2C and then the green on the bottom is that we liked everything. So that's what those are showing you.
And you can see that certain states which are large states that provided a lot of feedback, you know, some of them actually have -- Texas is on two different of these because they had people that provided comments that fit into either of those categories.

(Slide.)

DR. HEIMBACH: And now this is each state represented across the bottom and then divided by the comments that they received, whether they would be, say, for example, in the middle, the gray were neutral. They really didn't indicate by their comment what they were supporting. Whereas the colors mean the same. The red didn't like anything, the blue liked Acuity, the one color of green which is a little bit darker liked the B2C and the light green liked both.

So you can see, if you kind of cross your eyes and quit at it, maybe you could see that one of them is supported over another but it's essentially a mixed group of feedback that we got on these, on this particular view of it.

But when we look at the framework preference, just by again grouping the actual comments -- and
remember, you know, those multiple comments submitted would be counted as each individual comment so I don't think the numbers are as particularly helpful, but it is still important to review them.

So the people that liked anything, there were 8.7, they're super happy no matter what we do. That is 8.7 percent.

The people that don't like anything is the biggest number, unfortunately. Forty percent thought, we don't like this at all. And you can see on the map where those people came primarily from.

And then you can see that the B2C had 10.5 percent, really widely spread around the country of people that preferred that specific framework. And then the Acuity Circles had 35 percent support, and again widely spread around the country.

(Slide.)

DR. HEIMBACH: What about the threshold? We asked people for whether they would like 29, 32, 35. And you can see that, of the comments, the majority remarkably preferred 29, even though we didn't actually show you any modeling from 29. That was still the
number that was preferred.

Now, we also did those individual webinars that I told you about. And I would say that the feedback that you obtain on a webinar is very different than the face-to-face feedback. And so the special public comment cycle was definitely the best thing we could possibly do, given the circumstance. But it's not optimal. Being at the meeting, gathering the data, gathering the feedback, I think we had probably better sense of what the regions really wanted.

But having been on almost every one of these webinars, I still feel that we had good participation and good engagement. It just was not perfect. And then the actual number of votes, you know, would be smaller than you would expect for the region. But on the other hand, mostly the people that voted were people that had liver programs which, you know, that is not every program in the region.

But you can see how the regions gave their comments there and whether they liked AC or B2C, whether they liked 29 or 35. And in general, again, I would say the regional feedback was split with five
coming for AC and six, plus or minus, because 11 really
didn't like anything so it's hard to know how to count
them, but B2C may be slightly favored by the regions.
But it's hard to gather a clear guidance from the
regional feedback because it was fairly split.

(Slide.)

DR. HEIMBACH: Over to societies, these are
usually organizations that we really do value very
strongly the input. The ASTS had a lot of positive
feedback about the process and everything, and at the
end of the day really didn't come to weighing on one of
the two models and sort of came to the conclusion that
a population-based model would be their strongest
preference.
The AST, it was a long comment. I think, in
general, their support was for B2C. I think they
subsequently had additional comments that would suggest
it was more for the AC model. But on the day of
November that we were in Chicago, we had a comment from
them that looked at B2C as being their favored option.
The AOPO was just providing a supportive
comment, not really coming down on one side or the
other, at least as we interpreted that comment. Except some would interpret that comment to be for B2C because that would be a more incremental of the two policies.

NATCO seemed to be in favor of B2C but they definitely sung the comments that would be in support of a population-based model.

(Slide.)

DR. HEIMBACH: What other evidence did we look at? Well, it's important to recognize when we were trying to figure out the threshold, what we could see that analyzing and considering that lower threshold, though we didn't have modeling, we knew that it would, of course, expose a greater percent of the wait list to the broader sharing. And so when you go from 35 to 32, you can see that that change in the threshold results in slightly more flying. It also improves the variance in the median MELD at transplant in the direction that we want, and it had a positive impact on wait list mortality. So we would presume that going to 29 would have the same impact.

And then we can see the percentage of the list that is exposed is significantly greater. This would
just be a snapshot. But also considering that right now, the median MELD at transplant in the United States happens to be 29, you know, that would be another reason that we would consider that threshold.

Another important point that the Liver Committee looked at carefully when we looked at all of the public comment was the fact that, when you look at the wait list mortality, this is what this figure is showing you, for each specific MELD score, the patient's risk of death does go up. But it goes up more steeply in certain points of the curve. So the curve is not just a straight line, it's a -- it gets more steep. And the point of steepness where it really takes off is between 28 and 29. So a patient becomes even more urgent right at that split threshold. So there was another reason that the committee looked at that 29 as a threshold that we might want to broaden the sharing to.

So considering all of that, the committee is recommending to the board today a B2C at that sharing threshold of 29.

Why did we pick the B2C? what was the main
things that was driving the committee to choose this?

Well, as I mentioned when I showed you the modeling, both models do improve disparity. Not only compared to what we're doing today but also compared to the policy that we passed this time last year. So we were certainly encouraged by that.

We were discouraged, as I mentioned, by the fact that the AC model did require flying for approximately 71 percent of organ recoveries. So that is a greater percentage of flying. What is the big deal about flying? What that means is it takes longer for the organ recovery to happen because you have to not only just get in the car and go there but you have to organize travel. You have to fly a team. There is that longer time where the team is not available to work in their own center. All of these considerations lead to logistical challenges that were concerning for the committee members, as well as the logistics of allocating over a broader area, especially in a population -- a highly dense population area.

(Slide.)

DR. HEIMBACH: So that's that point that I'm
citing right now. With a 500-mile circle in a densely populated area includes potentially a larger area than would be needed to optimize the system. And the logistical challenges of allocating to a large number of different centers for every -- each and every organ offer.

It's interesting to look at the people that supported the different models. And the group that was most supportive of B2C actually were the people that were representing the OPOs. I think they recognize the logistical challenges of simultaneously offering -- you know, there's one candidate being offered numerous livers and while initially that seems like very favorable for that one candidate, they actually don't need to get 45 offers in one hour; they just actually need two good offers or one good offer. And that simultaneous offering to the same candidate has the potential of sort of what we would say clogging the system and actually slowing things down.

And I read a comment that I thought was fairly compelling that I wanted to share, which was from the public comment, that wasted time is the enemy of
maximizing the gift of organ donation, which I thought was fairly compelling. And I think just in the way our system is currently structured and the technology that we currently have, this is an issue in the areas of extremely dense population. It's definitely not an issue on some parts of the country, where a 500-mile circle is actually smaller than the area of allocation that we're using today. Because there is a big patch where there's no people. So, you know, the mileage doesn't mean anything. But on the East Coast, of course, there's not very many patches without people in them. So that's why it's really important to consider that density map.

(Slide.)

DR. HEIMBACH: Another reason that people favored the B2C was that it represents a step-wise change which could be revised to the population-based model rather easily, simply by thinking about ways that you could eventually or in a short order replace that 250-mile circle with a larger circle in less densely populated areas.
For example, if you look at that map that I showed you, you can say that there's a line going right down the country, which is the Mississippi River, and that rather neatly divides it between a very densely populated area and a less densely populated area. You know, that would be a method that you could make the step-wise change to reflect the population-based model that the committee actually was excited about to begin with.

So those would be the main reasons. I will -- I think it's very important to represent to you today that we were not -- I do not come to you with a unanimous decision from our committee to support B2C. We had a lot of voices on our committee in support of the AC model because it has a lot of great benefits that you already saw, specifically that it did the best for the variance and it did the best for the wait list mortality. So there were a lot of strong proponents for the AC model, as well as strong proponents for the B2C. And we were fairly evenly split, frankly, between these two. But at the end, the majority of us were in support of B2C for the reasons that I've highlighted
for you.

In terms of how we came to the threshold of 29, we actually, as I mentioned to you, asked for this feedback in public comments. Because we knew that this could potentially improve the system more than we saw with the modeling at 32. That if we had originally had thought to ask for 29, you know, that might have been favored. And when we actually put it out there, even without modeling, we got quite a lot of people responding that they were in favor of that at 40 percent. In fact, that would be the one data point that had probably the most support of anything in the entire public comment.

So that seemed almost relatively easy to come to this decision. Although, as we mentioned, we had requested modeling and HRSA understood that we just weren't going to be able to have that modeling. I think even without that modeling, we would expect the impact to be what we want it to be and that's how we came to 29. Because it represents an inflection point, so there is a biologic basis behind that. And it exposes a greater proportion of the list, especially
given that that median MELD at transplant in the U.S. is around 29. That's a moving target but that would be at the time what we looked at.

(Slide.)

DR. HEIMBACH: So the specifics to the policy. This is basically a broader distribution policy that, as I've highlighted earlier, it's a big circle for the status one candidates, the most urgent candidates, and then it's for the MELD/PELD candidates down to 29, a 250-mile circle. And then 15 to 28, a 150-mile circle. And then it just walks back up before it finally goes nationally.

Another, I think, very exciting part of this is it does prioritize pediatric candidates in a way that they were previously not prioritized. So we were able to address an urgent need for our pediatric patients within this same policy, so that pediatric donor livers will be allocated to pediatric recipients before they will be allocated to adults.

What we do today is we allocate to children in the region and then adults in the region and then to children, you know, in a bigger area. This will skip
the adults in the smaller area, do the children in the larger area and then come back to the adults in the smaller area.

We also were able to preserve one of, I think, the more popular components of our policy from December of 2017, which is this idea for these more challenging-to-place donor livers, those donor livers that come from DCD donors and from donors that are greater than age 70, to actually allocate those to what we would consider the more local area. Under the old policy, it would have been the DSA. Of course, we don't have a DSA anymore but we are using the 150-mile circle as sort of the best surrogate that we have for the DSA. Recall, of course, this is a 150-mile circle around the donor hospital. All of these circles are around the donor hospital. First, they will go to the status one candidate and then it will go to the 150-mile circle around that donor hospital.

This policy also has a component that we had to change for the NLRB, the National Liver Review Board. So this is a policy actually that passed this board in June of 2017. And a part of that policy was
how were we going to do the scoring system and the
system that we passed in June had this concept of
median meld at transplant for the area of distribution,
which at the time was the DSA.

So in order to fix the score for these
candidates in the National Liver Review Board, we had
to figure out how to do the score and we had a novel
scoring system that was fixed to this median MELD at
transplant, so it accounted for the fact that around
the country, there are differences in the scores that
are needed to access transplant. So that system had to
change because we don't have the DSA, we weren't
allowed to use the DAS to calculate the median MELD at
transplant.

So what we came up with as the surrogate for
that is now a circle around the transplant hospital,
because we are really interested in what is the
experience of the transplant patient when we're talking
about accessing transplants. So we put a circle around
the transplant hospital that was 250 miles. So
basically every transplant that is happening within
that 250-mile circle would be used to calculate this.
We subtracted certain things like living donor transplants because those are typically done at lower MELDs. But for the most part, sort of the usual allocation sequences were used to calculate this. And that basically is what we are proposing for the NLRB component.

(Slide.)

DR. HEIMBACH: A couple of more specifics that we have to address, intestine. We are the Liver/Intestine Committee, even though we never talk about that. We had to come up with an intestine allocation system. We suggested to use a 500-nautical-mile circle around the donor hospital, because intestine is a really small number of candidates and small number of intestines and this seemed to be the best way to do that.

We also had to handle SLK. That's the Simultaneous Liver Kidney Policy. Previously, when a candidate was allocated both a liver and a kidney at a score of 35 and higher, the policy required the kidney to be shared with the liver, even if it wasn't from the same DSA where the candidate was listed. Of course,
now the DSA is gone and so we have to come up with a new plan for that. And what we are recommending is that when a patient is listed and being allocated a liver and they are listed for a liver/kidney, the kidney would follow that liver when the candidate has a score of 29 or higher and the donor is within a 250-mile circle. And then on the other side of that, if their score is less than 29, it would be a 150-mile circle.

Additional components of the policy, we are ending the Region 9 variance. Region 9 has always had a single -- essentially, their four DSAs were combined to be one. Since DSA and region is not part of the new policy, that variance is not relevant anymore so that would be going away.

We are continuing a national split liver variance that is currently in existence. We are not recommending to change that. It doesn't really have any effect on this policy.

Hawaii has a current variance and we are recommending that we keep that variance. And we are also recommending that we extend the same Hawaii variance to Puerto Rico. And that is that if a blood
group O liver is recovered in Hawaii, that it would be allowed to be allocated to blood group A and B recipients before it would be shared more broadly. And that just has to do with the unique geographic components of the isolation of Hawaii and actually Puerto Rico from the mainland of the United States. We also had to handle the fact that, in Alaska, this is actually quite farther than a 500-mile circle from any other spot, and there is no transplant hospital in the current time that is doing liver transplant in Alaska. So we had to have a different system because there are livers recovered in Alaska but then they wouldn't be allocated except nationally, and that doesn't really make any sense because then it would have to go to Florida the same as it would have to go to Washington. So what we did basically, as if the liver originated from the airport, Sea-Tac, and then we put the circle around that. So important to highlight how was this proposal changed in response to public comment? So as you already heard earlier, what we put out was B2C at
32. But after we got the public comment, we are recommending to the board today that this threshold be lowered to 29. And SLK would also go down to 29 to match this.

We had initially thought when we put out our public comment that we would not extend the Hawaii variance to Puerto Rico but, based on the feedback we got in public comment, it seemed that the majority of the comments would be in support of doing this. And feedback we got especially from the Minority Affairs Committee and the Patient Affairs Committee was in support of this as well and that really swayed our committee to feel that this needed to be extended to Puerto Rico.

We did not have the solution that I outlined to you for Alaska until after public comment. We just didn't have time to handle that one, so we figured that out later.

We also came to the realization that, after we implement the NLRB, we would like to have at least a three-month gap between the NLRB and then the broader distribution implementation because of the interaction
between the median MELD at transplant in the NLRB but also just because of the fact that these are both major changes and there's a lot of programming and other things that need to be carefully analyzed to make sure there's no bugs or problems. And to put these two too close together, we felt, would be asking for significant trouble.

So we -- I did want to take a moment to reflect on the proposed amendments because, actually, I think it's important for you to hear from the committee, specifically when we had already talked about some of these amendments, what the feedback was. So in a structured way, I am just going to walk through these. I am, of course, going to be sitting here if you have questions. I can still provide additional feedback. But I just want to preemptively provide to you feedback from the committee about the amendments.

So first of all, B2C versus AC model. We will hear an amendment today that the board instead consider the Acuity Circle model instead of B2C. I tried to highlight for you already why the Liver Committee would be in more support of the B2C. And that's primarily
because it's a stepwise change that balances the broader sharing with logistical considerations and it is a policy that is amenable to modification to the population-based circle model.

(Slide.)

DR. HEIMBACH: Again, just to highlight that map and how that changes, here is a 500-mile circle in the Northeast. And you can see all of these dots are transplant hospitals and all of these colors are regions. And this circle is currently, you know, putting almost five regions together in one allocation sequence. So that is going to be a big lift for those OPOs and for those centers to manage. So that would be our reason.

But again, the committee was very split on these two. I think there are many, many strengths to the AC model and it was a difficult decision for our committee to come to a recommendation.

Other amendments, the idea of a 500-nautical-mile circle for MELD 35 and higher. I think this is a really important consideration. And we actually talked about it for about the last 10 minutes of our committee
meeting in Chicago. And unfortunately, this is not an idea that was discussed in public comment. So I think we all felt that it would be a hard thing to add on at the last minute because nobody had ever heard of it. And it is very likely to present the same logistical challenges as the Acuity model, only amplified. So that 500-mile circle will encompass more patients more times. Rather than the narrow bands of the AC model, this would be sharing over 500 miles a lot.

And when we think about -- we look at the published data from Edwards, et al., that was sent to you by Rio, who provided a letter with references for why this idea would be a good one, and if you read that paper, the primary impact of our policy, which was Share 35 -- now Share 35 is a policy that we currently have where, for the whole region, we're sharing for candidates who are most ill with a 35 and higher -- the primary impact of that policy when we look at it is that the transplant rate was increased for those 35 and higher and they had less deaths in 35 and higher. But overall, we did not have less deaths, which would be expected because we don't get to do more transplants.
We are doing the same number of transplants, we are just trying to prioritize them to the more sick candidates because that is what the system directs us to do.

And so the patients who are just under that, in the 29 to 34 cohort, actually experienced a higher wait list mortality. Now, certainly, they're not as at risk as the 35 and higher. But overall, there was not a change in mortality in the publication from Edwards, et al.

So what we were hoping for, potentially, although we don't know because this allocation that is recommended here to go to 35 and higher, the 500-mile circle, has not been modeled. We're hoping that exposing the list down to 29 so that the patient can be transplanted when they're 29 and higher before they get to this time of 35 and higher, potentially could mitigate this. So we're sharing broadly over an even broader area that would be an answer potentially to address this consideration of changing to add that 500-mile circle for 35 and higher.

It is also important to know that MELD as a
model becomes less predictive in patients with a MELD greater than 35. So the C static becomes less predictive when the patient is over 35 and that's probably because there are less candidates over 35 because, as soon as they get to 35, they can be transplanted or they actually don't survive. So there's not a lot of time for them to be at that score. So that's potentially why MELD is less predictive. But it is not as predictive as it is in the lower 29 to 35. So it's not as good at picking who should be transplanted as it is in the lower meld scores.

What about the threshold of 29? That is also an amendment in various different places. How did we get to 29? There's I think several amendments requesting it to be a different number. This 29 was supported in public comment. It is medically justified. It allows more patients to be exposed compared to 32 or 35. And it's important to recognize, I think Amendment 5 does change that threshold from 29 back to 32, or at least that's how I read that amendment.

So there is another amendment which is to
raise the bottom sharing threshold to 20, rather than the current, which is 15. Why is it 15? Well, it's 15 today because the work that was done a long time ago was able to demonstrate that a score of 15, a patient who had a 15 and higher had a better chance of surviving if they underwent transplant. Whereas, a patient who was under 15, because there is a slight risk of dying from the transplant itself or from complications immediately after the transplant, that patient was so stable on the wait list that they might actually be better off just continuing to wait than to undergo the risk of transplant.

And so that, very recently, actually, in November of 20018, there was a publication to show that, because of the new system of MELD which is called MELD Na, so MELD sodium, we actually changed the MELD system to incorporate an additional variable that, according to the -- you know, an easy way to think about the conclusion is 20 is the new 15, according to this paper. So a patient with a score of 20 actually behaves more like a 15 did in the past. So their risk of dying at a 20 is actually, you know, closer to what
it used to be at a 15. Maybe we're better at taking
care of these patients, maybe MELD does something
different.

The bottom line is that this publication
actually just came out. We actually discussed this in
our leadership because I was aware of this publication
before it was published. We talked about it in August.
But it wasn't something that was part of the public
comment so we couldn't just tack it on there. And so
we thought, well, this might be an important concept to
consider for a future revision but it actually only
just came out. It has not been discussed in public
comment, it has not been modeled as part of the current
proposal. And so, certainly, you could consider adding
it.

But it's important to recognize something to
consider, that given that the median MELD at transplant
is 29 nationally, patients who are transplanted in the
15 to 19 range, it's about 12.6 percent of the
transplants done, they're likely identified as an in-
need patient and they're being done with what I would
call grafts of opportunity, rather than as a primary
offer. So for whatever reason, this patient is thought to be more sick. When the liver can't be or shouldn't be or is not suitable for a candidate with a higher score, they are being transplanted into these candidates. Maybe it's just a late reallocation, for whatever reason that these transplants are being done. So if we make this change, it's uncertain what the impact would be. It might be helpful, it might not change disparity and outcomes as significantly as we would like.

(Slide.)

DR. HEIMBACH: MELD exceptions. So this is really important. I'm adding a slide here for those of you who are -- especially for the patient members of the board to understand what is a MELD exception. Because it's important to understand what a MELD exception is in order to consider the next series of proposed amendments.

So a MELD exception does not mean that a patient is getting a sneaky access to transplant. A MELD exception is a way that we handle specific conditions of patients. So the first thing is that
patients in the United States today with chronic liver
disease are getting a transplant -- most of them are
transplanted on something called the MELD score which
is a score that is calculated from four different lab
tests. And that score is predictive of death for a
patient, death from liver failure over the next three
months unless they are able to access transplant.

And the MELD score is pretty good. It has
what we call a C-statistic, meaning, you know, a pretty
good model. If it was 0.5, then it would be as good as
flipping a coin, but it's actually over 0.8, it's at
about 0.84, 0.86, depending on, you know, what data set
you look at.

However, there is a group of patients that
have chronic liver disease and they have a specific
complication of their specific complication of their
chronic liver disease that also increases their risk of
death, such as hepatocellular carcinoma or another
problem called hepato-pulmonary syndrome. Those are
the first two most common reasons for MELD exceptions.
And their -- this patient's risk of death is due to
this very specific complication.
This is a standard, well-accepted complication of cirrhosis that our community has agreed that the patient needs to have access to transplant. But their risk of death is not reflected by their risk of liver failure, which is what the MELD score captures. Therefore, they have to have a different system. They need to have a specific, assigned score that reflects that risk. And where we have not done as well is what is that specific assigned score to reflect that risk? We have not done as well with this. Our goal has always been not to over-prioritize or under-prioritize these exception patients compared to the non-exception patients. We wanted to always come up with a score that provides a similar transplant rate for these two groups.

And so the proposed amendment is that we would cap exceptions below the threshold of broader sharing, so that the patients with exceptions could only access transplant within the 150-mile circle rather than in the 250-mile circle. But the problem with this, which originally seemed like a good idea when we were using a higher threshold for sharing, but when we're sharing at
29, there's -- this is only going to target the areas of the country where they have a very high median MELD at transplant.

So under the current modeling, what we looked at right now today, patients in Denver and in Los Angeles and in San Francisco would be impaired by this proposed amendment in a way that the rest of the country would not. And so there, with the new NLRB, patients are going to have a fixed score and all of the standard exceptions are supposed to be at median MELD at transplant minus three except for oxalosis and hepatic artery thrombosis. So patients with HAT, if they were going to be median MELD at transplant minus three, so say they're -- in one area, that would be a 35 minus three, should be 32. But if we're going to cap them below 29, then they're going to be at minus -- whatever that is -- six and they won't be able to move from that score because it's a fixed score.

So that works really well in all of the other parts of the country where the median MELD at transplant minus three is under the cap. But when it's over the cap, it will just -- very specifically, this
amendment would target these particular patients in a way that the committee -- we talked about this. This was a very hard discussion that we had. We had a lot of blood, sweat and tears over this because there are a lot of different opinions on this. And the committee specifically would oppose this amendment because of the selective impact on patients who are already in a high-disparity area. They would be then subjected to this fixed numeric score that allows reduced priority compared to everyone else. That's directly in opposite of the goals of this proposal.

And so remember that HCC and other exception patients are now going to be having a fixed score and it will not increase. And what we looked at before, back before June of 2017 when we were originally designing the NLRB scoring system, the modeling predicted, in fact, that the transplant rate for the exception patients will go down under NLRB. And we were not ever able to meld the two modeling systems together. We were never able to model NLRB with the new proposed distribution changes, so we're not entirely certain what's going to happen.
But specifically looking under the current distribution system, the NLRB would predict that we're going to reduce the transplant rate for exception patients.

(Slide.)

DR. HEIMBACH: Importantly, you can see in the past, we were very wrong. The patients with exception scores were at a way higher transplant rate than the regular MELD patients. But with our policy changes and most specifically -- it was pretty flat here for a long time -- but when we did cap and delay in 2015, that basically put it right where we want. So this is from the most recent SRTR report, we can see that the transplant rate now for HCC and non-HCC patients is actually just about the same. So it really doesn't seem to be useful to further disadvantage HCC patients specifically in the high-meld areas by this particular amendment.

So in terms of the 150 as a tiebreaker, this is an idea that is a compelling idea. It's just not an idea that was ever discussed in public comment or by the committee. It would likely have not a significant
potential impact but it is a compelling idea. We really have no specific comment about this.

The B2C proximity points, we do have -- we did talk about this quite a lot. We discussed proximity points and decided not to use them. So therefore, proximity points were not modeled and they are not part of the public comment that we sent out. We never asked for feedback on proximity points. Adding additional points to what we would say is a local would reduce the impact of B2C on disparity, so it would move it further in the direction that we don't want. It would also add significant complexity to programming. This was something we noted a lot in the December of 2017 model, there were really a lot of challenges with the programming with the proximity points. And also, of course, when we tried to explain this and write it down and make a table that was clear for patients to follow, it was really a challenge with the proximity points.

Of course, if we go with AC model, that is already built into the system and was one of the strengths of the AC model, is that these sharing bands, it's a four-point spread which actually we came up with
because of the concept previously of these proximity
points.

So the idea of a threshold transition. What
this is, is this idea that we would just kind of go
slow and we would adopt this in sort of like really
slow steps forward. We would start at one threshold
for some six months and then we would go to the next
for six months and then we go to the next.

Again, this is an idea that was not part of
the public comments. It was not ever discussed in our
committee and so we really have not had a lot of time
to consider this.

By design, this would slow the implementation.
This would, I think, delay improvement in access to
lifesaving treatment. And the transition would happen
very slowly and so it would be harder to detect issues
until three or four years into the transition. And
maybe that's the goal of this, probably it is, so that
maybe we would get a signal. But in some ways, it's
hard to notice that the water is dripping on your head
and over time you don't really notice that you're
completely wet. So I think sometimes it's easier if
you see the impact right away and you can make a change because it will be a statistically significant impact; whereas, if it's happening very slowly, sometimes it's harder to recognize.

It is also unknown if the slow transition will be a benefit or not a benefit. It's also uncertain -- in my mind this is not an opinion of the committee but just myself, as I was thinking about whether this would impact the current litigation process, would this be perceived as a stall tactic? And I can't obviously answer that.

So we are also being asked to consider an amendment which would be the Region 8 split liver variance and have this be going to the whole country. This is a variance that was already discussed by the committee. We're in support of this. It has not been out for public comment. We're in support of sending it to public comment to get broader feedback.

What this is is something that Region 8 wants to do as what we would say is a demonstration project. This has historically been done. For example, MELD Na was done in one region to see if it actually worked.
So they want to do this specific way of doing split livers which has potential of increasing the number of transplants that are being done. You know, there are positives and there are negatives to it and we're excited for this to go out for public comment to get more feedback. And that's actually happening because the next public comment happens in February.

This proposal is unrelated to the current policy. And so it doesn't, in the mind of our group, make a lot of sense to talk about it now.

I think just to highlight the fact that the process is typically a committee would develop a policy. The committee would send the policy out for public comment, of course with the input of the POC. And then after the public comment, we would refine or revise. You know, if it was good, it would go right to the board. If it needed more work, it would be given more work and then it would go back to public comment. Or it would just be so terrible that it would never go anywhere again. But that's the process. We eventually would bring the proposal to the board.

And so we have been trying to do that.
Starting in mid-June and through November, we've -- our full committee has met almost every single week to bring you the policy that we're bringing you today. And so I think if we want to try to make new policies at the level of the board, we will have to have a lot more board meetings to get all of those details right. We do have a system, we have a process, and I think that it's important that we think about that process. And if we need to make amendments, we should make amendments. But if we -- this is an amendment that probably is best considered in February rather than today.

(Slide.)

DR. HEIMBACH: So this is just the usual details. I think I have spoken to all of the amendments and represented the views of the committee on those amendments. Just to talk to you about the details that are important, the NLRB, how would the members implement these proposals? The NLRB liver programs just need to understand that the median MELD at transplant would be calculated instead of in the DSA as it was previously, it would be a 250-mile circle
around the recipient hospital.

It's a little confusing because this is the recipient hospital, whereas all of the other circles are around the donor hospital. But it's not that confusing. It's just important to recognize that slight difference.

For the purposes of the change in that policy for distribution and allocation, that both the transplant hospitals and the OPOs would need to change, prepare for this change. There's going to be a difference in offer patterns. Depending on which model we choose it may or may not be slightly larger. We would have to build relationships with programs and OPOs that we previously hadn't been working with a lot. We would have to prepare for expected changes in the frequency, the mode of travel for organ recovery, potential staffing changes, modify organ recovery arrangements, meaning that we would consider recovering more for each other than we have in the past.

And then in terms of the timeline, we're still thinking for the NLRB the first quarter of '19 and the other policy to follow that, which at least
three months and maybe more months, it's hard to say.  
But we're ready to roll with the education, already 
we've got the modules good to go.  
Where in the strategic plan does this fit?  
Already Sue told us that it was improving equity and 
access to transplant. We're hoping that this proposal 
will improve geographic disparity and access to 
transplant. And also it touches the goal of efficient 
management of the OPTN in that we would hopefully 
alleviate the legal risk to the OPTN regarding the use 
of DSA and regions in the policy, which is very 
important. This is a time-sensitive issue. This has 
come to us specifically on a time line and we were 
asked to deliver by December of -- of now. So that is 
the situation that we are in.  
(Slide.)  
DR. HEIMBACH: And there's the fiscal impact 
slide that I think is always a part of everything. We 
made it really small so you couldn't see.  
(Laughter.)  
DR. HEIMBACH: But it's really the big one 
here, whatever that's called, the enterprise situation.
And so now I am going to hand over to the board policy group to give their recommendation.

MS. DUNN: All right. Thank you, Julie, for that very thorough presentation.

Yolanda, you coordinated the group policy board.

DR. BECKER: I would like to thank Julie and the members of the Liver and Intestine Committee for the tremendous amount of work that was done on this policy. And also to the SRTR for the modeling that was completed.

Our board policy group had this -- only this policy to assess and we had a very robust discussion. Julie presented much of the work that was done, with the exception of the amendments.

And in terms of recommendations to the board, so in board policy groups, as many of you all know from having participated, one of the recommendations is whether or not to put it on discussion or consent. Clearly, this was going to be on our discussion agenda. The second is to make a recommendation to the board in terms of how to vote on the policy.
After our very robust discussion, our board policy group actually remained undecided in terms of how to recommend to the board how to vote. Because we felt that an undecided vote would reflect our desire to allow for a full board discussion without any perception of bias.

So our board policy group recommendation is actually undecided. And we hope for a robust discussion, as has been requested by all members.

MS. DUNN: All right, thank you, Yolanda.

I would open the floor now for questions, high-level questions for Julie, reminding that these are really high level, not down into the amendments because we have a discussion process for the amendments. So any top-level questions for Julie on the deliberations of the Liver Committee or on what she presented on outside of the amendments?

Simon.

DR. HORSLEN: So one thing I need, want to understand, you said for the B2C one of the advantages is you could later build in a population density model. Help me understand why you can't do that with the
Acuity model as it exists?

DR. HEIMBACH: So it would -- the Acuity model, as you know, is in three layers. And so the layering of that system is already -- we envisioned it that it would be a population-based model that would only share when it needed to share. You know, how would we do that in, you know, those three layers? You certainly could change that. It's just not as intuitive how that would be changed but it absolutely could be changed.

All of this -- we should never think that this is going to be the end. When we did MELD in 2002, MELD was very hard fought. There was a lot of angst about that. I had a lot of heart-to-heart discussions with Russ Wiesner who was the chair of the committee during that time and happened to luckily be at my center, has always been a good mentor to me. And he said there was tons of, you know, angst about that as well.

And we were able to, I think, modify that continuously so that it has continued to perform very well for us. Not perfect but it's pretty good.

So I think this new policy would be the same.
We would be able to make a change. B2C might be a little bit more facile because it's a simpler system but, certainly, there are changes that could be made to either system.

MS. DUNN: Okay, thank you Simon. Susan Orloff.

DR. ORLOFF: Thank you -- has to stay on.

Julie, thank you for an amazing amount of work and presentation, as well as the board member and SRTR. I had a couple questions on the data that was presented. There was one slide that you were looking at, the regional public comment and voting. And our Region 6 said that AC was unanimous. And I actually have a copy of the public comment and voting and there were 23 members that voted and 22 of them were for B2C, 17 strongly for it, five for it and one opposed. And then when we looked at the MELD threshold, it was 35 was 18 folks and then 32 was three and then 29.

So my concern is that the data that was presented, I mean, it just was in error. And so I don't want to misrepresent our region as well as just perhaps are there other errors in the data? That's one
question I have.

I know the data -- crunching all this data must have been incredibly difficult.

The second thing is, on the data with wait list mortality, and this was mentioned on our call, I mentioned this with our call and some other people, I think, have. Is that the wait list mortality lists the wait list mortality just deaths on the wait list and it does not include those removed from the wait list because of being too sick. And in some areas, that can be up to 50 percent of the patients dying by being removed from the risk.

And so I think if you're going to calculate a metric like that, we should probably include that as previously have been included in the SRTR data and it's not included in this data.

And the third thing is, when you show the current policy and the data from the current policy, it's my understanding that that is modeling based on 2013 and we are now in 2018. And so I'm concerned that, you know, now that we've had a lot more Share 35 and other, you know, changes in our way of approaching
behavior and transplantation, that the current data
could be very different from the 2013 modeling. And so
those are just a few things that I -- just in terms of
the data that was presented, that I wanted to make a
comment and see what thoughts were.

DR. HEIMBACH: Yeah, Susan, thanks so much for
your comments.

I am going to defer your last point to the
SRTR to speak specifically about the model because I
know they are here for us today. So I will let them do
that.

The second point was one that was really
contentiously discussed in our group and that was about
this idea of whether -- how we counted the wait list
mortality and if removal from the wait list was counted
as a death. Of course, in our current -- when we're
monitored for outcomes, that's how we do it.

But in all of the modeling that's ever been
done by the SRTR, they've done it the exact same way,
which is the way they did it this time. So this was
not a nefarious change in how they did it, it was just
a lack of understanding of the liver community, that
that's how they've always been doing it. We actually just didn't realize that that's how they have always been doing it.

So it's not different this time as it was in any of the other models that we've received. And in the data that you can see, you can see the current wait list mortality is calculated that way. So the way we viewed this data from the committee's standpoint was that we could compare to how it is currently and then what would be projected to be the delta, so what would be changed under the model. So the current would be with the wait list removals not counted as death but counted as a wait list removal, and then how would the new policy change that. So at least we could have that. Granted, it's not counting them in the say way we're counted.

And with regard to the comment about Region 6, I certainly made these slides myself and I'm sorry if I misrepresented Region 6. That was not my intent.

DR. ORLOFF: Okay, well, thanks.

DR. HEIMBACH: I do know that your opinion -- what your group felt like. So sorry about that.
DR. ORLOFF: It's all right. I also think that our programs in terms of outcomes do have to look at removal from the wait list, so that -- in terms of variability and the -- for too sick to transplant, I mean, South Carolina has a much higher wait list mortality than does New York.

DR. HEIMBACH: Yes. But again, it's reflected in the comparison to the current model as opposed to the delta.

But I would like the SRTR to comment on your third question if they could.

MR. SNYDER: Yes, Jon Snyder from the SRTR. Thanks for the opportunity to clarify.

The last question about the timing, the cohort we used for the modeling was 2013 to 2016 with up to three years of follow-up total. So it wasn't just the 2013 cohort.

The question about the -- Julie addressed this fairly well. But the question about the wait list mortality versus removal for too sick, as well, Dr. Orloff is correct that our -- a lot of our analyses that we do for public consumption, we include removals
for being too sick for transplant within the mortality calculation. It's obviously a negative outcome.

We have never done that in the simulations that we publish because of the way that the cohorts are constructed. I won't go into too much detail but historically, we have presented two different types of pretransplant mortality metrics, one being deaths while on the wait list, which is what the committee got in their preliminary report. We labeled that wait list deaths. And that is simply deaths in the simulated cohort that happened while the patient was on the list so it does not include a removal for too sick.

The second type of analysis that we've supplied for many simulation requests in the past was something we call pretransplant deaths, which included deaths following removal. So again, we weren't looking specifically at removals for too sick, we were actually following those patients beyond removal using other death sources for deaths that may have happened after they were removed.

In early discussions with the Liver Committee, we had asked the committee to -- we had given them a
list of various -- I'll use the word numerous metrics that we could provide the committee. And given the short time line, we had asked the committee if there were metrics we could perhaps pare down the list, just so that we could get the reports back to the committee on a faster turnaround. So the committee actually chose between the two wait lists, requested the wait list mortality metric, which is not the pretransplant mortality metric.

So we recognized later, after the misunderstanding, that this was probably not well understood by the committee, so we turned around a report to the committee as quickly as we could that included the pretransplant mortality as well. But none of the simulation results we've provided historically included the wait list removals for too sick in that outcome. If that helps.

DR. ORLOFF: Thanks, John. Can I just ask you one more question regarding some of the statistical gymnastics that I'm not good at?

That is, if you funnel livers from one state to another, how does that not -- in a big volume, how
does that not impact the wait list mortality in the state that's losing livers, say Tennessee to New York? I mean, how does that -- how could you lose, say, 40 livers but not have any increase in your deaths? I just don't understand that.

MR. SNYDER: Well, it depends what you're looking -- if you're looking at counts versus wait list mortality rates, right? So the -- when you're shifting them, you're getting those livers out to the people who are sicker, so you are stopping deaths there. But the people that were then jumped if they were, indeed, less sick, had a lower death rate than the ones that they were going to. And so in essence, that's how it works. I don't if that's a clear explanation --

DR. ORLOFF: I know you don't want to get into the weeds but I think there is some variation of wait list mortality despite MELD scores. I'll let somebody else talk. Thank you.

DR. HEIMBACH: Susan, I just want to clarify. In the public comment document that we reviewed as a committee, on page 25, it clearly says that Region 6 is exactly as you reflected it. And when I made the
slide, I just mistyped it. Sorry, the threshold is 35, you guys asked for 35, and I just wrote AC instead of B2C. So I'm really sorry for that mistake.

DR. ORLOFF: Thanks. Appreciate you looking it up.

MS. DUNN: Thank you, Sue. Tim.

DR. SCHMITT: I just had a quick question. Have we ever made a prioritized list of what's the most important component of the final rule? It seems like we've spent an inordinate amount of time on one aspect of the final rule without looking at all the other ones.

Has your committee, Julie, in your mind, made improvements on all aspects of the final rule with your recommendation, or just do we move one up to push one down and what is the priority?

DR. HEIMBACH: I'm not sure if I'm the best person in this room to answer this question. I'm looking in the corner over there.

But I will say that we did get a specific directive in 2012 to work on the specific component that we have been working on since 2012, which is that
difficulty in accessing transplant and around the
country how it's different depending on the geographic
disparity. So obviously there are important things.

We certainly did not want to change it so
that, you know, we would specifically impact a
different component like, you know, making the --
making the system so inefficient that it would just
shut down. So we have been trying to respect all of
the components and also address the specific one we
were asked to address.

MS. DUNN: And that was the point in the
letter from the Secretary. But James, I think you
could add a little more clarity to that?

MR. ALCORN: Yeah, could we go back to the
slide that has the final rule on it, specifically
Section 121.8?

(Slide.)

MR. ALCORN: And so I would like to explain
what the structure of this section looks like. Now,
this is only one subsection of the OPTN final rule.
But it's the section of the OPTN final rule that deals
with the development of allocation policies. And
that's really what we're sitting here talking about

today. We're not talking about the development of
membership requirements, we're not talking about the
board governance requirements, we're not talking about
the registration fee. The reason I say that is those
are all other things that are in the final rule. Those
are in other places like 121.4.

And today, we are talking about an allocation
policy and 121.8 is the most on point section of the
OPTN final rule for this.

So in looking at the final rule and
specifically this section, there is a hierarchy in this
section. So such allocation policies, subparagraph A,
let's jump down to subparagraph A because you'll see
that this is phrased differently. "Shall not be based
on the candidate's place of residence or place of
listing, except to the extent required by paragraphs A,
Sections 1 through 5 of this section."

So the way that I would read this section is
what this says is this sets the default of the rule.
This sets what the status quo is, right? And this is
consistent with other parts of the final rule, which
is, "Organs shall be distributed as broadly as possible."

And then the burden is really upon the board and the OPTN to defend any choice that is not distributing organs as broadly as possible. Now, the writers of the final rule, you know, and everybody else in the transplant community recognizes that it does not necessarily make sense to have every organ offer be nationally. And so that's what Sections 1 through 5 of this are talking about.

So the first section that you look at under here says they shall be based on sound medical judgment. The way that I've described this to many folks says that this is not a popularity contest. This has to be based on evidence. And the OPTN has long worked over many decades to make sure that our policies are based in evidence.

The second one being they shall seek to achieve the best use of donated organs. And so as it relates to this allocation policy, as yourself are these frameworks going to be increasing or decreasing the amount of transplants? And roughly, the answer is,
no, as Julie mentioned, that wasn't the goal of this specific allocation policy. And so there isn't -- you won't see a large impact there.

Same thing on number 5, they shall be designed to avoid organ wastage. So maybe you want to, you know, decrease the geographic distribution of organs in order to, you know, not have organ wastage. You also have another way to look at that. But you can look at the number of organs that are being transplanted but again you don't see much of a change there.

Also in number 5 you see avoiding futile transplants. You can look at post-transplant outcomes and again you don't see any negative impact there from any of these models.

And then we really come down to the two parts of number 5 that are really in conflict as it relates to this particular proposal, promoting patient access to transplantation. As Julie has said, you know, the committee has looked at many metrics but primarily the variance in median MELD at transplant to measure the access to transplantation. And then, two, promoting the efficient management of organ placement. Not
necessarily the entire organ transplantation system or health care but organ placement. And there the committee, you know, again looked at many different metrics but primarily focused on the number of organs that are going to be flying.

So again, to kind of answer the direct question, is there a hierarchy in here? Yes, there is. Paragraph 8 sets out a hierarchy that says, the default is that organs shall be transplanted as broadly as possible, broadly as feasible is another phrase you'll see elsewhere in the final rule. And then it's the board's burden to come up with the evidence, because again these have to be based on sound medical judgment, to justify any restriction that would not have organs be distributed as broadly as possible.

I don't know if HRSA or your legal counsel would like to add anything in addition to that. But that is the basis of how we've explained this to the Liver Committee and for those who were on board preview calls, how we've also explained this portion of the final rule.

MS. DUNN: Any comment from HRSA at that
point?

MR. McLAUGHLIN: We agree with James.

MS. DUNN: I think Emily is coming up here, too, Chris.

MS. LEVINE: Yeah, I think James did a great job of explaining the overview. And I think from our perspective, you see the way it's worded. And I think it is significant that the way that the geography is drafted is different, that's it's rather than a shall to shall not. And that's why in the HRSA's introductory remarks we explained the importance of justifying, to the extent that you're imposing a geographic limitation, that it needs to be tied to one of these other factors. And not only that it has to be tied to them but the language is that it has to be to the extent necessary to achieve one of these other regulatory requirements.

But I don't think there's anything else to add. Thank you.

MS. DUNN: All right, thank you.

I think next up is Rob Kochik.

DR. KOCHIK: Hi, Julie. I hope that sometime
soon you get to sleep without seeing circles and population bases in your dreams. So may you live that long, right?

You've obviously been intimately involved in this since the beginning and you just did a great job of sharing the committee. But I would also, I guess, like to hear -- you know, you're a transplant surgeon and intimately involved in all of this. And I think at least in a public comment somewhere it was that you really thought Acuity was the way to go. So I wondered if you would be able to share anything about that. And then I have another comment after that.

DR. HEIMBACH: Yeah. You know, when I'm asked my individual opinion, which model does the best at what we're trying to do, you know, I think that's, you know, one way to look at it. I think my job today is to represent the view of the committee. And what I'm bringing to you is B2C, because that is what our committee supported with a majority vote.

You know, what I like about the Acuity model is that it is closer to the population-based model, which is what I really think we need to have. I think
-- I'm excited that both models move us in the right
direction. And I think the strengths of the models,
I've already highlighted.

You know, obviously, I think AC is a bigger
change. You can see it's a bigger change. Is it too
big of a change? You know, on the East Coast,
potentially. That's the feedback we got in public
comment.

Where I am, we already fly 70 percent of the
time. It's just what we do. It's not a big problem
for us. But I'm in a sparsely populated area. So, as
a transplant surgeon, you know, for us flying is the
normal thing. But, you know, we don't -- I don't
allocate with 30 other centers for one liver. And I do
think there's logistical challenges that cannot be
overlooked with that.

So I do think this is a complex question. And
I think that whichever model we move forward with,
we've got to be very careful that we're ready to make
changes that need to be made as quickly as we can make
them and we've got to monitor everything closely.

DR. KOCHIK: And just one more comment. As
one of the OPOs in New York, you know, we've had the
statewide sharing for about 20 years which is, you
know, some broad. I was just doing some calculations
looking at our last eight years, and the least number
of times that livers went out of our DSA was 70
percent. And there's been times when 86 percent of the
livers went out of the donation service area. So, you
know, we certainly support the broader sharing.

MS. DUNN: Thank you, Rob.

Joseph Hillenburg, please.

MR. HILLENBURG: So it's my hope as a patient
rep that this is the -- that Maryl does not have to
deal with this -- is the first OPTN president in three
years that doesn't have to deal with this, because
we've voted on it now three Decembers in a row.

But my immediate question is, in terms of
patient representation in the policy development
process, both within the Liver Committee and when it
was reviewed by the Patient Affairs Committee, can you
-- could you highlight that a little bit, please?

DR. HEIMBACH: Yeah, I think we are so lucky
on our Liver Committee that one of our committee
members is a patient but he's also a transplant center hepatologist. So we've always had a patient on our committee.

Many times, and I've been on the committee now for a long time, maybe forever, I'm not sure. But I've been on the committee for a long time. And a lot of times the patient representative is less vocal because, you know, of the strong personalities on the Liver Committee. But this time, you know, Dr. Bachs has been very vocal and he has been a huge influence on the policy development. He's been a strong voice for us.

We have also greatly appreciated the input that we got from the Patient Affairs Committee. They are the reason that the -- and the Minority Affairs Committee, both are the reason that the Puerto Rico variance is happening the way that it is. So I think those voices have been a really helpful part.

And we've also worked with the Pediatric Committee, which has a strong representation from the patients' side of things to incorporate the pediatric component that is part of this policy, which I think is -- I didn't want to highlight it too much because I
don't want someone to try to take it out of their policy. But it's a really good part of the policy and we've been able to do something that should have been done 10 years ago, which is great.

So I think, you know, the feedback from the patients, you can read all of the comments on the public comment website. We had a lot of patient feedback. And the patients, definitely, the comments that we read would be in support of the Acuity model.

It's hard to count the comments because, you know, some of them are -- you can see it's the same comment pasted in there by 35 people. But definitely the patient voices came through strongly and they were for the Acuity model more strongly than the B2C.

MS. DUNN: Thank you. Chris Anderson, please.

DR. ANDERSON: Thank you. I also want to echo the appreciation of the Liver Committee, especially on this tight time frame.

I want to echo what Dr. Orloff said earlier, that, you know, calculations are one thing but it's hard to imagine that if you shift livers, you're not just shifting deaths at least to some degree.
Also, and this may be a question that's difficult to answer but I will at least pose it as a comment. So the Ethics Committee, to my understanding, had some concerns about unintended consequences of these proposals, both of them. Particularly, unintended consequences to rural or vulnerable patient populations, partly because of the quick time frame that the Liver Committee had to work under.

And so, you know, this -- these proposals shift organs to try to make median MELD at transplant as our variable one, which is difficult if not impossible to achieve. But median MELD at transplant is really a surrogate for access to an organ once you are waitlisted. So what we have to be careful of and what I think the Ethics Committee was telling us is that there can be unintended, indirect consequences of these policies to patients who -- in their access to a transplant center; i.e., patients who have liver disease who may or may not have good liver care in their community or their center.

And I would just say that on the HRSA website right now, the number one part of their strategic plan
is increasing access to quality health care and
services in the United States. So we have to be very
careful that trying to follow one HRSA direction does
not hurt the other. So that's a comment and the
question may or may not be answered.

DR. HEIMBACH: Yeah, and I think this is a
comment that was reflected in quite a bit of the public
coment that we got, is the concern for the patient
that's not even able to access the wait list so they're
sort of not counted. And obviously, that is a concern.
It's a big, huge concern in the United States, access
to health care. It's, you know, part of the, you know,
biggest component of the most recent national election
probably related to access to health care. So I think
it's a big deal.

It's -- it's a hard issue for our committee to
get our arms around and figure out how policy
development we can make here can influence that. But
it's certainly an important component. And it applies
around the country, specifically in the Southeast but
also with the Indian reservations around the country.
There's a whole bunch of unmeasured people, no doubt.
MS. DUNN: Stefan Tullius.

DR. TULLIUS: I think there has been a huge amount of work that went into this and a huge amount of discussion, and one would hate to see those reoccurring and resurfacing again in a few years. So at the end, it seems from the request by HRSA and the final rule that a population-based model would come closer to meet the expectation.

The B2C model seems to be a step towards that, not reaching it entirely. So isn't the Acuity Circle model the one that meets the expectation more than the B2C model?

DR. HEIMBACH: No, when we were talking about it, before we got the modeling, we thought that as a committee, or at least the group of the committee that was excited about that population-based model, that this would be a surrogate for that. When we saw how the modeling performed, it didn't seem to perform in the exact same way that we expected. We had a lot of traveling in the very dense areas.

We thought we would have less traveling in those dense areas because there would always be a
candidate within 150 miles so you would never need to use the 500-mile circle in the densely populated area. But that doesn't seem to be what happened with the modeling. So that's the reason we had to look at it more closely.

And, you know, we still really liked -- a lot of people really liked the AC model but there are logistical impacts and sharing over a broad area in the densely populated. It didn't perform as well as we expected in that way. So that's the situation.

MS. DUNN: I have Charlie and then Jerry McCauley and then if there are others, we could take some others. Otherwise we would move into the amendments.

MR. ALEXANDER: Maybe my comments are a little premature then. But I just remember looking back when I was UNOS president and watching Jim Wynne stand in front of the room and just make us be mindful of policy on the fly and the dangers of that.

So I want to just make that comment, that the Liver Committee has made this recommendation. And they are obviously closest to the impact of these
recommendations. And I know it wasn't a unanimous vote and everyone standing up, agreeing completely. But I do think, as we consider all options, we should be respectful of the committee's recommendation.

And I do want to make just the one comment about geography and proximity and geographic concentration. You know, these circles in a little program on the Mid-Atlantic Region will go to Canada, to Georgia, to Ohio, 12 OPOs and 40-plus transplant hospitals for my local donors. You know, so I think if we are in agreement that something like B2C is the way to go, I would love for us to consider some staging of that, because as much as we all ideally would like to do this right away, we should have pilots and airplanes and transportation folks as a part of this conversation, because that is going to be a logistical challenge for sure. Nothing we can't overcome, but I do believe that the staging would be incredibly helpful.


DR. McCAULEY: Well, I think there is sort of
an 800-pound gorilla in the room. And that gorilla is that we have to make a decision today. And so we can't kick the can down the road. Otherwise, it may very well be taken out of our hands.

So of the two, of the proposals, I won't weigh in on either one, but I just remind the group that this is not a time that we can send this back for revisions or additional modeling. And I think the modeling, frankly, is fast and dirty. And I would be very concerned about some of the things we've corrected in the Kidney Committee. After 25 years, we finally got equity for ethnic minorities. It took 25 years to do that. And so I haven't heard anything about that with any proposal. Maybe you did it, I don't know.

But it just sounds like it's been so fast that my guess is we don't have that data. However, I think we have to make a decision today and we can't say, well, we don't have enough data so we just won't do anything. I think we have to make a decision or the decision will be made for us.

DR. HEIMBACH: I just want to clarify, we actually did do that modeling for gender and age and
race. And there was no specific -- and also several other newer things, like the measurements of increased, you know, community risk score, so the less healthy communities, we looked at that as well.

The only area that was different was age, and there was actually an improvement for the pediatric candidates, so they did a little bit better than any of the other groups. But, for looking specifically at Asian and other specific race and then also looking at women versus men, there was no difference in those different analyses.

DR. McCAULEY: I'm reassured by that.

MS. DUNN: Todd Pesavento.

DR. PESAVENTO: Thank you. I really appreciate how much work you've put into it, and I'm sure the Kidney Committee will have as much work in the future, which I think is even a much more greater problem, just because of the magnitude of patients that are affected.

I guess one comment is I'm concerned about 40 percent of the people that didn't like any of these policies. So no matter what decision we reach today, I
think we have an enormous sales job. I wouldn't say sales, I'd say explanation of how this can benefit certain patients and the thoughtful process that went behind that. Because that means at least half the people don't like whatever we're going to decide.

I would say that, you know, number one, based on sound medical judgment, I think most of us professionals can disagree on the same set of data. So just because there's an inflection point at MELD 29 doesn't necessarily mean that that is, you know, the gospel and that is what we have to do. Everyone can look at that and kind of reach their own decision and balance that with other factors that go into that.

I think the unintended consequences for this policy or other policies in the past are important. And I think that you can't model behavior and I think that has happened with many other policies. And so I think a reasonable but cautious approach is really important.

And then lastly, in terms of being able to modify policy, of course that is an option. But it does take years. HCC is an example. I think we are
just now starting to address how that has affected patients to the benefit of some and to the hindrance of others. And so I think as we move forward, I think it should be thoughtful, but I think it should keep in mind that -- I wouldn't say a slow, cautious approach because I think it should be an important solution to solve the problem. But I don't know that it has to be the most extreme approach. And I think efficiency of the system is exceedingly important because we need to help patients throughout the entire country, not just certain areas that are disproportionately affected right now. Thank you.

MS. DUNN: Susan, do you have a new comment or continue --

DR. ORLOFF: Am I allowed to have one more, quickly?

MS. DUNN: Sure, sure.

DR. ORLOFF: That was very well said, Todd. Thank you. And I really appreciate everybody's comments. I just wanted to -- maybe this is addressed to HRSA more than Julie.

When we had a think tank discussion in Miami
about two years ago, two and a half years ago, I think Stuart Sweet was president, and we talked about metrics and life years benefit was one of the metrics. And that is something that, you know, as you drive up the competition to list the sickest patients or the highest MELD patients, it seems to me that what you're doing is you're actually just transplanting those sickest patients but you're not giving life benefit, necessarily, across the nation.

For a 22-year-old that has PSC and is very sick but MELD score is 29, versus a 69-year-old who has a cancer, whose MELD score in well-compensated liver disease, his MELD score is 34, well, they're going to get a benefit of about three years, whereas the young PSC patient could get a life benefit of, say, 30 years.

So I am just wondering with this broader sharing and competition driving people to transplant people they may not have transplanted before, just so they can, you know, be a part of the game and the competition, what are your thoughts about that? Because it is something we discussed and people were pretty enthusiastic about looking that -- looking to
life years benefit as an important metric.

MR. McLAUGHLIN: I think that if you -- if the OPTN were to choose to develop a policy to -- you would develop an allocation policy that would maximize life year benefit.

DR. ORLOFF: Um-humm.

MR. McLAUGHLIN: And so if you were to do that, you still would need -- the OPTN board would need to justify that policy based on these criteria that are on the screen. And so there is no restriction to the OPTN developing such a policy. But there has been -- you know, that's been discussed many times over the past 10 to 12 years and it has never moved forward. But that certainly is an option for the OPTN to consider.

DR. HEIMBACH: Yeah, and I would say, just to add to that because I have been on the committee for a thousand years, so I know that we did something called Net Benefit that was from the Ann Arbor Group and we tried really hard to develop a model that was predictive of post-transplant survival. And the problem is that there's not a great way to measure post
-- to predict, from the patient who is sitting in your clinic today, you know, what is the most likely to predict that he will be alive in five years.

So we're really good at predicting who is going to die but we are not as good at predicting who was going to survive post transplant. The strongest predictor was the center where they got transplanted. And if you would like to put that into the model, that would cause some hairs to be raised.

(Laughter.)

DR. HEIMBACH: I'll tell you that. And the other problem with Net Benefit was that we actually were going to do more old people with cancer, because those people do die on the list. And the Net Benefit predicted we were going to walk out of there doing more old people with cancer because that young guy with PSC lives a long time, both with and without transplant. And the old guy with cancer doesn't.

So we tried really hard to do that and we -- and the U.K. is working on this and we are certainly keeping our eyes open. And I -- you know, I put Patrick Kamuth on the committee because we wanted to
try to get some more innovative thinking on that. But, you know, it's a big challenge and it's just not a challenge for today.

Because the challenge for today is to address the fact that, you know, if you are sitting in the ICU in one city, it's different than if you're in another city and we don't want that to be true. And that was very eloquently described to our committee by Terry Bachs who was that guy sitting in the ICU waiting for a transplant. And he told us what that was like.

And he said, you know, when you're that patient, you want it to be -- you want to feel like you have an equal chance, not a better chance and not a worse chance but an equal chance as the other guy in a different city. And so we have been trying to get to something that can provide that.

Once we've got that, hopefully we can change it -- you know, women are disadvantaged by MELD. We would like to address that. There are so many projects that need to be addressed. And if we could find a better system to prioritize long-term outcomes, that would be ideal. And I'd love that we could do that
down the road, that would be great.

MS. DUNN: All right, we will have Theresa Daly and then I think we'll move to the amendments.

MS. DALY: Dr. Heimbach, kudos to you and your team. I know exactly what you're going through right now, and bless you for all you do.

I guess I'm just hung up on the word "best."

So if we're to seek the best use of the donated organs, I just want to feel comfortable moving forward, with all the time crunches and all of the political ramifications and everything that you guys have been put through, that this is really the best. Because some of the things that I was staring at before, you know, looking at decreased wait list mortality and decreased MELD variances and, you know, the timing of being out in the field, we were really looking at a bump of, you know, 1.8 hours to two hours. More organs will be in the air and it looks like, you know, the B2C versus Acuity model, I mean, just from my uneducated point of view, it looked like the difference was logistics and efficiencies.

So does that make B2C more efficient and the
best that we can do? Or is it better for us to kind of settle and push something through and get something done? Or is it really -- is that the best that we can do or is something more on the Acuity model really the best that we can do if we're really looking to decrease disparities, save lives and move organs?

DR. HEIMBACH: Was that a question?

MS. DALY: Yeah, I guess I'm looking for some reassurance here. Because I just keep hearing logistics, logistics efficiencies. To make sure it's really best and we're not just settling on a quick solution because it makes everybody happy, it's palatable and we can do it?

DR. HEIMBACH: Yeah, I could say there's nothing quick about what we have brought to you today. I would say, is it possible that there is a better solution? Certainly. And I think it would be naïve to think that what we are going to pass today will be the same in two years. We will have changed it. You know, I heard a comment from someone else that it takes a long time. But in fact, when we did MELD, within the first 18 months, we changed it three
times in the first 18 months. So right away, we're going to make a change. We'll probably have something that needs to be changed. Whether we go with AC or B2C, I think they both have strengths that we've heard today, they both have downsides.

I think B2C probably represents a step forward that's not as big of a step as AC and I think that's probably where the committee felt more comfortable going at the end of the day because it keeps everything in more of a balance so that, you know, then we can continue to modify that towards a -- the more optimal model. But I think both of them do a lot for the community that isn't being done today.

MS. DUNN: Thank you. So Tara, and this is last and we'll move to the amendments.

Chris, oh, I'm sorry. I didn't see you.

Sorry, Chris.

MR. McLAUGHLIN: I just wanted to reiterate, based on Theresa's comment, just say something I said earlier again. You know, if the board determines that a particular geographic limitation is justified based on a factor such as efficiency, the board needs to
explain why the geographic limitation is necessary for
the sake of that efficiency.

MS. DUNN: Okay, thanks, Chris. Tara.

MS. STORCH: Just real quick. So I'm Tara Storch, I'm a donor mom. And number 5, the very first, shall be designed to avoid wasting organs. So one of the questions I have, Julie, is the fact -- is it -- is B2C or Acuity model, which one has the least amount to avoid wasting those organs? Because when we said yes to organ donation, I would -- it would be very difficult to hear that it may be thrown away because of the procedure and the process. So, avoid wasting organs, which model gives you the least amount of that?

DR. HEIMBACH: Yeah, I think that's a really critical point. And it has to be one that is -- whichever system we adopt, we have to monitor that end point very, very closely.

The reassurance that can be provided is we did look at that after we went to Share 35, which was the last big change we made in terms of distribution, where we were sharing for the entire region for patients at a 35 and higher and we looked specifically -- because
people thought, oh, my gosh, we're going to have these late reallocations or transplanting these really sick people and the organ is going to be 270 miles away and it's not going to be used.

And in fact, we didn't see that. So we monitored that end point and we didn't see it with the broader sharing under Share 35. So I am -- I am hopeful that we would be able to manage it in either scenario.

You know, it's hard to be certain about which one would have a bigger risk of it or not. It's hard to say. Especially, because of the amendments, I don't actually know for sure what the B2C finally would look like.

I think the B2C that we're proposing and the AC model, both I think we could -- we could handle. If we start adding in the amendments, it becomes more difficult to know.

MS. DUNN: Good question.

All right, so the next thing is before we start considering the substantive amendments, I do have one technical correction to the committee proposal. So
if you could bring up the resolution which -- nobody will be able to read it. I guess we'll just to this, straight to the Amendment 1.

So the tables that are in the current resolution actually refer to the donor -- we need to ensure that the language refers to the donor hospital and not to the donor residence. So we're not talking about where the donor actually lives in their home. It really needs to be the donor hospital.

So I would entertain a motion for this very first amendment so that we correct this, which is the incorrect language.

Bill.

MOTION

DR. FREEMAN: So moved.

MR. ALEXANDER: Second.

MS. DUNN: All right, one of them. And if everybody would please vote?

MS. RHOADES: The vote is 37 yes, zero no, one abstain.

MS. DUNN: Okay, thank you.

So the first person I am going to call on is
Dr. Ken Brayman, who has proposed tabling the proposal, which would have the effect of reverting back to the December 2017 policy -- policy that was voted on by this body last December.

Dr. Brayman.

DR. BRAYMAN: Thank you very much. And I appreciate the opportunity to share my thoughts.

I am very concerned at this point. And I certainly admire the work of the Liver and Intestinal Committee, and I appreciate the perspective that HRSA has as to the need to move things forward.

But I am very concerned that using distance from donor hospital fails to fully comply with NOTA in the final rule. And I will outline my thoughts on this shortly.

I'm very concerned that significant areas of disagreement remain within the liver transplant community and, in particular, members of the Liver Transplant Committee concerning the proposals being put forward today. I am very concerned we are being pressured, unfairly in my view, by HRSA's insistence on a short time line. And this has resulted in a
breakdown of our normal policy-making process; i.e.,
where is all the modeling?
I am also concerned that we continue to debate
differences in regional OPO performance versus broader
sharing of organs. And clearly, organ donation is
highly influenced by our local communities. The impact
of the current proposals on local organ donation is a
major concern.

In the interests of our patients, UNOS, the
OPTN and the integrity of our independence and policy-
making processes, I urge you to join me in supporting a	
tabling of the consideration of the committee proposals
and allow us to return to the most recently approved
liver proposal, while we continue to work diligently
and transparently with HRSA and the transplant
community to address equitable liver allocation.

In December 2017, after years, literally years
of protracted deliberation, the OPTN board of directors
approved a policy which was generally agreed upon and
was a reasonable compromise. Less than one year later,
before the approved policy had even taken effect, there
was now a rush to change the allocation model that was
the result of many years of hard work and modeling. HRSA directed the OPTN to adopt a liver allocation policy that eliminates DSAs in OPO regions and that is, quote, compliant with the OPTN final rule, end quote.

The proposals under discussion today are not compliant with the final rule. Criticisms against DSA are acknowledged. But the solution is not to rush yet another allocation policy through that clearly does not comply with the final rule. The proposals being put forward focus disproportionately on reducing median MELD at transplant, a flawed metric that does not equate with whether candidates have equal access to transplantation.

The final rule requires that an allocation policy be designed to avoid wasting organs, to promote the efficient management of organ placement, and to promote patient access to transplantation. The current proposals lay the groundwork for continued litigation from both the current plaintiffs and others who will argue that both B2C 29 and Acuity Circles are arbitrary and capricious.

Each scenario modeled for the proposal reduces
the number of transplants, increases organ wastage and delays donor surgeries. The broader two-circle model with sharing threshold at 35, scenario five in the SRTR modeling for those that remember it, was the last harmful and least disruptive to allocation that was proposed and approved by the board in December 2017.

The current proposal's failure to properly consider socioeconomic inequities in the OPTN's narrow interpretation of patient access is inconsistent with legislative and regulatory intent. The proposals fail to consider both socioeconomic inequity and fail to promote access to transplantation.

Under the final rule, the OPTN board of directors is responsible to develop policies that further the OPTN's mission. The proposed policy has not been designed to promote patient access to transplantation but only considers access to transplantation for those already on the wait list.

Congress has had and continues to have significant, ongoing concerns about the ability of low-income populations and ethnic minority groups to have access to transplantation sources, including access to
the wait list. As such, both proposals are legally untenable and should not be supported.

The cumulative effect of allocation policies on socioeconomic inequity and promotion of patient access to all stages of transplantation services can consider a patient's -- a candidate's place of residence to achieve the optimal use of donated organs and promote patient access to transplantation. A lawful and equitable liver allocation policy should result in a greater number of organs being made available in states with higher wait list mortality rates and lower access to quality health care.

The median MELD at transplant is a flawed metric to assess severity of a patient's illness in the geographic equity of liver allocation policy. Ironically, the OPTN relies on median MELD at transplant across DSAs to conclude that livers are unfairly allocated. The OPTN states that DSA's may not be considered when forming allocation policies, yet the OPTN relies on those geographic boundaries to measure median MELD at transplant disparity.

I summary, significant concerns are raised
about the specific proposals and the policy development process. Acuity Circles will be particularly devastating to rural communities. I urge the OPTN and the board to defer further discussion on the hastily derived proposals -- I appreciate the work of the Liver and Intestinal Committee. But under the current consideration, we need new models that take an incremental approach to simultaneously address organ procurement flaws, to improve access and transplantation overall.

As a field and a board, we are obliged to take care of the most vulnerable populations. When NOTA was drafted and when the final rule was implemented and subsequently amended there was no intention to prejudice allocation or access to transplantation. We need to do the right thing.

We need to table the discussion on the current proposals. We need to implement the December 2017 plan and we need to get moving on a legally tenable plan to fix both liver allocation and organ donation.

And I appreciate the perspectives of the other members of the board and I recognize that perhaps I'm a
salmon fishing upstream and there are many grizzly bears that are about to take a chunk out of my side. But when you think about the current situation and the inequities that are likely to follow and the litigation, it makes no sense to move forward with the B2C or the Acuity Circles at this point.

What we need to do is double down on our effort to work with HRSA to figure out what's compatible and what's likely to move forward. And to put forth these proposals right now, just to eliminate the language of DSA and OPO is ludicrous. And, furthermore, we're doing it based on geography but related to the donor hospital. So it's really no different.

Thank you very much.

MS. DUNN: Since we have a letter directed from HRSA to move away from the December policy, I am going to turn this over to HRSA to respond, please.

MR. McLAUGHLIN: Right. I just want to reiterate that, you know, we had a July -- also in a July 31 letter to the OPTN, HRSA informed the OPTN of its determination that the OPTN had not justified or
could not justify the use of donation service areas and OPTN regions in the liver allocation policy or the revised allocation policy from December 2017 under the requirements of the final rule. So neither DSAs nor regions were created to allocate organs equitably or to optimally distribute donated organs. So our guidance is resulting from the consideration of the critical comments plus the feedback that was received from the OPTN about these structures. So we've provided -- we have -- you know, the bottom line is that the DSAs as they are currently defined don't meet the requirements of these final rule criteria. And I think I also want to give a little bit of further information about the language in the rule about promoting patient access to transplantation. And 121.8(a)(5) does say that policy should be designed to promote patient access to transplantation. And we have reviewed references to the term "patients" in provisions in the final rule. And the term "patient" or "transplant patients" are used numerous times in the
regulatory text. And in many instances, these references to patients and transplant patients are best understood as references to transplant candidates, at least to persons who are patients of a transplant program and may soon be put on the waiting list, and not to the broader set of individuals who may benefit from organ transplantation.

And there are numerous references throughout the rule to these -- you know, the references vary each time they're used. But generally, you know, it's appropriate to maintain that the reference to promote patient access to transplantation is limited to promoting access to transplantation for persons on the waiting list.

So you can read the language in multiple ways. But it's reasonable to read the language concerning patient access to refer to transplant candidates. So we can continue to talk about that but that is a reasonable way to interpret the regulatory language. So I'm happy to take further questions.

DR. BRAYMAN: I don't really understand your response. I'm sorry. But could you clarify that and
simplify it? Because what -- we're not suggesting that
we don't want to work together. We do want to work
with HRSA and we respect your perspective. But HRSA
has forced an artificial time line on the process. And
it's well intended but it's not to the benefit of the
system. It's to the detriment of individuals. And, in
particular, individuals of underrepresented minorities
and socioeconomic inequity. And we haven't adequately
modeled this because it is going to have a negative
effect on the ability of people in rural areas to
access transplantation. And I don't think that you
intended that. And that's the issue which we need to
address.

And I don't think the Secretary would favor
that, either. And certainly the congressional
deleagtes in the House of Representatives and the
Senate from 42 out of the 50 states that don't favor
these particular proposals wouldn't favor it either.

So I'm really lost. Because we're looking to
partner with HRSA right now and certainly you all have
been very patient as we as a community have tried to
figure this out. But what we don't need now is, you
know, basically a line in the sand. Because you're going to get something which is going to have a lot of unintended consequences and I don't think that's what you really want.

(Continued immediately on following page.)
MR. McLAUGHLIN: Our position is that neither DSAs nor regions were created to allocate organs equitably or optimally distribute donated organs, let alone to improve transplant candidate access to transplantation. Or to the address the cumulative effects of allocation policies on socioeconomic inequities.

So the board needs to address that. And that by maintaining a system that -- you know, with the DSAs and regions, we're not -- there is no evidence that they were determined to improve or reduce the inequities or to improve access. And so by staying with that model, there isn't the evidence -- you know, the board -- if the OPTN board wishes to do that, they'll need to provide justification for doing so.

MS. DUNN: All right. Bill Freeman, please.

DR. FREEMAN: First of all, I'm from salmon country. And, Ken, I appreciate your metaphor very much.

I am also a former fed bureaucrat. So I think I can do a little bit of translation. I hope I'm not
stating things wrong. But when the law says patients
and they refer to waitlisted patients, it means that
they were not concerned about access before getting on
the wait list.

I happen to be from a population, as well as
you and Chris, a population that doesn't get on the
wait list, is not provided the kind of care that is
needed to stay on the wait list to get good care. I am
very concerned about that, like you.

But I would differ with you on this regard. I
don't believe that allocation will solve anything about
that problem. I think we need to talk about
disparities and how to deal with them. I've been doing
that for 40 years and believe strongly in that.

So I would like actually have to have all of
those of us who are especially concerned about the
disparities to work within UNOS and with our partners
to deal with that problem. I just don't think
allocation of people on the wait list is going to have
anything to do with access to good transplantation
care, and that's what you are concerned about and I am
concerned about, Susan and Chris and so on. Thank you.
DR. SCHMITT: Can somebody explain to me how a circle is not -- is better than a DSA or better than a state model? I know that Region 3, I think, proposed a state model which would follow population boundaries that are already established. It would help you promote donation in your area and it kind of follows the support systems where patients go to their centers. It just made a lot of sense to me, the state.

I mean, if a circle is placed on Wichita, which is where we get most of our donors and patients from right now, most of those donors will go somewhere else but the patients will still come to us for transplant. And the circle doesn't make any sense to me.

MS. DUNN: Julie, do you want to take that from the deliberations of the committee?

DR. HEIMBACH: Yeah. You know, I have to say both, I think, Ken and Tim were making the point about the new policy of a circle being, you know, equally subject to litigation because it's equally arbitrary. And in the committee, when we were first told that, you
know, we had to do this, we, I think, probably went through these stages of Kubler-Ross and, you know, denial. And we started with saying, of course, the circle is just as arbitrary. I was waving my hands and saying this myself quite a bit.

Until I came to understand the fact was we're dealing with a legal situation. This is a law. And the original design of the OPO did not consider any of the things.

A circle is applied equally to everybody. So that's why it works, from a legal perspective. Whereas a DSA, you know, there are so many variations in the size geographically and the population served by the DSAs from, you know, really teeny to massive, 18 million people in one DSA. So there's such a huge variation.

So walking through that, that's why the circle is different than the DSA and the region. And, of course, the region tends to follow the state. And so we certainly entertained or heard the proposal that came from Region 3. It was vetted before the Geography Committee in full but we also talked about it in the
Liver Committee. And, you know, could that work. And unfortunately, the states are not created equally, as you can see, in terms of the -- some of them have transplant centers, some of them don't. They are very many different sizes. And access is very different. And the population health in the state is different, you know, in terms of the disease incidence and all of those things don't make it optimal for organ distribution. So those were the reasons that we heard and what we talked about.

But we certainly saw those points that you raised and I saw them myself. And it took me a long time to understand what arbitrary meant and why that was not a suitable thing to do.

MS. DUNN: Simon, please.

DR. HORSLEN: I'd like to really point out how hard the committee has worked to get to these levels. We hear that the time line is different but the hours of work that's been put into this I would suspect equals all other policy development. And this isn't just a rushed policy. There are clearly things that are beneficial to various groups that give advantage
there.

And so I think to suggest that the Liver Committee and all those involved have rushed this, I think, is unfair.

MS. DUNN: I see no other speakers. I would call for a motion.

DR. PESAVENTO: At the risk of being a salmon, I will just tell you that I will represent my region. Initially, when we presented our different proposals, our region strongly -- this is Region 10. So they strongly supported no change. At great personal risk, I had to implore them to have something better than no proposal and so we did come up with an alternative. But that was our initial -- the consensus from our group.

I guess, so a couple different things. One is I would say I think the Liver Committee has put in an enormous amount of effort, and I really greatly appreciate that. But I think was a failure to acknowledge how truncated this process has been compared to any other proposal at least I've been a part of that had such important magnitude. So to say
that something that went from December until now -- or, I'm sorry, June until now is not a short time frame, I don't think that's being -- I don't think that's being accurate, despite all the effort that's been put in, which I think I greatly acknowledge.

And then I just -- I wonder about arbitrary. So when we talk about circles and you look at population densities, is it not just as arbitrary that a circle that encompasses 50 million people would be different than a population density that includes like 50,000 people?

DR. HEIMBACH: You know, so I don't know if arbitrary is the right word because it's still --

DR. PESAVENTO: Or disparity.

DR. HEIMBACH: -- the same size. But does it do the same thing? Obviously, it does not.

And so that's why it's really important to look at the proposal. It's why we initially were excited about a population-based model. And if this model performs the way we want, that's great. If it doesn't, how can we change it and what would we change? And that's, I think, the path forward. And I think
that's really critical.  
Because obviously the impact of a circle of a 
certain size in an area which is densely populated is 
different than a circle of a certain size in an area 
that is more sparsely populated. I would agree with 
that assessment.  
But on the other hand, you know, the two 
models are substantially -- are different enough to say 
that if you are favoring one versus the other, then 
that would guide you to select one or the other.  
MS. DUNN: Brian, if you could speak to kind 
of the organizational risk related to the letter that 
we received from HRSA back in June, please?  

MR. SHEPARD: Sure. I mean, I think we've -- 
we all know how we got here. We have some risk of 
judicial intervention. But even if you hold a 
differing opinion of what the risk of that particular 
intervention is, we have a very clear letter from the 
Secretary that insists that the OPTN adopt a new policy 
that does not include DSA by this meeting.  
The Secretary, in the regulation, has the
power to -- to tell us what a policy is. That's never happened before. And I think that the Secretary and the HRSA representatives have been careful not to tell us what the solution is. But I think a decision not to move forward on one of the -- at least one of the liver options today would carry tremendous organizational risk and potentially harm our ability to make these decisions in the future.

MS. DUNN: Thank you. Chris.

DR. ANDERSON: Just a quick comment. So being from the region that proposed a state-based system, or at least to the Geography Committee proposed it, at also risk of being a salmon, we would feel that there is absolutely nothing arbitrary about a state boundary. And I believe -- I suspect all 50 states' attorneys general would agree with that.

States are a unit of health care based on Medicaid and other insurance policies. Every state's Blue Cross, for example, is a little different. States are also a -- have to make their own, to some degree, donor -- not allocation but donor policies.

So I'll just make that comment from my region.
I'll also make the comment that many members of the Liver Committee expressed the sentiment that they were disappointed that HRSA chose not to defend that policy because they did not feel that that policy -- the previous policy which was reached by consensus by the transplant community, which did move toward decreasing median MELD at transplant, they did not feel that it was arbitrary and capricious. And there was disappointment, a great disappointment, that our HRSA partners did not defend that.

So that's a comment I'll just make and I'll leave it there.

MS. DUNN: Ken Brayman.

DR. BRAYMAN: Right, well, I just want to state again that I think if we were to pass one of these now, there will be a number of unintended consequences. And I'm respectful of Brian's position, because it is very disconcerting to get a letter -- it's kind of like getting a letter from the IRS that, you know, you did something terrible.

Well, you know, the OPTN hasn't done anything terrible but it's earth shattering, because it sets a
new precedent in terms of how we handle our relationship and our oversight from HRSA. And maybe this is the beginning of a new chapter. But maybe it isn't. And maybe the community in general has to say, we're going to work with you but we're not going to put into place a policy which is going to result in certain litigation and that is going to take years, years. And it won't be just like, you know, the government. It's going to be, you know, lawyers from different states. Attorney generals are already lining up in terms of figuring out what their next steps are going to be.

Now, maybe you're all aware of it and maybe you're not. But it is -- it has grave consequences as to whether we move forward with this today or not.

And I wish that the Secretary was here so that we could have a discussion about the pros and cons of moving forward. Because essentially, that's what this comes down to. I mean, yes, we have the letter and we understand that it's put the UNOS and the OPTN in a very precarious position. But does that really make us want to do something that is fundamentally wrong and injurious to patients and the system as a whole? I
don't think so.

MS. DUNN: Steve Potter.

DR. POTTER: Well, I mean, we are in the position we're in and so we have a lot of work to do tonight. So reluctantly, maybe I'm foreclosing the discussion, but I would like to make a motion we vote on this amendment.

MOTION

MS. DUNN: Is there a second?

DR. JOHNSON: Second.

MS. DUNN: All right, the proposal is up here on the screen to table the current proposal, which would revert us back to the December 2017 policy. One is yes, two is no and three is abstain.

DR. REDDY: Can you repeat that again?

MS. DUNN: Sure. One is yes, that you would table the proposal. Two is -- did I do this right?

Yeah, yeah, that's right. Getting nervous here.

One is yes, two is to not table the proposal, which is the Liver Committee's proposal, and three is to abstain. Is that clear?

Susan, you're looking --
One is that you want to table the Liver Committee's recommendation and revert back to the December '17 policy. Two says we're going to not revert back to the '17 policy. We're going to move forward with the discussion of the proposal from the Liver Committee and continue the discussion of the amendments.

Steve.

DR. POTTER: You've had the polls open while you were explaining that. So is it true that just the last button push for those of us who may -- or do you want to reopen -- re-clear the thing and vote again, since there was some lack of clarity there?

MS. DUNN: All right, let's redo it. We don't know the vote.

They're going to clear it.

So one is yes, that we're tabling the proposal from the Liver Committee. That's Dr. Brayman's amendment, basically, is to say we will scrap what the Liver Committee has done, we'll revert back to the December '17 proposal or policy -- actually, policy.

Two is that we are going to not table the
proposal, that we are going to continue the discussion
with what the Liver Committee has put forward and
continue with the discussion of the amendments that are
out there.

Okay. Ready to vote?

Charlie's isn't working? Okay.

Everybody is nervous. Get these things out.

MS. RHoades: The vote is five yes, 35 no and
one abstain.

MS. Dunn: Okay. All right.

I think we are having great discussion. It's
hard but -- oh, Jason.

(Pause.)

MS. Dunn: All right, just had a question
about the number of people voting. All right.

I would just say we're not in Chicago. But,
you know, that's --

(Laughter.)

MS. Dunn: All right. Right now, the next
details.

vote that we have up is an amendment related to
adoption of the Acuity Circle model. I would refer you to
the Visio chart. This is where we're at right now. We
are at Amendment 3. And this will be the decider as to whether we go down the pathway of Acuity or whether we stay on what the Liver Committee has proposed in B2C. and then you can see amendments will follow from whatever we decide at this point.

So at this point, I will call on Dr. Charlie Miller to explain his amendment.

DR. MILLER: Thanks, Sue. It’s been actually 25 years since I've uttered a word at the UNOS board meeting.

MS. DUNN: Well, welcome back.

DR. MILLER: Thank you.

And as I was sitting here, I was remembering back 25 years ago to the discussions that left me with a little PTSD. And they were exactly the same as they were today.

And as I was fiddling with your toy, I actually came up with a better solution. And that is I shared the toys with my people around me and I started building a solidarity chain for the board. Okay?

Because, trust me, I think I'm the oldest guy in the room -- maybe -- oh, okay, sorry. Thank you. But
anyway, it doesn't matter if I'm the oldest guy in the room or not.

(Laughter.)

DR. MILLER: But these issues are contentious and they're divisive and we can't let it continue to divide. So just in symbolism for our solidarity as a board and our solidarity with the most important people, our patients and our donor families and our donors, I'm going to pass this down. Anybody that wants to contribute to the chain, please do. And then we can lay it out in the middle of the room. And if you need any help, I'll be happy to walk by and help you.

So thank you for giving me this opportunity. Julie, you're terrific. You have done a fantastic job.

(Applause.)

DR. MILLER: You have brought to this table two very good options for us to consider. And it's my job today to convince everybody here, in very plainspoken language that uses published fact, refers to some legislation, regulation that's already been referred to 100 times today, and hopefully relies on a
little bit of common sense, that the Acuity model is a simple, elegant model that does absolutely everything we need it to do right now, in a far -- in a superior way, I don't know about far superior, but a superior way to B2C 29.

Now, I just made a couple of slides and so I can go through this.

(Slide.)

DR. MILLER: Now, in contrast to the B2C 29, the Acuity circle model creates distribution based on really a more granular assessment of patient urgency along that steep slope that Julie showed with her graph between 29 and 35. This is a really critical thing. It's not -- it's not subtle.

But this model also maintains some local priority of distribution at each one of those granular categories. This is a great balance.

What we're really talking about when we are talking about AC versus B2C is a balance -- I'm sorry, Tim. Which -- what do you want? What are we going to prioritize?

And I'm going to say this 10 times. We need
to prioritize what's best for the patients, and the
geographic constraints need to be somewhat
underprioritized. And the AC model provides that
balance, and I want to show you how that looks.
(Slide.)

DR. MILLER: We've heard it 100 times now and
we saw it on paper, the AC model produces a
significantly better reduction in mean MELD at
transplant variation. And it's even more -- it's even
more significant when you apply it only to -- you don't
include the exception patients. For the not-exception
patients, it produces a very, very significant decrease
in mean MELD at transplant. And there is absolutely no
signal of futility, speaking to Tara's question before.

Now, this is my reading of the literature and
just about everybody else's. Counterintuitively, and
we've heard how it's going to increase costs and you're
going to be flying all over the place. You're not
going to be flying all that much more, number one.

But counterintuitively, the broader you share
-- and sharing is broader with the AC model -- actually
reduces the cost to the transplant system and will not
at all cause any encroachment on cold ischemia time safety thresholds. That, I can guarantee you; 1.7 hours versus two hours is insignificant. This has been published by David Axelrod in the American Journal of Transplantation, and Eric Edwards and a group of people here in UNOS that looked at other forms of broader sharing, and this is what the -- the findings were. And I think we shared those papers with the entire board, I hope. I know I shared it with the --

MR. ALCORN: They are cited in the briefing paper, and we can make them available for anybody who wants to read them.

DR. MILLER: Okay, no that's good. Because we shared it with the Policy Committee, I know. I thought it was going to be shared with the board. Okay. So I'm on the Geography Committee. I don't know how I got that. But the Geography Committee was almost unanimously in favor of continuous -- and you're going to hear about this from Kevin tomorrow -- continuous or borderless distribution framework. And really, it's the belief that that framework really
speaks to the density model. And that the AC most
closely approximates this framework from the
mathematical and practical standpoint. And it will be
quite easy to translate this into the borderless
language that may be coming down the line and will be
the recommendation of the Geography Committee.

So AC is -- I want to show this in the next
slide that Jim -- go back one, let me see what I wanted
to say. That was -- can you go back one? Go back two?

MS. DUNN: You only have three, don't you?

DR. MILLER: I'm still on the first one. I'm
still on my first slide, I'm sorry. I don't have the
controls here.

So the Acuity Circle model is a form of
iterative or semi-discrete -- maybe Jon could better
give a term to it -- but I call it iterative,
continuous distribution, with the iterations being
those three MELD point differentials between 29 and 40.
So you're already building in 29. There's no talking
about that. And it maintains distribution first most
locally, 150 miles. And then, only then to 250. And
only if nobody wants it in 250 miles does it go out to
500. So you're taking the sickest groups first, prioritizing out. And it would be easiest to translate into the borderless distribution.

So the AC model -- and this is -- maybe it's a little gratuitous. But in fact, the AC model tonight is the only one we're considering that's been modeled. B2C 32 was modeled. B2C 29 was modeled for reasons Chris has clearly explained. And that is not -- that is not my best argument but it's a fact. Sorry, Chris.

Next slide.

(Slide.)

DR. MILLER: Now, I wanted to get up -- actually, I will.

Can everybody hear me? Because I can speak really loud.

MS. DUNN: No, you need the mic, Charlie.

DR. MILLER: Then I'll have to do it like this.

MS. DUNN: Here is a laser pointer.

DR. MILLER: I have been rehearsing this for days. I wanted to look like Steve Kornacki with the political maps, you know? You know.
Mr. Alcorn, you did a beautiful job.

So you can see the difference. This tells you exactly what the difference of the models are. With B2C, you're prioritizing -- the darks go from left to light on the right. That means the priority is really -- I really wanted to use my arms. Okay, but now I got a pointer. Thank you.

So the priority goes this way. That's geography. That's the priority of the B2C is geography. Only then do you come down with a big block this way and it doesn't work for patients. It works for logistics and geography.

Acuity is actually beautiful. This is -- we're not even talking about the 1As and Bs. That's settled, settled law. But here are these four, four MELD point variations that come down to 29, where first you share here. So the colors gradually go diagonally. So it's both geography but primarily it's MELD, in the right priority of the sickest patient first. So this is what creates the mean MELD at transplant reduction. This will work.

So actually my presentation is not too long.
So if I could have my last slide?

(Slide.)

DR. MILLER: I'll just tell you what my conclusions are. So I think what I've shown you today, graphically and philosophically, best increases the likelihood of donated organs being allocated to more medically urgent candidates. Even if those candidates are not as close in proximity to the organ donor as someone less urgent. That's clear. And that is our most important goal to prioritize because we will not be able to rationalize to HRSA anything less than prioritizing that variable and then showing why we can't do anything better with regard to geography.

It best performs with respect to waiting list mortality. It is in the data. It best reduces geographic variations in mean MELD at transplant. It does not increase the probability of futile transplants or organ wastage. It promotes access to transplantation for those patients on the waiting list. And it is silent regarding access to potential candidates with liver disease. There is just no way to get to that.
And finally, it really represents the most appropriate common-sense balance of patient need and geographic considerations. So I kind of think AC weighs patients' needs 60 and the geography 40, where the B2C is just the opposite. And that 20-point differential is what makes this critical.

Thank you for the privilege of the floor.

MS. DUNN: Thank you, Charlie. I see we have a number of mics lit up. Yolanda, you're up first.

DR. BECKER: Thank you, Charlie. Having read and knowing what the Liver Committee has deliberated through, I appreciate everything that you've said about AC and the presentations with AC and B2C. I would like to point out that the -- and I think everybody knows this -- the Liver Committee's vote was very, very close.

As I think you all know, setting precedent of not following our expert committees is not a good precedent to set. However, I am not in error in speaking that the committee did deliberate and it was a very close vote. It wasn't overwhelmingly one direction versus another.
So I think that, no matter which direction we go, I don't think we are in opposition to the committee. And I hope that the Liver Committee -- Liver and Intestine Committee understands that and, Julie, if you have any perspective on that, I just want to say that either way we go, the vote was close in the committee.

DR. MILLER: I have something to say. My guess is, if it had been unanimous, I wouldn't be sitting here making this argument. It was like one vote. And probably, if you redid the vote five minutes later, it would have been just the opposite. So that's why we're here today.

MS. DUNN: Tara.

MS. STORCH: Just a couple things. You know, the longer we wait on deciding this, the more people that are going to die. And it's really up to us to move this forward.

And B2C and Acuity Circles, there really is no perfect model and there's going to be consequences with both. And as a board, we have to do the best we can.

But the question I have is, with the Acuity
model, will there be more wait time for the donor families? Because that is very difficult already, to increase the time that we have to wait makes it harder.

DR. MILLER: I need clarification. Waiting for?

MS. DUNN: For the organ procurement to take place.

DR. MILLER: Oh, oh. So, you know, I would say, no. The logistics constraints of that have to do a lot with actually the thoracic organs more than the liver, okay. So thoracic organs, lungs, are already being placed according to this type of geographic distribution. And there's much more waiting in sturm und drang about that as teams fly in.

Now livers, actually livers are pretty simple. Almost anybody in any OPO has a surgeon that can take it out and ship it somewhere else. So it shouldn't really impart any delay.

MS. DUNN: So I am going to call on Danyel. She has asked to answer this question. And then I think I'm going to go to Charlie since you're lit up and you're at an OPO and I think it's good to hear from
some OPO folks on this. So, Danyel.

MS. GOOCH: Not a popular response but it's a reality. I don't think liver will increase procurement time because lung already has. The procurement time, the time our families had to wait, used to be 12 to 18 hours at a high end. We're going to 36 hours for some cases.

So I don't think liver will add to it because we've already, unfortunately, increased that burden for our donor families.

MS. DUNN: Thank you, Danyel. Charlie.

MR. ALEXANDER: So I hope this isn't an underinformed question but the SRTR had sent impact documents out previously that showed Acuity, AC at 250 plus 500 and 300 plus 600. Are they different things?

DR. HEIMBACH: Yes.

MR. ALEXANDER: They are? So which one are we talking about? Just so we're clear what we just looked at here, 250?

DR. HEIMBACH: Well, I don't know what Charlie's amendment was. But the one we've been speaking about is 250, 500. I assume that's Charlie's
amendment but I don't know that.

DR. MILLER: It is. It is, just because I chose that in deference to the Liver Committee's debate on those two.

MS. DUNN: Okay, so going with 250, 500 is what the amendment is.

MR. ALEXANDER: I just want to make sure we're looking at the right document.

MS. DUNN: Where are we? Joseph?

MR. HILLENBURG: I have a couple points. I want to, in your mind, please, reflect back to James's diagram. I think that is a good illustration of some of the differences in terms of especially the wait list sequence in terms of the match run.

But one point -- there's a few points here. But one is B2C 29, if you look at the differences in the mortality rates, it seems scarcely better than the status quo. Which you can attribute that to either be the policy that's in effect now or the one that was passed last December. And is that legally defensible?

That's an important point. Will we wind up in this same situation in whatever period of time because
we made a choice that is -- really doesn't -- doesn't help patients?

I'd like to -- and a couple people mentioned -- I think Charlie mentioned the paper from 2017. I just wanted to quote a couple things here.

One of the things is, so the level of distribution in the B2C proposal that lumps together and prioritizes more local candidates -- I'm sorry, this isn't from the 2017 proposal but I just want to quote this -- prioritizes more local candidates with a wide range of MELD from 15 to 28 is not based upon sound medical judgment and clearly violates the components of the final rule.

I think that was in the letter that went out to the board. Whether you agree with that, I just wanted to call attention to that.

What the B2C proposal in fact proposes to do is to substitute a 150-mile radius for DSA and distribution, which clearly does not do enough to eliminate geographical inequitable difference in access to transplant for waitlisted candidates. The B2C proposals are -- quoting further down the letter -- the
B2C proposals are modeled to perform even more poorly for non-exception -- i.e., lab MELD -- candidates than the distribution proposal which was approved by the UNOS board last year and which was found to be noncompliant with the final rule.

And then going back to the 2016 paper from Sumner Gentry, where -- I'm going to try and cap this out -- the -- that was the paper that modeled the four or eight region -- four, eight-district model. But there that I think carries over here. And that is the -- that proposal or that set of proposals also included more flight time or more travel time by flight, by aircraft, and one of the things that people have been focusing on as a negative for Acuity Circles is the cost of that additional -- those additional resources. The amount of time in the air, et cetera.

I think Charlie addressed the cold ischemic time facet. But I would ask you to consider the increased cost in terms of the transplant -- the transport of the organ and that could potentially be offset, and the modeling does show this, that that is potentially offset by the reduction in time on the wait
list, because that candidate would possibly not be in the ICU for that period of time. So I guess in closing I just want to mention, you know, we're here to serve the patients and honor the intent of the donor family. I don't think B2C benefits patients to the same degree as Acuity Circles. And the patients have spoken on this. As Julie mentioned and as some of the -- as the public comment has indicated, the patients have said what they want. Is it consistent with the final rule to enact a policy that is really no better? So I hope we can find agreement here in a manner that benefits patients. And with luck, we can -- we can enact a policy that we feel good about. So thank you.

MS. DUNN: Thank you, Joseph. Next up is Steven Potter, please.

DR. POTTER: Charlie, thank you for that presentation. So I quote you from your presentation. You said regarding B2C that it works for logistics and geography, end quote. And, you know, those are not to be dismissed. And I think it would be good if we could
hear from some of our OPO colleagues about what sounds to me like real concerns with the AC model because of the added complexity, the numbers of flights, the flight time, transportation difficulties. So maybe you can expand on that?

MS. DUNN: Charlie Alexander and Diane. We're going to hear from some OPO people, Charlie Miller, for a minute.

MR. ALEXANDER: Sure. I mean, I appreciate the consideration.

I think, as I understand it, I think the B2C model gives us a little opportunity to stage, perhaps. Maybe Acuity not so much. I think that's probably the biggest thing.

But the reality is, we who operate the OPOs will do whatever it takes to make these cases happen. I think logistically, there are going to be certainly some challenges in geographically compressed areas where we're going to be kind of competing for flight resources.

When lung went into place back in November, last November, our fly-outs increased, I think,
sevenfold for our lung programs. And it's really hard to pin down -- you know, planes are all over the place, by the way. If anybody wants to be a pilot, you have a great future. There are no pilots left that will do these short-notice nighttime charters. So that's been our challenge.

But I think we'll figure it out. It logistically will be very, very difficult. It will be very expensive despite what Dorey and Sumner said. It's going to be really expensive. So, you know, those are the things that are on our mind.

MS. DUNN: Diane.

MS. BROCKMEIER: I would just concur with what Charlie said. Pretty universally, when you talk to folks across our industry, while planes are on the ground, the shortage of pilots is critical. And the FAA has also introduced more restrictive flight hours. So local charter companies -- and that seems to be the most common model today for much of the organ transport -- is becoming in some places almost like a crisis kind of situation.

The cost is not arbitrary, either. So we talk
about just adding a few miles. But every hour you add on a plane is doubling your cost. So -- not that costs should be the factor. But we had the same experience, Charlie, with the lung -- the implementation of the lung model. And our local flights -- ours are up fivefold. So it's a real consideration and it's a challenge. But we will -- we will make sure it happens, you know, to stay in compliance and make sure that patients get transplanted.

And to Tara's earlier point, I think that is the challenge we continue to battle is, how do you maximize the gift from generous families, which means time today. At the same time, make sure that the right patients get the organs that are in dire need. So, thank you.

MS. DUNN: And, Rob, another OPO perspective? I was kind of looking on this side of the room. I wasn't leaving you out over here.

DR. KOCHIK: No worries. I think, you know, it's really the balance of all of it. I think families tell us they want the best use for the best gift for the best patient, balancing time. We've also had some
families say that they actually appreciated the extra
time that it took. So it's a balance. And I'll leave
it with that.

DR. MILLER: I just want to say something. We
just heard a fascinating presentation before about
organ perfusion, normothermic organ perfusion. And,
you know, this really takes -- changes the equation
completely. No longer do you end up worrying just --
you don't really worry about ischemia time, you worry
about the time you're going to take to resuscitate the
organ on the normothermic machine pump. And it changes
the equation dramatically.

And so I don't think there's any concern --
not for nothing, the flying times, Steve, between B2C
and AC were 1.7 hours versus two hours and that's not
an increased cost, it's not an increase anything. It's
20 minutes of what we call screw-around time in the
business. It happens everywhere.

And actually, most of the increase -- and
Kevin knows this -- most of the increased time that it
takes for the time between extraction of the organ and
implantation has to do with things completely unrelated
1 to transport of any kind.

2 MS. DUNN: All right, thank you for that. Bob
3 Goodman.
4
5 MR. GOODMAN: I am interested about the
6 incremental costs. Both Diane and Charlie talked about
7 multiple-fold of increase of flying, which obviously
8 carries additional expense. I'm assuming those
9 expenses, and maybe I'm wrong, get transferred over to
10 the transplant hospital. So I would love to hear maybe
11 either of you two guys chat about that, or someone from
12 one of the transplant hospitals talk about how those
13 expenses are being absorbed. Are we trying to look at
14 changing reimbursement? Are we going to be proactive
15 in how we handle that? Is that something we can do or
16 help with in some way, shape or form?
17
18 So that's my question.
19
20 MS. DUNN: So I can certainly speak from the
21 OPO perspective, is that it does -- the charter flights
22 outside of your service area do get passed on generally
23 to the transplant programs. And then that becomes --
24 and maybe Theresa could speak to this -- but it
25 generally then becomes part of the negotiated contract
conversations with the third-party payers. So that --
I mean, that's short of the short answer. You might want to have another answer. Or Tim? Where is Tim?
Over here, Steven as well --

MS. DALY: We do a lot of fly-outs. We're mostly an importer only. And we're flying our liver teams, our lung teams and our heart teams quite often. I think that what we had seen especially kind of in the heart world with the adoption of the NAT positive HCVs is that we can justify a lot of what we're doing now with the shorter CT ICU times. And I think the same thing would be translated. If we can keep people in the hospital a shorter amount of time, especially in the ICU, then we can justify the amount of fly-outs that we're doing.

MR. GOODMAN: So, if you don't mind, so the Axelrod article if you will that talks about there's a balance to the whole system as a result, you're essentially sort of backing that up. You're saying you're seeing somewhat from a reality standpoint.

MS. DALY: So at least I can tell you in our recent experience with HCV NAT-positive hearts, we've
looked at ICU stays for ABO blood groups that would have traditionally have been over a year, and we're getting people transplanted in less than 46 days.

MS. DUNN: Significant.

All right, Chris Anderson, you're up next.

DR. ANDERSON: Just to counter a little bit about what Dr. Miller put forward is I'm not sure that either proposal really -- really has a big effect on futility or organ wastage. But neither proposal increases transplant. And the way I read it, both proposals decrease transplant.

The Acuity Circles, while the median travel time, you are correct, doesn't look different, we have to remember that's a median time or an average time, I can't remember which. So there will be big extremes on either end.

The actual percentage flying is 10 percent higher in the Acuity Circle than the B2C, at least the B2C 32 that we model. So those costs are real. And, yeah, the Axelrod paper says the system absorbs it. But the real cost to the transplant centers and OPOs is the increased flying.
So we're -- I hate to put it like this but, for essentially the same patient benefit, i.e., you're changing the median MELD at transplant two points between the two proposals. So is spending all that extra money on jet fuel worth what I would argue is clinically insignificant, two MELD points?

MS. DUNN: Tara.

MS. STORCH: Yeah, so I had mentioned the wait time for the donor family. Don't get me wrong, the time we would have with our family members is a gift. But it is -- it's a heartbreaking, bittersweet gift of that lengthened time.

You know, all we wanted really were for Taylor's organs to go to the -- to be the perfect gift for the perfect people at the perfect time, and we fully trusted the system to make that happen.

And I have full confidence that this board can go forward and make a decision tonight.

I do have a question though for Dr. Miller. So you had mentioned the Acuity model was 60/40 heavy for patient. So is that data driven or is that opinion driven?
DR. MILLER: I was being facetious, I said it's my -- but it's kind of how I tried to make -- that's what I think it is. I think it's more heavily weighted for patients' needs and less on logistics. And it's just the balance. And it's not huge but, even 60/40 creates a 20 percent difference and I think that's really significant. And I think it's therefore the only one that's defensible.

By the way, just something on cost. Not for nothing, I do run a transplant center for a living. These costs, Chris, are put on the Medicare cost report. And at least a large proportion of them will be reimbursed through Medicare.

MS. DUNN: Laura.

MS. DePIERO: You know, I just want to echo a little bit about what Tara said, being a donor mom. Watching my son wait, we already had completed -- my daughter also died at the same time. So we also had to worry about waiting for her. But to watch my son go through all of those tests, and the longer you wait and the longer you see them having more and more tests, it's difficult to watch and it is bittersweet.
But I also think, too, logistics is also part of it. We didn't rest easy until we got word that, you know, everything was complete, the transplants were done. So I think also from a donor family perspective, the farther away those organs go, it also does play a little bit of a role in our emotions from the donor family side. Because for us, we didn't rest easy until we knew everything was done and the organs had been transplanted and he was safe and sound in his new home.

DR. MILLER: Is there any -- is there any data in the SRTR or anywhere that there's a difference in time from explant to implantation between 250 miles and 500 miles? I doubt it.

MS. DUNN: I don't know the answer to that. I'd kind of like to keep -- interesting point. But can we kind of keep moving through?

DR. MILLER: Yeah, sure.

MS. DUNN: Yolanda.

DR. BECKER: I'd actually like to call the questions. I know we do Robert's Rules very loosely. I think we've had a robust discussion and I would suggest that we call the question. The hour is late.
MR. ALEXANDER: Second.

MS. DUNN: I just want to ask one question, since we're -- Chris, did you have anything new to add? And I just wanted to make sure, Bill, did you have anything new to add?

DR. ANDERSON: I did have one new thing to add. And I would just say that, Charlie, the Medicare cost report does not absorb all those costs. The third-party payer negotiation includes the donor organ. And at least in my state, Medicaid does not go to the cost report. So that -- that part -- the donor organ and the flights have to come out of the Medicaid reimbursement.

And so if you increase costs to a center and you perhaps have a medium to small-size center that's going to decrease their transplants, that becomes a real burden. And that gets to where we're talking about the indirect access to health care for potential recipients.

So to me, B2C helps get us toward our goal, which I think we all agree on. But, you know, you can justify through the other parts of the final rule,
i.e., efficient management, avoid futile transplants, they both do it. And best use of resources, that B2C is probably the best at least first step toward that.

MS. DUNN: Anything new, Bill?

DR. FREEMAN: Just one point about the cost. As I understand it, the costs are renegotiated every year. So the increase in cost from starting this program would be six months of unreimbursed increase before it's renegotiated, average of six months.

Most donor families are nondirected donors. And I am a nondirected donor although a living donor. I'm also a physician. And I can say as a nondirected donor, at least one nondirected donor, I would be incensed if I did not trust that the system was going to put my kidney in the person who needed it the most, period, end of statement.

I would not want to have a system where other things interfered with that, like how much is it going to cost more. I'm sorry. I firmly believe that Acuity is the way to go.

MS. DUNN: Thank you. And very, very last, last comment for this. Sue Orloff. Anything new?
DR. ORLOFF: It was just more about when we're flying more, if we go to no DSAs for then kidney allocation, you know, we have lung and heart, I'm just wondering again about the logistics. But it goes further when -- how can you have that many planes in one place to take the organs to different places? And I think it was mentioned already that that's been a problem already with the amount of flying in some places.

But I think that will be magnified in terms of having enough planes that can transport these organs. So that's just my next comment. Thank you.

MS. DUNN: Thank you.

MOTION

All right, we have a motion on the floor and a second. The vote. We're going to move on to the vote. What's up on the screen, utilize Acuity Circles for liver distribution.

A yes vote means that we would go toward -- everything, all subsequent conversations would be around Acuity Circles as the new liver distribution policy. A no means that we would stay with B2C as the
Liver Committee has proposed.
So yes, one, means going to Acuity. Two, or number two, goes to B2C. And three is abstain. But we'll take the vote.
MS. RHOADES: The vote is 24 yes, 14 no, zero abstain.
MS. DUNN: Okay. So if you pull out your updated December 3 sheet, we are shifting gears. We will not be entertaining any amendments on the B2C side; we now are moving forward as a community with the Acuity Circles.
So the next -- the next amendment up, I believe, is number 13, who is Macey. Macey Henderson, you have the floor.
MS. HENDERSON: Thank you so much.
Those in the liver transplant community have long thought that a MELD score of 15 represented a cutoff point to receive benefit for liver transplant. Bob Merion's landmark paper in 2005 showed that patients with a MELD score of 15 did not benefit from a transplant. In other words, their survival was better on the wait list than it was after transplant. At that
time, it made sense to offer livers to patients with a
MELD of 15 or above before patients with lower MELD
scores who did not tend to benefit from liver
transplant. This was the rationale for Share 15 that
was implemented years ago.

What we are asking for today is an update.
Much has changed since then. First, the new MELD score
now incorporates the patient's serum sodium, adjusting
for those candidates with hypernatremia and higher
mortality.

Second, pretransplant care for liver
transplant candidates has improved. A more recent
analysis also discussed by the liver committee by
Najeeb, et al. -- can you please show the slide, next
slide?

(Slide.)

MS. HENDERSON: -- has now shown that the
cutoff for benefit for MELD sodium occurs at 20 rather
than at 15. Using the new MELD score that incorporates
sodium, and given other advances in pretransplant care,
we want to align policy with current data and evidence,
since we have the opportunity to do so today.
Other authors have also proposed alternative scenarios to improve disparity and they have independently called for wider distribution at a MELD score higher than 15.

The proposed amendment would allow more candidates who would benefit from transplant to have access to this lifesaving treatment. It is based on sound medical judgment and most importantly, it aligns our policy with the current science and the final rule.

Thank you very much.

MS. DUNN: Thank you, Macey. Does anyone have questions or comments about this amendment?

All right, hearing none -- oh, Simon, sorry. I thought you were the parliamentarian for a second.

Go ahead.

DR. HORSLEN: This is all well and good for adults. But where is the data that supports that for PELD? It will affect how kids have access to livers, potentially.

MS. DUNN: Julie?

DR. HEIMBACH: I don't have an answer to yours because this is all -- as I mentioned earlier, I just
want to point out again that this is new data. We are interested in this data but it is not part of the policy that we developed. It wouldn't be possible to include something that was published in November of 2018 in the policy that we modeled starting in the summer and this is not the process that we normally follow.

So it's compelling and it's exciting to have new data and put it in at the last minute. But I think it's a real threat to how we make policy and I just want to point that out.

I think this will help. It will help a little bit. It won't help enough to justify throwing out how we make policy in order to have the latest and greatest data included.

MS. DUNN: Thank you. Anyone want to respond to that? All right, then I would say then we'll move forward with the vote.

If you could put the slide up? Here it is, the amendment. A one, meaning yes. That means that we would replace the classifications of at least 15 with the MELD -- this says MELD/PELD -- of course of 20.
And then a two would be not to move forward with this amendment. So is that clear? One supports it, two is not in favor of it.

MS. RHOADES: The vote is nine yes, 25 no, one abstain.

MS. DUNN: Okay. All right. So I'm guessing that will move forward with the Liver Committee in some discussions, as most policies do and conversations do.

All right, the next amendment that we have up here, I think this is Chris. I believe that you're up with the exception cap amendments.

DR. ANDERSON: So these are very similar in nature. One is for -- I may have to --

MS. DUNN: Call a friend?

(Laughter.)

DR. ANDERSON: No, no --

MS. DUNN: I would certainly understand that. Just right now, don't look at me. Don't look at me for that.

DR. ANDERSON: I would love to call a friend right now.

Since someone brought up Jim Wynne a while
ago, I will say that he texted me and suggested that we all get some liquid refreshment to grease the discussion.

    MS. DUNN: I think that's a dandy idea.

    DR. ANDERSON: However, the spirit of this is really to support sharing for the sickest patients and then all patients. But to balance the efficiency of the systems, balance our resource use and ensure that the truly sickest patients are getting the organs at these higher MELD levels.

    So there is a difference between a high MELD exception and a truly calculated high MELD patent in most instances. That's the spirit of why we instituted the HCC delay and the HCC cap. That policy was not reintroduced into this policy, although the Acuity was a change so I'm not as familiar with the Acuity model.

    But I proposed a cap for all exceptions such that the exception patients would not interfere with allocation to the truly sickest patients, i.e., the MELD 35 and above. Much like we do today with HCC.

    There are obviously some exceptions to this policy. For example, hepatic artery thrombosis
exception and I believe hyperoxaluria, the real high
mortality exceptions that we give and we give them a
lot of points in recognition of that, would be not in
this amendment. But the HCCs and the other routines
would.

So I don't know which one I want to use, to be
honest. I think 32 makes sense because in the Acuity
Circle, there is a break point at 33. And I really
think Amendment 16 probably was submitted and the
language ought to say if we don't chose to cap all
exceptions at 32, then we should reinstitute the HCC
cap which is currently 34. So that was my initial
confusion when I read this. So I think that's the
spirit of my amendments.

So I might say that Amendment 16 that we would
vote on if Amendment 15 is not passed is specific to
HCC. Much like we do today, it caps at 34.

MS. DUNN: Okay. All right.

Any questions? Joseph?

MR. HILLENBURG: So I'm a little concerned
about -- I don't recall the -- going back to the
amendment language, I thought it just mentioned MELD.
But here, we're talking about PELD, too. I'm extremely concerned about the potential impact upon pediatrics.

DR. ANDERSON: You are correct. And my -- my amendment was only meant to be MELD. I did not want to do it for PELD because it's just too -- we don't know what that will be and it's a different animal. So, yes, that's a good point, and I appreciate it.

MR. HILLENBURG: So we can consider that stricken then?

DR. ANDERSON: Correct. I appreciate you bringing that up.

MS. DUNN: Simon.

DR. HORSLEN: MELD doesn't cover all pediatrics. Pediatrics goes up to 18; 12 to 18s have MELDs. I think it's important that we consider pediatrics as a group and not the scoring system.

MS. MILLER: So this is just something that's a little bit unclear on the title here. This is actually only -- as the amendment is written, it's only candidates who are at least 18 and so only MELD scores for the 18 plus.

MS. DUNN: Okay. Pediatric people okay with
that? All right.

MR. SHEPARD: Yeah, it's Resolution 8, it's Amendment Number 15, if you're following along in your amendment book. It is one of the loose pages that was added this morning. So it's sitting on your amendment book, it's not in the staple. But it's Resolution 8, Amendment 15.

MS. DUNN: Maryl.

DR. JOHNSON: And it's probably just that I'm not as familiar with liver as a lot of the people in the room. But I'm a little bit confused when you say not including hepatic artery thrombosis and not including this and that. And I just want to make clear that I understand which -- is it just HCC you're recommending a cap for, and if so, that's 32 or 34?

I'm sorry, I'm confused.

DR. ANDERSON: Me, too, sometimes.

So Amendment 15 would be what I'm proposing is for adult patients, greater than age 18, we cap all exceptions except HAT and hyper oxalosis at 32.

Amendment 16 would be specific for HCC at a MELD cap of 34 to reflect current practice.
So the exception scores, so the majority of exceptions granted are for symptomatic issues in patients with liver disease. Or if the center, for example, feels that something about them is not reflected in MELD. There are some cancer exceptions, cholangiocarcinoma and HCC.

But when we get into the higher MELDs, which is why we put a cap for HCC in the past, we do a couple things. We artificially drive up the median MELD at transplant based on exception scores rather than truly calculated MELDs which are truly reflective of mortality. And so that's the spirit of this amendment.

You know, at the end of the day, I want to be sure that the truly sickest patients get access to the sharing organs.

MS. DUNN: Randee -- or Julie did you want to respond?

DR. HEIMBACH: I just want to make just a point of clarification that most exceptions are standard MELD exceptions, not for specific reasons that, you know, the center thinks the patient needs it. Actually, the majority of the exceptions are standard
and the vast majority are for HCC. All the other
standard exceptions are dwarfed by HCC, which is the
predominant situation.

MS. DUNN: Okay, thank you. Randee.

MS. BLOOM: Thank you. I'm most concerned
from the patient perspective, maybe from the
perspective of people who want to be donors or want
their families to be donors, to be able to message this
change and all the future improved changes, to be able
to easily articulate the fairness of the opportunity.

So can I explain the necessity to cap, which
may actually be vital to the discussion, can I explain
it correctly by saying we want there to be exceptions
for medical reasons determined by an individual
clinician at an individual site but because we can't
quantify that in advance because we don't -- we're not
giving only objective scores to that, that we are
trying to make it so there is a ceiling, that's your
cap opportunity here. And then say, that's why if you
don't qualify for an exception, which you don't want to
because that makes you sicker, you don't qualify for an
exception, the playing field is leveled.
If we can say that we are making these enhancements, these changes for fairness, geographically and now exception limitations, then I would say we are messaging to become a donor family, if that's the decision is made, because there is this effort towards this lack of -- these exceptions to reduce disparities, to reduce chances of lack of fairness? I think that makes our message outside this room much, much stronger, defensible. Not legally but PR wise. And we must recognize that so we can potentially have as many or many more donors. Thanks.

MS. DUNN: Julie.

DR. HEIMBACH: I think it's important for the group to recognize that the cap has been historically an important part in fairness because it previously prevented patients from getting access to the Share organs, which were meant to go for the patients with the very highest mortality. And in the past, when we allocated for exceptions, they got a score and every three months the score would go up until they would have a chance to access transplant.

And it did lead to some, you know, things
where there would be a very stable patient that was
going ahead of a very critically ill patient. And so
we capped it at 34 to prevent that.

But going forward, we're actually not going to
be doing that elevator system, every three months going
up. Going forward, we're going to be a fixed score
which is supposed to be three points below the median.
So three points below what is average. So the very
sickest patient should be well above that and still
accessing transplant. And the HCC patients which are
stable, they definitely need to be transplanted, they
have no other treatment option which is curative and
eventually they will die of their disease, but they do
have more time than the most critically ill patients.
So we have been trying to balance that all along. And
going forward, they are going to be at a fixed score
that is three points below the median.

So the cap is, in the view of the majority of
the committee, probably it is not needed. That is what
we feel.

I think under the B2C model, there was a grave
concern that we had that it was going to disadvantage a
group of patients. Under the AC model, you know, if we capped at 34, then it would have to be a 37. And it's possible that there would be a group at 37 and we could disadvantage that group. But the -- with the new system of the NLRB, we do believe that the cap would not be needed.

That was the view of the majority of the committee. But not -- again, it was not a strong majority. Like everything else, we -- we had a strong minority that had a different view.

MS. DUNN: Yolanda.

DR. BECKER: So I think I would like to reflect back on something that Julie said a little bit earlier. With due respect to all the well thought out amendments, we do have a process. And we do have time for that process to take place.

And I would suggest that we defer to the Liver Committee and in its deliberations to go forward with any of the further amendments.

MS. DUNN: Okay, and Bill -- oh, Charlie, you were first.

DR. MILLER: Actually, I just have a question
of clarification. Chris, is what Julie said, with the
new NLRB, does that change your thoughts? Or is
that --

DR. ANDERSON: I guess if that's really going
to happen, and again I'm not entirely sure how it
interacts with Acuity. I proposed these initially
because B2C was what the committee proposed. So it
made sense with that.

I think it makes sense if there's going to be
a MELD exception elevator such that the median MELD at
transplant is artificially elevated for those patients,
we need to cap that, I think. And I also think that it
-- just as we've seen in the past, it will interfere
with the truly sickest perhaps getting access to
organs.

So if it's truly capped now, then I will have
to say it probably doesn't make any difference. But
when does that take effect, Julie?

DR. HEIMBACH: The NLRB is going live before
this policy, at least three months before. That's the
plan. And it would take effect whenever we go live
with the NLRB.
MS. DUNN: Bill.

DR. FREEMAN: As a living donor again, and unlike my -- what I said the last time, I want this to go through what Julie was talking about, go through the process. I agree entirely with my mentor, Yolanda. Thank you.

MS. DUNN: Sudhakar.

DR. REDDY: I think I agree with Chris in general, the concept of capping, so that we don't overprioritize something which we don't intend to. But at the same time, since we are going into a new allocation model and Liver Committee felt that probably they would be transplanted before they reach this gap point, is that amenable to you, Chris? I'm asking you specifically to table this proposal for future discussion to see how things evolve with the new model. Or would you still prefer to vote now?

DR. ANDERSON: I'd be amenable to tabling it, with the caveat that I can reintroduce them as we see what happens.

DR. REDDY: That's what I propose, an amendment to this amendment.
MS. DUNN: All right, so Chris, both of them you're taking off? All right.
   Let me ask the powers that be here.
   Oh, and we have one last one, one last amendment. Expand the existing split liver variance.
   Which, Chris, I think your name is attached to that.
   DR. ANDERSON: So I need a gold star or something. I need multiple free drinks.
   MS. DUNN: Drinks are right when we walk out the door, just so you know.
   (Laughter.)
   MS. DUNN: They're going to have some platters right there waiting for us.
   DR. ANDERSON: So this amendment is made entirely because I believe and others I've spoken to believe that this is a way to incentivize centers to split livers and increase the number of patients we transplant.

   There is an existing variance that centers can apply for or ask to participate in that allows a center to select a liver that is allocated to a patient and if they choose to split that liver and utilize either the
anatomic right lobe or the anatomic right tri-seg in that patient that it allocated to, that then they may use the anatomic left or the anatomic left lateral segment for another patient at their center that appeared on the match run, or at a patient at an affiliated pediatric center who appeared on the match run.

What the variance does not allow is, if you accept a liver for a patient and you split the liver and you intend to put the left side of the liver in that patient that you then be able to use the right side on a patient on the match run at your center or affiliated center.

And so my amendment proposal is to simply expand that variance such that if a center chooses -- if a center and their patient, I would say, because the patients need to be informed of this, there is a slight increased risk, that if the patient -- the recipient and the center choose to split a liver, that they could then utilize that other piece, other segment, for another patient on their list, as long as they appear on the match run, whether you use the right first or
the left first.

So that is in line with what Region 8 has proposed to pilot. And I can certainly understand the argument of letting them pilot it. But at the same time, this -- this incentivizes splitting livers and, as someone who has split livers, and we split in my center now, negotiating with other centers in the middle of the night on a match run or knowing that you're going to send another piece out, that disincentivizes any individual center to take that risk and do it.

So this is something that I feel, while it's a small number, it is an increase in transplant, it is an increase in using organs and it is, in my mind, consistent with what a donor family would want, if they can transplant two people instead of one.

MS. DUNN: Thank you. Sudhakar.

DR. REDDY: I just would like to reiterate and strongly support this proposal. And I would like all of my colleagues to consider that.

And Chris has clarified to me now that it does not apply to the left -- if left lateral segment is
offered to a pediatric recipient, the right tri-segment will be offered according to the match run. So that reassures me --

DR. HEIMBACH: No, that's not correct, according to the Region 8 variance.

MS. DUNN: It's they'd keep it.

DR. REDDY: Okay, let me clarify that. If -- if the left lateral segment is offered to a pediatric recipient, the right tri-segment should be offered according to the match run. On the other hand, if an adult patient has been offered a liver and the center decides to split, to use either the right lobe or the left lobe, that center can keep the remaining lobe to use it to a different recipient. Is that -- is that what you're proposing, Chris?

DR. ANDERSON: So you and I talked about this last night. So what I said is I would accept a friendly amendment to my amendment for that.

So basically what you're saying is if the center that is deciding to split is the adult center, this would take precedent or this would go into effect. If it was a pediatric center using the left lateral, it
would not. And I can agree to that. I think the right tri-segs are more likely to be used on the match run than others.

But that is not what Region 8 proposed. That would be -- that would be a Chris Anderson amendment with a Dr. Reddy amendment to the amendment.

DR. REDDY: I would propose that amendment.

DR. ANDERSON: At the end of the day, you know, the spirit of this is, even though the numbers are small, this would encourage transplant, encourage centers to split and get more patients transplanted.

MS. DUNN: Julie.

DR. HEIMBACH: And I think there is a lot of excitement about this. I can see that reflected in the room and there is a potential path forward. What is being proposed in February is a variance supported by Region 8 which is coming out as a closed variance. Certainly, you know, it could be an open variance and so that other regions could choose to participate or not participate.

But right now, it hasn't even been out for public comment. And what you're talking about is
making a policy that has never been out for public
comment, which is quite a -- quite a leap of -- I mean,
it's just really going forward faster than we would
normally do it. So it hasn't been to the community
yet. Nobody has had any chance to comment on this.

So what you're talking about is making a
policy in advance of what is proposed to go out for
public comment in February for Region 8 as a
demonstration project. Instead, taking that and
applying it to the whole country without ever asking
anyone in the country if they support it. You know,
that's quite a change from how we normally work.

And the path forward could be to change our
variance from 8 to more broadly. That would be an
option, I think.

MS. DUNN: And that is going out in February,
as it's on schedule right now.

Let's see, Theresa.

MS. DALY: I'm going to wait a second.

MS. DUNN: You're going to wait a second.

Steve Potter.

DR. POTTER: So doing something faster than we
want that we're uncomfortable with. Is that the first
time that's occurred to you tonight? Because that's
what we've been doing all evening, right?

So, you know, I would just point out that this
is the only thing we've heard tonight that actually
supports the strategic goal number one, increase the
number of transplants. So from just kind of a simple,
common-sense standpoint, it sounds like a win.

MS. DUNN: All right, Dr. Chinnakotla is on
the phone. He wants us to know that he strongly
supports the amendment as well.

Let's see. Maryl.

DR. JOHNSON: I guess my question really
relates to the time line. And I think if the proposal
is going out for the variance for a specific region in
February, you know, whether, you know, doing the
broader variance proposal at that time might not delay
this but would allow the community to actually comment
on it and allow the committee to really look at it and
make sure we have all the language straight and
everything. Because I'm a little confused about which
segment is going where.
And I think if the public comment is going out, I guess I'd need some help from policy about the time line. So that would actually come back to the board June?

MS. DUNN: June, yes.

MR. ALCORN: Yeah, Maryl. If I can answer that? So the current Liver Committee, they have a project approved by the Policy Oversight Committee and the Executive Committee that would be sending out a new split liver variance that would be going out in the spring, wintertime. That would come back to the board in June.

I was just chatting with Julie here. There is plenty of -- there is time left if the Liver Committee wanted to expand upon that variance to include the discussion that is coming out of the board meeting here today.

As it does relate to the comment that was just made though about making, you know, policy decisions rather quickly, there is one thing about this that's a little bit different than just moving quickly, which is obviously something we want to do is be responsive to
the community.

With all the different changes that we talked about earlier, we look at whether or not that's kind of within kind of the post public comment scope of changes. You know, it's a question we get from the committees a lot, is how big of a change can you make post public comment?

And the rule that we generally say to folks is that you want your changes to be within the scope of some way that somebody reading the public comment proposal could reasonably anticipate that this is a change that could come out of this.

So as you may recall, the liver proposal that went out, they asked for feedback on Acuity and B2C. they asked for Acuity on caps, they asked for Acuity on caps, they asked for Acuity on circle sizes. They did not ask for feedback on the split liver variance.

Which is why I would say that this is not a change that a reasonable reader of that proposal could expect to come out of this board conversation. The board does not have a rule that, in legislative terms, we'd call it a germaneness rule. But that is something
that we caution the committees not to do as a post
public comment change, and it's something I would also
cautions the board not to do as well.

MS. DUNN: Thank you. Matt Cooper.

DR. COOPER: I don't know if I can follow
that. I'll just give James my gold star then. Because
I think that's exactly what -- the board is here to be
the board. The Liver and Intestine Committee should do
the job of the Liver and Intestine Committee and
evaluate this. There's no urgency to doing this right
now. Although, again, I support Steve's idea of
increasing the numbers of transplants.

But we just gave credit, over and over again,
to all the work that Julie and the committee have done.
Let's let them do this work. They're the experts on
this. And then they'll bring it back to us and we'll
figure out and try to avoid all the unintended
consequences and everything that we started this
cornered conversation with. I'm begging people, let's not do
this. This is not the way that the board should
function.

MS. DUNN: Tim Schmitt.
DR. SCHMITT: I'm just going to agree. I don't think Region 8 exists anymore so we can't have a variance because the circles will alter everything. (Laughter.)

DR. SCHMITT: It just can't happen.

MS. DUNN: And Theresa Daly.

MS. DALY: I echo Dr. Cooper and I almost said Dr. Alcorn.

MS. DUNN: All right. (Laughter.)

MR. ALCORN: I got a promotion today. Thanks, guys.

MS. DUNN: Bill Freeman.

DR. FREEMAN: So just to show where it does, I think, need to be verified. It looks like the wording, as I understand it, is actually confusing if not self-contradictory. On the one hand, it says the potential recipient registered at the same transplant hospital -- excuse me. It's going to use the same match run, it says in one place. Sorry, I misread it, versus it's going to be the local hospital if it doesn't go to a pediatric.
That's already self-contradictory. This really does need to be seen and worked on by the committee.

MS. DUNN: All right. Chris.

DR. ANDERSON: So just for clarification, it has to be an affiliated. So the spirit of that is they're pediatric programs affiliated with adult programs where the surgeons or other staff go back and forth. So the patient does have to appear on the match run. And the patient at both hospitals will have to appear.

DR. FREEMAN: I'm just saying that it should go to the -- we've already gone through this with the Acuity model. It needs to go to the person on the basis of the Acuity model.

MS. DUNN: All right. Maryl.

DR. JOHNSON: I'd like to call the question on this amendment.

MS. DUNN: All right.

Nobody is waiting. All right. I'm hearing voices.

We're voting on the amendment.
I think what we're voting for, if I'm -- I don't have the words. Brian, say what we're voting for now.

MR. SHEPARD: Right. It's Amendment Number 14 to Resolution 8, which is in your stapled packet. A yes vote is to move forward with that policy now and a no would leave it out of this policy but could leave the Liver Committee with their existing plan to get a public comment in January, February.

DR. HORSLEN: With the friendly amendment?

MR. SHEPARD: So far, no, we have not incorporated the friendly amendment into that.

DR. REDDY: In fact, if we move forward, I would like to propose that friendly amendment. But I am also persuaded, after hearing that we could wait until June, too. So that's another amendment. And again, the sponsor, Chris, has to agree with that. I'm okay to hold off that friendly amendment because I'm willing to wait until June, myself.

MS. DUNN: Okay, so Chris, it comes back to you.

DR. ANDERSON: So, Julie, could I change the
amendment to have the board change it from Region 8 to
countrywide for public comment?

DR. HEIMBACH: I mean, I think -- I don't know
what the process is. But I'm certainly hearing this
feedback. I am sure I will bring it to the committee
and I would expect that there would be -- I don't know,
is there a rule about this that anybody could help me
with?

MS. DUNN: James, help --

MR. ALCORN: Yeah, so in the past when we've
had things like this, and even last week I've talked
with some board members about this, that if there seems
to be a policy preference from the board on something
that's during development, we can bring that feedback
back to the sponsoring committee. We don't need a
formal action from the board to do that.

Chris, I think your idea about expanding this
beyond the region will gain some support on the
committee. I know there were some folks on the
committee that said, this wouldn't work in our region.
But I think this is a good conversation for the
committee to have and then the broader liver community
to have during public comment that we can then bring back to this board in June.

DR. HEIMBACH: Can I just get clarification for the committee about specifically whether we're handling the left lateral segment in the way that the Region 8 variance is written? If their pediatric recipient at their affiliated hospital is getting the left lateral segment, they're keeping the right tri-segment for their adult patient.

It doesn't sound like that's what Dr. Reddy wanted. I don't know what you wanted.

DR. ANDERSON: That is not what Dr. Reddy wanted. But I think if we're going to say that we would like for the Liver Committee to ask for public comment beyond Region 8, then what we should do is probably wait for public comment and then --

DR. HEIMBACH: And ask for it on those two components?

DR. ANDERSON: -- revise the policy and bring it to the board in June.

DR. HEIMBACH: Okay, thanks.

MS. DUNN: All right. Charlie.
DR. MILLER: Chris, I actually congratulate you on bringing this forward. I think it's important. I think there's a really big difference between left lateral segment, right tri-seg splits and left-right splits that very few people in the country are doing. But you should be congratulated because you are.

I think getting public comment and including this friendly amendment in the conversation of looking at those differently is very critical and I think we could end up just where you want to be in six months.

MS. DUNN: So, Chris, I guess, not to put you on the spot. Would you like to remove this from the vote? Or would you like us to move forward with it?

DR. ANDERSON: We'll remove it from the vote.

If you'll buy me a drink.

(Laughter.)

MS. DUNN: I'll buy you a drink. Hell, I'll buy you a bottle. I'll buy you a bottle there, Chris.

DR. MILLER: We will all buy a drink.

(Laughter.)

MS. DUNN: Oh, my goodness.

And I believe -- oh, we have to vote yes/no on
MR. ALCORN: We need to vote on the overall proposal.

MS. DUNN: Oh, on the whole package, on the overall.

MR. ALCORN: Yes.

MS. DUNN: We have to vote. Yeah. All right.

MR. ALCORN: The proposal as amended.

MS. DUNN: Okay, the proposal as amended. Do we have a slide on that? You don't have the slides.

They're the slides over here.

So in the meantime, while they're pulling up the slide, dinner is at 7:30. Drinks are probably on the way to dinner. And the movie will be at 8:15.

And I think kind of the comments that we've had today, the engagement from all of you, disagreement among people around the table but thoughtful conversation. We're moving forward into a new era and we are part of history in what has happened in the organ procurement transplant network. So I kind of get choked up at things like this.

So thank you for all of your thoughtful
consideration, participation. And I'll see you at the movie. They're not lounge chairs but you can bring in your drinks. You can bring in dinner. And it's at 8:30, not 8:15.

And who is going to the movie? I think most people were. It's a fabulous movie; if you haven't seen it, I highly encourage you to see it. You'll see yourselves in certain parts of it. All right.

We were waiting for the slide.

MR. SHEPARD: Which means what we've got is the committee's proposal with Amendment Number 1, which was the technical amendment about donor hospital versus donor residence. And then the amendment to use the Acuity Circle model instead of the B2C, which is substantively the bulk of the proposal itself. Although technically, there's other language in there. So it's Resolution 8 with Amendments 1 and 3.

MOTION

DR. JOHNSON: I make that motion.

MS. DUNN: Is there a second?

MR. GOODMAN: Second.

All right, all in favor? One is to vote for
Resolution 8 as amended, two is no, three is abstain.

MS. RHOADES: The vote is 30 yes, seven no, two abstain.

MS. DUNN: All right. Our agenda says that maybe we would have gone to pancreas but we're not.

(Laughter.)

MS. DUNN: It is the prerogative of the chair. Heck, it's 7:30 at night.

So we will see everybody in the morning. I think breakfast is at 7:30. We'll see you out in the lobby here. And thanks for all your work today.

(Whereupon, the meeting was recessed, to reconvene at 9:00 a.m., Tuesday, December 4, 2018.)

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